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eflexis®

GRIFOLS

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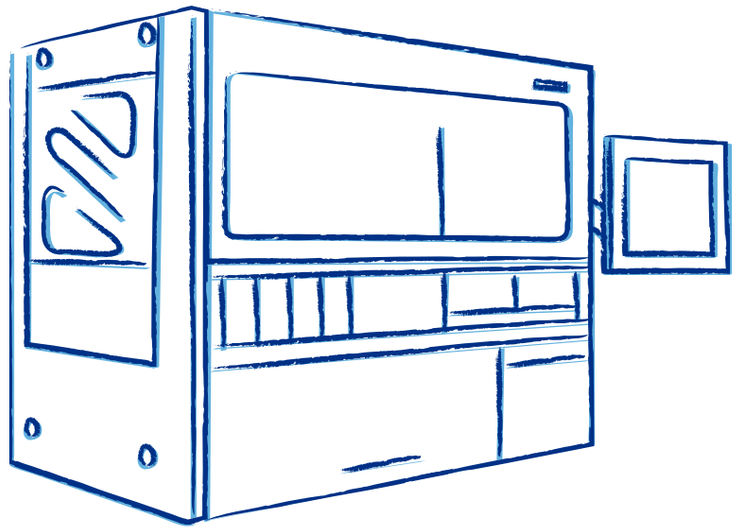
Erytra Eflexis® Instructions for Use



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Instructions for Use

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Erytra Eflexis®

Instructions for Use

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Manufactured by: **Diagnostic Grifols, S.A.**
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PLEASE READ THESE INSTRUCTIONS CAREFULLY BEFORE STARTING TO WORK WITH THE ERYTRA EFLEXIS® ANALYZER

Information about analyzer Safety can be found in Section 2.

The symbols used in these Instructions for Use are as follows:

WARNING: Indicates the possibility of personal injury, loss of life, or harm to the environment if the instructions are not followed.

CAUTION: Indicates the possibility of the following if instructions are not followed:

- Instrument damage.
- Incorrect results.

NOTE: Used for clarifications or additional or emphasized information.

The defined terms used in these Instructions for Use are as follows:

Supervisor:	The individual or group responsible for the use and maintenance of the equipment and for ensuring that Operators are adequately trained.
Operator:	The person who operates the equipment for its intended use.
Qualified Technician:	The person responsible for the installation, repair, and special maintenance of the equipment who has been specifically trained for this purpose.

All restrictions that refer to the Supervisor shall also apply to the Operator.

Contents

About this Manual ..... **xiii**

1 Introduction **1-1**

1.1 Intended Use 1-1

1.2 Principle of Operation 1-1

1.3 Product Limitations 1-2

1.4 Operator Training 1-2

2 Safety Information **2-1**

2.1 Warnings and Cautions 2-1

2.1.1 Health and Safety Notices 2-1

2.1.2 Results Reliability Notices 2-2

2.1.3 Electrical Notices 2-2

2.1.4 Installation Notices 2-3

2.1.5 Software Operational Notices 2-4

2.1.6 Analyzer Operational Notices 2-4

2.1.7 Grifols Gel Card and Reagent Notices 2-5

2.1.8 Sample Notices 2-6

2.1.9 Functional Areas Notices 2-8

2.1.10 Maintenance Notices 2-8

2.1.11 Transport and Storage 2-9

2.1.12 Disposal Notices 2-9

2.1.13 Warranty Notices 2-10

2.2 Equipment Markings 2-10

2.3 Accessory Markings 2-15

2.4 Read Before Using 2-16

3 Erytra Eflexis® Specifications **3-1**

3.1 Technical Specifications 3-1

3.2 Functional Specifications 3-2

3.3 Program Specifications 3-5

3.4 Regulations 3-6

4 Description of the Erytra Eflexis® Analyzer **4-1**

4.1 Basic Operating Principles 4-1

4.2 Overview of the Erytra Eflexis® Analyzer 4-1

4.2.1 Commands and Controls 4-2

4.2.1.1 On/Off Switch 4-2

4.2.1.2 Start Button 4-2

4.2.1.3 Upper Door 4-2

4.2.1.4 Lower Door 4-3

4.2.1.5 Push-Buttons for Opening Drawers and Racks 4-3

4.2.1.6 Push-Button to Open and Load STAT Samples 4-3

4.2.1.7 Touch Screen 4-3

4.2.1.8 Traffic Light 4-3

4.2.1.9 Blue Leds on Racks and Containers 4-4

4.3 Description of the Instrument Components 4-4

4.3.1 Erytra Eflexis®: Upper Level 4-4
4.3.1.1 Pipetting Arm 4-4
4.3.1.2 Dilution Station 4-5
4.3.1.3 Reagents and Samples Station 4-5
4.3.1.4 Card Transport Arm 4-5
4.3.1.5 Grifols Gel Card Station 4-5
4.3.1.6 Service Racks 4-5
4.3.1.7 Incubators 4-6
4.3.1.8 Centrifuges 4-6
4.3.1.9 Reader for Image Processing 4-6
4.3.2 Erytra Eflexis®: Lower Level 4-7
4.3.2.1 System Solution Containers 4-7
4.3.2.2 Disposable Container for Card Waste 4-8
4.4 Moving the Instrument for Relocation or Storage 4-8
4.5 Accessories 4-8
4.5.1 Grifols Bench 4-9
5 Description of the Erytra Eflexis® Software 5-1
5.1 Software Functions and Features 5-1
5.1.1 Controller and Manager 5-1
5.2 The Main Analyzer Software Screen 5-2
5.3 Opening Drawers & Racks 5-3
5.4 Virtual Keyboard 5-3
5.5 Description of the Warning Area 5-4
5.6 The Acoustic Alarm 5-5
5.7 The Fluidic Icon 5-5
6 Description of the Controller Software 6-1
6.1 The Main Controller Screen 6-1
6.2 Status of Analyzer Screens 6-1
6.2.1 Viewing Missing Cards & Reagents Information 6-2
6.2.1.1 Cancel Orders 6-4
6.2.1.2 Print Missing Resources 6-4
6.2.2 Viewing Missing Sample 6-4
6.2.2.1 Cancel Orders 6-5
6.2.2.2 Print Missing Resources 6-5
6.2.3 Viewing Sample Information 6-5
6.2.4 Viewing Reagent Information 6-8
6.2.5 Viewing Gel Cards Information 6-9
6.2.6 Viewing Container Information 6-10
6.2.6.1 Unload Containers 6-12
6.2.6.2 Direct Drain Lab Connection 6-12
6.2.7 Viewing Incubator and Centrifuge Information 6-12
7 Work Procedure 7-1
7.1 Work Procedure Overview 7-1
7.2 Preparing for Work 7-4
7.2.1 Starting the Analyzer 7-4
7.2.2 Performing Initial Checks 7-4

7.2.3 Preparing Samples and Reagents 7-4
7.3 Loading Reagents, Gel Cards and Samples 7-6
7.3.1 Loading Reagents and Diluent 7-6
7.3.2 Loading Grifols Gel Cards 7-7
7.3.3 Loading Samples 7-8
7.3.3.1 Sample Holders 7-8
7.3.3.2 Loading Samples 7-9
7.3.3.3 Identifying Samples Manually 7-10
7.3.3.4 Procedure 7-12
7.4 Loading Missing Items and Resolving Resource Issues 7-13
7.4.1 Loading Missing Reagents or Diluents 7-13
7.4.2 Loading Missing Gel Cards 7-14
7.4.3 Loading Missing Samples 7-14
7.4.4 Emptying the Service Rack 7-15
7.4.5 Refilling the System Solutions Containers 7-15
7.4.6 Emptying the Waste Solution Containers 7-16
7.4.7 Emptying the Card Waste Disposable Container 7-17
7.5 Unloading and Shutting Down the Analyzer 7-18
8 Manager: The Data Management Software 8-1
8.1 The Main Manager Screen 8-1
9 Programming Tests with the Worksheet 9-1
9.1 Worksheet Description 9-1
9.2 Programming the Worksheet 9-2
9.2.1 Automatically Programming the Worksheet 9-2
9.2.2 Manually Programming the Worksheet 9-3
9.2.2.1 Manual Programming By Sample 9-3
9.2.2.2 Manual Programming By Profile 9-3
9.3 STAT Programming 9-5
9.3.1 Loading and Programming STAT Samples 9-5
9.3.2 Designating Samples Already in the Analyzer as STAT 9-5
9.3.3 Programming a Crossmatch Profile 9-6
9.3.4 Automatical Crossmatch Programming 9-6
9.3.5 Manually Crossmatch Programming 9-6
9.3.6 Modify Crossmatch Assignments 9-8
9.3.7 Ordering and Filtering Samples on the Worksheet 9-9
9.3.8 Executing the Workload 9-10
9.3.9 Status of the Workload 9-10
9.3.10 Cancel Workload 9-12
10 Displaying and Validating Results 10-1
10.1 Results Screen Overview 10-1
10.2 Reviewing Results 10-3
10.2.1 Viewing Detailed Results Information 10-3
10.2.2 Viewing Traceability Information 10-6
10.3 Validating Results 10-7
10.3.1 Validating Normal Results 10-7
10.3.2 Reviewing and Validating Exceptional Results 10-7

10.3.3 Reviewing and Accepting Execution Processing Incidents Results 10-9
10.3.3.1 Incidents During Card Reading 10-9
10.3.3.2 Incidents During Test Execution 10-12
10.3.4 Reviewing and Accepting Special Microtube Grade Results 10-15
10.3.5 Reviewing and Accepting Discrepancies Results 10-17
10.3.6 Reviewing and Accepting Specials Results 10-17
10.3.7 Reviewing Results with Inconsistencies 10-18
10.4 Modifying the Reaction Grade 10-21
10.5 Rejecting Results 10-22
10.6 Exporting Results to LIS 10-22
10.7 Printing and Saving Results Reports 10-23
10.7.1 Printing Report 10-23
10.7.2 Saving Report Data 10-24
11 Searching Results in Database 11-1
11.1 Searching and Viewing Results in the Database 11-1
11.2 Printing Searched Results 11-4
11.3 Saving Searched Results 11-4
11.4 Resending Results to LIS 11-4
12 Quality Control 12-1
12.1 Configuring Quality Control Policy 12-1
12.2 QC Status of a Profile 12-2
12.3 Load Quality Control Samples 12-2
12.4 Programming Quality Control Protocol 12-4
12.4.1 Automatic Quality Control Programming 12-4
12.4.2 Resolving QC Warning 12-4
12.4.3 Manual Quality Control Programming 12-5
12.4.4 Processing Quality Control Samples 12-6
12.4.5 Reviewing Quality Control Samples 12-7
12.4.6 Viewing Detailed QC Results Information 12-8
12.4.7 Validating Quality Control Results 12-9
12.4.8 Validating Unexpected Results 12-9
12.4.9 The Quality Control Warning 12-10
12.4.10 Exporting Quality Control Results 12-10
12.4.11 Printing and Saving QC Results Reports 12-12
12.4.12 QC Database Searches 12-12
12.4.13 Executing Patient Samples Linked to QC 12-12
12.4.14 Viewing Patient Detailed Results Information 12-14
12.4.15 Printing and Saving Patient Samples 12-14
13 Configuring User Access 13-1
13.1 User Configuration Overview 13-1
13.2 User Groups and Access Permissions 13-1
13.3 Creating New Users 13-2
13.4 Reset Password 13-4
13.5 Modifying User Data 13-4
13.6 Changing Passwords 13-4

14 Maintenance 14-1
14.1 Maintenance Plan 14-1
14.1.1 Maintenance Screen Overview 14-1
14.1.2 The Maintenance Summary Tab 14-4
14.1.3 The Decontamination Tab 14-5
14.1.3.1 Obtaining a Track Record of Decontamination Actions 14-5
14.1.3.2 Recording Manual Decontamination Actions 14-6
14.1.3.3 Performing Fluidic System Decontamination 14-7
14.1.4 Probe Replacement Tab 14-7
14.1.4.1 Obtaining a Track Record of Probe Replacements 14-8
14.1.4.2 Replacing Probe 14-9
14.1.5 The System Solution Registry Tab 14-11
14.1.5.1 Obtaining a Track Record of System Solution Use 14-12
14.1.5.2 Recording System Solution Traceability Information 14-12
14.1.6 Technical Service Operations Registry Tab 14-13
14.1.6.1 Obtaining a Track Record of Technical Service Operations 14-14
14.1.6.2 Recording Technical Service Operations 14-15
14.1.7 The Activation/Deactivation Modules Tab 14-15
14.1.7.1 Obtaining a Track Record of Module Activation/Deactivation Events 14-16
14.1.7.2 Activating/Deactivating Modules 14-17
14.1.8 The Backup Tab 14-19
14.1.9 Daily Maintenance 14-20
14.1.10 Checking for Spills 14-20
14.1.11 Check for the Growth of Microorganisms 14-21
14.1.12 Weekly Maintenance: Cleaning the Analyzer Surfaces 14-21
14.1.13 Cleaning the External Surfaces 14-21
14.1.14 Cleaning the Touch Screen 14-22
14.1.15 Cleaning the Internal Surfaces 14-22
14.1.16 Monthly Maintenance: Decontaminating the Analyzer 14-22
14.1.17 Decontamination Material Required 14-23
14.1.18 Decontaminating the Fluidic System 14-23
14.1.19 Decontaminating the Probe 14-24
14.1.20 Decontaminating the Dilution Station 14-24
14.1.21 Decontaminating the Analyzer Surfaces 14-24
14.1.22 Decontaminating Racks and Samples Holders 14-25
14.1.23 Decontaminating the Liquid Containers 14-25
14.1.24 Preventive Maintenance 14-25
14.1.25 Database Backups 14-26
14.1.25.1 Restoring the Database 14-26
14.1.25.2 Restoring the User Database 14-26
15 Erytra Diagnostic 15-1
16 Transport and Storage 16-1
16.1 Storing the Instrument 16-1
16.2 Unpacking the Instrument 16-1
16.3 Placing the Instrument in Its Location Place of Operation 16-1
16.4 Installation Procedure 16-1

17 Equipment Disposal 17-1
18 Warranty 18-1
19 Troubleshooting 19-1
19.1 Incident List 19-1
19.2 Low-Level Incidences 19-1
19.2.1 Controller 19-1
19.2.2 Manager 19-3
19.3 High-Level Incidences 19-5
19.3.1 Manager 19-11
20 Maintenance Services 20-1
20.1 Adjusting the Screen Position 20-1
20.2 Manual Opening of the Upper Door 20-1
20.3 Decontamination Certificate 20-2

List of Figures

Figure 1. Laser Product Label 2-11
Figure 2. Biological Risk and Risk of Injury from Probes Labels 2-11
Figure 3. Moving Parts Label 2-12
Figure 4. Sample Rack Position Labels (Left View) 2-13
Figure 5. Sample Rack Position Labels (Right View) 2-13
Figure 6. Reagent Racks Position Labels 2-13
Figure 7. Grifols Gel Card Drawer Position Label 2-14
Figure 8. Biological Risk Label 2-14
Figure 9. Biological Risk Label 2-14
Figure 10. Packaging Label 2-14
Figure 11. Product Label 2-15
Figure 12. Power Switch and Power Connection Label 2-15
Figure 13. Electrostatic Discharge (ESD) Label 2-15
Figure 14. Biological Risk Label 2-15
Figure 15. Overview of the Erytra Eflexis® Analyzer 4-2
Figure 16. Push-Buttons 4-3
Figure 17. Overview of the Upper Level of the Erytra Eflexis® Analyzer 4-4
Figure 18. Overview of the Lower Level of the Erytra Eflexis® Analyzer 4-7
Figure 19. System Solution and Waste Solution Container 4-7
Figure 20. Disposable Container for Card Waste 4-8
Figure 21. Overview of the Grifols Bench 4-10
Figure 22. Main Screen of Manager of Erytra Eflexis® Software 5-2
Figure 23. Map of the Analyzer Showing the Buttons that Opens the Analyzer Drawers, Racks and the Upper Door. 5-3
Figure 24. Icons Available in the Bottom Part of the Erytra Eflexis® Software 5-5
Figure 25. Fluidic Icon Activated in the Bottom Part of the Erytra Eflexis® Software 5-5
Figure 26. Main Screen of Controller of Erytra Eflexis® Software 6-1
Figure 27. Main Screen of Status of the Erytra Eflexis® Analyzer 6-2
Figure 28. Status > Missing Cards & Reagents (Example) 6-3
Figure 29. Status > Missing Samples (Example) 6-4
Figure 30. Status > Samples (Example) 6-6
Figure 31. Sample with Well Incident Icon (Example) 6-7
Figure 32. Status > Reagent Screen (Example) 6-8
Figure 33. Status > Cards Screen (Example) 6-9
Figure 34. Status > Containers Screen (Example) 6-11
Figure 35. Status > Containers Screen with Dual Mode (Example) 6-12
Figure 36. Status > Incubators & Centrifuges Screen (Example) 6-13
Figure 37. Rack for Reagents 7-6
Figure 38. Sample Holder 7-9
Figure 39. Holder for Pediatric Samples 7-9
Figure 40. Procedure for Closing the Disposable Card Waste Container 7-17
Figure 41. Procedure for Assemble a New Disposable Card Waste Container 7-18
Figure 42. Main Screen of Manager Software 8-1
Figure 43. Overview of the Worksheet (Example) 9-1
Figure 44. Samples Selection Window 9-4

Figure 45. Worksheet Showing a Workload (Example) 9-4
Figure 46. STAT Screen (Example) 9-6
Figure 47. Donor Assignment Window (Example) 9-7
Figure 48. Worksheet Showing a Crossmatch Workload (Example) 9-8
Figure 49. Worksheet Samples Ordering Window 9-9
Figure 50. Color Code of the Worksheet 9-11
Figure 51. Results Screen (Example) 10-1
Figure 52. Profile Information Results Screen (Example) 10-4
Figure 53. Picture of an Example of Reaction Grades 10-5
Figure 54. Test Traceability Information (Example) 10-6
Figure 55. Results Screen Showing Inconsistencies (Example) 10-19
Figure 56. Profile Information Results with Pending Review Inconsistencies 10-19
Figure 57. Inconsistencies Result Window (Example) 10-20
Figure 58. Profile Information Results with Reviewed Inconsistencies 10-21
Figure 59. Profile Information Screen with Modified Results (Example) 10-22
Figure 60. Report Tool Bar 10-24
Figure 61. Search Results Filter Screen 11-1
Figure 62. Pagination of the Results Found 11-3
Figure 63. Overview of the Quality Control Module 12-2
Figure 64. View of QC Samples in the Worksheet Screen (Example) 12-3
Figure 65. Worksheet with Quality Control Warning Requirement (Example) 12-4
Figure 66. Quality Control Sample Requirement Information in Status > Missing Sample Screen (Example) 12-5
Figure 67. Results Associated to an Expired QC Kit (Example) 12-6
Figure 68. QC Results Screen in Quality Control Module (Example) 12-7
Figure 69. Profile Information Result Screen for an Expected QC Result (Example) 12-8
Figure 70. Profile Information Result Screen for an Unexpected QC Result (Example) 12-9
Figure 71. Exported QC Results in Database Screen of Quality Control Module (Example) 12-11
Figure 72. Profile Information Result Screen for an Exported QC Result (Example) 12-12
Figure 73. QC Results Screen for Patient Samples 12-13
Figure 74. Traceability Print Report with Exported Pass and Exported QC Status (Example). 12-15
Figure 75. Users Screen (Example) 13-3
Figure 76. Overview of the Maintenance (Example) 14-2
Figure 77. Maintenance Summary Screen (Example) 14-4
Figure 78. Decontamination Screen (Example) 14-5
Figure 79. Decontamination Filter Screen 14-6
Figure 80. Manual Decontamination Registry Window 14-7
Figure 81. Probe Replacement Screen 14-8
Figure 82. Probe Replacement Filter Screen 14-8
Figure 83. Probe Replacement Process 14-10
Figure 84. Probe Replacement Registry Window 14-11
Figure 85. System Solution Registry Screen 14-11
Figure 86. System Solution Filter Screen 14-12
Figure 87. System Solution Registry Window 14-13
Figure 88. Technical Service Operation Registry Screen 14-14
Figure 89. Technical Service Operations Filter Window 14-14
Figure 90. Technical Service Inspection Registry Window 14-15

Figure 91. Activate/Deactivate Modules Tab 14-16
Figure 92. Module Activation/Deactivation Filter Window 14-17
Figure 93. Modules Availability Window 14-18
Figure 94. Activate/Deactivate Modules Registry Window 14-18
Figure 95. Probe Replacement Registry Window 14-19
Figure 96. Backup Tab 14-20
Figure 97. Erytra Diagnostic Program Loading Window 15-1
Figure 98. Diagnostic Menu Tab 15-1
Figure 99. Erytra Diagnostic Window 15-2
Figure 100. Execution Report 15-3
Figure 101. Erytra Diagnostic Tool Bar 15-3
Figure 102. Incident Error Message 19-1
Figure 103. Adjustment of the Tension of the Articulated Arm of the Touch Screen 20-1
Figure 104. Adjustment of the Position of the Screen 20-1
Figure 105. Location for the Manual Opening of the Upper Door 20-2

List of Tables

Table 1. Container Identification Labels 2-12
Table 2. Technical Specifications 3-1
Table 3. Functional Specifications 3-2
Table 4. Accessories 4-8
Table 5. Reactions Grade 10-5
Table 6. Type of Results 10-7
Table 7. Incidents During Card Reading 10-9
Table 8. Incidents During Test Execution 10-12
Table 9. Special Microtube Grade Results 10-15
Table 10. Specials Results 10-17
Table 11. Search Criteria Filters 11-1
Table 12. Additional Search Criteria Filters 11-2
Table 13. Permited Actions for each Access Level 13-1
Table 14. Maintenance Plan 14-1
Table 15. Low-level Incidences Controller Descriptions 19-1
Table 16. Low-level Incidences Manager Descriptions 19-3
Table 17. High-level Incidences Descriptions 19-5
Table 18. High-level Incidences Manager Descriptions 19-11

About this Manual

PLEASE READ THESE INSTRUCTIONS CAREFULLY BEFORE STARTING TO WORK WITH THE ERYTRA EFLEXIS®.

These Instructions for Use provide instructions for configuring and operating the Erytra Eflexis®.

Information about analyzer Safety can be found in Section 2.

This instrument is protected by international patents affecting the entire unit and its parts.

Highlighting and Quotation Conventions

Highlighting and quotation marks are used to convey specific meaning within the context in which they are used. The context and meaning of the highlighting and quotation marks are defined below.

All uppercase letters are used for:

- Acronyms.
- Copyrighted and trademarked terms where uppercase is the expected form.

Italics are used for:

- Titles of other documents.
- Minor emphasis within normal text.
- Table and figure titles.

Bold is used for:

- Headings.
- Text that needs to be delineated from surrounding text.
- Program interface buttons, fields, screens, windows, and menus.
- Especially important information such as warnings, cautions, and notes.

Double quotation marks are used for:

- Section names in cross-references.

Formatting Convention for Software Commands

The formatting convention used to convey a sequence of one-step software commands is **First Level > Second Level**, with each level shown in bold and separated from the preceding level by an arrow (**>**). To indicate selections from a dialog box, the selection names are shown in bold, but without arrows.

For example:

- From the main screen of the Erytra Eflexis® software, press **Others > Analyzer**.
- Select the **System Solution Registry** tab.
- Press the **System Solution Registry** button.
- From the **System Solution Drop-Down** menu, select **WASH_SOLUTION_A**.

Definitions

- **Grifols diluent:** Is a generic name to designate the diluent manufactured by Grifols for preparing human red blood cell suspensions or others dilutions used with the Grifols gel cards. Please contact to Grifols service representative for further information.
- **Grifols System Solution:** Is a generic name to designate the A and B solutions manufactured by Grifols for the washing of the Grifols analyzers' fluidic system. The Grifols System Solutions must be diluted prior to use. Please contact to Grifols service representative for further information.

- **Grifols gel card:** Is a generic name to designate the gel card of 8 microtubes manufactured by Grifols. Please contact to Grifols service representative for further information.
- **Grifols red blood cell reagents:** Is a generic name to designate the red blood cell reagents manufactured by Grifols for testing used with the Grifols gel cards. Please contact your local Grifols service representative for further information.

Trademarks

The following terms are trademarks:

THESE TERMS...	ARE TRADEMARKS OF...
ERYTRA EFLEXIS®	Diagnostic Grifols, S.A.
DG Gel®	Grifols, S.A.
WINDOWS	Microsoft Corporation

Any other brand names in this Instructions for Use are trademarks of their respective companies.

1 Introduction

THIS ANALYZER IS INTENDED FOR *IN VITRO* DIAGNOSTIC USE.

These Instructions for Use are intended for the users of the Erytra Eflexis® and contain all the information necessary to safely and adequately work with the analyzer.

Read all information contained herein carefully before starting to work with the equipment.

If you have any questions, contact your local Grifols service representative before starting any operation.

These Instructions for Use must be accessible at all times to all personnel who work with the analyzer.

1.1 Intended Use

The Erytra Eflexis® is a fully-automated analyzer designed to automate *in vitro* immunohematological testing of human blood utilizing gel card technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Compatibility Tests, and Direct Antiglobulin Tests.

As a standalone analyzer or interfaced to the customer's Laboratory Information System (LIS), the Erytra Eflexis® automates test processing functions and data management requirements using Grifols gel cards and digital image processing.

1.2 Principle of Operation

The Erytra Eflexis® is designed to automate all necessary operations and procedures to process gel immunohematology tests, allowing laboratories to:

- Create test profiles and optimize profile implementation in the shortest time and with the most accurate results possible.
- Increase process safety and traceability by eliminating possible identification and transcription errors.
- Increase analytical reliability by standardizing all steps, eliminating possible handling and processing errors, and interpreting the results with objective criteria.
- Reduce the danger of contamination for Operators by reducing Operator interaction with the samples and reagents during the analytical process. Operator interaction is limited to the loading and unloading of the analyzer.

In addition, the Erytra Eflexis® adapts to the needs and differing operational workflows in immunohematology laboratories, donation centers, transfusion centers, and clinical testing laboratories, as well as different work rhythms (routine, emergency) and the flow of samples processed over different shifts.

The Erytra Eflexis® automates the following gel immunohematology tests:

- ABO Red Cell and Serum Grouping.
- Rh(D) Typing.
- Antibody detection.
- Antibody identification.
- Rh phenotyping (C, E, c, e, K).
- Extensive phenotyping.
- Direct Antiglobulin test.
- Compatibility Tests (Crossmatching).

These tests are used at blood banks to assess compatibility between donors and recipients for blood transfusions, and to diagnose mother-fetus blood type incompatibilities.

The basis for all tests performed using this equipment is the reaction between the red blood cell antigen (present in the sample or reagent) and the corresponding antibody (present in the serum/plasma or reagent). This reaction causes red blood cell agglutination, which is viewed after filtering through the gel microtubes on a Grifols gel card.

1.3 Product Limitations

- The Erytra Eflexis® is only designed to automate the processing and reading of the immunohematology tests described in Section 1.2, and must not be used for any other type of test.
- The analyzer can only be used with Grifols gel cards and reagents authorized by Grifols.
- The analyzer can only work with profiles containing tests validated by Grifols.
- The analyzer can only use accessories designed and manufactured by Grifols.
- Positive identification of samples and reagents is dependent on the samples, diluent, and reagents being identified by barcodes. To ensure maximum reliability in the identification of samples, the use of barcodes containing a checksum is recommended.
- Result processing includes a review and validation step (Section 10.2). Special attention must be paid to any result containing a warning (processing incidence, special result, or doubtful or discrepant reaction), which must be reviewed individually and resolved by the Operator.

1.4 Operator Training

Use of the Erytra Eflexis® is limited to skilled personnel who have received specific training on the use of this equipment. The Operator must also have Laboratory Technician-level training and knowledge of immunohematology.

2 Safety Information

Grifols takes no responsibility for unauthorized modifications of the equipment or the software or for failure of operating personnel to heed the warnings and cautions outlined in these Instructions for Use.

2.1 Warnings and Cautions

Before operating the equipment, review and become familiar with these warnings and cautions. Adherence to the warnings and cautions will help protect you, your colleagues, the equipment, the test results, and ultimately your patients.

2.1.1 Health and Safety Notices

WARNING: Use the analyzer only for the operations described in these Instructions for Use.

WARNING: Unless specifically instructed to do so, do not drop or put anything into any opening in the analyzer.

WARNING: Do not use the analyzer if it is not working properly or if it is damaged.

Examples of damage include:

- Damage caused by dropping the analyzer.
- Damage caused by spilling liquid on or into the analyzer.
- Damage caused by transport or storage under conditions outside of the transport or storage conditions listed in Section 3.1 or severe stresses during transport.
- Damage to the power cord or its plug.

WARNING: Do not use the analyzer in the presence of flammable gases or volatile products. Do not put flammable, explosive, or chemical materials into the analyzer.

WARNING: Inappropriate use of this analyzer can increase the risk of personal injury or damage to the equipment.

WARNING: The centrifuge has not been designed as a biosafe system. It should not be used for centrifuging hazardous materials which are known or suspected to be contaminated with toxic, radioactive, or biosafety hazards.

WARNING: Chemical and Biological Hazards: Appropriate safety precautions must be followed. Appropriate personal protective equipment must be worn when working with hazardous materials in and around the equipment. Dispose of chemical and biological waste, including empty sample and reagent containers or tubing, in accordance with regulatory requirements. In the event of a spill of sample or reagent material, follow appropriate protocols for spill response and disposal.

WARNING: Take appropriate precautions when working with potentially hazardous materials, including the following circumstances:

- When handling samples. Treat these as potentially infectious material.
- When working with liquids in and around the equipment.
- When handling waste and waste containers. They may contain biohazardous waste.
- When performing maintenance activities always wear appropriate protective equipment when working with hazardous materials.

WARNING: Any part of the analyzer that comes into contact with blood, serum samples, or any other biological liquid should be treated as potentially infectious.

WARNING: Fuses must only be replaced by Qualified Technician.

CAUTION: Do not use accessories which are not designed and manufactured by Grifols. To order accessories, contact your local Grifols service representative.

CAUTION: The analyzer may only be disassembled by Qualified Technician. Before disassembling, the equipment must be unplugged.

CAUTION: The use of the Erytra Eflexis® for any procedure other than those procedures specified by the manufacturer shall automatically invalidate any type of warranty.

CAUTION: This equipment must be used only by Supervisors, Operators, or Qualified Technician.

CAUTION: For the correct performance of the instrument, it is important that:

- The barcode labels are adhered securely to the tubes, vials, or bottles.
- The barcode labels are not hand-written or defective.
- The barcode labels are correctly positioned facing the identification window.
- The specifications described in Section 3 are complied with.

2.1.2 Results Reliability Notices

CAUTION: Erytra Eflexis® results must be reviewed and validated by an Operator with the appropriate rights.

CAUTION: Results must be reviewed following the Instructions for Use of Grifols gel cards.

CAUTION: If a sample barcode is entered manually by using the virtual keyboard or an external barcode reader, the results could be incorrectly assigned to the wrong sample ID. The user is responsible for ensuring that entered barcode data are correct.

CAUTION: In any case, the system requires double blind entry for all manually entered barcodes.

2.1.3 Electrical Notices

WARNING: To avoid risk of electric shock, the analyzer should be connected to a grounded power outlet.

WARNING: In the event that cleaning solution or other liquids are spilled into the analyzer, the analyzer must be unplugged, cleaned, and decontaminated. The analyzer must only be disassembled by Qualified Technician and it must not be plugged in again until it has been fully inspected by Qualified Technician.

WARNING: Do not remove the service or cover panels as serious injury or electrical shock may result.

WARNING: No tool should be used to remove components or to access internal parts without first disconnecting the analyzer from the power supply.

WARNING: The instrument should not be placed next to or stacked on top of other equipment that is not included in the system. If the analyzer needs to be placed next to or on top of other equipment,

verify normal operation in that configuration.

WARNING: Do not let the equipment or its power cord come into contact with hot surfaces.

CAUTION: Do not use this device in close proximity to sources of strong electromagnetic radiation, as these can interfere with the proper operation of the instrument.

WARNING: Electromagnetic compatibility and electrical safety tests have been performed using the power cord supplied by the manufacturer. Using a power cord other than the one provided with the reader, may result in increased electromagnetic emissions and/or compromise the performance of the reader. If another power cord is used, observe the reader and other instruments nearby to verify that performance is not affected.

2.1.4 Installation Notices

WARNING: Any unpacking, packing, or transport of the Erytra Eflexis® must be carried out by Grifols service representative.

WARNING: The instrument must be decontaminated before transport or storage.

CAUTION: This equipment shall only be installed by Grifols service representative.

CAUTION: Only the original packaging should be used to pack the instrument for transport or storage.

CAUTION: Exposure to intense light should be avoided as this could affect the operation of the analyzer.

CAUTION: Keep the air outlets free of any dirt or obstruction, such as threads, hair, dust, etc.

CAUTION: Do not use the analyzer outside of the specified working conditions.

CAUTION: Do not place the instrument outdoors.

CAUTION: The drawers when opened require 18 inches (46 cm) of space in front of the instrument.

CAUTION: Do not put the instrument in a location that would make it difficult to access for maintenance purposes or for Technical Service work.

CAUTION: Do not put the instrument in a location that would make it difficult to use the power switch.

CAUTION: Make sure that the instrument is completely level and with no obvious slant.

CAUTION: The operating conditions stated in Section 3.1 relate to the instrument only. Refer to the Instructions for Use of the reagents to be used with the Erytra Eflexis® for additional information regarding their environmental conditions of use. Do not use the Erytra Eflexis® outside the specified operating conditions.

CAUTION: If the instrument has been stored under environmental conditions different to those of the working area, it must remain under the working area environmental conditions for no less than an hour before being plugged in.

⚠	**CAUTION:** Do not allow the instrument or its network cable to come into contact with surfaces that are too hot to touch.
⚠	**CAUTION:** Do not place the instrument where it could get wet.
⚠	**CAUTION:** Do not place any object on the instrument.
⚠	**CAUTION:** Check that the electrical installation the instrument will be connected to meets the rules and regulations of electrical input and use (including the earthed connection).
⚠	**CAUTION:** Make sure that the instrument is completely level and with no obvious slant.

2.1.5 Software Operational Notices

⚠	**CAUTION:** To avoid the loss of data due to a temporary corruption of the system, make a backup copy of the results stored in the Erytra Eflexis® Database on a regular basis.
⚠	**CAUTION:** If an error occurs during the execution of a backup, an error message will appear on the screen. If the problem persists, contact your local Grifols service representative**.**
⚠	**CAUTION:** Grifols has validated tests and profiles with the approved reagents. These tests and profiles are locked and may not be modified.
⚠	**CAUTION:** The profiles, reagents, and results that appear on the screenshots of these Instructions for Use have been included as examples only.
⚠	**CAUTION:** To ensure the correct management of traceability and expirations, make sure that the hour and date settings match your geographical location. For more information, contact your local Grifols service representative.
⚠	**CAUTION:** Backup the **Database** before restoring it. To do this, follow the instructions described in Section 14.1.8.

2.1.6 Analyzer Operational Notices

⚠	**WARNING:** To avoid injury, do not open the door while tests are being processed.
⚠	**WARNING:** The probe pose a biological risk because their ends are sharp and they are in contact with samples and reagents. Use caution when touching the probe.
⚠	**CAUTION:** Only OEM parts (including reagent containers, System Solution containers, and waste containers) may be used with the analyzer.
⚠	**CAUTION:** Incorrect results can occur when the wrong type of System Solution is placed in the wrong System Solution container (A or B) causing potential carryovers and/or level detection malfunction.
⚠	**CAUTION:** The use of different System Solutions or solutions with a concentration different from what is specified can cause cross-contamination by insufficient washing and can cause incorrect results.
⚠	**CAUTION:** Do not use System Solutions after their expiration date. The use of degraded System

Solution can cause cross-contamination by insufficient washing and can cause incorrect results.

CAUTION: Avoid dropping or banging the holders, as the holders are fragile and may come apart or break. If a holder comes apart after being dropped, it should not be put back together or reused. Do not use a holder if it is not intact.

CAUTION: Do not use a non-specified holder in the instrument.

CAUTION: If any deformity of the tubing, connectors, or the System Solution containers is observed, discard them and replace them with new ones, as they could cause significant damage to the analyzer.

CAUTION: The door should only be used in the cases described in Section 2.1.9 and should not be used under normal working conditions. Opening the door during the execution of a workload is not allowed by the software as it interrupts, and cuts off the power to, the modules on that level and cancels the tests in progress, resulting in loss of information and possible unexpected analyzer behavior.

CAUTION: To assure positive identification of reagents and samples, the opening of the upper door results in the loss of reagent and sample identification information. Reagents and samples are re-identified when closing th upper door.

NOTE: Each System Solution container has a unique position inside of the Erytra Eflexis® analyzer in order to avoid the possible interchange of these containers inside of the analyzer. Only waste containers 1 and 2 are exchangeable between them. Contact your local Grifols service representative for installation.

2.1.7 Grifols Gel Card and Reagent Notices

CAUTION: To handle gel cards, follow the Grifols gel card Instructions for Use.

When preparing and loading gel cards, ensure the following:

- The gel card foil seal is in place and correctly aligned.
- The gel card is placed in the card holder with the proper barcode orientation.
- The gel cards being processed should only be manually removed from the Erytra Eflexis® under error conditions and directions from the software.

CAUTION: Incorrect results can occur when incorrect samples barcodes are manually entered. The user is responsible for ensuring that manually entered barcodes are correct.

CAUTION: Remove the caps from the vials and bottles before loading them into the analyzer.

CAUTION: Do not keep the Grifols gel cards, diluent, or reagents inside the analyzer for an extended period of time as the conditions may not be optimal for storage. See the Instructions for Use for the Grifols gel cards and reagents for further information.

CAUTION: To handle Grifols gel cards, diluent, and reagents, follow the corresponding Instructions for Use.

CAUTION: To avoid spills inside the analyzer, do not use vials which are too full.

CAUTION: To execute tests correctly:

- Load re-suspended red blood cells reagents only.

- The vials must be completely dry and with the barcode label in good condition.

CAUTION: The Grifols gel cards should be loaded into the Erytra Eflexis® in the original packaging after removing the lid, if present.

CAUTION: Do not use the locations designated as Service Racks to load Grifols gel cards. The Service Racks are used by the analyzer to hold only those Grifols gel cards which must be reviewed or those Grifols gel cards with unused wells for reuse by the analyzer.

CAUTION: Review the Grifols gel cards discarded in the Service Rack, as they may have a result with an incidence or a special result associated with them (see Section 10.3.3).

CAUTION: The exchanging of caps or the incorrect placement of the System Solution containers could be a source of cross-contamination between the reagents and/or the samples and could lead to incorrect results.

CAUTION: Cover the reagents and save or discard them according to their Instructions for Use.

CAUTION: When removing Grifols gel cards from the Service Racks, make sure not to discard any gel cards that have results that need review.

CAUTION: The presence of foam, bubbles, or drops on the reagent vial walls may affect the dispensing of the reagent, causing a possible error in the results.

2.1.8 Sample Notices

CAUTION: Before loading samples into the analyzer, confirm that RBCs are centrifuged. Only centrifuged samples must be used.

CAUTION: The use of the following samples may lead to false positive readings or cause problems during sample analysis. Do not use such samples:

- Samples that are hemolyzed, lipemic, or icteric.
- Samples that are cloudy.
- Samples with clots, fibrin, or particles.
- Frozen samples that have not been centrifuged.
- Old samples (collection time > 7 days).
- Samples with insufficient volume.
- Samples with an incorrect proportion of plasma to cells.
- Samples with a serum separator.

CAUTION: The presence of foam, bubbles, or drops on the sample tube walls may affect the dispensing of the sample, causing a possible error in the results.

CAUTION: Remove the caps from the sample tubes before loading them into the analyzer.

CAUTION: When a sample ID is entered manually, the positive identification function is not activated and it is the responsibility of the user to make sure that the identified samples are correctly positioned.

CAUTION: The manual identification of samples increases the risk that samples will be misidentified.

CAUTION: In order to obtain reliable results, load centrifuged samples (serum, plasma, or red blood cells) and reagents at ambient temperature.

CAUTION: Inaccurate dispensing can cause incorrect test results. The accuracy of dispensing can be adversely affected by the following:

- Incorrect labeling that causes sample tubes to appear larger than they are.
- The use of non-specified tubes (such as tubes with metal).
- The use of a cup in specified tubes.
- Incorrect detection of tube diameter.
- The use of sample tubes with a serum separator.

CAUTION: The use of sample tubes outside of the listed specifications can cause a malfunction of the instrument. To use a non-specified tube, contact your local Grifols service representative.

CAUTION: To guarantee maximum reliability during sample identification, it is recommended to use barcodes containing a checksum.

CAUTION: Confirm that the level of plasma above the surface of the cell layer in the tube is sufficient for the tests that are to be executed on that sample. A sample tube with an insufficient level of plasma should not be loaded into the instrument for processing.

CAUTION: Do not keep samples inside the analyzer for an extended period of time as the conditions may not be optimal for storage.

CAUTION: It is the responsibility of the user to load double tube samples in the positions expected by the Erytra Eflexis®. Placing them in an incorrect position can lead to incorrect results.

CAUTION: If improperly centrifuged whole blood samples are loaded into the instrument, the instrument may not be able to sample the appropriate plasma volume to produce valid test results.

CAUTION: To identify the Quality Control samples manually, enter the barcode number from the sample tube.

CAUTION: If serum is used from a red top tube, it should not contain red cells. Serum should be removed from the clotted red top tube and placed into its own clean labeled tube.

CAUTION: The reliability of a laboratory result and its interpretation depends greatly on the quality of the samples. For this reason, it is important that samples are managed properly from the time they are obtained until they are processed. Follow the guidelines listed in Section 7.2.3.

NOTE: Erytra Eflexis® has been validated to ensure that carry-over between samples or reagents is reduced to an extent that will not affect the results of the immunohematology tests. However, under certain situations (serums with very high titers) the washing and/or contaminating agent concentration may not be reduced to levels low enough to completely rule out any potential carry-over issue.

CAUTION: The Erytra Eflexis® analyzer configuration to work with the ISBT 128 barcodes of 13 digits or the non introduction of the control digit during the manual identification disable the checking of the correct identification of the sample.

NOTE: If Erytra Eflexis® is configured to identify samples with ISBT 128 barcodes of 16 digits, a check of the manual control digit introduced by using the keyboard is performed during the manual identification.

2.1.9 Functional Areas Notices

WARNING: The centrifuge within this analyzer should not be used independently. It is designed for the automatic loading and unloading of the material described in these instructions and should not be used for any other purpose.

WARNING: The centrifuges are not designed to be handled by the Operator under any circumstances.

WARNING: Grifols gel cards must be manually removed from the Service Rack.

WARNING: The Operator's normal interaction with the analyzer should be done using the drawers and racks. The use of the door is limited to:

- Resolving analyzer incidences.
- Fully unloading the analyzer.
- Maintenance purposes (cleaning or repair).

2.1.10 Maintenance Notices

WARNING: During cleaning and decontamination processes, suitable personal protection equipment must be used by the Operator.

WARNING: Cleaning of the equipment surfaces, the Dilution Station, the Washing Station of the probe shall be carried out with the equipment unplugged.

WARNING: Take care to not spill liquids into the equipment openings.

WARNING: The Waste Solution containers should be emptied regularly. Handle, label, and dispose of all liquid wastes in accordance with site procedures and local, state, and federal regulations and practices.

WARNING: Do not disassemble the instrument. If there is liquid inside the instrument, the cleaning and decontamination operation should be carried out by Qualified Technician. Contact Grifols service representative.

WARNING: Some cleaning or decontamination products, such as sodium hypochlorite solution, may be corrosive, irritating for the skin and eyes, or toxic if inhaled, absorbed, or ingested.

WARNING: The contents of the waste containers should be emptied regularly. Handle, label, and dispose of all waste in accordance with site procedures and local, state, and federal regulations and practices.

WARNING: Waste materials should be disposed of according to local regulations.

WARNING: During the use of the decontamination liquid, adhere to the following recommendations:

- The corresponding Instructions for Use.
- Laboratory security rules.
- Current local risk prevention legislation.

WARNING: If the liquid containers are cleaned with sodium hypochlorite, intensive rinses with purified water should be performed in order to remove all traces of the sodium hypochlorite before using the container again.

WARNING: Do not scrub the touch screen directly with cleaning agents as there is a danger that they will leak inside and result in an electric shock to the Operator, as well as the deterioration of the touch screen.

WARNING: Ethyl alcohol is highly flammable and irritating. Read the Safety Data Sheet (SDS) before use and follow appropriate precautions.

CAUTION: It is advisable to turn off the analyzer using the power switch during extended periods of inactivity.

CAUTION: To ensure good performance of the Erytra Eflexis®, the maintenance schedule and procedures described in Section 14 must be followed. Failure to perform the appropriate cleaning, maintenance, or **Quality Control** procedure at the necessary time can result in damaged parts, operating and/or reading inaccuracy, and/or compromised results.

CAUTION: Do not use the analyzer if the maintenance plan described in Section 14 has not been followed.

CAUTION: Before starting the cleaning and/or decontamination procedures, all samples and Grifols gel cards should be removed from inside the analyzer.

CAUTION: The acrylic plastic of the front door and side panels should always be cleaned with mild and not abrasive products, in order to avoid any scratching of the plastic. Do not use alcohol or other organic products on these panels.

CAUTION: Do not use caustic chemical agents to clean the touch screen.

CAUTION: Before performing any maintenance operations, remove all of the samples and reagents from the instrument.

2.1.11 Transport and Storage

WARNING: The instrument must be decontaminated before transport or storage.

CAUTION: Only the original packaging should be used to pack the instrument for transport or storage.

2.1.12 Disposal Notices

WARNING: The analyzer should be completely cleaned and decontaminated and all remains of samples and reagents removed before disposal.

WARNING: The analyzer contains electronics. Electronics can contain hazardous materials. Dispose of all electronics in accordance with local, state, and federal regulations.

2.1.13 Warranty Notices

CAUTION: Repairs should be carried out only by authorized personnel.

CAUTION: The use of analyzer for any procedure other than those procedures specified by the manufacturer shall automatically invalidate any type of warrancy.

2.2 Equipment Markings

The equipment is marked with the following labels:

(1) Laser product label.
(2) Biological risk from probe.
(3) Risk of injury from probe.
(4) Moving part.
(5) Identification of the containers.
(6) Identification of the positions for sample holders.
(7) Identification of the positions for reagent racks.
(8) Identification of the positions for Grifols gel card racks and orientation of the barcode.
(9) Biological risk from the Service Racks and their contents.
(10) Biological risk from the connection for emptying into the laboratory drain.
(11) Equipment packaging.
(12) Identification label showing the basic technical characteristics of the unit.
(13) Switch and connection to the electrical network.
(14) Electrostatic discharges (ESD).

The following symbols are used on the labels:

SN	Serial number
REF	Catalogue number
	Permitted temperature range during storage and transport
	Permitted relative humidity range during storage and transport
IVD	Medical product for *in vitro* diagnostics
CE	The Erytra Eflexis® analyzer meets the requirements of Directive 98/79/EC
	Year of manufacture

Indicates that the Erytra Eflexis® analyzer is subject to selective waste collection at the end of its useful life, as established by Directive 2012/19/EU on Waste Electrical and Electronic Equipment (See Section 17)

Manufacturer

(1) Laser product label

Located two in the head on the Pipetting arm and one Card Transport arm, these three labels warn of the danger posed by the barcode laser. They also contain the information required by standard EN 60825-1: "Laser product safety. Part 1: Equipment classification, requirements and safety guide."

Figure 1. Laser Product Label

(2) and (3) Labels warning of biological risk and risk of injury from the probe

These are located on the front of the Pipetting arm, where the dispensation probe is located. This probe poses a biological risk because it is in contact with samples, reagents, etc., and a risk of injury due to the sharpness of its ends.

Figure 2. Biological Risk and Risk of Injury from Probes Labels

(4) Moving parts label

Located in the centrifuge pots, this label warns of the danger of opening these elements because both provide access to moving parts that could cause injuries to the Operator while in motion.

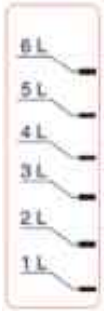
Figure 3. Moving Parts Label

(5) Container identification labels

These labels are located on the front of the unit and on the lids of the System of Waste Solution containers. They are also located on lower folding door, where they are visible when the containers are removed. Their function is to identify the contents and location of each container.

Table 1. Container Identification Labels

	Identification label for the lower folding door area of the diluted System Solution A container.
	Identification label for the front of the diluted System Solution A container.
	Identification label for the lid of the diluted System Solution A container.
	Identification label for the lower door area of the diluted System Solution B container.
	Identification label for the front of the diluted System Solution B container.
	Identification label for the lid of the diluted System Solution B container.
	Identification label for the lower door area of the Waste Solutions container, as well as to the card disposal blister.
	Identification label for the front of the Waste Solutions container. This label also warns of the biological risk of the contents.
	Identification label for the lid of the Waste Solutions container.
	Identification label for the front of the decontamination container.
	Decontamination container lid identification label.



Volume label for all System Solution containers.

(6) Identification labels for sample holder positions

Located at the base of the corresponding sample rack, these identify the relative position of the sample tube positions on the holder.

Figure 4. Sample Rack Position Labels (Left View)

Figure 5. Sample Rack Position Labels (Right View)

(7) Identification labels for the positions on the reagent racks

Located on the reagent racks themselves, these identify the relative position of the vial positions on the rack.

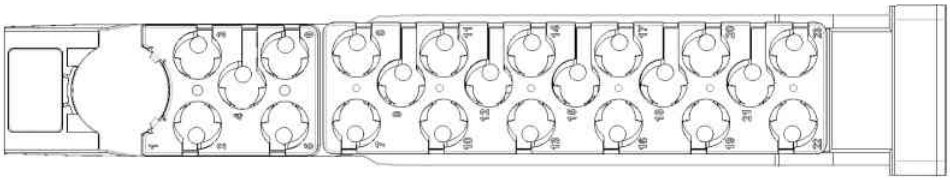


Figure 6. Reagent Racks Position Labels

(8) Identification labels for the Grifols gel card rack positions

Located at the base of the corresponding card drawers, these identify the relative position of the card racks within the drawer, and indicate how the Operator should orient the barcode.

Figure 7. Grifols Gel Card Drawer Position Label

(9) Label warning of biological risk from the Service Racks and their contents

Located at position 4 of card drawers, it identifies and warns of the biological risk posed by the cards contained in the Service Racks.

Figure 8. Biological Risk Label

(10) Biological risk from the connection for emptying into the laboratory drain

Label located on the bottom left and back of the analyzer, warning of the biological risk of the connection for direct emptying of Waste Solutions into the laboratory drain.

Figure 9. Biological Risk Label

(11) Equipment packaging label

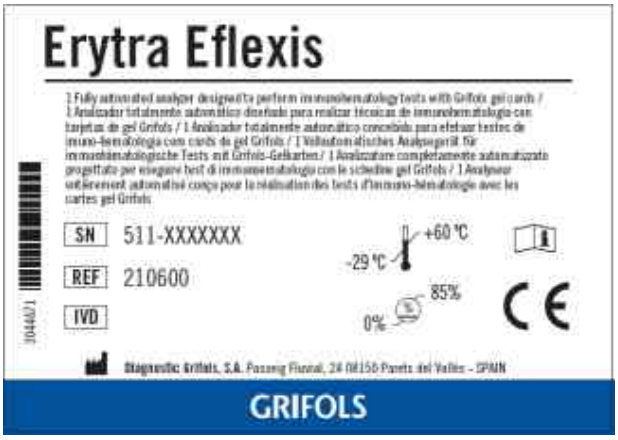


Figure 10. Packaging Label

(12) Identification label showing the basic technical characteristics of the unit

Label located on the bottom left of Solution A container of the equipment, containing technical information on the unit (network voltage, frequency, power, fuses), as well as the model, serial number, date of manufacture, name and address of the manufacturer, and compliance information.

Figure 11. Product Label

(13) Label for the switch and connection to the electrical network

Located on the bottom right and back of the analyzer, this label indicates the position of the main switch and the connector for the electrical network cable.

Figure 12. Power Switch and Power Connection Label

(14) Electrostatic discharge (ESD) label

Located next to the connections (RS 232, USB and LAN), this label warns of the risk of electrostatic discharges that could damage the analyzer, and indicates that the pins on such connections must not be touched with the hands to avoid fortuitous discharges.

Figure 13. Electrostatic Discharge (ESD) Label

2.3 Accessory Markings

(1) Biological risk from the Card Waste blister and their contents

Symbol printed on the bag itself, warning of the biological risk from the cards contained in the blister. The blisters are single-use.

Figure 14. Biological Risk Label

2.4 Read Before Using

- Use the equipment only for the purpose described in these Instructions for Use.
- Do not insert objects in any opening on the equipment, unless specified in these Instructions for Use.
- Do not use the equipment or accessories if they do not operate properly or have suffered any damage. Some examples of typical defects are:
  - Visible damage due to a fall.
  - Visible damage due to spilled liquids.
  - Visible damage due to storage in unfavourable conditions for a long time, or due to inadequate transport conditions.
  - Damage to the electrical cable or its connector.
- Do not use the equipment in a dangerous atmosphere, or with hazardous materials for which it was not designed.
- Do not use accessories other than those supplied or recommended by the manufacturer.
- Do not introduce flammable or explosive materials, or chemicals that interact vigorously, in the centrifuge.
- Keep the air outlets free of any dirt or obstruction, such as threads, hair, dust, etc.
- The network fuses must only be replaced by Qualified Technician.
- The unit may only be disassembled by Qualified Technician, for either internal cleaning and/or repair purposes. Before proceeding to disassemble the unit, unplug it from the electrical outlet.
- Disconnect the unit or leave it in an inactive state after use.

3 Erytra Eflexis® Specifications

The following sections contain information on the technical, functional specifications for the analyzer and accessories.

3.1 Technical Specifications

Table 2. Technical Specifications

FEATURE	TECHNICAL SPECIFICATION	
MODEL	Erytra Eflexis®	
POWER SUPPLY	**Voltage:**	100-240 V ~
	Frequency:	50-60 Hz
	Maximum input power consumption:	600 W
	Consumption in inactive state:	30 VA
	Fuses:	2 x T6.3AL 250V, 5 x 20 mm
PROTECTION AGAINST ELECTRIC SHOCKS	**Class:**	I
INSTALLATION CATEGORY	Overvoltage category II (local levels, instruments, portable equipment, etc.)	
DIMENSIONS	710 mm (depth) x 1100 mm (width) x 910 mm (height) without touch screen	
WEIGHT	Approximately 173 kg	
OPERATING CONDITIONS	Indoor use	
	Temperature:	15 ºC to 30 ºC
	Maximum relative humidity non condensing:	85%
	Maximum altitude:	3000 m
	Power supply maximum voltage fluctuations:	±10% of nominal voltage
TRANSPORT AND STORAGE CONDITIONS	**Temperature:**	-29 ºC to 60 ºC
	Maximum relative humidity non condensing:	85%

CAUTION: The operating conditions stated in the preceding table, relate to the instrument only. Refer to the Instructions for Use of the reagents to be used with the Erytra Eflexis® analyzer, for additional information regarding their environmental conditions of use. Do not use the Erytra Eflexis® analyzer outside the specified operating conditions.

WARNING: Do not use this device in close proximity to sources of strong electromagnetic radiation, as these can interfere with the proper operation.

3.2 Functional Specifications

Table 3. Functional Specifications

MODUL	SPECIFICATION
Sample Station	
Sample loading capacity	Up to 72 tubes simultaneously
Sample loading system	Up to 6 removable holders with 12 positions
Continuous sample loading	Yes
Emergency sample management	Yes
Sample containers	Generically, plastic or glass tubes with the following dimensions: 9 ≤ Ø ≤ 16 mm and length ≤ 100 mm
Positioning of the samples	Continuous and random in samples racks
Sample identification	• Automatic by barcode reading. • Manual with identification.
Positive sample identification	Yes
Number of probes	1
Minimum sample volume	250 µL
Sample dilution	Yes, by using the Grifols diluent
Grifols diluent	Diluent authorized by Diagnostic Grifols, S.A.
Dilutions	Yes, using a Dilution Station with a self-washing cup
Level detection	Yes, on the probe
Correct aspiration detection	Yes, on the probe. Automatic and in real time, with obstruction detection
Sample barcode type	• Interleaved 2 of 5. • Code 3 of 9. • Codebar. • EAN 8 / EAN 13 / JAN 8 / JAN 13.

	• Codes 128 A, B & C (ISBT 128). • Others under configuration.
ISBT barcode management and interpretation	Yes
Reagent Station	
Reagent positions	Up to 46 positions
Reagent agitation	Yes, up to 34 positions
Reagent loading system	Through up to 2 removable, independent and random-access racks
Authorized reagents	• Grifols reagents. • Reagents authorized by Diagnostic Grifols, S.A.
Reagent vials	17 ≤ Ø ≤ 21.3 mm diameter
Automatic Reagent Identification	Yes, by barcode reading
Positive reagent identification	Yes
Minimum reagent detection volume	5% of the volume of the reagent in the vial, with a minimum of 225 µL
Dead reagent volume	• Grifols reagents: 225 µL. • Grifols diluent:7,5 mL. • Others: 1 mm over the bottom of the tube.
Level detection	Yes, on the probe
Correct aspiration detection	Yes, on the probe. Automatic and in real time, with obstruction detection
Card Station	
Gel card loading capacity	A maximum of 200 cards
Card loading system	Grifols gel card racks, directly in the 2 independently opening drawers
Continuous gel card loading	Yes
Number of different gel card types on board	Up to 8
Incubator	
Incubation temperature	24 ºC 37 ºC
Incubation time	15 minutes (if appropriate)

Number of incubators	3 independent incubators
Incubator capacity	12 cards
Centrifuges	
Number of centrifuges	2 independent centrifuges
Centrifugal capacity	12 cards
Centrifugation time	9 minutes
Reading Station	
Reading system	High-resolution color reading using a colour CCD camera
System Solutions and Waste Solutions	
System solutions	• System Solution A diluted for the fluidic system. • System Solution B diluted for external washing and final washing of the fluidic system.
Containers	• 1 container for System Solution A. • 1 container for System Solution B. • 2 containers for Waste Solutions. • 1 blister for processed gel card disposal. • Option to double the capacity of System Solution A and B with the external liquid waste drainage configuration activated.
Waste liquid drainage	Option to drain waste liquid directly to the laboratory sink
Container capacity	6 liters (each)
Container weight (when full)	≤ 6 kg
Container monitoring	Yes, by monitoring the volume by weight
Capacity of the card disposal blister	Up to 100 gel cards
Others	
LIS connectivy	Yes • Unidirectional. • Bidirectional.
LIS connectivity mode	• Query All. • Query by Sample.
Total speed	50 Grifols gel cards/hour
Useful life	7 years
Disposal material	No

Outputs to peripherals	Standard interfaces: • 3 RS 232 connection. • 8 USB ports. • 2 LAN connection.
Remote connection	Yes. To authorized Operators by using the website Erytra Eflexis® software application. It provides access to: • **Worksheet**. • **Results**. • **Database.** • **Quality Control**. • User management. To Qualified Technician by using the Team Viewer for: • Support and maintenance purposes.

3.3 Program Specifications

The Erytra Eflexis® analyzer presents an integrated computer with the software preinstalled. The main characteristics of the Erytra Eflexis® analyzer software are:

- Execution of immunohematology tests.
- Digitalization and Image processing to obtain the reaction grade of the reaction.
- Validation and report making, including the exporting of results to the LIS (Laboratory Information System).
- **Database**.

Other characteristics and services offered by the whole system:

- A color-coded user friendly interface which aids and improves the understanding of the information and its analysis.
- Grouping of tests by profile and the simultaneous programming of the profile to a sample.
- Management of requests through the **Worksheet**.
- Validation by profiles of tests.
- Exporting of results to the **Database** and/or to the LIS.
- Availability of alarm algorithms that allow the detection of incidences when processing, reading and/or in the later results.
- Display of analyzer status and autonomy (System and Waste Solutions, gel cards, reagents, etc.) and of the sample petitions.
- Real-time display of the incubation and centrifugation steps.
- Management of reagent lots, allowing you to work with different reagent lots simultaneously.
- User access control.
- Total traceability of results: Users, analyzer, batch of reagents, reader, etc.
- Bidirectional interface with ASTM protocol (compatible with LIS).
- Remote connection via http protocol which allows the validation and access to **Database** Results remotely.

3.4 Regulations

The Erytra Eflexis® analyzer is CE marked in accordance with the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

4 Description of the Erytra Eflexis® Analyzer

This section provides a description of the Erytra Eflexis®, including the basic Operating Principles, the overview of the analyzer, the description of the Instrument Components and the Accessories.

4.1 Basic Operating Principles

The Erytra Eflexis® automatically performs the steps described in the procedures for most gel immunohematology tests:

- Positive sample identification to ensure that the results will be correlated with the sample barcodes at all times.
- Positive reagent and diluent identification.
- Positive Grifols gel card identification.
- The transporting of Grifols gel cards between the different modules in the instrument.
- Sample dilution.
- The dispensing of serum and/or plasma into the microtubes of the Grifols gel cards.
- The dispensing of suspensions into the microtubes of the Grifols gel cards.
- The incubation of the gel cards.
- The centrifugation of the gel cards.
- The reading and semi-quantification of the reaction grade in the Grifols gel card microtubes.
- The interpretation of the results.
- The data analyzed can be stored, displayed, validated, and printed. In addition, the analyzer provides integrated features, such as STAT analysis and a **Quality Control**.

4.2 Overview of the Erytra Eflexis® Analyzer

The Erytra Eflexis® analyzer can be divided into 2 well differentiated levels.

- Upper level: Area designed to hold the Reagent Station, the Sample Station, the Card Station and its management (selection, load, read, centrifugation and storage of processed cards for review) and the Dilution Station. The dispensing of reagents and samples in the microtubes of the cards is done directly in the incubators at the middle part of this level by means of a Pipetting arm with 1 probe. The movement of the Grifols gel cards is done by means of a Card Transport arm fitted with a clamp.
- Lower level: Stores the System Solutions, the Waste Solutions and the card waste drawer. This level also contains the **Start** button and USB connections.

Figure 15. Overview of the Erytra Eflexis® Analyzer

(1) On/Off switch (at rear).

(2) **Start** button.

(3) Upper door of the analyzer which allows access to the upper level for service access.

(4) Lower door of the analyzer for access to the lower level.

(5) Push-buttons for opening drawers and racks.

(6) Touch screen.

(7) Traffic light.

(8) Connection for the emptying of Waste Solutions into the laboratory drain (at rear).

4.2.1 Commands and Controls

4.2.1.1 On/Off Switch

The master switch is on the back right (Figure 15, no. 1) of the instrument and controls the electrical mains power input. It has two positions:

1. **|:** On (to the left when facing the front of the instrument).
2. **O:** Off (to the right when facing the front of the instrument).

It is advisable to turn off the analyzer at this switch during long periods of inactivity.

4.2.1.2 Start Button

The **Start** button is found on the front right hand side of the analyzer (Figure 15, no. 2) and it is in charge of turning on the Erytra Eflexis® analyzer instrument. It has a green light indicator which shows if the instrument is on or off (ON/OFF).

4.2.1.3 Upper Door

The Erytra Eflexis® analyzer has a top door (Figure 15, no. 3) that automatically slides up allowing access to the whole internal surface area of the analyzer: Pipetting arm, Dilution Station, Sample Station, Reagent Station, Card Station, Centrifuges, Incubators and Reader. Its use is reserved for servicing, such as cleaning its inside.

A button found on the main menu of the Erytra Eflexis® analyzer software (Figure 23, no. 4) opens the upper general door.

WARNING: The Operator's normal interaction with the analyzer should be done using the drawers and racks. The use of the upper door is limited to:

- Resolving analyzer incidences.
- Maintenance purposes (cleaning or repair).

CAUTION: The upper door should only be used in the cases described above and should not be used under normal working conditions.

Opening a door during the execution of a workload interrupts, and cuts off the power to, the modules on that level and cancels the tests in progress, resulting in loss of information and possible unexpected analyzer behavior.

CAUTION: To maintain positive identification of reagents and samples, the opening of the upper door results in the loss of reagent and sample identification information. Reagents and samples have to be re-identified by opening and closing their respective drawers and racks.

4.2.1.4 Lower Door

The Erytra Eflexis® analyzer has a lower folding door (Figure 15, no. 4) which allows total access to System Solution containers and waste bottles, as well as to the Card Waste blister at any time. This door opens by pressing the front of the door to release it and then pulling it out.

4.2.1.5 Push-Buttons for Opening Drawers and Racks

The analyzer has push-buttons (Figure 15, no. 5) on the front of the instrument which, once the software is running, allow the reagent and sample racks and the drawers in the Card Stations to be opened.

Push-buttons 1 and 2 provides access to optionals Reagent or Sample Stations; buttons 3 and 4 provide access to the Sample Station and buttons 5 and 6 provide access to the Card Station (Figure 16).

Figure 16. Push-Buttons

4.2.1.6 Push-Button to Open and Load STAT Samples

The analyzer has **STAT Loading** button  located on the push-buttons (Figure 16) on the front of the instrument which, once the software is running, allow the loading of STAT or urgent samples at any time.

4.2.1.7 Touch Screen

The Erytra Eflexis® analyzer is supplied with an integrated computer and touch screen. The position of the screen is adjustable and is installed either to the right or the left of the analyzer. The screen allows adjustment to suit individual Operators (see Section 20.1).

4.2.1.8 Traffic Light

The Erytra Eflexis® analyzer has a traffic light which allows monitoring its status from a distance. When the traffic light is green it means that the analyzer is working correctly and has all of the necessary resources to execute the programmed tests. When the traffic light turns yellow, there is a system abnormality that requires Operator attention.

If the abnormality is not corrected, the traffic light will eventually turn red, indicating that the analyzer has stopped. In this case, an acoustic alarm will also be activated.

4.2.1.9 Blue Leds on Racks and Containers

Each rack and container of the Erytra Eflexis® analyzer has a blue LED associated. These LEDs are off when the racks or containers are required by the analyzer. When the LED is on, they can be removed from the analyzer.

4.3 Description of the Instrument Components

The Erytra Eflexis® analyzer is designed to permit complete Operator flexibility to interact with it at any time. This is why the analyzer has different drawers and racks. They can be opened by using the analyzer software or by using the corresponding push-buttons which are located below them (Figure 15, no. 5).

Each level has the following parts:

4.3.1 Erytra Eflexis®: Upper Level

Figure 17. Overview of the Upper Level of the Erytra Eflexis® Analyzer

(1) Pipetting arm.
(2) Sample Dilution Station.
(3) Reagents and Samples Station withup to 4 separate sections.
(4) Card Transport arm.
(5) Grifols gel Card Station with 2 separate drawers.
(6) 3 incubators.
(7) Service Rack.
(8) Reusable card rack (available in further version).

4.3.1.1 Pipetting Arm

The Erytra Eflexis® analyzer has one Pipetting arm with one probe for aspiration and dispensing of samples and reagents into each Grifols gel cards (Figure 17, no. 1). The probe has a dual function: First, it perforates the protective film of the microtubes that are going to be used and, second, it dispenses the correct volume of reagents and samples into the microtubes. Depending on the test to be processed, the system may dilute the sample in the Dilution Station before dispensing.

The arm is also equipped with a sensor which detects the presence of tubes, vials and bottles, and a barcode reader for their identification.

4.3.1.2 Dilution Station

The Dilution Station is located on the upper level of the Erytra Eflexis® analyzer (Figure 17, no. 2) and is where any necessary dilution of the samples with the Grifols diluent is done, before being dispensed into the microtubes of the Grifols gel cards.

The Dilution Station has one chamber. It is also self-cleaning and does not use any disposable components.

4.3.1.3 Reagents and Samples Station

The analyzer allows the continuous loading and unloading of reagents and samples through up to 4 sections that are in the Reagents and Samples Station (Figure 17, no. 3).

The loading of reagents can be performed through up to 2 reagents sections that can be loaded at the positions 1 and 2 of the Reagent and Sample Station. Each Reagent Rack holds 2 stations. The small station is for the storage of reagents and diluents that do not require re-suspension while the large station is for the storage of reagents that do require re-suspension. The Reagents and Samples Station can hold up to 46 reagents vials (10 positions for reagents that do not require re-suspension and 34 for reagents that do require re-suspension) and 2 diluents bottles (Figure 6).

The loading of samples can be performed through up to 3 sample racks that can be loaded at any position of the Reagents and Samples Station. Each rack can contain 2 removable holders which hold 12 tubes each. The total capacity of the Reagents and Samples Station is up to 72 sample tubes (Figure 4 and Figure 5).

4.3.1.4 Card Transport Arm

The Erytra Eflexis® analyzer includes a Card Transport arm (Figure 17, no. 4) that is equipped with a gripper for the transport of Grifols gel cards. The arm is also equipped with a sensor which detects the presence of Grifols gel cards and a barcode reader for gel card identification. To activate and deactivated the Card Transport arm, consult Section 14.1.7 of this manual.

4.3.1.5 Grifols Gel Card Station

The analyzer allows the continuous loading and unloading of Grifols gel cards through the 2 drawers of the Grifols gel Card Station (Figure 17, no. 5). Each drawer can hold 4 Grifols gel card racks. The total capacity of the Grifols gel Cards Station is 8 racks, including the Service Racks. The Grifols gel card racks can be loaded directly into the Erytra Eflexis® analyzer in their original packaging (without the lid is present), exactly as they are delivered by the manufacturer Diagnostic Grifols, S.A.

NOTE: The instrument performs a Grifols gel card recount each time that the drawer is closed by reading their barcodes. To speed up the identification process, the instrument reads the first gel card in the holder and then assumes that the rest of the gel cards in the holder are of the same type (during test processing each Grifols gel card will be identified individually). If the instrument cannot read the first Grifols gel card, it then attempts to read the next two cards. If it cannot read any of the first three Grifols gel cards, the cards in that holder appear in red on the **Status > Cards** screen (Figure 33) and cannot be used for test processing until they are identified by the instrument.

4.3.1.6 Service Racks

The Erytra Eflexis® analyzer has Service Racks (Figure 17, no. 7) to store Grifols gel cards that have a process incidence or a result incidence associated with them, so that they may be physically reviewed by the Operator.

The analyzer also stores partially used gel cards in the Service Rack so that they are available for the instrument to reuse.

All the cards left in the Service Rack will have the following icon associated  , once their detailed results are displayed on the **Results List**.

Each time a Service Rack drawer is opened and closed, the instrument attempts to identify all of the Grifols gel cards in the Service Racks.

The number of Service Racks in the analyzer can be configured. For more information, please contact your local Grifols service representative.

4.3.1.7 Incubators

The Erytra Eflexis® analyzer has 3 independent incubators (Figure 17, no. 6) located on the middle of the upper level. Each incubator is made up of a block of 12 positions for Grifols gel cards. These incubators can be set to incubate at either 24 ºC or 37 ºC, depending on the need at the time and on the tests to be performed.

The incubation will be done at the temperature and for the amount of time defined by the test to be performed.

It is possible to configure that none of the incubators is reserved for the processing of the STAT samples. For more information, contact your local Grifols service representative.

Should any of the incubators become disabled; the Erytra Eflexis® software can continue functioning with the rest of the incubators. To activate and deactivated incubators, consult Section 14.1.7 of this manual.

4.3.1.8 Centrifuges

The Erytra Eflexis® analyzer has 2 independent centrifuges situated under the upper level. Each centrifuge can hold 12 Grifols gel cards and is programmed to centrifuge Grifols gel card*s* according to the parameters defined by the test.

The Card Transport arm positions the Grifols gel cards in a precise manner in each of the baskets of the head of the centrifuge. When the number of Grifols gel cards to be centrifuged is not even, the instrument takes a supplementary unprocessed card from one of the racks of available unprocessed Grifols gel cards to balance out the load in the centrifuge. This balance card will be returned to its original position when the centrifugation step has ended.

⚠ **CAUTION:** The centrifuges within this instrument should not be used independently. They are designed only for the automatic loading and unloading of the materials described in these instructions and should not be used for any other purpose.

⚠ **CAUTION:** The centrifuges are not designed to be handled by the Operator under any circumstances.

Should one of the centrifuges become disabled, the Erytra Eflexis® software can continue functioning with the remaining centrifuge. To activate and deactivated incubators, consult Section 14.1.7 of this manual.

4.3.1.9 Reader for Image Processing

The reader for image processing is situated on the lower level of the Erytra Eflexis® analyzer and uses a color CCD camera to capture and process Grifols gel card images. This allows the instrument to determine the reaction grade in each microtube and to apply the necessary algorithms in order to ensure a correct result.

The reader also captures the images of the gel card wells before the card is processed, to check the initial state of the gel in the microtube.

4.3.2 Erytra Eflexis®: Lower Level

Figure 18. Overview of the Lower Level of the Erytra Eflexis® Analyzer

(1) 1 container for the System Solution A.

(2) 1 container for the System Solution B.

(3) 2 containers for the System Solution waste.

(4) 1 Disposable Container for the card waste.

4.3.2.1 System Solution Containers

The Erytra Eflexis® analyzer uses some autoclavable, volumetrically marked (Table 1), specially designed containers for storing System Solutions A and B, Waste Solution and Decontamination Solution (Section 4.3.2). The containers have a capacity of 6 liters.

The unloading of the lower level containers should be done by the analyzer software or by manually removing them when the containers leds are switched on. For more information, see Section 5.3.

It is possible to configure the Erytra Eflexis® to drain waste liquids directly to the laboratory sink. This configuration also allows placing System Solution containers in the waste containers, which doubles the total capacity of A and B System Solutions. For more information, contact your local Grifols service representative.

NOTE: Each System Solution container has a unique position inside of the Erytra Eflexis® analyzer in order to avoid the possible interchange of these containers inside of the analyzer. Only waste containers 1 and 2 are exchangeable between them. Contact your Service Technician for installation.

Figure 19. System Solution and Waste Solution Container

(1) Identification label.
(2) Volumetric marking.
(3) Connector.
(4) Handle.

4.3.2.2 Disposable Container for Card Waste

The Disposable Container for Card Waste is a single-use plastic container for the storage of gel cards discarded by the Erytra Eflexis® analyzer. The total capacity of the tray is 100 gel cards.

Figure 20. Disposable Container for Card Waste

(1) Disposable Container for Card Waste.
(2) Cover.
(3) Tabs.

4.4 Moving the Instrument for Relocation or Storage

WARNING: Any unpacking, packing, or transport of the Erytra Eflexis® must be carried out by your local Grifols service representative.

WARNING: The instrument must be decontaminated before transport or storage.

CAUTION: Only the original packaging should be used to pack the instrument for transport or storage. To relocate the instrument or to put the instrument into storage, contact your local Grifols service representative.

4.5 Accessories

Table 4. Accessories

CODE	NAME	DESCRIPTION	QUANTITY
213713	Samples holder	Holder to load samples into the analyzer	1
213724	Pediatric samples holder	Rack to load pediatric samples into the analyzer	1
210601	Erytra Eflexis® rack for samples	Rack to load samples into the Erytra Eflexis®	1

CODE	NAME	DESCRIPTION	QUANTITY
210602	Erytra Eflexis® rack for reagents	Rack to load reagents into the Erytra Eflexis®	1
234179	System Solution container	Container designated to hold diluted System Solution (A or B) or decontamination solution	1
234180	Waste Solution container	Container designated to hold liquid waste generated by the Erytra Eflexis®	1
213723	Red labels for the sample racks	Labels with barcodes to configure the sample racks according to the tube type	1
213791	Grey labels for the sample racks	Labels with barcodes to configure the sample racks according to the main tube type	1
213798	Yellow labels for the sample racks	Labels with barcodes to configure the sample racks according to the main tube type	1
210603	Erytra Eflexis® Card Waste Container	Disposable container for card waste	1
213796	DG Clean Erytra® Rack Adaptor	Adaptor that has to be placed in the nonstirring reagent rack in order to allocate the DG Clean reagent	1

In addition to the accessories listed above, the following components can be used with the Erytra Eflexis® analyzer:

- An external barcode reader is attached to the analyzer for the identification of samples and cards.
- A printer, to print copies of the results (Section 10.7.1).

4.5.1 Grifols Bench

The Grifols Bench is an optional accessory table specially designed to facilitate the analyzer operation and increase its autonomy.

The table is equipped with:

- An area (Figure 21, no. 1) that allows increased storage capacity of potentially infectious waste material (System Solution Waste and Card Waste).
- A drawer (Figure 21, no. 2) of a suitable size to store all the material used on the Erytra Eflexis® (holders, racks, etc.) The drawer can be accessed by pulling out from the lower part of the drawer. The drawer includes a removable work table which can be used when loading and unloading the analyzer (Figure 21, no. 3).
- A “free use” area (Figure 21, no. 4) for the storage of other elements such as a small refrigerator or a printer is available.

It measures: Depth - 1324 mm, width - 804 mm and height - 818 mm.

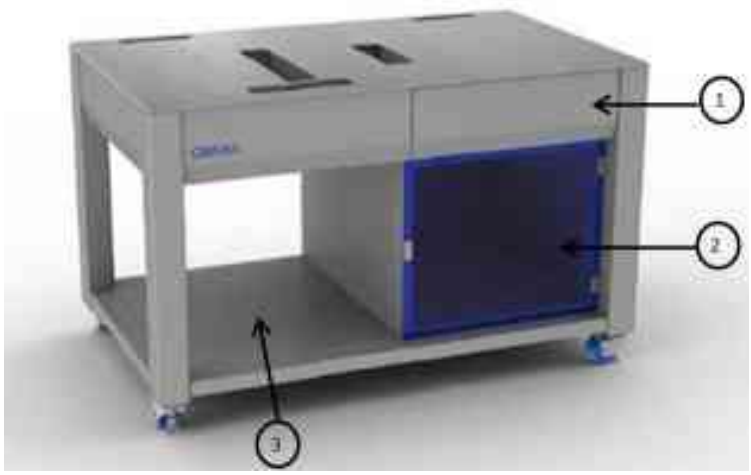


Figure 21. Overview of the Grifols Bench

(1) Waste area.

(2) Drawer.

(3) “Free use” area.

5 Description of the Erytra Eflexis® Software

This section provides a description of the Erytra Eflexis® software, including the software funtions and features, the main analyzer software screen, the opening of drawers and racks, **Virtual Keyboard**, description of **Warning Area** and the acoustic alarm.

5.1 Software Functions and Features

The Erytra Eflexis® comes with an integrated computer with the software preinstalled. The main functions of the analyzer software are:

- Execution of immunohematology tests.
- Digitalization and image processing to obtain the reaction grade.
- Validation and report making, including the exportation of results to a Laboratory Information System (LIS).
- Retention of test results in a **Database**.

The software provides the following features:

- A color-coded interface which helps with the understanding of the information and its analysis.

5.1.1 Controller and Manager

The Erytra Eflexis® software can be divided in 2 parts:

Controller: It is the part of the software in charge to manage the hardware of the analyzer to execute the immunohematology tests. The software provides the following features:

- Display of analyzer status, walk-away time (System and Waste Solutions, Grifols gel cards, reagents, etc.), and sample requests.
- Real-time display of the incubation and centrifugation steps.
- Management of reagent batches, making it possible to work with different reagent batches simultaneously.
- Maintenance management.

Manager: It is the part of the software in charge to manage results (review, modify, validate and store). The software provides the following features:

- Management of requests through the **Worksheet**.
- Grouping of tests by profile and the simultaneous programming of the profile to a sample.
- Validation by profiles of tests.
- Exporting of results to the **Database** and/or to the LIS.
- Availability of software algorithms that allow prompt detection of incidences when reading and/or in the later results.
- User access control.
- Total traceability of results: Users, analyzer, batch of reagents, reader, etc.
- Bidirectional interface with ASTM protocol (compatible with LIS).
- Remote connection via http protocol which allows the remote validation and access to **Database** Results.

CAUTION: The profiles, reagents and results that appear on the screen shots of these Instructions for Use have been included as an example only.

NOTE: The information contained in these Instructions for Use refers to the Erytra Eflexis® program 1.1 or later version.

5.2 The Main Analyzer Software Screen

Press the **Start** button (Figure 15, no. 2) to start the software. (For more information on starting the Erytra Eflexis®, see Section 7.2.1). Once the software has started and the Operator has logged in, the main screen of **Manager** displays (Figure 22).

Figure 22. Main Screen of Manager of Erytra Eflexis® Software

(1) **Controller** button (to access to the **Controller** software).
(2) **Worksheet** button.
(3) **Results** button.
(4) **Database** button.
(5) **Quality Control** button.
(6) **Others** button.
(7) **Warning Area**.
(8) **Help** button (to display the color code of the **Worksheet** shown in Figure 50).
(9) The user ID for the active user.
(10) The **Display Map** button (to display a map of the Erytra Eflexis®).
(11) The **Virtual Keyboard** button (to display the virtual keyboard).
(12) The **Shut Down** button.
(13) **User Access Control** button.
(14) The **Change Password** button.
(15) Configurable instrument name.

5.3 Opening Drawers & Racks

To open a drawer using the software:

1. Press the **Display Map** button  (Figure 22, no. 10) to display a map of the analyzer with buttons for each of the different analyzer drawers and racks (Figure 23).
2. Press the button for the drawer or rack to be opened (Figure 23, no. 1 and 2).

Figure 23. Map of the Analyzer Showing the Buttons that Opens the Analyzer Drawers, Racks and the Upper Door

(1) Buttons for Racks from 1 to 4: Access to the Reagent & Sample Station.

(2) Buttons for Drawers 5 and 6: Access to the Gel card Station.

(3) Button for access to System and Waste Solution containers and Card waste blister.

(4) Button for open the upper door.

The drawers and racks can also be opened with the push-buttons on the front of the instrument, (Figure 15, no. 5). For more information on opening drawers and racks with the push-buttons on the instrument (Figure 16).

5.4 Virtual Keyboard

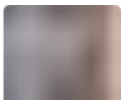
The software automatically displays a virtual keyboard to be used for entering alphanumeric characters in the fields of the software interface, for the manual identification of a sample, or for the identification of the Operator. To display the virtual keyboard, press the **Virtual Keyboard** button  located at the bottom of the touch screen (Figure 22), or press on an editable field on the touch screen.

NOTE: To move the virtual keyboard, press and drag on the top bar of the virtual keyboard.

NOTE: To close the virtual keyboard, press the **Close** button in the upper right-hand corner of the virtual keyboard.

5.5 Description of the Warning Area

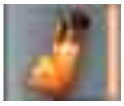
The **Warning Area** is displayed on the left hand side of the screen to let the Operator know about analyzer requirements or incidences that can be resolved by Operator intervention. If these requirements or incidences are not resolved within a reasonable amount of time, they can become high-level incidences and could cause the interruption of the process due to lack of resources. Normally, these warnings only appear when the software detects a need in one of the following resources or components for the completion of the workload.



Quality Control Warning: Derived from the Quality Policy. The warning turns on if:

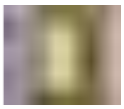
- QC Pending: The analyzer is pending the analysis of a **Quality Control** protocol for one or more profiles according to the Quality Policy and/or the programmed rate.
- QC Failed: A processed **Quality Control** has not met the programmed acceptance criteria.

To resolve this issue, see Section 12.4.2.

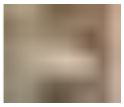


Sample Incident Warning: There are issues with the sample tubes (identification issues, lack of volume, clots, etc.) that must be resolved so that the analyzer can finish the execution of all of the programmed profiles for these samples. See Figure 29 for more information on the types of incidences that trigger the **Sample Incident Warning.**

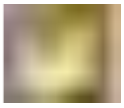
Missing Samples Warning: Some sample tubes are not present within the analyzer for the execution of the programmed profiles. To resolve this issue, see Figure 29.



Missing Reagents and/or Diluent Warning: A needed reagent and/or diluent is not available, or the volume of a reagent and/or diluent is not sufficient to finish the programmed workload. To resolve this issue, see Figure 28.

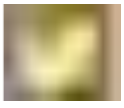


Missing Gel Cards Warning: The analyzer does not have enough Grifols cards available to finish the programmed workload. To resolve this issue, see Figure 28.

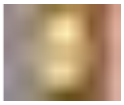


System Solution A Container Warning: The System Solution A container needs to be refilled so that the analyzer can finish the programmed workload. To resolve this issue, see Figure 34.

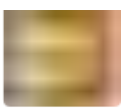
System Solution B Container Warning: The System Solution B container needs to be refilled so that the analyzer can finish the programmed workload. To resolve this issue, see Figure 34.



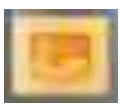
Waste Solution Container Warning: The Waste Solution containers need to be emptied so that the analyzer can finish the programmed workload. To resolve this issue, see Figure 34.



Cards Waste Container Warning: The Card Waste container needs to be emptied so that the analyzer can finish the programmed workload. To resolve this issue, see Figure 34.



Service Racks Warning: The Service Racks need to be emptied or changed so that the analyzer can finish the programmed workload. To resolve this issue, see Figure 33.



Maintenance Warning: This warning is activated under the following conditions:

- When there are one or more disabled modules.
- When there are one or more actions (decontamination procedure, Technical

Service inspection, system restart, etc.) that have expired (these appear in red in the **Summary** screen, see Section 14.1.2).

- When there is an action that is about to expire (these appear in orange in the **Summary** screen).

To resolve these issues, see Section 14.1.1 in the **Others > Analyzer** screen.

Press the activated icon to see the **Status** screen, which contains the information needed to resolve the incidence.

NOTE: When one or more of these warnings are activated, the analyzer's traffic light (Figure 15, no. 7) changes from green to yellow. Once these incidences are resolved, the analyzer status returns to normal and the traffic light turns back to green.

5.6 The Acoustic Alarm

When an error occurs in the Erytra Eflexis® analyzer, the system sounds an acoustic alarm for the purpose of alerting the nearest Operator of the error. Simultaneously, the **Alarm** icon  is activated on the screen of the Erytra Eflexis® software (Figure 24).

Figure 24. Icons Available in the Bottom Part of the Erytra Eflexis® Software

It is possible to stop the acoustic alarm by clicking anywhere within the screen or by clicking on the  icon itself.

5.7 The Fluidic Icon

When the instrument is performing a prime or a rinse, the fluidic action is shown as being currently performed by the activation of the **Fluidic** icon  on the screen of the Erytra Eflexis® software.

Figure 25. Fluidic Icon Activated in the Bottom Part of the Erytra Eflexis® Software

6 Description of the Controller Software

This section provides a description of the **Controller** software including analyzer status and **Maintenance** screens.

6.1 The Main Controller Screen

To access to **Controller** software press **Controller** button (Figure 22, no. 1) in the main screen of **Manager** (for more information on starting the Erytra Eflexis®, see Section 7.2.1. The main screen displays (Figure 26).

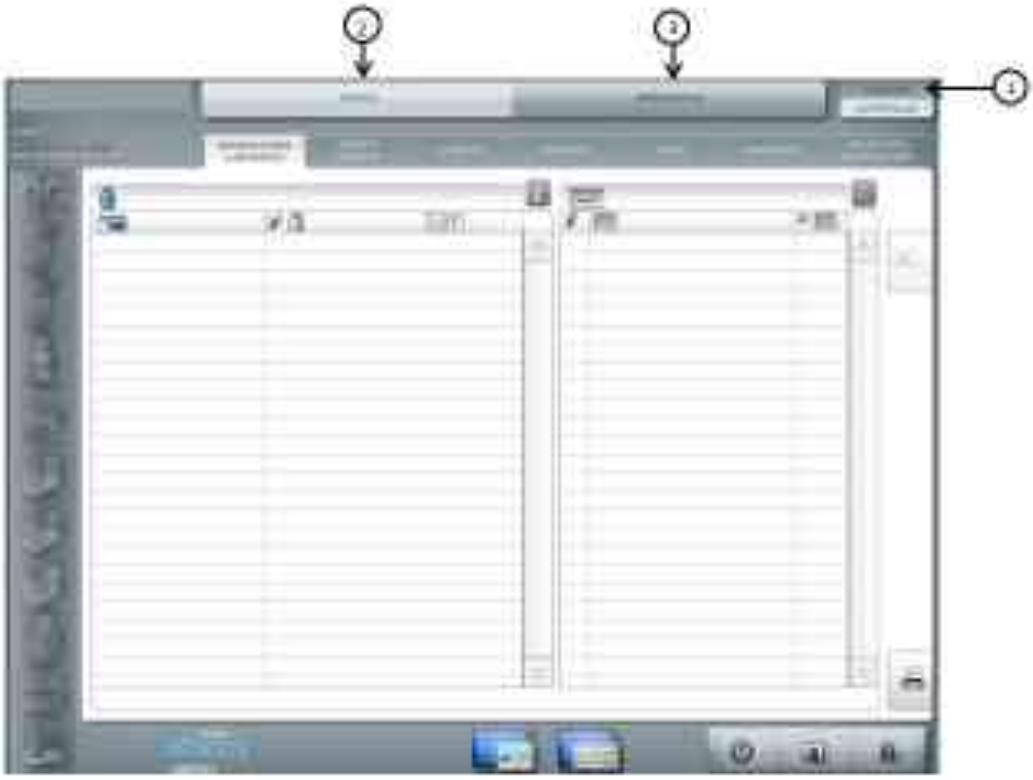


Figure 26. Main Screen of Controller of Erytra Eflexis® Software

(1) **Manager/Controller** button (to **Manager** software).

(2) **Status** button (to access to the status screens of analyzer).

(3) **Maintenance** button.

NOTE: To have information about the buttons or information displayed on the **Controller** software that are not described in this section see Section 5.2.

6.2 Status of Analyzer Screens

Press **Status** button in **Controller** main screen. The main screen displays with access to dedicated dashboards with the status of the different part of the analyzer:

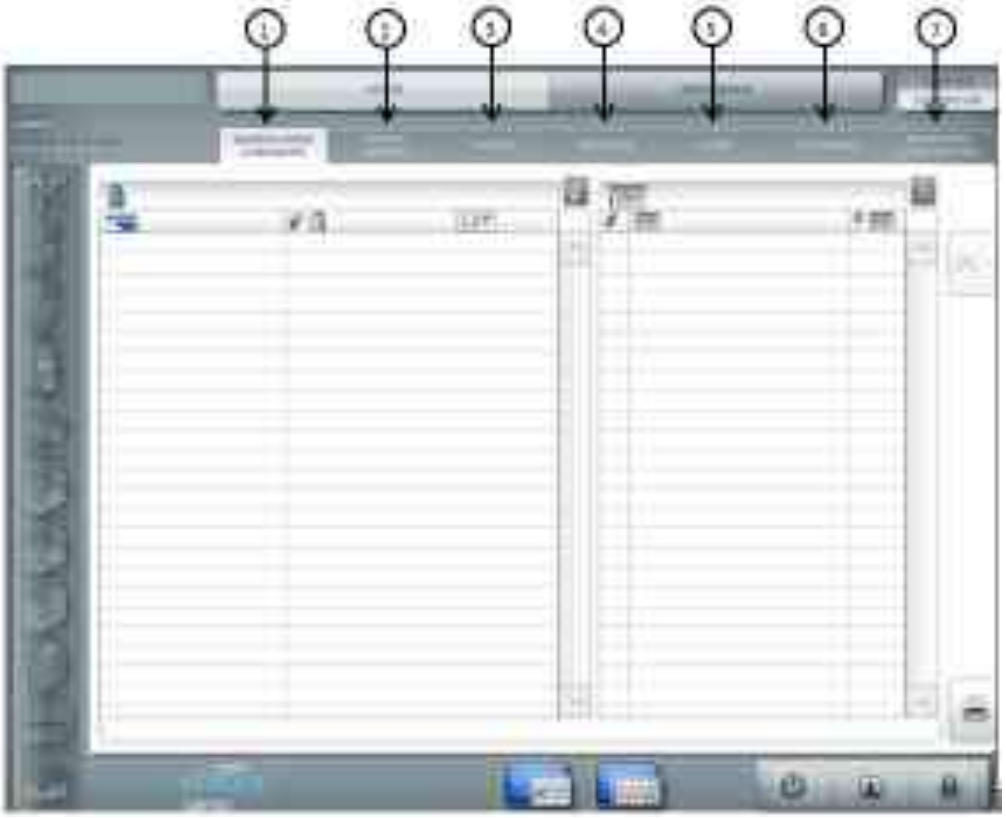


Figure 27. Main Screen of Status of the Erytra Eflexis® Analyzer

(1) **Missing Cards & Reagents** tab (to access to the required but not loaded cards and reagents information).
(2) **Missing Samples** tab (to access to the required but not available for processing samples information).
(3) **Samples Status** tab.
(4) **Reagents Status** tab.
(5) **Cards Status** tab.
(6) **Containers Status** tab.
(7) **Incubators & Centrifuges** tab.

6.2.1 Viewing Missing Cards & Reagents Information

To view detailed information of all the cards & reagents that are required to finish the workload (Figure 28) but are not loaded on the analyzer press **Status > Missing Cards & Reagents** (Figure 27, no. 4 and 5).

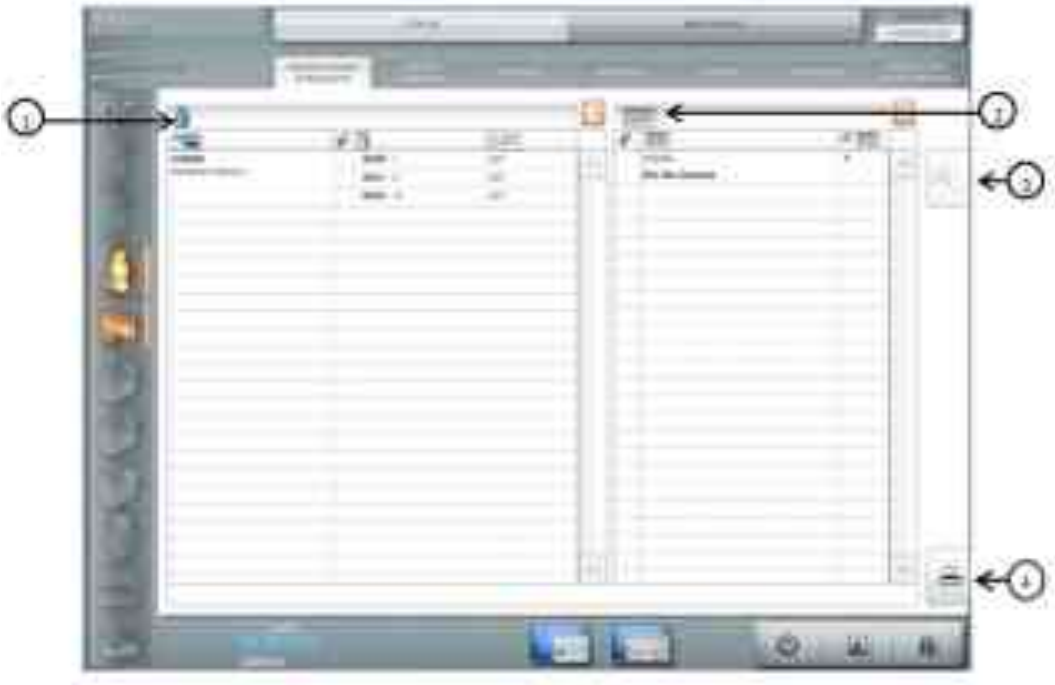


Figure 28. Status > Missing Cards & Reagents (Example)

(1)  table: Detailed information about the reagents and/or diluent that must be loaded to execute the programmed workload.

(2)  table: Detailed information about the cards that must be loaded to execute the programmed workload.

(3) **Cancel** button.

(4) **Print** button.

The following table describes the meaning of the icons in connection with the missing reagents & diluent and cards.

Icon	Description
	**Missing Reagents** warning.
	Shows the commercial code of the required reagent or diluent.
	Informs if these reagents or samples are related to process a STAT sample.
	Specifies the name and identifier code of the vial required to end the ordered workload.
	Lot of the vial required to end the ordered workload.
	**Missing Card** warning.

Shows the commercial code and name of the required gel card.

Informs about the number of cards required to end the ordered workload.

6.2.1.1 Cancel Orders

To cancel the pending requests associated to a missing resource (reagent, diluent or card):

1. Select the specific missing resource.
2. Press **Cancel** button  .

The Erytra Eflexis® will cancel all the requests linked to the selected resource.

6.2.1.2 Print Missing Resources

To print the relative information to the missing resources:

1. Select the resources of interest (reagent, diluent or card).
2. Press **Print** button  .

The Erytra Eflexis® will print the list directly through the printer without displaying in the screen.

6.2.2 Viewing Missing Sample

To view detailed information of samples that are required to finish the workload but cannot be processed by the analyzer (Figure 29) press **Status > Missing Samples** (Figure 27, no. 2).

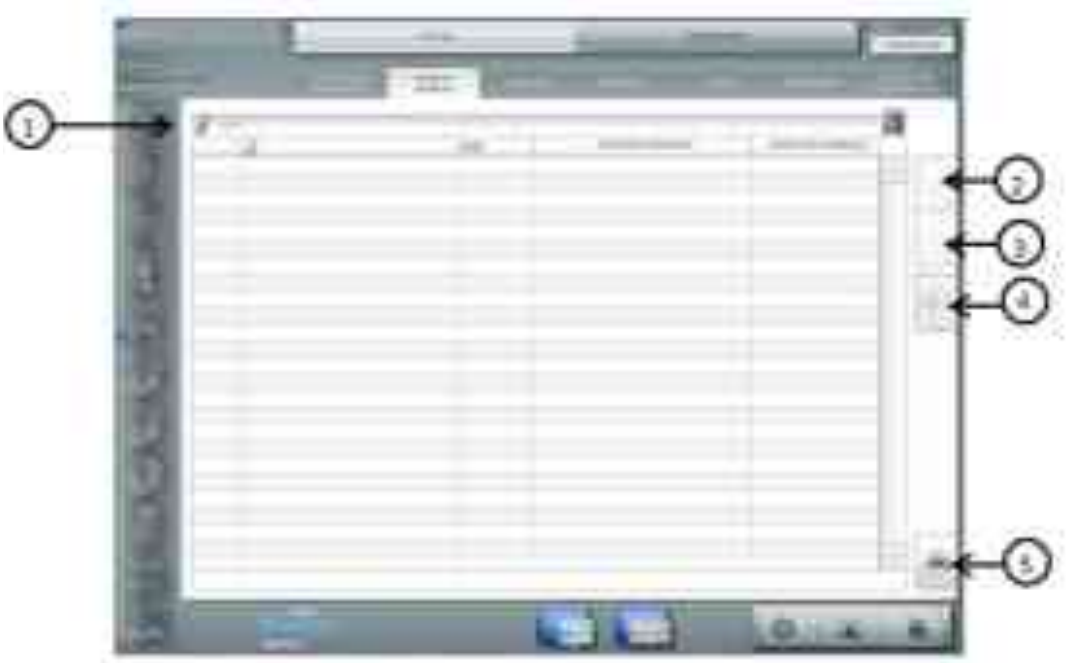


Figure 29. Status > Missing Samples (Example)

(1)  table: Detailed information about the samples that have incidences and must be solved to execute the programmed workload (affected profiles).

(2) **Select All** button (to selects all the active sample on the table).

(3) **Deselect All** button (to deselect the previous selection).

(4) **Cancel** button.

(5) **Print** button.

The following table describes the meaning of the icons in connection with the missing samples:

Icon	Description
	**Missing Sample** warning.
	Shows ID number.
	Informs about the time when the analyzer required this sample.

6.2.2.1 Cancel Orders

To cancel the pending requests associated to a missing sample:

1. Select the specific sample.
2. Press **Cancel** button  .

The analyzer will cancel all the requests linked to the selected sample.

6.2.2.2 Print Missing Resources

To print the relative information to the missing samples, press **Print** button  . The analyzer will print the list directly through the printer without displaying in the screen.

6.2.3 Viewing Sample Information

To view detailed diagram of all of the samples present within the analyzer (Figure 30), press **Status > Samples** (Figure 27, no. 3).

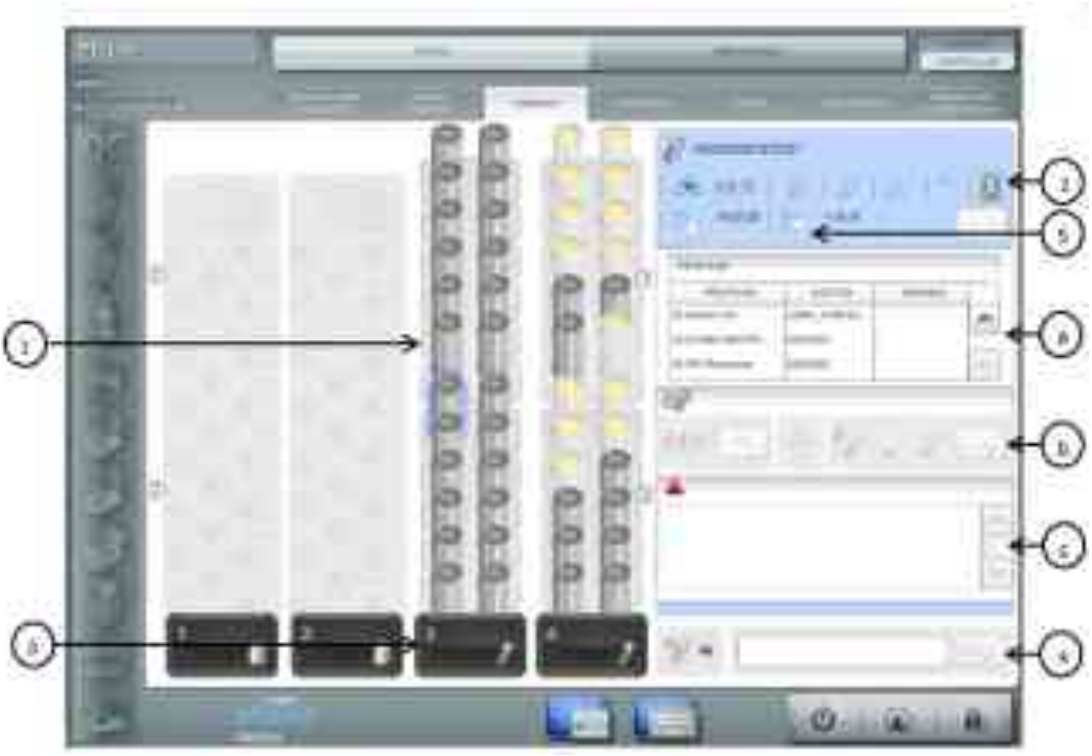


Figure 30. Status > Samples (Example)

(1) Diagram of the samples within the Erytra Eflexis® analyzer.

(2) Detailed information about each sample including the status of the profiles in execution (a), incidences associated with the sample (b) and results (c).

(3) Push-buttons for opening the rack.

(4) The **Search** button  to search for samples within the analyzer by barcode.

(5) Expected time for obtaining the profile result.

The following table lists the status icons that may appear in connection with a sample, including icons that indicate sample incidences that must be resolved before the sample can be processed.

Icon	Description
	Shows “old” for being loaded into the analyzer more than 8 hours ago (the **Sample Incident Warning** icon will also be activated).
	Insufficient volume (the **Sample Incident Warning** icon will also be activated).
	Presence of clot (the **Sample Incident Warning** icon will also be activated).
	New sample tube.

Diameter of tube not identified (the **Sample Incident Warning** icon will also be activated).

Barcode not identified (the **Sample Incident Warning** icon will also be activated).

Sample was manually identified.

If the sample tube appears as deactivated, it means that the sample is not in use and has no associated requests. Sample tubes that appear as deactivated can be removed from the analyzer.

The program also displays the status of the sample according to the color-codes in the following table:

Icon	Icon Description	Description
	Light Grey	The sample has been correctly identified and has not pending requests to process neither results associated.
	Dark Grey	The sample has been correctly identified and has pending requests to process.
	Green	The sample has been correctly processed and all of the requests have finished, so it can be removed from the analyzer.
	Dark Yellow	The sample has a request that is pending due to the need for a reagent, Grifols card, and/or System Solution.
	Light Red	The sample has some kind of incidence but the sample is not required.
	Dark Red	The sample has some kind of incidence (Figure 30, no. 2).

The sample may also have a **Well Incident** icon  (Figure 31), indicating that the affected sample has been processed and the system has encountered one of the possible incidences indicated in Section 7.4.3.

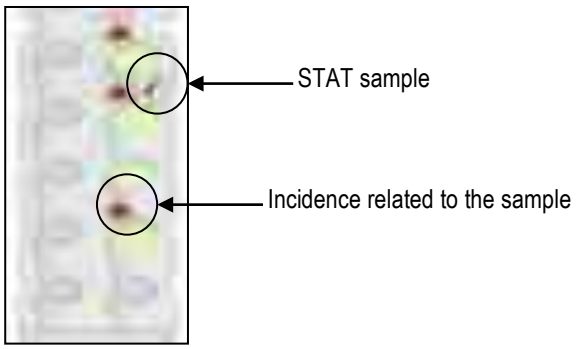


Figure 31. Sample with Well Incident Icon (Example)

To obtain more detailed information about any of the samples present within the analyzer, select the sample. On the right hand side of the screen (Figure 30, no. 2, a) information related to this sample will appear, including the following:

- Patient identification.
- Type of tube.

- Status of the programmed profiles.
- Time when the sample was loaded into the analyzer.
- Result incidences.
- Expected time to obtain the results.

6.2.4 Viewing Reagent Information

To view information about the reagents, press **Status > Reagents** (Figure 27, no. 2). The analyzer displays a detailed diagram of all of the reagents present within the analyzer (Figure 32).

Figure 32. Status > Reagent Screen (Example)

(1) Diagram of the reagents within the Erytra Eflexis® analyzer.

(2) Detailed information about each reagent including the barcode, commercial name, position and volume.

(3) Push-buttons for opening the racks.

(4) Incidents associated to the selected reagent.

(5) The **Search** button  to search for reagents within the analyzer by barcode.

During the identification of reagents, as well as during execution of the workload, the following symbols may be activated in the **Status > Reagents** screen:

Icon	Description
	Problem in identifying the reagent barcode. Open the rack and make sure that the barcode is facing toward the identification window.

Reagents placed in the wrong holder position of the reagent rack. Open the reagents rack and move any reagent that require re-suspension into the appropriate position.

Low reagent volume. Open the rack and replace the reagent vial or bottle with a reagent vial or bottle with adequate volume and press **New Reagent** button or load a new vial or bottle in a new holder position.

Reagent expired. Unload the expired reagent and replace with a reagent that has not expired.

A clot has been detected in the reagent. Open the rack and check the reagent for clots. If clots are detected, load a new reagent and press the **New Reagent** button.

New Reagent button. Use this button to load a new reagent that substitutes the previous one in its exact same position in the rack.

6.2.5 Viewing Gel Cards Information

To view information about the gel cards, press **Status > Cards** (Figure 27, no. 5). The analyzer displays a detailed diagram of all of the cards present within the intrument (Figure 33).

Figure 33. Status > Cards Screen (Example)

(1) Diagram of the cards within the Erytra Eflexis® analyzer.

(2) Diagram of the cards within the Service Rack of Erytra Eflexis® analyzer.

(3) Push-buttons for opening the drawer.

(4) **Summary Card** button to list a summary of the cards that are inside the analyzer by indicating the available cards, not used cards and the gel cards with incidences.

(5) Snapshot of the selected rack with more detailed information.

To obtain more information about the cards loaded in each rack, press the corresponding rack. A snapshot will display (Figure 33, no. 5) with detailed information:

Icon	Description
	Number of gel cards available.
	Number of gel cards with incidences.
	Lot of the card.
	Expiration date.
	Gel cards available.
	Gel card with incidence: A red dot indicates the indicence that affect the card. Incidents are: • Expired. • Not readable. • Unexpected card type. • Wrong gel level. • Artifact found.
	Gel cards to be reviewed (only if a Service Rack is selected).
	Gel card to be reused (only if a Service Rack is selected).

6.2.6 Viewing Container Information

To view information about the System Solution and waste containers and Card Waste containers, press **Status > Containers** (Figure 27, no. 6). The Erytra Eflexis® displays a detailed diagram of the containers present within the analyzer (Figure 34).

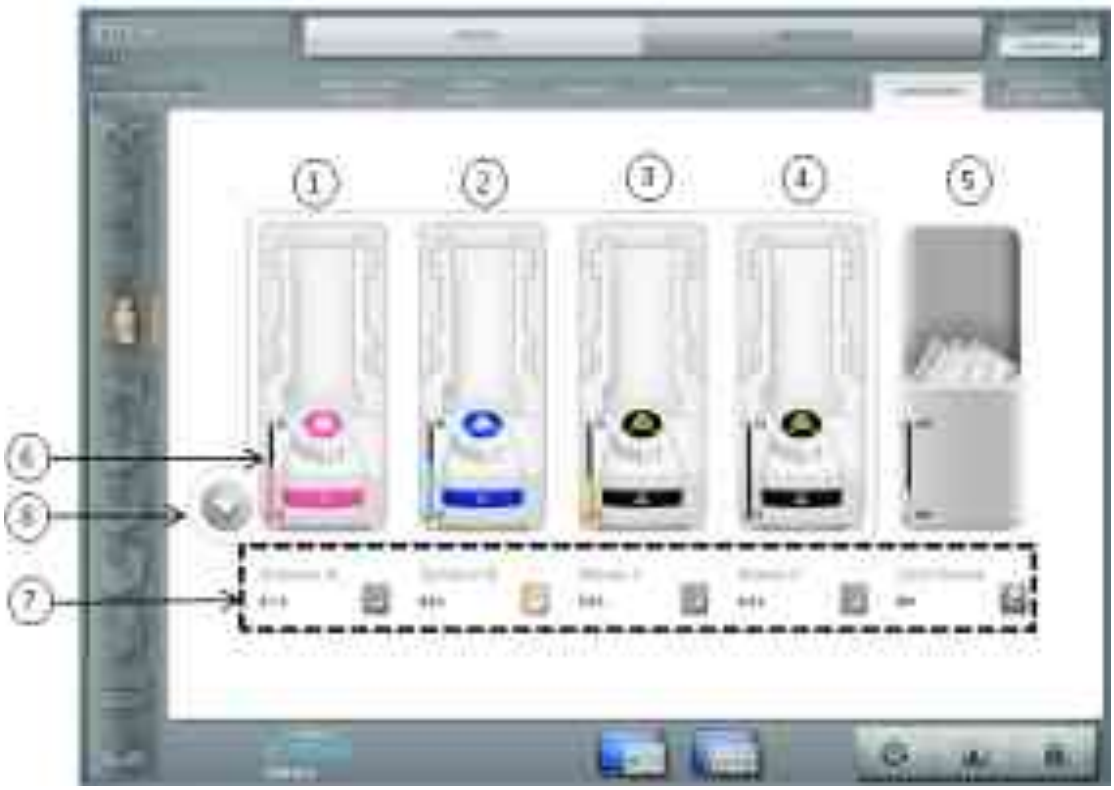


Figure 34. Status > Containers Screen (Example)

(1) Diagram of System Solution A container.

(2) Diagram of System Solution B container.

(3) Diagram of Waste Solution container 1.

(4) Diagram of Waste Solution container 2.

(5) Diagram of the Card Waste container.

(6) Level indicators. It appears in each container to indicate the volume available in each container loaded into the analyzer.

(7) Volume information.

(8) The **Unload Containers** button (to stop the fluidic system before unloading any container from the analyzer).

When the liquid levels drop below the level required to end the workload or the capacity of the container is not enough, the warning icon appears in the **Warning Area** (see Section 5.5) and in the **Containers** status (Figure 34):

Icon	Description
	There is not enough System Solution A.
	There is not enough System Solution B.
	There is not enough capacity in the Waste Solution container.

There is not enough capacity in the Card Waste container.

6.2.6.1 Unload Containers

Each container of the Erytra Eflexis® analyzer has a blue LED associated, see Section 4.2.1. These LEDs are off when the container inserted is required by the analyzer. When the LED is on, they can be removed from the analyzer.

To open a container with LED on:

1. Pull out the container until the container disengange. Hold the container with two hands.

To open a container with LED off:

2. Go to **Status > Container** (Figure 27, no. 6) and press the **Unload Containers** button (Figure 34, no. 8).
3. Erytra Eflexis® stops the fluidic system.
4. Once the safety removal message is shown on the screen and the LED is on, pull out the container. Hold it with two hands.

6.2.6.2 Direct Drain Lab Connection

It is possible to configure the instrument so that the liquid waste generated can be drained directly to the laboratory sink. To do this, please contact your local Grifols service representative (Figure 35).

Figure 35. Status > Containers Screen with Dual Mode (Example)

6.2.7 Viewing Incubator and Centrifuge Information

To view information about the incubators and centrifuge status, press **Status > Incubators & Centrifuge** (Figure 27, no. 7). The analyzer displays a usage diagram of the 3 incubators and 2 centrifuges (Figure 36).

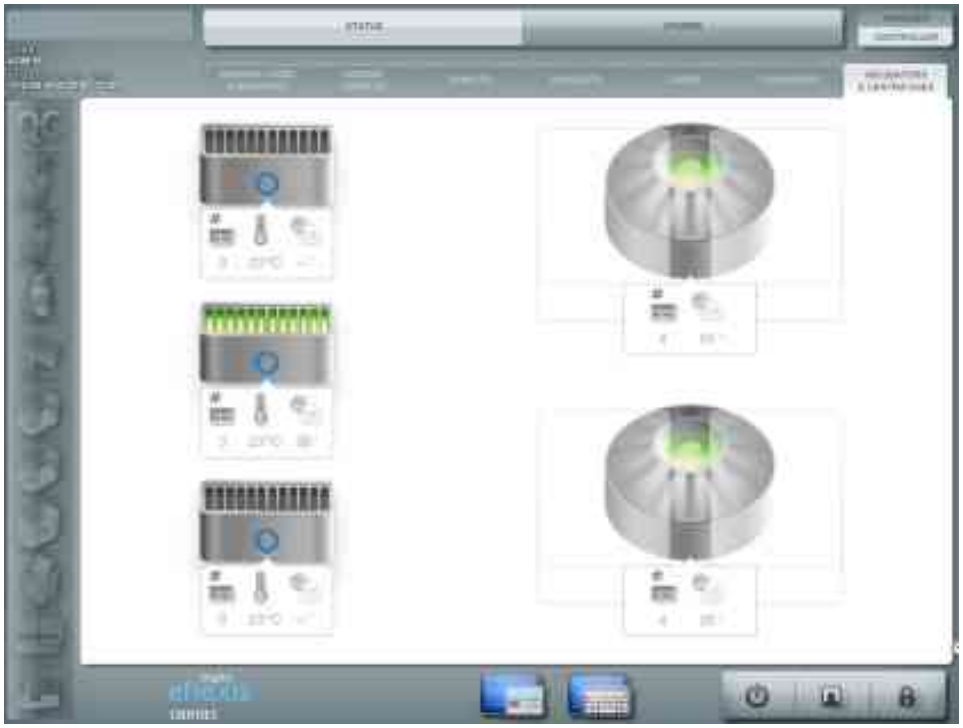


Figure 36. Status > Incubators & Centrifuges Screen (Example)

(1) Diagram of incubators status. Slots in green are in use.

(2) Diagram of centrifuge status. Centrifuge in green is in use.

During the execution of the programmed workload, the following symbols may be activated in the **Status > Incubators & Centrifuges** screen (Figure 27, no. 7):

Icon	Description
	Analyzer is cooling the incubator.
	Analyzer is heating the incubator.
	Number of cards loaded into the incubator or centrifuge.
	Set up Incubation temperature.
	Time to the end.

7 Work Procedure

This section provides a description of the **Controller** software including work procedure, preparing for work, loading reagents, gel cards and samples, loading missing items and resolving resource issues and unloading and shutting down the analyzer.

7.1 Work Procedure Overview

Test processing consists of the following steps:

Prior to Testing

- Operator prepares reagents and samples.
- Operator turns on the analyzer.
- Operator loads reagents, gel cards, and samples.
- Operator programs the **Worksheet** (as needed).
- Operator starts test execution.

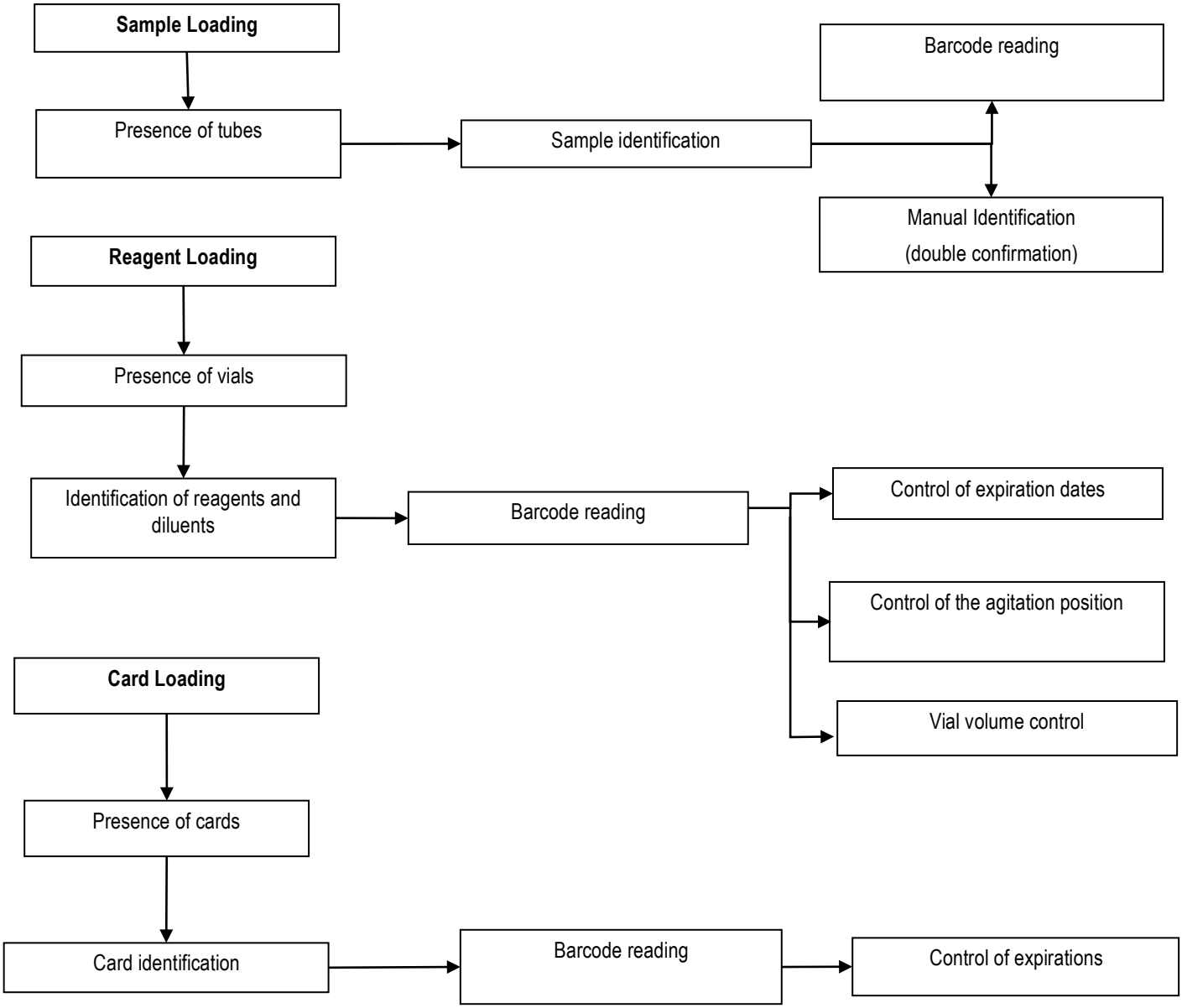
During Testing

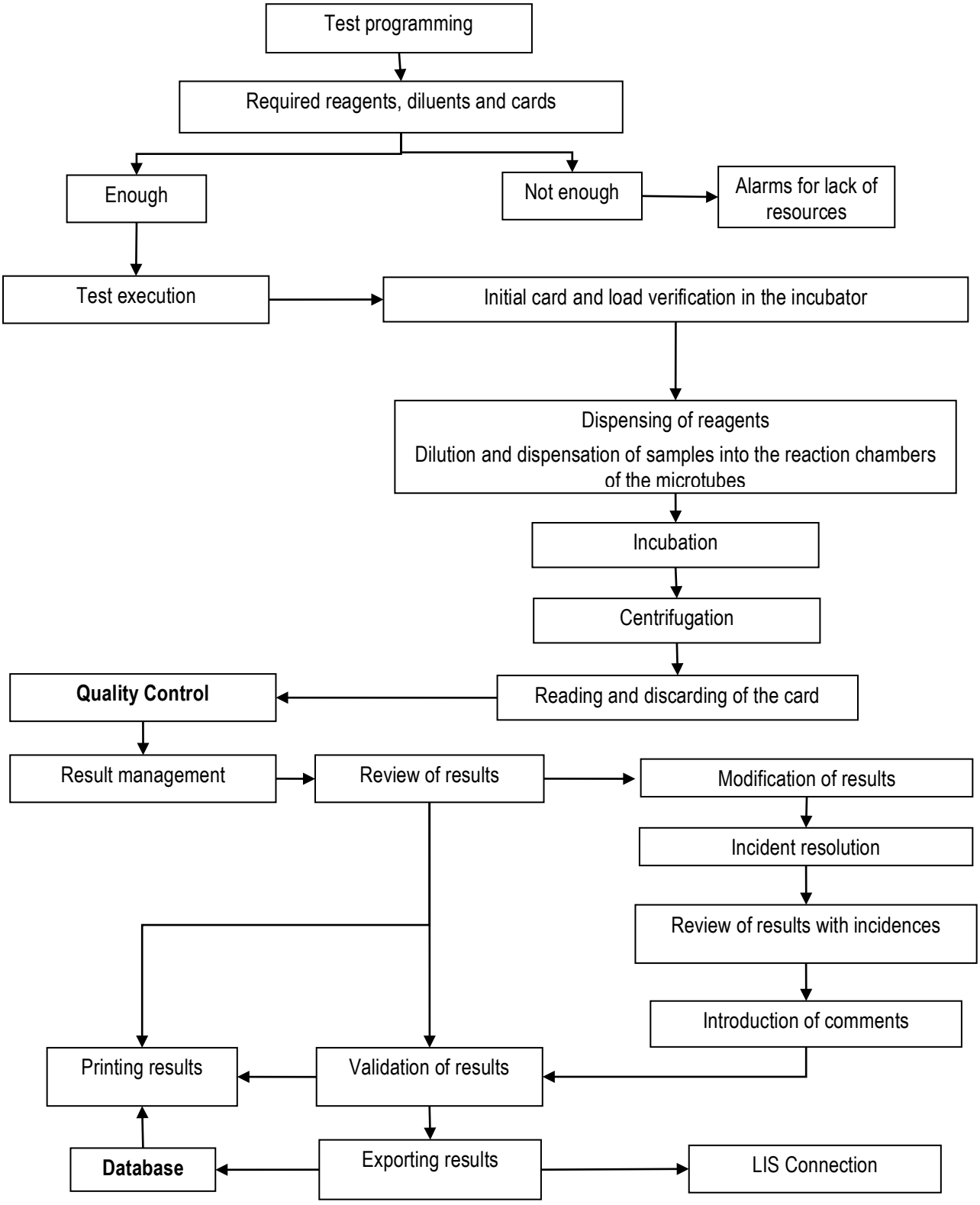
The following steps are performed to execute tests:

- The Erytra Eflexis® checks if there is a valid QC.
- The Erytra Eflexis® checks if all the required materials are present for test execution and alerts the Operator if any resources need attention.
- Operator addresses any resource requirements.
- The required gel cards are identified and photographed, and then moved to the appropriate incubator.
- Reagents are dispensed and samples are diluted (if necessary) and dispensed into the corresponding microtubes of the gel cards, in accordance with the procedure described for each test.
- The gel cards are incubated (if necessary).
- The gel cards are centrifuged.
- The gel cards are transported to the reader, where the camera takes photographs of the microtubes.
- The analyzer applies a reading algorithm to the digitalization of the image in order to obtain parameters that characterize it and make it possible to quantify the reaction grade.
- The analyzer applies an interpretation matrix for each test. These matrices combine the different results from the microtube reaction grades for the test to provide an interpretation of the results.
- The results are updated on the **Results** screen.
- The gel cards used for the analysis are either disposed of or stored in the Service Racks for later review (if the gel card has an associated incidence or special result) or future use (if the Grifols gel card has unused microtubes).

Following Testing

- Operator reviews and validates results.
- Operator saves and prints results (as required).
- Operator unloads and shuts down the analyzer at the end of the work day.


Sample Loading
Presence of tubes
Sample identification
Barcode reading
Manual Identification
(double confirmation)
Reagent Loading
Presence of vials
Identification of reagents and diluents
Barcode reading
Control of expiration dates
Control of the agitation position
Vial volume control
Card Loading
Presence of cards
Card identification
Barcode reading
Control of expirations


Test programming
Required reagents, diluents and cards
Enough
Not enough
Alarms for lack of resources
Test execution
Initial card and load verification in the incubator
Dispensing of reagents
Dilution and dispensation of samples into the reaction chambers of the microtubes
Incubation
Centrifugation
Reading and discarding of the card
Quality Control
Result management
Review of results
Modification of results
Incident resolution
Review of results with incidences
Introduction of comments
Printing results
Validation of results
Database
Exporting results
LIS Connection

7.2 Preparing for Work

7.2.1 Starting the Analyzer

Confirm that the analyzer is connected to the main power supply and that the power switch (Figure 15, no. 1) is turned on.

1. Press the **Start** button (Figure 15, no. 2).
2. The **Start** button's green light comes on and the Windows operating system loads.
3. After the **Access Control** window opens, enter the **Username** and **Password**.
4. Press  to enter the application.

NOTE: Each Operator will only have access to the options which have been configured for that user's profile level. For further information, see Section 13.

The yellow traffic light comes on. During startup the instrument starts the various modules and verifies the communication between them. The startup process takes approximately four minutes. When the startup process is complete, the traffic light turns green.

7.2.2 Performing Initial Checks

Before starting test processing, perform these initial checks.

Go to the **Status** screen (Figure 27, no. 6) and press **Containers.**

Check the status of the System Solution and waste containers.

- Confirm sufficient level of System Solutions A and B. (To load System Solution, see Figure 34 and Section 7.4.5).
- Confirm sufficient capacity in the Waste Solution containers. (To empty a Waste Solution container, see Section 7.4.6).
- Confirm sufficient capacity in the Card Waste container. (To empty the Card Waste container, see Section 7.4.7).

Open card drawers 5 and 6 (if using the default Service Rack configuration) and remove any gel cards that are completely used (Figure 17, no. 7) and see Section 7.4.7.

CAUTION: When removing gel cards from the Service Racks, make sure not to discard any gel cards that have results that need review.

Confirm that daily maintenance has been completed.

7.2.3 Preparing Samples and Reagents

Prepare samples and reagents to be loaded into the analyzer:

1. Confirm that all sample tubes meet the sample tube requirements. The following types of tubes (without lids if present) may be used for sample processing:
   - **Tube Type:** Plastic or glass (siliconized).
   - **Tube Diameter:** 9-16 mm.
   - **Tube Height:** ≤ 100 mm.
2. Confirm that all sample tube barcodes meet the specification listed in the following cautions:

CAUTION: To guarantee maximum reliability during sample identification, it is recommended to use barcodes containing a checksum.

CAUTION: The use of sample tubes outside of the listed specifications can cause a malfunction of the instrument.

To use a non-specified tube, contact your local Grifols service representative.

CAUTION: For the correct performance of the instrument, it is important that:

- The barcode labels are adhered securely to the tubes or vials.
- The barcode labels are not hand-written or defective.
- The barcode labels are correctly positioned facing the identification window.
- The specifications described in Section 3.1 are complied with.

NOTE: Before using pediatric sample holders, a configuration file must be edited. For more information, contact your local Grifols service representative.

CAUTION: If improperly centrifuged whole blood samples are loaded into the instrument, the instrument may not be able to sample the appropriate plasma volume to produce valid test results.

CAUTION: The reliability of a laboratory result and its interpretation depends greatly on the quality of the samples. For this reason, it is important that samples are managed properly from the time they are obtained until they are processed. Follow the guidelines listed in Section 7.2.3.

3. Confirm that the samples meet the sample quality requirements listed in the following cautions:

CAUTION: In order to obtain reliable results, load centrifuged samples (serum, plasma, or red blood cells).

CAUTION: The presence of foam, bubbles, or drops on the sample tube walls may affect the dispensing of the sample, causing a possible error in the results.

CAUTION: The use of the following samples can cause erroneous results or generate problems during the execution of the analysis:

- Samples that are hemolyzed, lipemic, or icteric.
- Samples that are cloudy.
- Samples with clots, fibrin, or particles.
- Frozen samples that have not been centrifuged.
- Old samples (collection time > 7 days).
- Samples with insufficient volume.
- Samples with an incorrect proportion of plasma to cells.
- Samples with a serum separator.

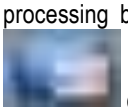
CAUTION: Confirm that the level of plasma above the surface of the cell layer in the sample tube is sufficient for the tests that are to be executed on that sample. A sample tube with an insufficient level of plasma should not be loaded into the instrument for processing.

CAUTION: If serum is used from a red top tube, it should not contain red cells. Serum should be

removed from the clotted red top tube and placed into its own clean labeled tube.

4. Remove reagents from the refrigerator and allow them to come to room temperature.
5. Resuspend reagent red cells.
6. Remove reagent caps.

7.3 Loading Reagents, Gel Cards and Samples

The Erytra Eflexis® allows the loading of samples, reagents, diluents, gel cards and System Solutions during processing by using push-buttons located on the front of the analyzer or by pressing the **Display Map** button  or in the corresponding **Status** tab.

7.3.1 Loading Reagents and Diluent

To load reagents and diluent into the analyzer:

1. Open the reagent rack.
2. Extract the rack.
3. Remove empty vials or bottles (if necessary).
4. Load a new vial(s) and/or bottle(s) into the appropriate reagent location (depending on whether the reagents being loaded require re-suspension), with the barcode facing the identification window of the corresponding rack (Figure 37).
5. Insert the rack until locked.

The Erytra Eflexis® performs the following actions:

- Checks for the presence of vials and bottles.
- Identifies the reagents and/or diluent.
- Verifies that the reagents and/or diluent have not expired.
- Confirms that RBC reagents are not loaded into the racks for reagents that do not require re-suspension.
- Checks the volume present in each vial or bottle.

To view information about the reagents and diluent in the analyzer, press **Status > Reagents (**Figure 32**).**

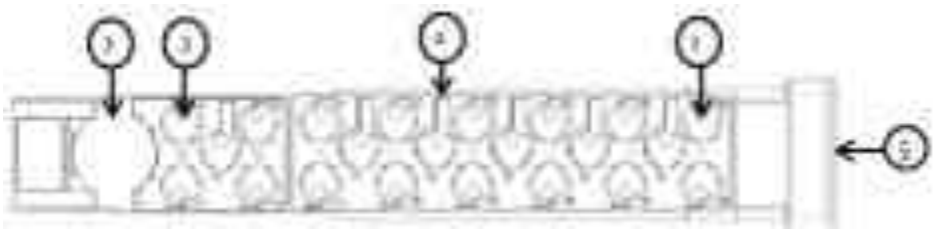


Figure 37. Rack for Reagents

(1) Locations for vials of reagents which require re-suspension.

(2) Locations for vials of reagents which do not require re-suspension.

(3) Location for a bottle of diluent or DG Clean reagent. Before loading the DG Clean, insert the DG Clean Adaptor in the diluent position.

(4) Identification window.

(5) Frontal side of the rack.

The reagents can be placed in any of the locations on the reagent rack which have been designated for them, as the system will locate and identify each of the reagents present in the Erytra Eflexis® analyzer by reading their barcodes.

CAUTION: To execute tests correctly:

- Load re-suspended and tempered RBC reagents only.
- The vials and bottles must be completely dry and with the barcode label in good condition.

WARNING: Remove the caps from the vials and bottles before loading them into the analyzer.

WARNING: The exchanging of caps could be a source of cross-contamination between the reagents and could lead to incorrect results.

WARNING: To avoid spills inside the analyzer, do not use vials which are too full.

CAUTION: Do not keep reagents inside the analyzer for an extended period of time as the conditions may not be optimal for storage.

7.3.2 Loading Grifols Gel Cards

To load Grifols gel cards into the analyzer:

1. Open a card drawer that has room for a gel card rack.
2. Remove the empty card racks (if this is the case).
3. Remove the lid from the gel card rack and place the entire rack into the analyzer with the barcodes facing to the left as described by the drawing on the base  .

CAUTION: The Grifols gel cards should be loaded into the Erytra Eflexis® in the original packaging after removing the lid, if present.

CAUTION: Do not use the locations designated as Service Racks to load gel cards. The Service Racks are used by the analyzer to hold only those gel cards which must be reviewed or reused.

CAUTION: Do not keep the gel cards inside the analyzer during a long period of time as the conditions may not be of an optimum nature. Please consult the Instructions for Use of the Grifols gel card for further details.

4. Close the drawer.

The Erytra Eflexis® automatically performs the following actions:

- Checks for the presence of gel cards and counts the number of gel cards present.
- Identifies the gel cards.

NOTE: To speed up the identification process, the instrument reads the first gel card in the rack and then assumes that the rest of the gel cards in the rack are of the same type (during test processing each gel card will be identified individually). If the instrument cannot read the first gel card, it then attempts to read the next two gel cards. If it cannot read any of the first three gel cards, the gel cards in that rack appear in red on the **Status > Cards** screen and cannot be used for test processing until they are identified by the instrument.

- Verifies that the gel cards have not expired.

To view information about the gel cards in the analyzer, press **Status > Cards** (Figure 33).

7.3.3 Loading Samples

Samples can be loaded and unloaded continuously through the up to 3 sample racks (Figure 30). Each rack has 2 removable holders (Figure 38) and each holder has 12 locations to hold sample tubes.

Once samples have been loaded, sample information can be viewed, including location, status, and other information.

The sample tubes can be placed directly in the holders without the need of adaptors, regardless of their size.

NOTE: Special tubes require to be configured. If in doubt, please contact your local Grifols service representative.

Once samples have been loaded, sample information can be viewed, including location, status, and other information.

If the analyzer is unable to identify samples automatically when they are loaded, samples must be identified manually before processing tests.

7.3.3.1 Sample Holders

All of the holders loaded into the analyzer must be identified with a barcode on each side:

The holders received with the instrument are already identified with a grey barcode label (as shown on the left and in Figure 38, no. 4). These holders will be used for the majority of the tubes used in the lab.

To use a different type of tube, contact your local Grifols service representative. Depending on the type of tube, it may be necessary to use holders with a different barcode (for example a red barcode label, as shown on the left), as well as configure the height and diameter of the tubes.

NOTE: The sample holders can be removed from the analyzer to aid sample loading.

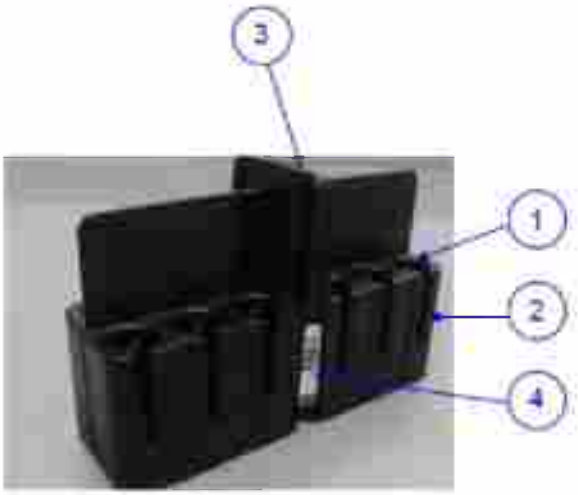


Figure 38. Sample Holder

(1) Locations for sample tubes.
(2) Identification window.
(3) Handle.
(4) Holder Barcode.

CAUTION: Avoid dropping or banging the holders, as the holders are fragile and may come apart or break. If a holder comes apart after being dropped, it should not be put back together or reused. Do not use a holder if it is not intact.

CAUTION: Do not use a non-specified holder in the instrument.

To use pediatric sample tubes, special holder for pediatric samples (Figure 39) must be used.

Figure 39. Holder for Pediatric Samples

Before using pediatric holders, check the information of Section 7.2.3.

7.3.3.2 Loading Samples

To load samples into the Erytra Eflexis®:

1. Press the **Display Map** button  and open the desired sample rack (Figure 24).
2. Remove the rack(s) and place the sample tubes holder into the rack(s) (Figure 4).
3. Place the tubes directly in its corresponding holder, facing the barcode towards the identification window (Figure 38, no. 1).

NOTE: Check that the sample tubes are firmly seated in the rack.

4. Load the holders into the sample rack.
5. Enter the rack until the analyzer blocks the rack. The analyzer will automatically identify the samples.

CAUTION: Do not keep samples inside the analyzer for an extended period of time as the conditions may not be optimal for storage.

NOTE: Erytra Eflexis® has been validated to ensure that carry-over between samples or reagents is reduced to an extent that will not affect the results of the immunohematology tests. However, under certain situations (serums with very high titers) the washing and/or contaminating agent concentration may not be reduced to levels low enough to completely rule out any potential carry-over issue.

The analyzer checks for the presence of the tubes and attempts to read their barcodes. If the analyzer is unable to read the barcodes, identify the sample tubes manually (see Section 7.3.3.3).

7.3.3.3 Identifying Samples Manually

If the Erytra Eflexis® is unable to identify one or more samples automatically, or if one or more of the samples do not have a readable barcode, an error message will appear on the screen.

NOTE: To ignore all of the unidentified sample tubes and continue processing the samples that have been correctly identified, press **Continue**.

To resolve the sample identification error message and identify the samples:

1. Press **Continue** to clear the error message from the screen.
2. Go to the **Status > Samples** screen (Figure 30).
3. Samples that could not be identified during the barcode read will appear in red.
4. Open the rack that contains the unidentified sample tube using the icon for the corresponding rack at the bottom of the screen.
5. Take the tube out and put it back in the rack, making sure that the barcode faces the identification window.

NOTE: While the sample is out of the instrument, confirm the sample's barcode number, as the manual identification must be done with the sample in the analyzer.

6. Enter the rack until is blocking.

If the error message does not reappear, the sample has been identified successfully.

If the error message reappears, press **Continue** to clear the error message from the screen.

7. Press the icon for the unidentified sample (in red), and then press the **Manual Sample ID** button  .

8. Enter the sample tube barcode number using the keyboard (which appears automatically after the text box is pressed) and press the **Confirm** button  to accept.
9. Confirm the manual identification by entering the sample identification again.

The sample appears in grey with a blue background on the **Samples** screen.

CAUTION: When a sample ID is entered manually, the positive identification function is not activated and it is the responsibility of the user to make sure that the identified samples are correctly positioned.

CAUTION: The manual identification of samples increases the risk that samples will be misidentified.

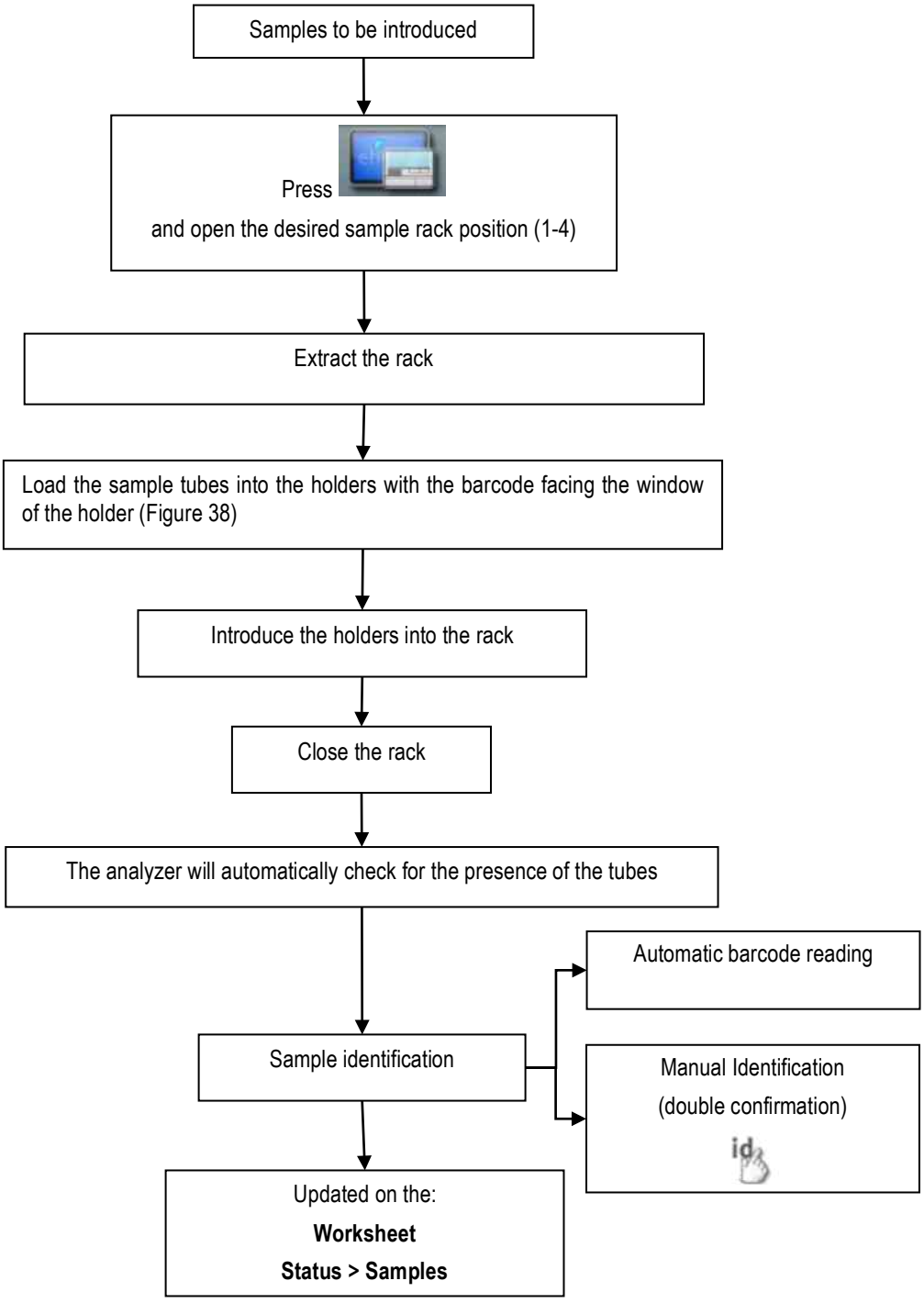
CAUTION: The Erytra Eflexis® analyzer confirguration to work with the ISBT 128 barcodes of 13 digits or the non introduction of the control digit during the manual identification disable the checking of the correct identification of the sample.

NOTE: If Erytra Eflexis® is configured to identify samples with ISBT 128 barcodes of 16 digits, a check of the manual control digit introduced by using the keyboard is performed during the manual identification.

When a rack is opened that contains samples that have previously been manually identified, a message displays to confirm that they are the same tubes. If not, the samples have to be manually identified again.

NOTE: To obtain more detailed information about the samples, press **Status > Samples** (Figure 30). The Erytra Eflexis® analyzer software will show a detailed diagram of all of the samples present within the analyzer (Figure 30, no. 1).

7.3.3.4 Procedure



7.4 Loading Missing Items and Resolving Resource Issues

Before executing the programmed workload, the Erytra Eflexis® automatically performs an assessment of the resources needed (reagents, diluent, gel cards, System Solutions, and waste capacity) to execute the set of programmed profiles. Also, during the execution of profiles, the Erytra Eflexis® software monitors in real time:

- The status and distribution of samples in the analyzer.
- The status and distribution of reagents and diluents in the analyzer.
- The status of System Solutions and Waste Solutions, and the capacity of the cards waste container and the Waste Solution containers.
- The status and distribution of gel cards in the analyzer.

When a system component is missing, or if there are not enough resources to execute all of the programmed profiles, the icon for the corresponding resource will light up in the **Warning Area** (Section 5.5) and the color of the traffic light (Figure 15, no. 7) will change to yellow.

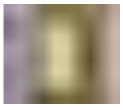
Press the illuminated **Warning** icon to open a screen with information about what should be done to resolve the incidence.

NOTE: The lack of resources for a particular request does not interrupt the execution of other requests which have sufficient resources. The analyzer continues with the execution until it has no more pending requests with available resources.

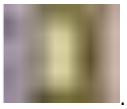
NOTE: Requested resources may be loaded at any time. However, if the lack of resources affects STAT requests, the analyzer continues with the requests that can be executed but the analyzer shows an error screen listing the required resources issues that must be resolved immediately. Two options are available:

- **Missing Samples:** Press this button to obtain information about the nature of the requirement.
- **Continue:** Press this button to close the screen. The STAT samples go to a "Stopped" status and will not be processed.

7.4.1 Loading Missing Reagents or Diluents

If a reagent or diluent is missing, or if the volume is not sufficient to execute the set of programmed profiles, the **Missing Reagents** and/or **Diluent Warning** icon will  appears in the **Warning Area**.

To load missing reagents or diluent:

1. Press  .

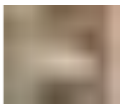
   The **Missing Reagents and Cards** screen displays information about the reagents and/or diluent that must be loaded to execute the programmed workload.
2. Open a reagents rack (Figure 16) with free locations using the corresponding button.
3. Remove the empty vial or bottle (if necessary) and place a new vial or bottle in the rack, with the barcode facing the identification window of the corresponding rack (Figure 37).
4. Insert the rack after blocking it.

Erytra Eflexis® proceeds to identify the reagents and or diluents loaded in the rack.

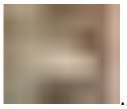
The **Warning** icon is deactived and the **Status > Reagents** screen is updated.

The pending workload is executed.

7.4.2 Loading Missing Gel Cards

If there are not enough gel cards to execute the programmed profiles, the **Missing Cards Warning** icon  appears in the **Warning Area**.

To load missing gel cards:

1. Press  .

   The **Missing Reagents and Cards** screen displays information about the gel cards that must be loaded to execute the programmed workload.
2. Open a cards drawer (Figure 16, no. 5) using the corresponding button.
3. Remove the empty card racks (if this is the case) and replace them with a new rack of gel cards with the barcode facing on the left as described by the drawing on the base  .
4. Close the drawer. The Erytra Eflexis® automatically identifies the gel cards.

The analyzer proceeds to identify all gel cards inside in the drawer.

The **Warning** icon is deactived and the **Status > Cards** screen is updated.

The pending workload is executed.

7.4.3 Loading Missing Samples

If any of the samples which are required to execute the programmed profiles are missing, the **Missing Samples Warning** icon  appears in the **Warning Area**.

To load missing samples:

1. Press the **Missing Samples Warning** icon  .

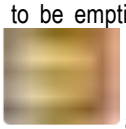
   The **Missing Samples** screen displays information about the samples that must be loaded to execute the programmed workload.
2. Open a samples rack (Figure 17, no. 3) using the corresponding button.
3. Extract the rack.
4. Load the required samples or resolve the incidence by pressing the **Set New** button  .
5. Enter until blocking the rack.

   Erytra Eflexis® proceed to automatically identify the samples loaded in the rack.

   The **Warning** icon is deactived and the **Status > Sample** screen is updated.

   The pending workload is executed.

7.4.4 Emptying the Service Rack

If the Service Racks are full or almost full, and need to be emptied before the Erytra Eflexis® can execute the programmed profiles, the **Service Racks Warning** icon  appears in the **Warning Area**.

NOTE: The racks in position 4 of card drawers (Figure 17, no. 5) are designated as the Service Racks by default.

CAUTION: Review the gel cards discarded in the Service Rack, as they may have a result with an incidence or a special result associated with them (Section 10.3.3).

The Service Racks may also hold gel cards with free microtubes which can be reused.

To empty the Service Racks:

1. Press  .
2. The **Status > Cards** screen displays information about distribution of gel cards inside the analyzer (Section 7.3.2).
3. Open the card drawers through the **Status > Cards** screen or by using the corresponding push-buttons.
4. Remove the complete rack from the Service Rack position and replace for an empty gel card rack. All the discharged gel cards should be reviewed later as they could have results to be reviewed (Section 10.3.3).

NOTE: The Service Rack contains full used cards that have results to be reviewed and partially used gel cards that despite could have results to be reviewed; they can be reused for a new test. To reuse them load into the Service Racks. The analyzer will reuse them automatically.

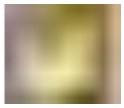
5. Close the drawer.

   The analyzer proceed to automatically identify and recount the cards loaded in the rack as described in Section 7.3.2 and identifies one by one the cards loaded in the Service Rack.

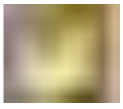
   The **Warning** icon is deactived and the **Status > Sample** screen is updated.

   The pending workload is executed.

7.4.5 Refilling the System Solutions Containers

If either System Solution (A or B) container is empty or almost empty, or there is not sufficient volume to execute the set of programmed profiles in the Erytra Eflexis® analyzer, a **System Solution Container Warning** icon  or  will appear in the **Warning Area**.

To refill the System Solution containers:

1. Press  or  (depending on the case).

The **Status > Containers** screen displays information about the volume of System Solution (A and B) available into the analyzer.

2. Dilute the corresponding Grifols System Solution following the Instructions for Use.
3. Unlock the appropriate System Solution container from the **Status > Containers** screen.
4. Remove the lid and refill the container with the appropriate System Solution.
5. Enter the container until locking it.

   The analyzer procees to automatically monitorize the volume in the containers.

   The **Warning** icon is deactivated and the **Status > Containers** screen is updated.

   The pending workload is executed.

WARNING: The use of different System Solutions or solutions with a concentration different from what is specified in the IFUs can cause cross-contamination by insufficient washing and can cause incorrect results.

CAUTION: If any deformity of the connectors or the System Solution containers themselves is observed, discard them and replace them with new ones, as they could cause significant damage to the analyzer.

CAUTION: Do not use System Solutions after their expiration date. The use of degraded System Solutions can cause cross-contamination by insufficient washing and can cause incorrect results.

NOTE: Although the System Solutions can be refilled while inside the analyzer, the containers can also be removed from the analyzer for refilling or for maintenance tasks.

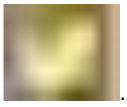
NOTE: It is recommended to record the Wash Solution lot information in the **Wash Solution Registry**. For more information, see Section 14.1.5.

7.4.6 Emptying the Waste Solution Containers

If a Waste Solution container is too full for the Erytra Eflexis® to execute the programmed profiles, the **Waste Solution Container Warning** icon  appears in the **Warning Area**.

NOTE: This signal will not activate on those instruments that have the waste liquid configured to drain to the laboratory sink.

To empty the Waste Solution container:

1. Press  .

   The **Status > Containers** screen displays information about the capacity available in the Waste Solution containers.
2. Unlock the appropriate Waste Solutions container (Section 6.2.6).
3. Unload the container from the analyzer.
4. Remove the lid from the container, empty the container and replace the lid.
5. Load the empty container back in the analyzer until locking it.

Erytra Eflexis® proceeds to automatically monitorize the volume in the containers.

The **Warning** icon is deactivated and the **Status > Containers** screen is updated.

The pending workload is executed.

WARNING: The Waste Solution containers should be emptied regularly. Handle, label, and dispose of all liquid waste in accordance with site procedures and local, state, and federal regulations and practices.

7.4.7 Emptying the Card Waste Disposable Container

If the Card Waste container is too full for the Erytra Eflexis® to execute the programmed profiles, the **Card Waste Container Warning** icon  appears in the **Warning Area**.

The Card Waste container use disposable, sealable blisters to prevent contact between the user and the discarded gel cards (Section 4.5).

To replace the card waste disposable container:

1. Press  .

   The **Status > Containers** screen displays information about the capacity available in the Card Waste container.
2. Open the lower door of the analyzer by pressing the middle button of the door.
3. Open the Card Waste container drawer from the **Status > Containers** screen.
4. Remove the Card Waste container by pulling forward.
5. Close the disposal container by following the procedure indicated in Figure 40.

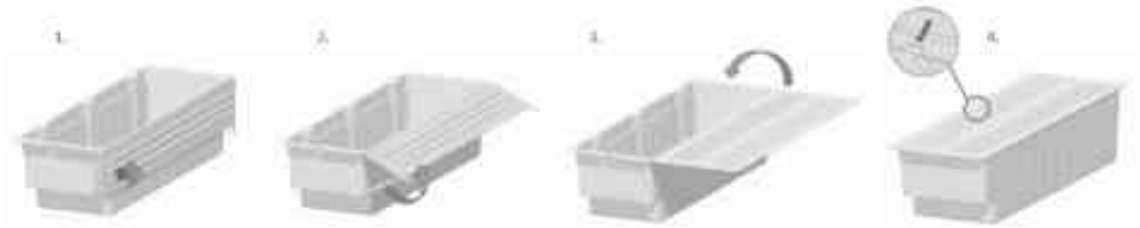


Figure 40. Procedure for Closing the Disposable Card Waste Container

WARNING: The disposable waste container and its contents should be emptied regularly. Handle, label, and dispose of all waste in accordance with site procedures and local, state, and federal regulations and practices.

6. Discard the disposable container into a laboratory rigid container for biohazardous waste.
7. Assemble the new container by following the procedure indicated in Figure 41.

Figure 41. Procedure for Assemble a New Disposable Card Waste Container

CAUTION: Once ensembled, check that the new container shows no signs of deterioration. If there are signs of deterioration, discard it and use another one.

8. Insert the container into the card waste position by ensuring that it is positioned in such a way that the upper opening is to the right.

CAUTION: For the proper functioning of the Erytra Eflexis® it is essential that the Card Waste container is carefully introduced, avoiding that any part of the blister is bent.

Erytra Eflexis® proceed to automatically monitorize the volume in the containers.

The **Warning** icon is deactivated and the **Status > Containers** screen is updated.

The pending workload is executed.

7.5 Unloading and Shutting Down the Analyzer

WARNING: Cap the reagent vials and diluent bottles and save or discard them according to their Instructions for Use.

WARNING: To avoid injury, do not open the analyzer while tests are being processed.

The Erytra Eflexis® should be unloaded at the end of every work day. To do this, proceed as follows:

1. Open and unload samples and reagents racks.
2. Go to **Status > Cards** screen (Figure 33) and identify those which should be kept in the fridge and that are marked with a (*) before their name.
3. Open the corresponding drawer and unload the corresponding gel card rack.
4. Remove any empty gel card racks.
5. Unload Service Racks and replace them for empties one.

NOTE: Be sure to review any gel cards that have associated special results or incidences. (Section 10.3.3).

6. Close the card drawers.
7. Empty Waste Solution containers.
8. Refill System Solution containers.

9. Press the **Shutdown** icon  .
   A message displays to confirm shutdown.

10. Click the **Confirm** button  to close the Erytra Eflexis® software.
    The analyzer rinses and empties the entire fluidic system automatically and shuts down when finished.

8 Manager: The Data Management Software

This section provides a description of the **Manager** software including analyzer status and **Users** screens.

NOTE: The **Manager** software has been designed with web technology. This permits authorized users to access the **Worksheet** and results not only from the analyzer but also from any remote desktop using http protocol (Remote Access).

During Remote Access, the same user privileges apply which have been configured locally. For more information about activating this service, contact your local Grifols service representative.

8.1 The Main Manager Screen

To access to **Manager** software press **Manager/Controller** button (Figure 43, no. 1) in the main screen of **Manager** (for more information on starting the Erytra Eflexis®, see Section 7.2.1. The main screen displays (Figure 42).

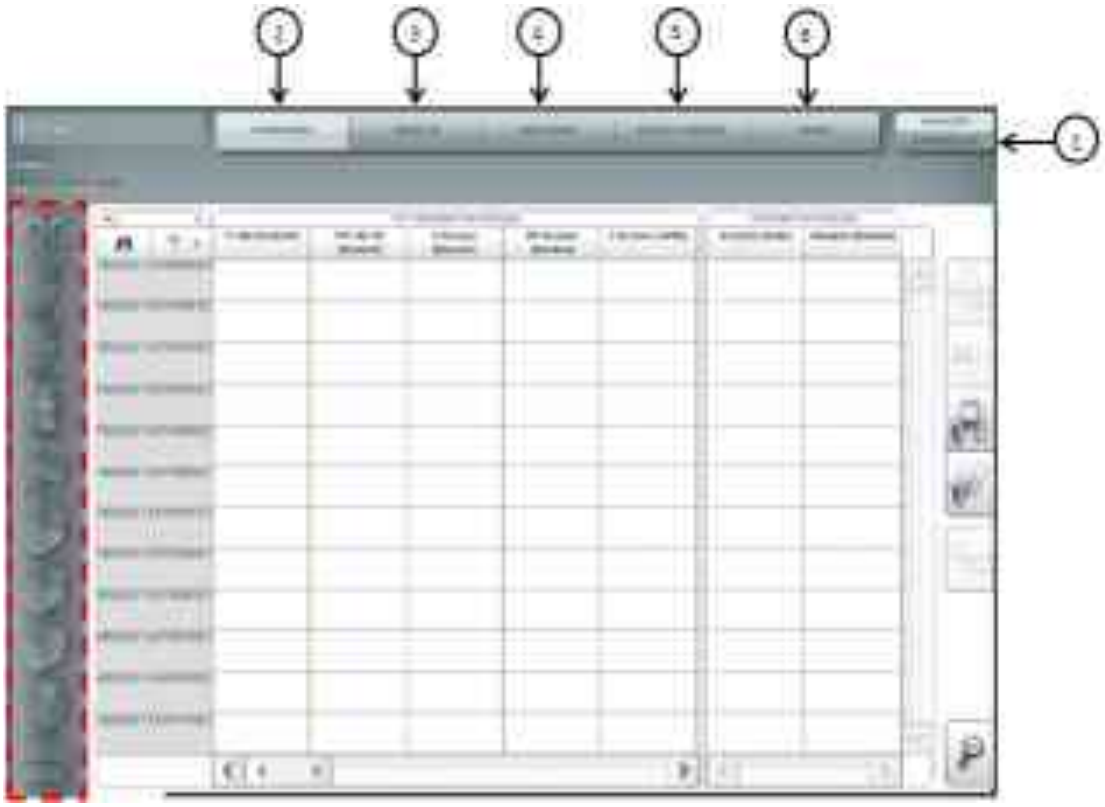


Figure 42. Main Screen of Manager Software

(1) **Controller Switch** button (to access to the **Controller** software). See more information in Section 7.1.

(2) **Worksheet** module button (to access to program techniques profiles to samples). See more information in Section 8.

(3) **Results** module button (to access to manage results). See more information in Section 10.

(4) **Database** module button (to access to results saved to the **Database**). See more information in Section 11.

(5) **Quality Control** module button (to access to **Quality Control** results). See more information in Section 12.

(6) **User's** module button (to access to users management). See more information in Section 13.

NOTE: To have information about the buttons or information displayed on the **Manager** software that is not described in this section check Section 5.2.

9 Programming Tests with the Worksheet

This section provides a description of the **Worksheet** and the programming tests.

9.1 Worksheet Description

Test requests can be programmed in the following ways, depending on whether or not the instrument is connected to a Laboratory Information System (LIS):

- **For instruments connected to an LIS:** The sample requests are programmed by downloading the workload from the LIS to the **Worksheet** (see Section 9.2.1). The analyzer automatically executes the tests once the samples are loaded according to the sample identification numbers read by the barcode reader.

NOTE: To configure LIS connection contact your local Grifols service representative.

- **For instruments not connected to a LIS:** The sample requests must be manually programmed from the **Worksheet** by selecting the corresponding fields for the desired profiles for each sample or by assigning a test profile to a group of samples (see Section 9.2.2 for more information).

The **Worksheet** module (Figure 43) can also be used to add additional test requests to the workload sent by a LIS. To perform manual programming, see Section 9.2.2.

NOTE: Requests not sent from a LIS are shown in the **Status > Samples** screen with the icon 

Figure 43. Overview of the Worksheet (Example)

(1) IDs for the samples that have pending orders or are into the analyzer, along with icons for samples that are STAT , samples that have been manually identified  , samples that have been designated as donor samples  or samples not present into the analyzer  .

(2) **Profiles** available.

(3) **Crossmatching Profiles** available.

(4) **Start Test Execution** button.

(5) **Cancel Test Execution** button. After selecting some requests, this buton allows cancelling them.

(6) **Donor Assigment** button.

(7) **STAT Assigment** button.

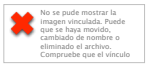
(8) **LIS Request** button.

(9) Button to enlarge the **Worksheet** (view 24 samples).

NOTE: If a Profile is not available, please contact your local Grifols service representative.

NOTE: The **Worksheet** contains information about all the samples that have orders pending, in process or processed (but not exported) and samples that despite to have all orders exported are inside the analyzer.

Press the sample ID for a sample on the touch screen to obtain the barcode number, as well as the types of information shown below:

Icon	Description
	Indicates that the sample is STAT sample.
	Shows the time the sample was loaded into the analyzer.
	Shows the time the sample results were avalaible.
	Shows the location of the sample in the analyzer (rack, holder, location).
	Performs a search of the sample selected in the **Status > Sample** screen.
	Indicates that the sample is part of a double tube (RBCs and plasma separate).
	Indicates that the test request for the sample did not come from the LIS.
	Indicates that the sample has been assigned as a donor for a crossmatch test.

9.2 Programming the Worksheet

9.2.1 Automatically Programming the Worksheet

If the analyzer is connected to an LIS, the **Worksheet** can be programmed by downloading sample test requests after they have been entered in the LIS:

1. Load the appropriate samples into the analyzer, if this has not been done already.
2. According to LIS connection, the requests will automatically download from LIS after samples identification. On the contrary, press **LIS** button (Figure 43, no. 8) to download them.

NOTE: Any samples with pending orders in the LIS that are not loaded into the analyzer when the workload is downloaded are displayed on the **Worksheet** but marked with the  icon. Once the sample is loaded, the icon is removed and the test processing begins automatically.

NOTE: If the analyzer is configured in a Grifols analyzer net, any requests related to samples that are not present into the analyzer will be cancelled and returned to LIS as cancelled. Therefore they will not be displayed in the **Worksheet** and they will be pending in the LIS for a subsequent LIS request.

The **Worksheet** is populated with the profiles and test assignments downloaded from the LIS and test processing begins automatically.

It is also possible to configure an automatic query to the LIS every time a samples rack is closed by the user, in order to automatically download the worklist. For more information about this option, contact with your local Grifols service representative.

9.2.2 Manually Programming the Worksheet

Manual programming of the **Worksheet** can be done in two ways:

- **By Sample** by selecting the field for the desired profile in the samples's row.
- **By Profile** by assigning a group of samples to the same profile.

9.2.2.1 Manual Programming By Sample

To assign tests to samples:

1. From the **Worksheet**, press the field in the samples' row for the profile to be assigned to highlight that field.

NOTE: Multiple fields can be highlighted by pressing and dragging down through those boxes.

2. After assigning all of the desired profiles, press the **Start Test Execution** button  to begin testing.

9.2.2.2 Manual Programming By Profile

To assign a profile to a group of samples:

1. From the **Worksheet**, press the Profile name at the top of the **Worksheet** for the profile to be assigned.
   The **Sample Selection** window opens (Figure 44):

Figure 44. Samples Selection Window

2. Press the appropriate check box for the desired group of samples to assign the profile:
   - **Not Initiated:** Selects all of the samples that do not have a profile request that is currently being executed (status of "**In Progress**", "**Queued**" or "**Pending**").
   - **Finished:** Selects all of the samples whose previous test request has finished (status of "**Pending Validation**", "**Validated**" or "**Exported**").
   - **Not LIS Origin:** Selects all of the samples that do not have an LIS request for that profile.
   - **All:** Selects all of the samples.
3. Press the **Confirm** button  to accept.

The samples that were selected are highlighted in yellow to indicate that this profile has been assigned (see Figure 45).

Figure 45. Worksheet Showing a Workload (Example)

4. After assigning all of the desired profiles, press the **Start Test Execution** button  to start test execution.

9.3 STAT Programming

When a sample needs to be loaded into the analyzer and processed before the samples previously programmed on the **Worksheet**, the sample must be loaded into the analyzer as **STAT** .

9.3.1 Loading and Programming STAT Samples

To load STAT samples:

1. Press the **STAT** button on the front of the analyzer.
   A sample rack opens.

NOTE: If there are no free locations in any of the sample holders, rack 4 will open. Remove the necessary number of samples from the holder. If these samples have pending orders, they will appear on the **Status > Missing Samples** screen (see Section 7.4.3 for more information).

---

2. Load the STAT sample(s) into the holder.
3. Enter the rack until blocking.
   The analyzer identifies the recently loaded samples as STAT samples and display them on the **Worksheet** with the **STAT** icon . If LIS connection is available, the requests will be downloaded from the LIS automatically. If not, press **LIS** button (Figure 43, no. 8). The analyzer will automatically order and begins processing the STAT samples as soon as possible.

NOTE: If LIS connection is not used, program the desired profile(s) to STAT samples from the **Worksheet** manually (see Section 9.2.2) and press the **Start Test Execution** button .

9.3.2 Designating Samples Already in the Analyzer as STAT

To designate as STAT samples that are already inside the analyzer:

1. From the **Worksheet,** press the **STAT** button (Figure 43, no. 7).
   The **STAT** screen opens (Figure 46) and displays two lists. On the left, is a list of all of the samples that are currently inside the analyzer and on the right is a list of the samples with STAT status assigned.

Figure 46. STAT Screen (Example)

2. Select the sample(s) to mark as STAT from the list on the left.
3. Press the **Move Sample** button  .
   The samples assigned as STAT will appear on the right side of the screen.
4. Press the **Confirm**  button.

The STAT samples will appear on the **Worksheet** with the barcode identification and the **STAT** icon and they will be executed as soon as possible.

9.3.3 Programming a Crossmatch Profile

A crossmatch profile can be programmed in the followings ways, depending on wether or not the instrument is connected to an LIS:

- **For instruments connected to an LIS:** The LIS automatically sends the donor and the recipient assignments and matches donors to their corresponding recipients when the workload is downloaded from the LIS to the **Worksheet** (see Section 9.2.1).
- **For instruments not connected to an LIS:** The donor and its respective recipients will be assigned manually from the **Worksheet** by following the procedure below.

9.3.4 Automatical Crossmatch Programming

If the analyzer is connected to an LIS, the **Worksheet** can be programmed by downloading sample test requests after they have been entered in the LIS, follow the steps described in Section 9.2.1.

9.3.5 Manually Crossmatch Programming

To add a new Recipient-Donor profile assignments manually:

1. Press the **Donor Assignment** button  on the **Worksheet** (Figure 43, no. 6).
2. The **Donor Assignment** window opens (Figure 47, no. 1) and displays information about all of the current Donor-Recipient assignments and the programmed profiles.

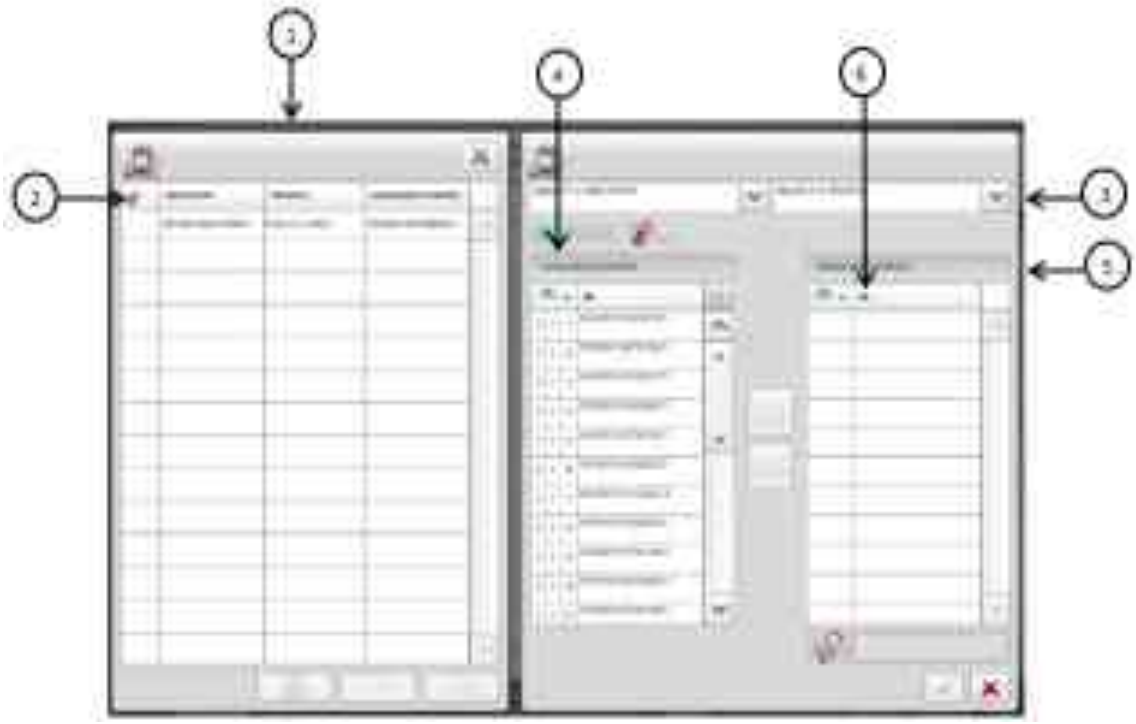


Figure 47. Donor Assignment Window (Example)

(1) **Crossmatch Summary** window.
(2) **Recipient ID** field.
(3) **Crossmatch Profile** (to programming the Recipient-Donor request).
(4) **Available Donors** (potentially all samples loaded into the analyzer).
(5) **Donors List** assigned to this recipient.
(6) **Donor ID Introduction** field.

3. Tap in the **Recipient** field (Figure 47, no. 1).
4. Introduce the Recipient ID by using an external barcode reader or manually using the virtual keyboard (Figure 22, no. 11).
5. The barcode will appear in the **Recipient ID** field highlighted in blue.
6. Select the crossmatch profile from the list of available crossmatch profiles (Figure 47, no. 3).
7. Tap on the **Donor ID** field.
8. Introduce the **Donor ID** by using an external barcode reader or manually using the virtual keyboard (Figure 22, no. 11).

   The donor is assigned to this recipient and its ID is updated on the **Donors List** (Figure 47, no. 5).
9. To assign more donors to the same recipient, repeat steps 6 & 7.
10. Press **Confirm** button  to save the assignment.

The assigned receivers are marked in yellow in the **Worksheet**, whereas the assigned donnors are marked in green and have the **Blood Bag** icon  as shown in Figure 48.

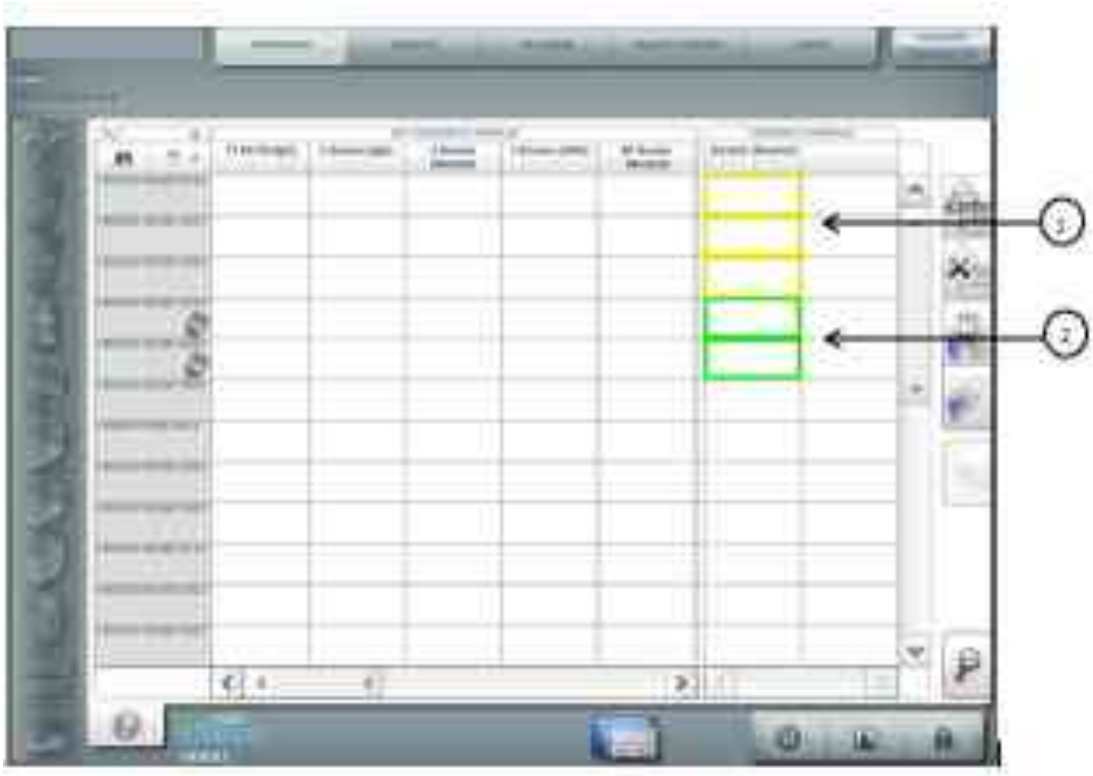


Figure 48. Worksheet Showing a Crossmatch Workload (Example)

(1) Sample assigned as a **Recipient** in a crossmatch test.

(2) Sample assigned as a **Donor** in a crossmatch test.

11. Press  to close the **Donor Assignment** window.

    Samples that are not on board on Erytra Eflexis® will appear on the **Status > Missing Samples** (Figure 29).

    Once the missing samples (donors and/or samples) are loaded, the execution automatically starts.

9.3.6 Modify Crossmatch Assignments

The assignments can be modified by using the **Crossmatching Summary** window buttons.

Button	Description
	Delete all Recipient–Donor profile assignments selected in the **Crossmatch Summary** window (Figure 47, no. 1).
	Add new Recipient–Donor profile assignments using the **Donor Assignments** window.
	Duplicate the Recipient–Donor profile assignments selected in the **Crossmatch Summary** window (Figure 47, no. 1) to assign the same profile requests to a differnt recipient**.**

To modify an assignment:

1. Select a Recipient-Donor profile assignment in the **Crossmatch Summary** window:
   - To modify the Recipient, select the desired recipient in the combo-box (Figure 47, no. 2).
   - To modify the crossmatch profile, select the desired profile in the combo-box (Figure 47, no. 3).
2. To add a new donor that are already loaded, select the desired ID donor on the **Available Donors** table (Figure 47, no. 4) and press the **Move Sample** button  .
   The donor is assigned to this recipient and its ID is updated on the **Donors List** table (Figure 47, no. 5).
3. To delete a donor that has already assigned to a recipient, select the donor on the **Donors List** table (Figure 47, no. 5) and press **Move Sample** button  .
   The donor is deleted from the **Donors List** table.
4. Press **Confirm** button  to save the assignment.
5. Press  to close the **Donor Assignment** window.

9.3.7 Ordering and Filtering Samples on the Worksheet

All samples that have a test associated in "**Queue**", "**Running**", "**Pending validation**" or "**Validated**" status appear by default on the **Worksheet**.

By default, the samples are displayed on the **Worksheet** sorted by the following criteria:

- STAT samples.
- Samples with incidences.
- Position.

Figure 49. Worksheet Samples Ordering Window

To change the order of the samples on the **Worksheet:**

1. Press the **Sort** button  that appears on the top of Sample ID column (Figure 43, no. 1).
   The **Sort** window opens.

2. To choose what sort of samples will be shown on the screen, select one of following filter criteria (Figure 49):
   - All samples.
   - Present samples.
   - Non-present samples.
3. To choose the order that the filtered samples will be displayed on the screen, select one of the following sort criteria under icon  :
   - **Barcode:** The samples are sorted alphanumerically, according to their barcode.
   - **Position:** The samples are sorted by location in the racks in order from rack 1 to 4.
   - **Incident:** Any sample with an incidence associated with their results will appear first on the **Worksheet**.
   - **STAT:** Any sample with STAT status will appear first on the **Worksheet**.

NOTE: If **All Samples** option is selected in the filter, the samples that are not present inside the analyzer will be displayed below ordered by ID barcode.

NOTE: QC Samples do not follow the above conditions are displayed at the end of the list.

4. Press **Confirm** button  to filter and sort the samples. To close the window without changing the sort order, press **Cancel** button.

9.3.8 Executing the Workload

1. If the Erytra Eflexis® is connected to an LIS:
   - And the samples are already loaded into the analyzer the execution of the workload begins automatically.
   - If the samples are not loaded, load samples as described in Section 7.3 to start testing.
2. To manually execute the programmed workload, press the **Start Tests Execution** button  on the **Worksheet.**

NOTE: If a Quality Policy is activated in the **Manager** software, **Quality Control** samples will be processed prior the patient samples. For more information about the **Quality Control**, see Section 12.

9.3.9 Status of the Workload

The **Worksheet** is updated in real time with the status of requests by outlining each field with an assigned profile in color, according to the color code shown in Figure 50.

Figure 50. Color Code of the Worksheet

A request evolves to the following status:

Color	Status	Description
	Selected	The sample has the test assigned.
	Queued	The sample has the request pending to testing.
	Queued without sample	The sample has the request pending to testing but the sample tube is not loaded.
	In process	The sample has been started processing.
	Pending validation	The sample is finished and its result is pending to be validated in **Results** screen (see Section 10).
	Validated	The sample is finished and its result is already validated in the **Results** screen pending to be exported to LIS and/or to **Database** (see Section 10).
	Exported	The request is finished and its result has been exported to **Database** (see Section 11).

If during the test execution verification process described in Section 7.2.2 the analyzer detects that there are not enough resources to end the test execution and the corresponding **Missing Warning** displays in the **Warning Area** (Figure 22, no. 7), the execution test is stopped and the status of the request in **Worksheet** is updated to **Stopped** status.

Icon	Status	Description
	Stopped	The resources loaded into the analyzer are not enough to finish the test execution.

To restart the execution of the test load the missing resources as described in Section 7.4.

9.3.10 Cancel Workload

To cancel an unfinished request (those which have a status of either "**In process**", "**Queued**" or "**Pending**"**):**

1. Select the request on the **Worksheet.**
2. Press **Cancel Test Execution** button  (Figure 43, no. 5).

   The analyzer cancels the request, stops the execution and update the **Worksheet** to cancel status:

Icon	Status	Description
	Cancelled	The execution of the test request has been cancelled by the user.

10 Displaying and Validating Results

This section provides a description of the **Results** screen, the review, validation, modification, rejection, exportation, printing, exporting and saving of results.

10.1 Results Screen Overview

The **Manager** software provides a detailed analysis of test results and makes it possible to view the images of each test, the reaction grade and the interpretations.

Manager software combines the results of each microtube that form part of a phenotype interpretation (forward group, reverse group, phenotype, etc.) to provide an interpretion.

In addition, the software provides real time information on the status of the **Quality Control** configured for the tests in the analyzer and the traceability of the reagents used.

To view the **Results List** (Figure 51) showing all of the profiles which have been executed but not yet exported, press the **Results** module on the main screen of **Manager** software (Figure 42, no. 3).

Figure 51. Results Screen (Example)

(1) Button to access the **Profile Information Results.** For more information see Section 10.2.1. One of 3 icons is displayed:

Results without incidences which can be validated without a detailed review.

Results with **Exceptional Result** (incidence or special result requiring review, acceptance and/or modification or rejection of the incidence or special result for its validation). See more information in Section 10.3.2.

Results affected by a not resolved QC status profile Validate and export all QC results of the QC kit to validate these patient samples.

See more information in Section 12.4.13.

(2) **Sample identification:** For a crossmatch test, the recipient ID appears in black while the donor ID appears in green between quotation marks.

The **STAT** icon shows that the sample has been processed as a STAT sample.

Results with **Delta Check** icon should be individually reviewed because the **Manager** software has encountered an inconsistency with a previous result a (see Section 10.3.7).

(3) **Profile:** Set of tests executed on the samples.

(4) **Test:** Individual test which are part of the profile.

(5) **Results:** Results with clinical significance which are obtained by the combining of the reaction grade of the microtubes which form a part of the executed test.

(6) **Profile Status:** "**Pending validation**" or "**Validated**" status. For more information see Section 9.3.9.

(7) **QC:** QC protocol status ("**Pass**" or "**Fail**"). See more information about **Quality Control** see Section 12.

(8) **Date:** Date and time of the reading of the profile test.

(9) **Action buttons:** See table below:

The following table lists the action buttons of the **Result** screen that are used to validate results:

Buttons	Description
	**Filter:** Search and view the results for samples that have not yet been exported and that match the search criteria (date, profile, state, barcode, incidence, sample, etc.).
	**Delete Filter:** Clears the current filter of the results being viewed and displays all of the results on the **Results** screen.
	Select All: Selects all of the active samples on the **Results** screen. Once selected, the following actions can be carried out on the selected samples: **Validate**, **Cancel Validation**, **Export** and/or **Print**.
	**Deselect All:** Deselects the previous selection.
	**Validate:** Validation confirms acceptance by the user (with the necessary privileges) of ALL of the results of all of the selected profiles and is performed after the confirmation of the message that appears on the screen. Only the profiles which show the icon  will be validated.
	**Cancel Validation:** Once the results are validated, they can be changed back to the status "**Pending Validation"** by selecting them and pressing this button.

Reject: If a result is not accepted by a user with the necessary privileges, it can be rejected by pressing this button before it has been exported. The result is sent to LIS with "**Cancelled**" status and the result is moved from the **Results List** to the **Database** of **Manager** software (see Section 11).

Export: Once a result is validated, it can be exported to the LIS and/or to the **Database** of **Manager** software. Exporting is done after confirmation of the message that appears on the screen by a user with the necessary privileges. Once a profile's results have been exported, the results move from **Results** screen to **Database** of **Manager** software (see Section 11).

Print: Prints a report with the results of the selected sample profiles. For more information see Section 10.7.1.

10.2 Reviewing Results

Results are classified in two categories:

- **Normal Results**  **:** Results that the **Manager** software is able to interpret and to provide a final results. See Section 10.3.
- **Exceptional Results**  **:** When the **Manager** software is not able to provide an interpretation. See Section 10.3.2.

NOTE: Exceptional Results (special results, results with incidences, and results with inconsistencies) can only be accepted by Operator with appropriate rights. See Section 13 for more information.

CAUTION: When accepting a result during the validation step, take into account, in addition to the result itself, any incidence deriving from the condition of the sample, the analyzer, the result itself, the **Quality Control** results, and any additional clinical information. Such incidences requires acceptance prior to the validation of the result.

10.2.1 Viewing Detailed Results Information

To view detailed results information press  or  (Figure 51, no. 1).

The **Profile Information Results** screen opens (Figure 52, no. 1), showing all the information related to the profile tests, including the images of the microtubes associated with every test, the interpretation and the possible errors and associated incidences.

Figure 52. Profile Information Results Screen (Example)

(1) General information of the sample.

(2) Profile information and the tests involved.

(3) Results of the tests.

(4) Images of the microtubes of the gel card associated with the selected test. To enlarge the image, press **Zoom** button .

(5) Result interpretation of the test.

(6) Reaction grade information.

(7) Navigation buttons: Access the **Profile Information Results** which appear on the **Results List** (Figure 51).

(8) **Traceability** button.

(9) The **Accept Results** button to accept incidences and/or special results (see more information in Section 10.3.2).

(10) Comments.

Underneath the photograph of every microtube, there is a button with the reaction grade provided by the **Manager** software (Figure 52, no. 5). See Reaction Grades table and Figure 53 for a picture of example of reaction grades.

Table 5. Reactions Grade

RESULT	REACTION GRADE	DESCRIPTION
Negative	0	Well-defined pellet of non-agglutinated red blood cells at the bottom of the gel column and no visible agglutinated cells in the rest of the gel column
Doubtful	?	The reading algorithm is not able to decide between "-" and "+/-". This is considered a **Special Result** (see below) and must be reviewed and manually assigned as a valid result. This may be caused by very few free red blood cells in the gel column or by small artefacts such as particles or bubbles in the gel.
	+/-	Barely visible small-sized clumps of agglutinated cells in the lower part of the gel column and a pellet of unagglutinated cells at the bottom. This is considered a **Special Result** (see below) and must be reviewed and manually assigned as a valid result.
Positive	1+	Some small-sized clumps of agglutinated cells most frequently in the lower half of the gel column. A small pellet may also be observed at the bottom of the gel column.
	2+	Small or medium-sized clumps of agglutinated cells throughout the gel column. A few unagglutinated cells may be visible at the bottom of the gel column.
	3+	Medium-sized clumps of agglutinated cells in the upper half of the gel column
	4+	A well-defined band of agglutinated red blood cells in the top part of the gel column. A few agglutinated cells may be visible below the band.
Double Population	DP	A band of red blood cells at the top part of the gel or dispersed through the gel column, and a pellet in the bottom as a negative result.

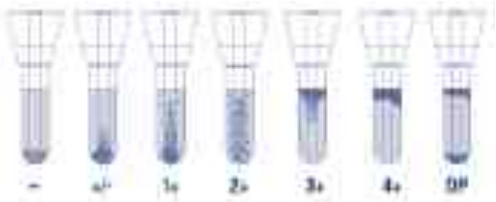


Figure 53. Picture of an Example of Reaction Grades

NOTE: In case that the software is not able to assign any of the previous results to the microtube, a Not Determined Result (NR) will be provided.

Once the reaction grade in the different microtubes which form part of the test is classified, the **Manager** software applies a mathematical algorithm to interpret the results and make a determination.

10.2.2 Viewing Traceability Information

To view all the information regarding the traceability of the test and the sample executed. To do this, press on the **Traceability** button  on the **Profile Information** screen. The **Test Traceability Information** window opens (Figure 54) showing all the information related to the traceability of the test:

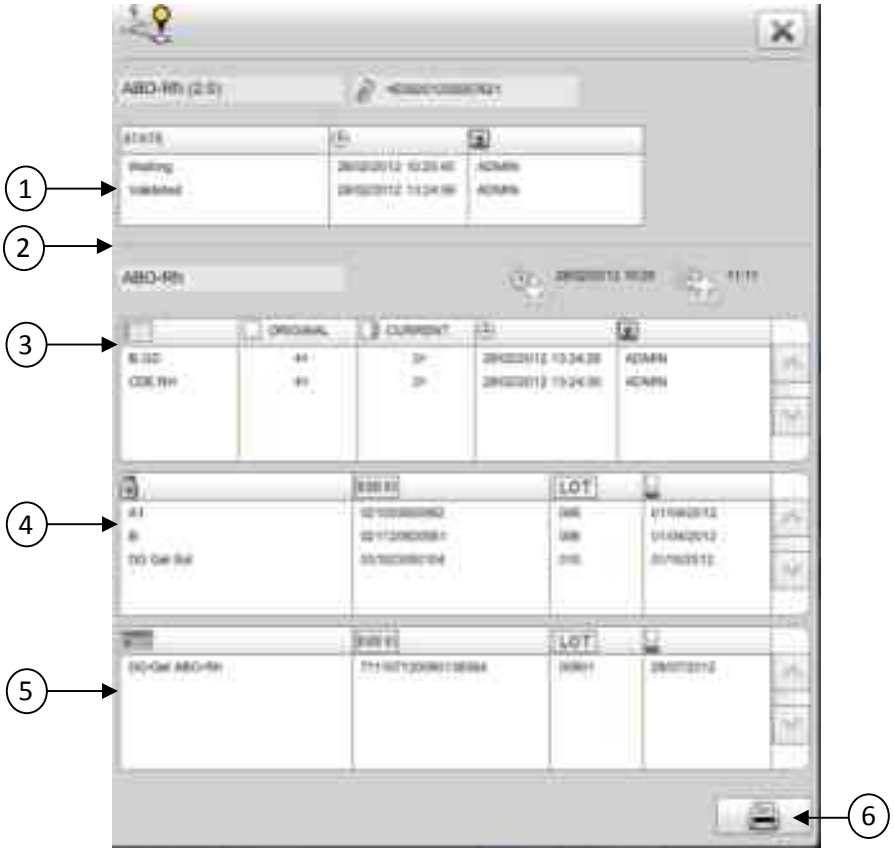


Figure 54. Test Traceability Information (Example)

(1) Test execution information: This section contains the following information: Test name, Sample ID, timing status and User involved in the execution.

(2) **Quality Control** traceability: This section contains the following information about the **Quality Control**: Lot number, expiry date, Finish QC time and QC protocol result. To see more information about **Quality Control** see Section 12.

(3) Results traceability: This section contains information about the microtubes which results has been modified. Traceability of the instrument result, time of the modificacion and the user responsible of this modification is also included.

(4) Reagents traceability: This section contains information about the reagents used in the test execution, including barcode, lot number and expiry date.

(5) Gel cards traceability: This section contains information about the gel card used in the test execution, including barcode, lot number and expiry date.

(6) **Print** button. Pressing this button, the traceability information is printed directly by the printing.

10.3 Validating Results

10.3.1 Validating Normal Results

Validation of the results confirms acceptance and can be done individually, by sample, by profile, or in multiple ways, as long as this does not produce discrepant results, special results or results with incidences.

CAUTION: Results must be reviewed and validated by an Operator with the appropriate rights.

Results that do not have an associated incidence, or are not exceptional results or do not have any inconsistence with the previous results do not need to be accepted before validated. To validate routine results:

1. From the **Results** screen, select the results to be validated. To do that, individual results or **Select All** button can be used.
2. Press the **Validate** button  .
   A window appears to confirm validation.
3. Press the **Confirm** button  .

NOTE: If the **Enable Passwords** option is activated (see Section 13.1) the software will request the re-identification of an user (**User** and **Password**).

Validated results will now appear in green in the **Results** screen and show a status of "**Validated**". After validation, results can be exported.

10.3.2 Reviewing and Validating Exceptional Results

There are some situations where the **Manager** software is not able to provide an interpretation and are displayed in red  in the **Results** screen (Figure 51, no. 1).

A list of the type results that are considered exceptional results and their category is shown in the table below:

Table 6. Type of Results

ICON	RESULT	DESCRIPTION
	**Special Microtube Grade**	• Double Population (DP) • Doubtful reaction grade (?). • Doubtful positive reaction grade (+/-). • No Results Determined (NR). • Any result or reaction grades previously configured as a special result in the Manager software.

ICON	RESULT	DESCRIPTION
	**Special Interpretations**	• Not interpretable Results (NI). • Positive Autocontrol. • Positive Direct Antiglobulin Test.
No icon	**Discrepant Interpretations**	• Discrepancies (Dis): When the result of combining the subgroup (i.e. forward and reverse) of the possible phenotyping interpretations of the test does not allow the software to obtain a clinical result because it is incongruous.

NOTE: To configure the **Special Result** or **Special Microlumn Grades** on the **Manager** software, contact your local Grifols service representative.

The results listed above must be reviewed and confirmed individually before it can be validated.

To review and confirm results:

1. Press  next to the sample ID in the **Results** screen to open the **Profile Information Results** screen (Figure 52).

   More specific information about the microtube grade and/or special results is available.

2. Retrieve the processed gel card with the exceptional result that has been stored in the Service Rack (if it has been configured to) and perform the actions described in the following sections, as appropriate.

NOTE: To aid the review process, the analyzer can be configured to store any gel cards with incidences in the Service Rack so that they will be available for review.

Cards with special results and special interpretation can be configured to leave the affected cards in the Service Rack for further review of the user.

To configure the Service Rack, contact your local Grifols service representative.

NOTE: It is possible to use the external barcode reader provided with the instrument for scanning the barcode of the gel cards left in the Service Rack and review their results by introducing the scanned barcode in the proper field of the filter.

For more information about Erytra Eflexis® configuration, contact your local Grifols service representative.

3. Repeat steps 1 and 2 for any other microtube of the sample profile that have special results.

4. Press the **Accept Results** button to accept the results for that sample profile. This button accepts all exceptional results in the profile, including the results of the reaction grade of the microtubes. Once results have been accepted, the same **Accept Results** button allows you to undo the acceptance**.**

NOTE: To reject the results, press  . The request and its results are deleted from the **Results** screen and archived in the **Database** of **Manager** software.

5. Press the **Confirm** button  to confirm acceptance.

6. If requested, enter **Username** and **Password**, and press  .
   Any **Exceptional Result** icon will change color from red to green:
   - From  to .
   - From  to  .

7. Add a comment (if desired) by pressing the **Comment** button  .
   Introduce the comment by using the virtual keyboard.

8. To validate the entire profile, press the **Validate** button  .

NOTE: Press  to return to the **Results** screen, where this profile can be validated individually or along with other results.

10.3.3 Reviewing and Accepting Execution Processing Incidents Results

During the execution of the test, incidences can occur which can affect the reaction grade. The software marks the affected microtube with the **Microtube Incident** icon  .

The possible incidences that can appear in the results are described below.

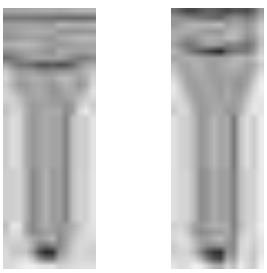
10.3.3.1 Incidents During Card Reading

The table below describes the different abnormal events that can be detected by the analyzer during the reading step, the results provided and the corresponding warning in the microtubes affected. A description of the most common actions that can be performed by the Operator is also included:

Table 7. Incidents During Card Reading

WARNING	RESULT PROVIDED	DESCRIPTION AND INCIDENCE RESOLVING
No RBC	NR	The analyzer has detected that the quantity of red blood cells in the microtube are below the expected range. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Confirm the absence or low quantity of RBCs. 3. If the incidence is confirmed: • Check that there are enough volume of reagent and its integrity. • Check that there are enough volume sample and its integrity. 4. Then reject the result by using the **Reject** button and repeat

WARNING	RESULT PROVIDED	DESCRIPTION AND INCIDENCE RESOLVING
		the test. If it is a frequent incidence, contact your local Grifols service representative.
RBC excess	NR	The analyzer has detected that the quantity of RBCs in the microtube is higher than expected. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Confirm the excess of RBCs. 3. Identify the sample tube. 4. Check the integrity of the sample. 5. This incidence does not invalidate the test: • If the quantity of RBCs is acceptable according to the visual reading, therefore proceed to modify the result as described in Section 10.4 and accept the test result by pressing **Accept Results** button . Then validate and export the result. • If the quantity of RBCs is not acceptable, reject the result by using the **Reject** button and repeat the test. If it is a frequent incidence, contact your local Grifols service representative.
Fibrin haemolysis	NR	The analyzer has detected the presence of fibrin in the top of the microtube. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Confirm the presence of fibrin. 3. Identify the sample tube. 4. Inspect the sample tube and check for the presence of fibrin. 5. Only in those cases that the fibrin strand is clearly visible in the microtube image and can be distinguished from the reaction pattern, modify the NR result to a valid result as described in Section 10.4 and accept the test result by pressing **Accept Results** button  . Then validate and export the result.
Haemolysis	Original result	The analyzer has detected hemolysis in the incubation chamber of the microtubes or the highest area of the gel column. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Confirm the presence of hemolysis. 3. Identify the sample tube. 4. Inspect the sample tube and check if there is or not presence of hemolysis in the tube. • If hemolysis is present:

WARNING	RESULT PROVIDED	DESCRIPTION AND INCIDENCE RESOLVING
		- Check the historical data of the patient to confirm or discard the presence of potential autoantibodies. - Confirm that the blood samples has been collected following standard blood sampling guidelines, it has been stored in appropriate conditions and the extraction date. - Check the storage and centrifugation conditions of the sample. Then, if appropriate, accept the microtube result by using **Accept Results** button , validate and export. • If hemolysis is not present, reject the result by using the **Reject** button and repeat the test.
Not classificable	NR	The agglutination pattern presented by the microtube does not match any of the known agglutination patterns used by the analyzer. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Check the result provided by the analyzer and modify the result according the visual reading. 3. Accept the microtube result by using **Accept Results** button . Then, validate and export.
Not detected volume	Original result	The analyzer has failed to detect the dispensed volume in the incubation chamber of the microtube. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. To review it, check in the Instructions for Use of the product to identify the volume needed for the performed test. Then, compare the processed card volume with the expected volume for this test. An example of the approximated expected total volumes after centrifugation for each test are: 75 µL 100 µL  • If the incidence is confirmed, check that there are enough volume of reagent and sample, reject the result by using the

WARNING	RESULT PROVIDED	DESCRIPTION AND INCIDENCE RESOLVING
		Reject button and repeat the test. • On the contrary, confirm the result provided by the analyzer or modify the result according the visual reading. Then, accept the microtube result by using **Accept Results** button .
Reading error	NR	An anormaly during the during the image digitalization process of the card makes imposible to obtain the results. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Modify the result according the visual reading of the gel card. 3. Accept the microtube result by using **Accept Results** button . If the incidence is recurrent, contact your local Grifols service representative.

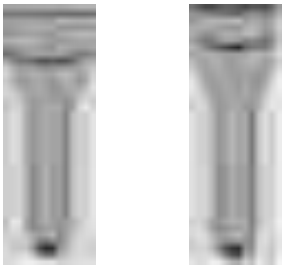
10.3.3.2 Incidents During Test Execution

The table below describes the different incidences that could take place during execution and the corresponding warning in the microtubes affected. A description of the most common actions that can be performed by the Operator is also included:

Table 8. Incidents During Test Execution

DESCRIPTION	RESULT PROVIDED	TROUBLESHOUTING
Over-incubation	Original result	The incubation time of the gel card has exceeded the tolerable time. Proceed as follow: 1. Reject the result by using the **Reject** button . 2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.
Over-centrifugation	Original result	The centrifugation time of the gel card has exceeded the tolerable time. Proceed as follow: 1. Reject the result by using the **Reject** button . 2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.

DESCRIPTION	RESULT PROVIDED	TROUBLESHOUTING
Loss sensitivity	NR	The time between reading and the end of centrifugation exceeded the tolerable time. Proceed as follow: 1. Reject the result by using the **Reject** button . 2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.
Missing validation step	NR	The gel card integrity check has not been performed. 1. Reject the result by using the **Reject** button . 2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.
RBC to serum timeout	Original result	The time between RBC and serum dispensations has exceeded the tolerable time. 1. Reject the result by using the **Reject** button . 2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.
Missing reagent incubation step	NR	Reagent (in tests that require 2 incubation steps) has not been incubated. 1. Reject the result by using the **Reject** button . 2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.
Missing incubation step	NR	The incubation step has not been completed or executed. 1. Reject the result by using the **Reject** button . 2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.
Missing pipetting step	NR	The pipetting step has not been completed or executed. 1. Reject the result by using the **Reject** button  .

DESCRIPTION	RESULT PROVIDED	TROUBLESHOUTING
		2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.
Missing centrifugation step	NR	The centrifugation step of the gel card has not been completed or executed. 1. Reject the result by using the **Reject** button . 2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.
Missing reading step	NR	The reading step of the gel card has not been completed or executed. 1. Reject the result by using the **Reject** button . 2. Repeat the test. If the incidence is recurrent, contact your local Grifols service representative.
Incorrect volume	Original result	The total volume dispensed in the microtube does not coincide with the expected volume in test where serum/plasma. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. To review it, check in the Instructions for Use of the product to identify the volume needed for the performed test. Then, compare the processed card volume with the expected volume for this test. An example of the approximated expected total volume after centrifugation for each test are: 75 µL 100 µL  • If the incidence is confirmed, reject the result by using the **Reject** button and repeat the test. • On the contrary, confirm the result provide by the analyzer or modify the result according the visual reading. Then,accept the

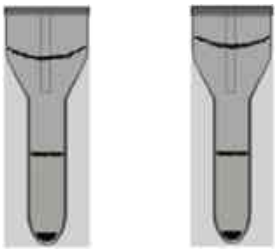
DESCRIPTION	RESULT PROVIDED	TROUBLESHOUTING
		microtube result by using **Accept Results** button .

To review and accept incidences, press the **Microtube Incident** icon from the **Profile Information** screen near the image of the microtube to obtain more information about the incidence.

10.3.4 Reviewing and Accepting Special Microtube Grade Results

The table below describes the different special microcolum grade agglutination which can be provided by the analyzer and the description of the most common actions that can be performed by the Operator:

Table 9. Special Microtube Grade Results

DESCRIPTION	TROUBLESHOUTING
DP (Double Population)	The analyzer has detected a band of red blood cells at the top part of the gel or dispersed throughout the gel column, and a pellet in the bottom as a negative result. Precaution should be taken in the interpretation of double population events. 1. Retrieve the card gel from the Service Rack and inspect it visually. To review it, check in the Instructions for Use of the product to identify the volume needed for the performed test. Then, compare the processed card volume with the expected DP pattern for this test. An example of the approximated expected pattern for DP after centrifugation for each test are: 75 µL 100 µL  2. Check for the absence of fibrin following the instructions described in Section 10.3.3. 3. If fibrin is discarded and the DP pattern is confirmed. • Read carefully the Instructions for Use of the gel card. • Check additional information on patient history about subgroups, transfusion or transplant events. • Follow the corresponding guidelines. • Perform additional testing, if necessary. 4. With this information: • Accept the microtube result by using **Accept Results** button . If **DP** result is accepted as a result, **Not Interpretable** result (NI) is reported by the analyzer in the result interpretation level (Figure 52, no. 5) after combining the corresponding microtubes that form part of that interpretation. The result is ready to be validated and exported (see more information in Section 10.3).

DESCRIPTION	TROUBLESHOUTING
	• Modify the result according the visual reading. See more information in Section 10.4. Then, validate and export the result.
Doubtful reaction grade (?)	The analyzer has detected a very weak reaction pattern "?" in that microtube that is lower than "+/-" agglutination grade. Given that this reaction can be in the limit of the sensitivity of the reader, this result must be confirmed by the user. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually: • Accept the microtube result by using **Accept Results** button . If "?" result is accepted as a result, **Not Interpretable** result (NI) is reported by the analyzer in the result interpretation level (Figure 52, no. 5) after combining the corresponding microtubes that form part of that interpretation. The result is ready to be validated and exported (see more information in Section 10.3). • Modify the result according the visual reading by assigning a valid result as indicated in Section 10.4. Then, validate and export the result.
Doubtful reaction grade (+/-)	The analyzer has detected a weak reaction pattern in that microtube corresponding to a "+/-" agglutination grade. Given that this reaction can be in the limit of the sensitivity of the reader, this result must be confirmed by the user. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Proceed according of the guidelines of the lab: • Accept the microtube result by using **Accept Results** button . If "+/-" result is accepted as a result, **Not Interpretable** result (NI) reported by the analyzer in the result interpretation level (Figure 52, no. 5) after combining the corresponding microtubes that form part of that interpretation. The result is ready to be validated and exported (see more information in Section 10.3). • Modify the result according the visual by assigning a valid result as indicated in Section 10.4. Then, validate and export the result.
Any result previously configured as a special result in the **Manager** software	The analyzer has detected a reaction pattern that agrees to an agglutination that must be reviewed under customer request (see more information in the introduction of this section). Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Confirm the result provide by the analyzer. 3. Proceed according of the guidelines of the lab: • Accept the microtube result by using **Accept Results** button . If a regular agglutination (from - to 4+) is accepted, the analyzer combines the result of the defined microtubes to provide the result interpretation. The result is ready to be validated and exported (see more information in Section 10.3). • Modify the result, if appropriate (see more information in Section 10.4). Then, validate and export the result.
NR (No Result Determined)	The reaction shows a pattern that is not reconized by the reader. Proceed as follow: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Modify the results according the visual reading. See more information in Section 10.4.

DESCRIPTION	TROUBLESHOUTING
	If a regular agglutination (from - to 4+) has been introduced, the analyzer combines the result of the defined microtubes to provide the result interpretation. The result is ready to be validated (see more information in Section 10.3).

10.3.5 Reviewing and Accepting Discrepancies Results

Discrepancies between forward and reverse groups may be observed. Proceed as follow:

1. Retrieve the card gel from the Service Rack and inspect it visually.
2. If the visual reading confirms the results obtained by the user:
   - Read carefully the Instructions for Use of the used gel card.
   - Check additional information on patient history. Discrepancies between forward and reverse groups may be observed in patients with low or non-existent levels of isoagglutinins: Newborns up to the age of 4-6 months, elderly persons, patients with immunodeficiency or with much diluted antibodies due to plasma exchange procedures.
   - Follow the corresponding guidelines to resolve.
   - Perform additional testing if necessary.
   - Accept the microtube result (if appropriate) by using **Accept Results** button .

     If the discrepant result is accepted as a result, **Not Interpretable** result (NI) is reported by the analyzer in the result interpretation level (Figure 52, no. 5) after combining the corresponding microtubes that form part of that interpretation.

     The result is ready to be validated (see more information in Section 10.3).
3. On the contrary, modify the results according the visual reading. See more information in Section 10.4.

   If a regular agglutination (from - to 4+) has been introduced, the analyzer combines the result of the defined microtubes to provide the result interpretation. The result is ready to be validated (see more information in Section 10.3).

10.3.6 Reviewing and Accepting Specials Results

The table below describes the different special results which can be provided by the analyzer and the description of the most common actions that can be performed by the Operator:

Table 10. Specials Results

DESCRIPTION	TROUBLESHOUTING
NI (Not Interpretable)	**Manager** software fails to obtain an expected interpretation when it combines the results of each microtube that form part of a phenotype interpretation (forward group, reverse group, group, phenotype, etc.). Proceed as follow to solve: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. Identify the cause of the NI: • If it due to a processing incidence, follow the procedure described in Section 10.3.3. • If it is due to a special microtube grade, follow the procedure described in Section 10.3.4. • If it is due to a discrepant result, follow the procedure described in Section 10.3.5.

DESCRIPTION	TROUBLESHOUTING
	• If it is due to a Positive control microtube, follow the Instructions for Use of the corresponding gel card. Repeat the test, if necessary.
AUTOCONTROL NOT NEG (Autocontrol Not Negative)	**Manager** software detects that a positive autocontrol. Proceed as follow to solve: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. If the visual reading confirms the results obtained by the user: • Read carefully the Instructions for Use of the used gel card. • Check additional information on patient history. • Follow the corresponding guidelines to resolve. • Perform additional testing if necessary. 3. Accept the results (if it is appropriate) following the procedure described in Section 10.3 or repeat the test.
DAT NOT NEG (Direct Antiglobulin Test Not Negative)	**Manager** software detects that positive direct antiglobuline test. Proceed as follow to solve: 1. Retrieve the card gel from the Service Rack and inspect it visually. 2. If the visual reading confirms the results obtained by the user: • Read carefully the Instructions for Use of the used gel card. • Check additional information on patient history. • Follow the corresponding guidelines to resolve. • Perform additional testing if necessary. 3. Accept the results (if it is appropriate) following the procedure described in Section 10.3 or repeat the test.

10.3.7 Reviewing Results with Inconsistencies

An inconsistency is considered a discrepancy between two results for samples that have the same patient identification number or sample barcode sample tube. **Manager** software can be configured to search for inconsistencies once a result has been obtained.

NOTE: Contact your Grifols service representative to activate this inconsistencies check and set the time period from when inconsistencies should start to be reviewed.

Once configured, the system checks for inconsistencies between results that are pending validation and any other result with the same patient ID or sample barcode (depending on what has been previously configured) that is one of the following status: "**Pending Validation**", "**Validated**" or "**Exported**". See Section 9.3.9.

If an inconsistency is encountered, the system will show the **Delta Check** icon on the **Results** screen (Figure 55).

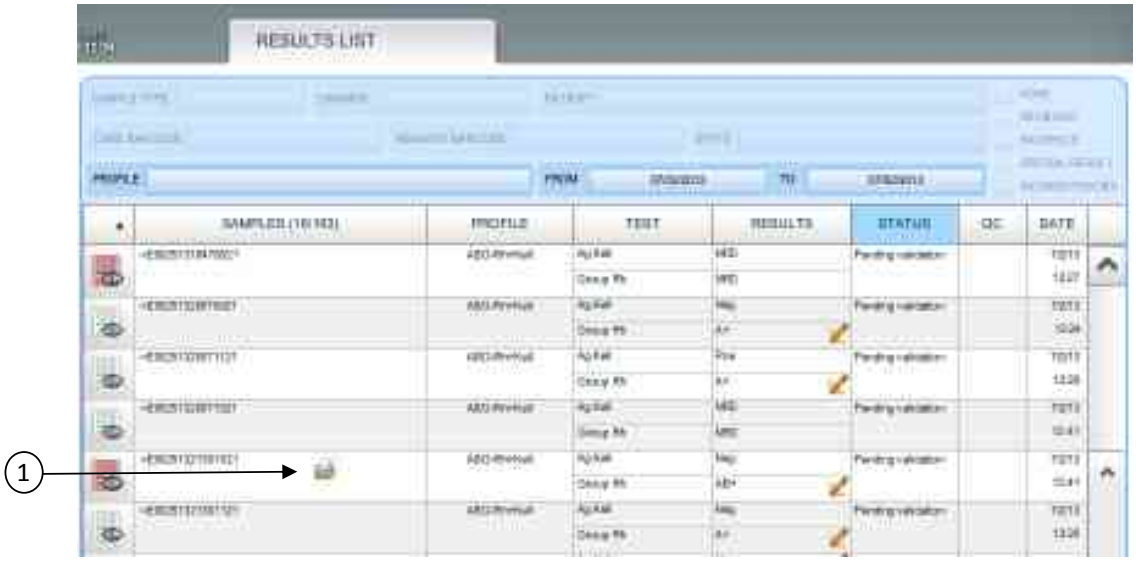


Figure 55. Results Screen Showing Inconsistencies (Example)

(1) **Delta Check** icon.

To review the inconsistency and validate the result:

1. Go to the **Profile Information** window by pressing  .
   The **Profile Information Results** screen displays (Figure 56).

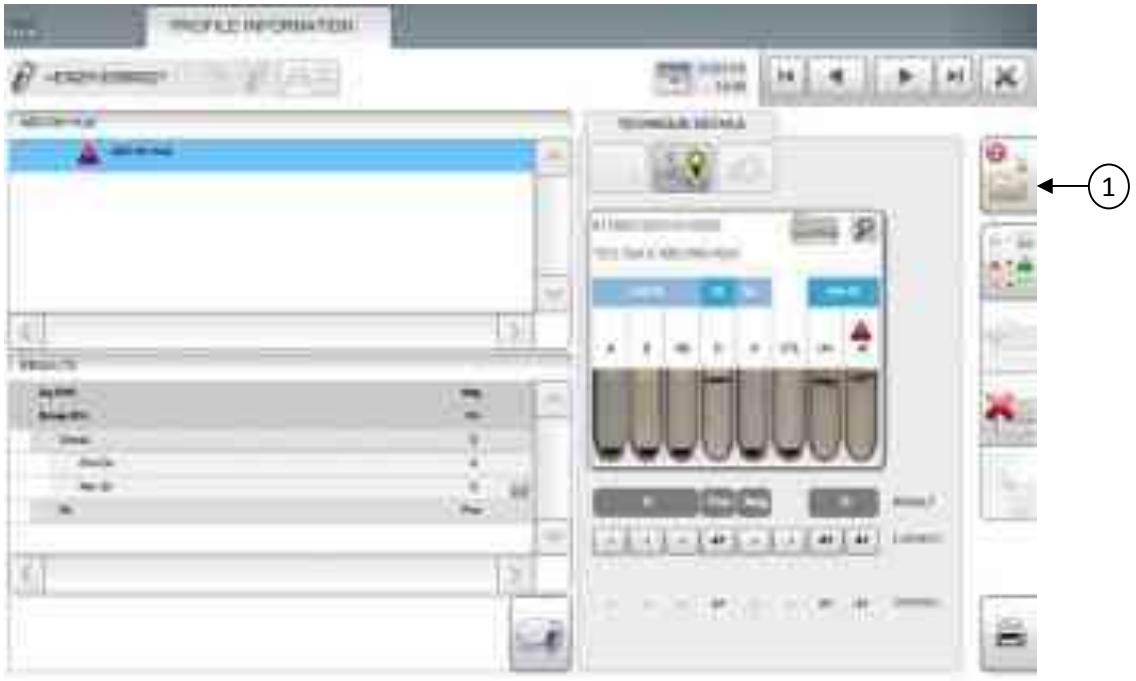


Figure 56. Profile Information Results with Pending Review Inconsistencies

(1) **Delta Check** icon.

2. Press the **Delta Check** button  to view more information about the inconsistency.

   The **Manager** software displays **Inconsistencies Result** window (Figure 57) with all the previous inconsistent results obtained in other executions for the same sample or for the same patient.

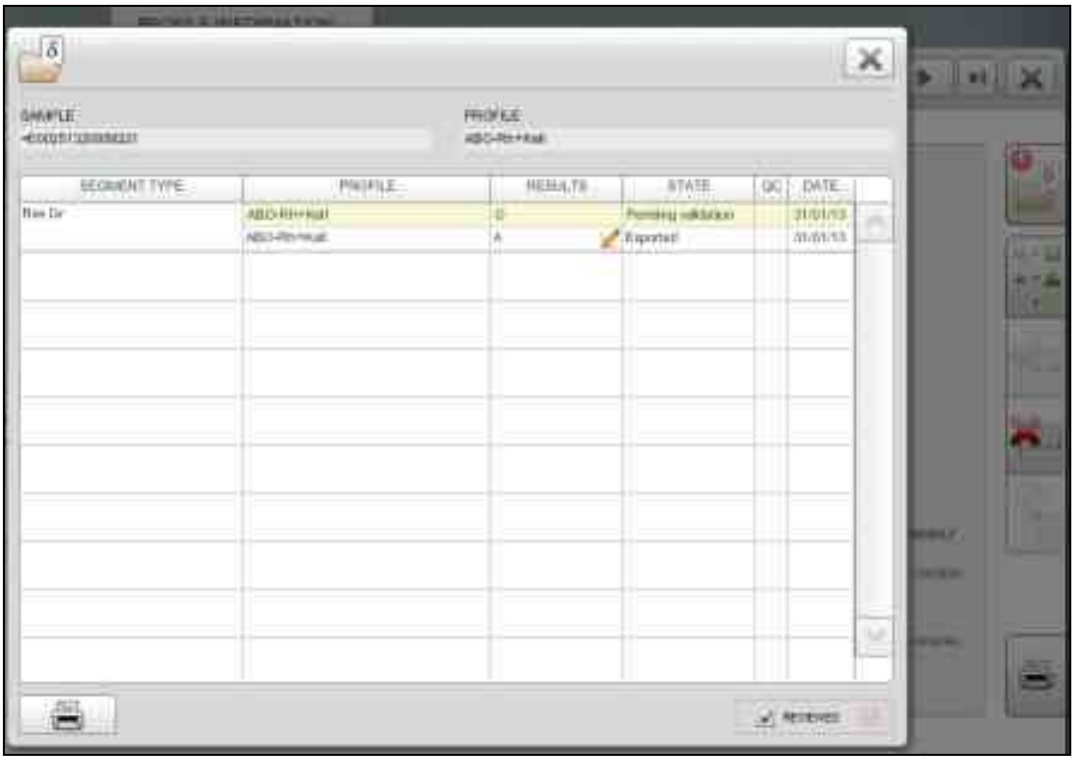


Figure 57. Inconsistencies Result Window (Example)

3. After reviewing the inconsistency, press the **Close** button  in the upper-right corner to close the window and accept the inconsistency.
4. Accept the confirmation message that appears.
5. Once the inconsistency is accepted, the symbol of the **Reviewed Inconsistency Delta Check** icon  remains associated to that result for traceability purposes. Therefore, the inconsistency, despite being accepted, can always be reviewed and the acceptance can be reversed if the result is in "**Pending Validation**", "**Validated**" status. If the result is exported, the acceptance can not be reversed.

NOTE: By default, if "**Detail of the Inconsistency**" window (Figure 57) (inconsitencies that are reviewed are marked as "**Reviewed**" in the **Inconsistency Detail** screen in Figure 58.

Figure 58. Profile Information Results with Reviewed Inconsistencies

(1) **Reviewed Inconsistency Delta Check** icon.

10.4 Modifying the Reaction Grade

The reaction grade obtained by the analyzer can be modified. The **Manager** software will automatically interpret the result using the new reaction grade.

To modify the reaction grade:

1. Press on the reaction grade (Figure 59, no. 3).
2. Select the appropriate reaction grade.

   A confirmation message displays.

NOTE: Press **Close** button  to cancel the action.

---

3. If requested, enter **Username** and **Password**, and then press  .
4. Add a comment, if desired, by pressing the **Comment** button  .

   The modifications will be updated on the line that corresponds to **Current** reaction grade (Figure 59, no. 3). The new interpretation results are displayed on the **Interpretation Results** level (Figure 59, no. 2).
5. Validate the results (see more information in Section 10.3).

The icon  is displayed next to any interpretation result that has had the modified reaction grade of microtube involved.

NOTE: Any modification made to the reaction grade is recorded by **Manager** software.

NOTE: The modification of a reaction grade can change the interpretation of a profile.

Figure 59. Profile Information Screen with Modified Results (Example)

(1) Images of the microtubes of the gel card associated with the selected test.

(2) Result interpretation of the test.

(3) Current reaction grade.

(4) Original reaction grade reported by the analyzer.

10.5 Rejecting Results

To reject a result:

1. Go to the **Profile Information** window by pressing or
   The **Profile Information Results** screen displays (Figure 56).

2. Press the **Reject** button . A confirmation message displays.

After confirming, the results are deleted from the **Results** screen and archived in the **Database** of **Manager** software.

10.6 Exporting Results to LIS

Once the Results are validated (see Section 10.3) the results can be sent to the Laboratory Information System (LIS), if it is configured.

To export results:

1. From the **Results** screen, select the results to export by pressing on each result or by pressing the **Select All** button to select all of the results on the **Results** screen.

2. Press the **Export** button  .

3. Press the **Confirm** button  to confirm.

   The selected results are sent to LIS (if configured) and moved to the **Database** screen.

   It is possible to configure that results without incidences are automatically validated and exported. To have more information about this option, please contact your local Grifols service representative.

10.7 Printing and Saving Results Reports

10.7.1 Printing Report

The **Manager** software provides different reports, which can be viewed and printed by the Operator at any stage after results have been generated.

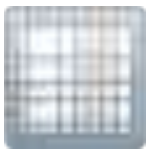
To print the results which appear on the **Results** screen (Figure 51):

1. From the **Results** screen, select the results to be included in the Report. To do that, individual results or **Select All** button can be used.

2. Press the **Print** button  .

3. Select one of the three types of report available:

   - Press  to obtain the **Reading Report** with all of the results of the sample profiles selected, with the interpretation of the results of each profile test, along with the reaction grade associated with each microtube.

   - Press  to obtain the **Results List Report** with the results of the sample profiles selected, with only the final interpretation of the results for each profile test.

   - Press  to obtain the **Traceability Report,** which includes the results of the sample profiles selected, with the image of the processed card microtubes, and their reaction grade.

NOTE: In order to print more detailed information in relation to a specific profile applied to a specific sample, enter the screen **Profile Information** and print it from there.

NOTE: To add the logo of the laboratory on the printed reports, contact your local Grifols service representative.

NOTE: When a new report is created the generation process could take some minutes as a function of the results selected.

4. Press **Print** button in the **Report Tool Bar** (Figure 60) to obtain a printed copy of the report.

Figure 60. Report Tool Bar

5. Press **Close** button on the top-righ of the window to close the report and continue working with the **Manager** software.

10.7.2 Saving Report Data

To save the report:

1. Follow the steps from 1 to 3 described on Section 10.7.1 to display the report with the desirable range of results.
2. Press **Save** button of the **Report Tool Bar** (Figure 60).
3. Select the directory to save the report and enter the file name.
4. Press the **Save** button.

   The report is saved on the selected directory.
5. Press **Close** button on the top-righ of the window to close the report and continue working with the **Manager** software.

11 Searching Results in Database

The **Manager** software has a **Database** (independent from the **Database** in any connected LIS) where all results are stored, including the images. All of these results and images are accessible to the Operator at any time.

11.1 Searching and Viewing Results in the Database

To search and view results that have been stored in the **Database** after exporting from the **Results** screen:

1. Press the **Database** button (Figure 22, no. 4).

   The **Search Filter** screen opens (Figure 61).

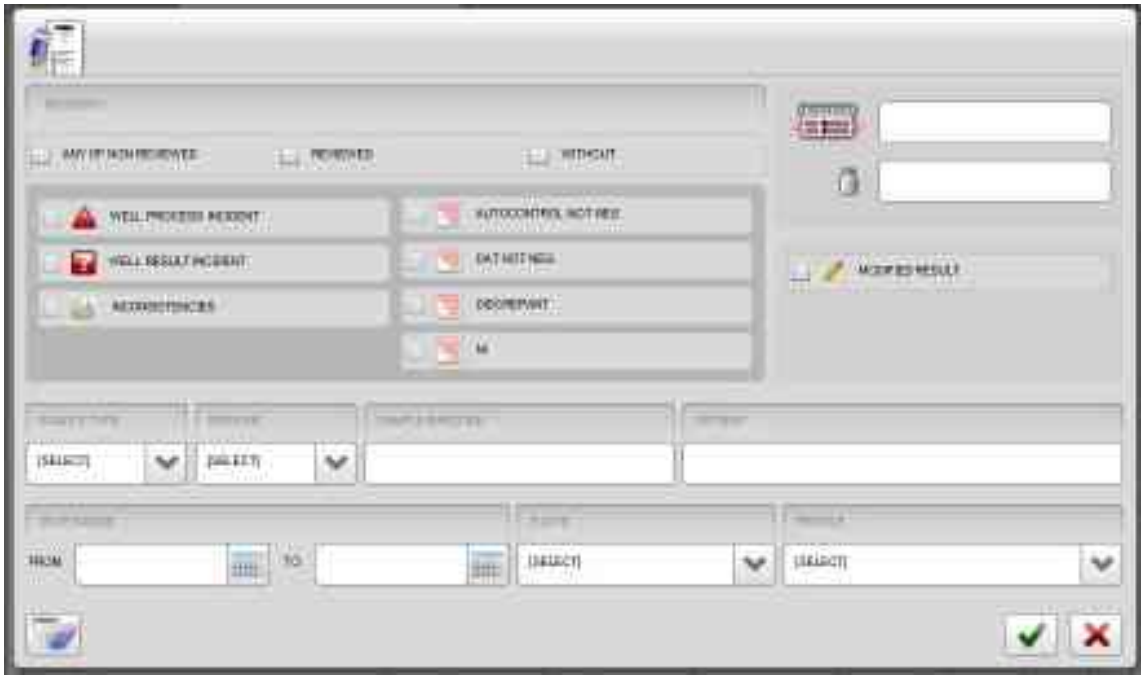


Figure 61. Search Results Filter Screen

2. Select one or several of the first category of search criteria filters:
   - **Results with/without Incidences**. The table below describes the available main filter:

Table 11. Search Criteria Filters

SEARCH CRITERIA	DESCRIPTION
Any of non Reviewed	The **Manager** software will display any result with incidences that has not been accepted by the Operator.
Reviewed	The **Manager** software will display any result with incidences that has been accepted by the Operator.
Without	The **Manager** software will display any result without incidences.

Additional filters can be added to this first category filter:

Table 12. Additional Search Criteria Filters

SEARCH CRITERIA	DESCRIPTION
Well Process Incident 	From the search described in the table above, the **Manager** software will apply an additional filter and will display the result with execution processing incidences only. See more information in Section 10.3.3.
Well Result Incident 	From the search described in the table above, the **Manager** software will apply an additional filter and will display the result with special microtube grades only. See more information in Section 10.3.4.
Inconsistent Results 	From the search described in the table above, the **Manager** software will apply an additional filter and will display the result with Inconsistencies only. See more information in Section 10.3.7.
Discrepant Results 	From the search described in the table above, the **Manager** software will apply an additional filter and will display the result with Discrepancies only. See more information in Section 10.3.5.
Special Results	From the search described in the table above, the **Manager** software will apply an additional filter and will display the result with Special results only. See more information in Section 10.3.6. An extra filter can also be applied to display: • Positive autocontrol. • Positive Direct Antiglobulin Test. • Non Interpretable result.

-  **Gel Card Barcode:** The **Manager** software will display the results obtained by using the gel card which barcode has been introduced in this field. Gel card barcode can be introduced manually or by using the external barcode reader.
-  **Reagent Barcode:** The **Manager** software will display the results obtained by using the reagent which barcode has been introduced in this field. Reagent barcode can be introduced manually or by using the external barcode reader.
- **Modified Results:** The **Manager** software will display the results that have been modified by the user only.
- **Sample Type:** The **Manager** software will allow filter the results to display by sample type (Patient or Donor) selecting the desired option in the drop-box.
- **Sample Rack:** The **Manager** software will allow filter the results to display by sample rack selecting the desired option in the drop-box.
- **Sample Barcode:** The **Manager** software will display the results obtained by the sample which barcode has been introduced in the **Sample Barcode** field. Sample barcode can be introduced manually or by using the external barcode reader.
- **Patient ID:** If demographic data is configured in the **Manager** software, the **Manager** software will display the results obtained by the patient ID which barcode has been introduced in the **Patient ID** field. Patient ID can be introduced manually or by using the external barcode reader.

- **Date Range:** The **Manager** software will display the results obtained during the time interval between **From** and **To**. To facilitate the introduction of the date, there is a small calendar accessible by clicking  .
- **Status Profile:** The **Manager** software will allow filter the results to display by Status of the profle ("Pending Validation", "Validated", "Exported" or "Cancelled") selecting the desired option in the drop-box. See more information about the status of the profiles in Section 9.3.9.
- **Profile:** The **Manager** software will allow filter the results by profile, selecting the desired option in the drop-box. Only profiles with executed results are available in the drop-box.

3. Click the **Confirm** button  to apply the selected filters. The **Database** displays the crossselection of results contained in the selected filters.

   The information appears on the screen in table form (Figure 62) with the following information:

   - Sample identification.
   - Profile.
   - Test.
   - Results.
   - Status.
   - Read date.
   - **Quality Control** status.

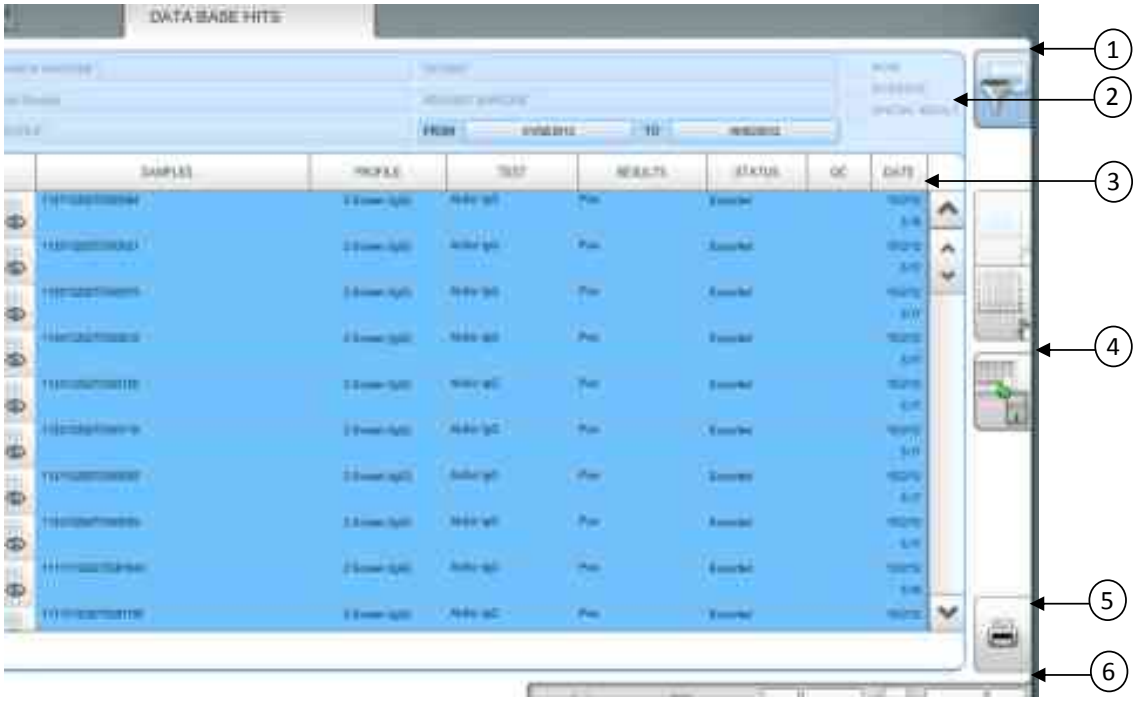
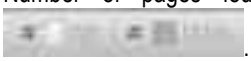


Figure 62. Pagination of the Results Found

(1) **Filter** button.
(2) Filter Information.
(3) Filtered results.
(4) **Export** button.
(5) **Print** button.

(6) Number of pages found matching this search criteria and the total number of listed results  . The **Page Navigation** buttons  allow movement between the different pages.

4. Press  , to access the **Profile Information** screen to see more detailed information about the tests contained in a specific profile. For more information see Section 10.2.1.

5. To perform a new search, delete the filter by pressing the **Delete Filter** button  and enter the new search criteria in the filter.

11.2 Printing Searched Results

To print the search results:

1. Select the desired results range. The **Select All** button and **Deselect All**  button allow the selection and de-selection of all of the results obtained by the search.

2. Press **Print** button  .

   The software allows you to choose from different report formats: For further information consult Section 10.7.1.

11.3 Saving Searched Results

To save search results in an electronic format follow the procedure described in Section 10.7.2.

11.4 Resending Results to LIS

If results are not successfully sent to LIS due to a connection problem, resent the results:

1. Search the result to be resent to LIS. See more information in Section 11.1.

2. Select the desired results range. The **Select All** button and **Deselect All**  button allow the selection and de-selection of all of the results obtained by the search.

3. Press the **Export** button  from the **Database** screen.

12 Quality Control

This section contains information on **Quality Control** overview, configuring the **Quality Control** module, Programming **Quality Control** samples, processing **Quality Control** samples, validating **Quality Control** samples, the **Quality Control** warning, exporting **Quality Control** results and the executing routine samples with Activated **Quality Control** configuration.

The **Manager** software ensures accurate test results through a dedicated **Quality Control** module for **Quality Control** samples management.

NOTE: To activate and configure **Quality Control** module, contact your local Grifols service representative.

12.1 Configuring Quality Control Policy

The **Quality Control** module can be configured with the following parameters:

- **QC Kit:** Set of **Quality Control** tubes defined together as a QC kit and included **Manager** software used to execute the **Quality Control** protocol. Once the **Quality Control** samples have been loaded into the analyzer, it automatically recognises and assigns the expected values of each tube for each test.

NOTE: Once a kit is activated, the **Manager** software automatically assigns the QC protocol to all tests on the **Worksheet** which contain the expected results of this kit and the the QC results automatically affect all these tests.

- **Frequency:** Defined in hours, after **Quality Control** samples are run, after which the **Quality Control** expires.
- **Enable Autovalidation of QC PASS:** The **Manager** software automatically validate any QC results with PASS results without needing review.

  It is also possible to configure the QC policy in a way that if the QC result is PASS, its results are automatically validated and exported. Furthermore, it is possible to leave them as pending validation. To configure it, contact your local Grifols service representative.

NOTE: Quality Control module settings are initially configured during installation. To change the configuration settings of the **Quality Control** module in **Manager** software, contact your local Grifols service representative.

NOTE: Once **Quality Control** module is activated, a prospective Quality Policy is followed according the defined parameters. This means that QC samples must be run with this profile with PASS results prior the test any patient sample with this profile.

To access to **Quality Control** module, press **Quality Control** button (Figure 42, no. 5) in the main screen of **Manager** software. The main screen displays (Figure 63):

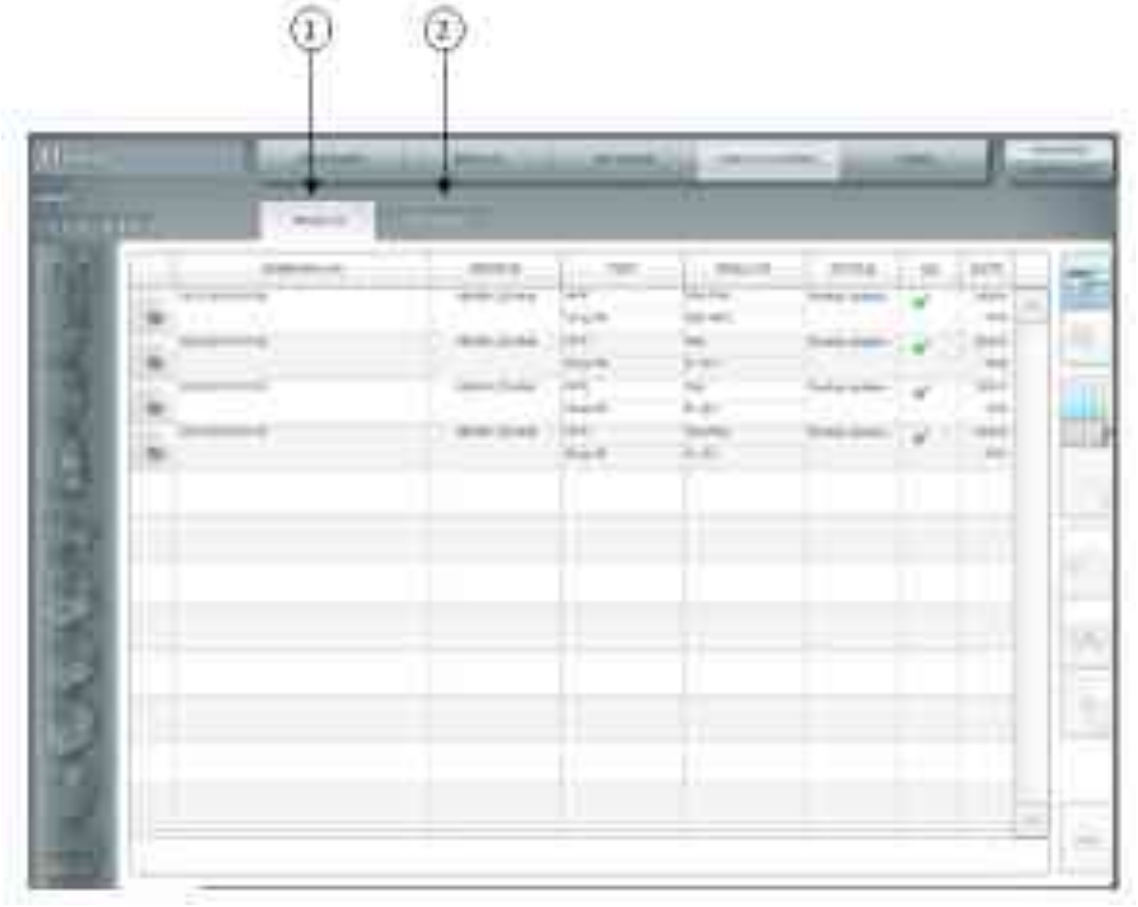


Figure 63. Overview of the Quality Control Module

(1) **Results** screen tab, where the processed and validated results are displayed.

(2) **Database** screen, where exported results can be recovered.

12.2 QC Status of a Profile

The QC status assigned to a profile can be:

- **Pass:** All samples of a QC kit have been tested by this profile, their results were in accordance with expected and they were obtained within the period of validity defined by the **Frequency** (see Section 12.1). Patient samples can be processed.
- **Fail:** The result of one or more samples of a QC kit does not match with the expected one. Patient samples can not be processed and the requests for this profile remains in **Stopped** status (see Section 9.3.9).
- **Pending:** There are any QC results assigned to this profile or the validity of the QC results of this profile is expired according the defined frequency. QC samples must be processed by this profile before running patient samples. Patient samples can not be processed and the requests for this profile remains in "**Stopped"** status (see Section 9.3.9).
- **Omitted:** The samples of a QC kit have not been completely executed (due to a lack of resources or the cancellation of the protocol during its execution) and the QC status was PASS before its expiration. This status enables to process patient samples.

12.3 Load Quality Control Samples

The **Manager** software has an internal **Database** with all the **Quality Control** kits available and their expected results. To load the QC samples into the analyzer proceed as follow:

1. Load the samples in any position of the sample holder follow the procedure described in Section 7.3.3.

   If the QC samples belongs to an activated QC kit (Section 12.1) the analyzer will recognize automatically these samples as a QC samples and they are displayed on the **Status > Sample** screen (Figure 30) with the **Quality Control** icon .

   They appear also in the **Worksheet** screen (Figure 64). If regular sample tubes have loaded into the analyzer, the QC samples will appear on the **Worksheet** below the regular samples.

CAUTION: To identify the **Quality Control** samples manually, enter the barcode number from the sample tube and then enter the barcode number again to confirm.

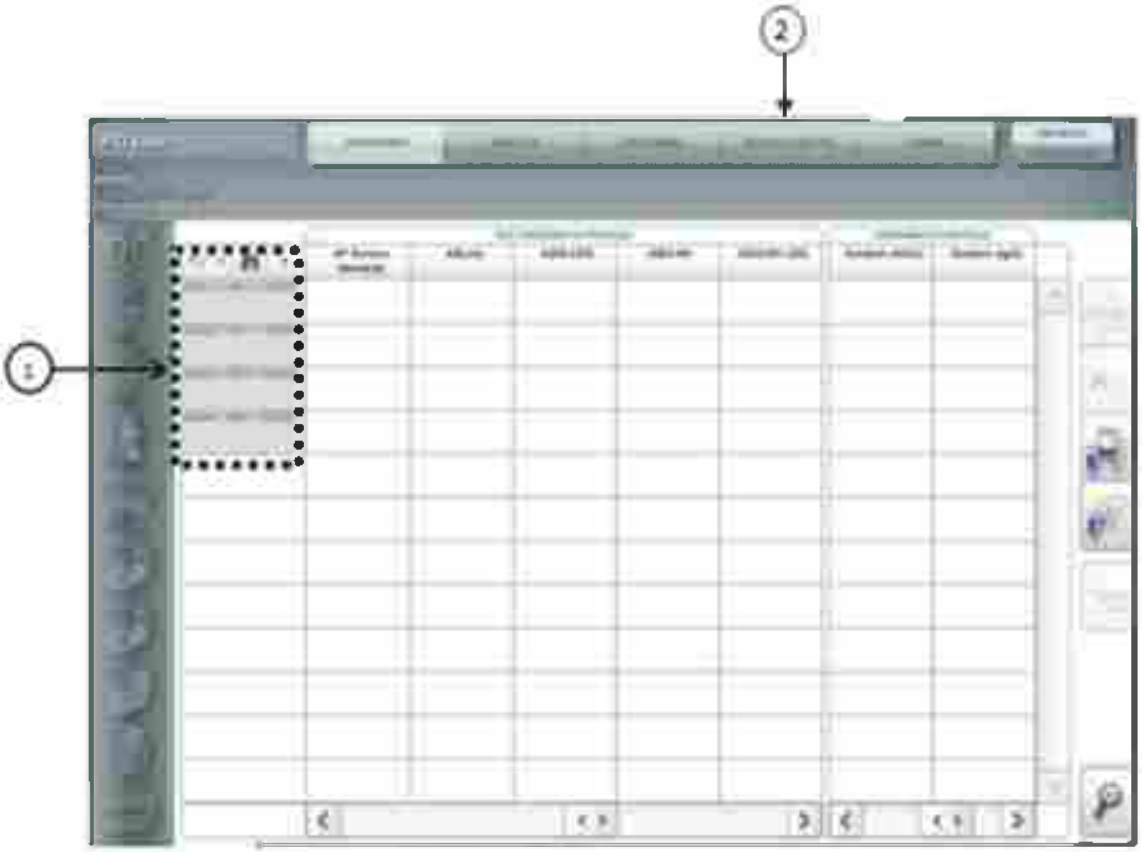


Figure 64. View of QC Samples in the Worksheet Screen (Example)

NOTE: Quality Control tubes will be flagged with the **Old Sample** icon 96 hours after being loaded and identified by the analyzer (when the instrument has not been switched off during that period).

12.4 Programming Quality Control Protocol

12.4.1 Automatic Quality Control Programming

Once the **Worksheet** is programmed (see Section 8) the **Manager** software checks if there is any profiles that is controlled by the **Quality Control** protocol and the QC status of each profile with requests assigned (see Section 12.2).

- If the QC status of a profile is "**Pass**", the profile is executed to the patient samples immediately.
- If the QC status is "**Pending"** (because it has expired or they have not been previously processed) and:
  - The QC samples tubes are into the analyzer, the QC samples are processed by this profile immediately. Patient samples requests remains in a "**Stopped**" status until the QC results have been finalized with **Pass** status. Once the QC status turns to "**Pass**", the analyzer will continous processing patient samples with this profile.
  - If the QC sample tubes are not on board, the **QC Warning** icon  and **Missing Samples** icon  is activated in the **Warning Area** (Figure 22). Additionally, the Traffic light (Figure 15, no. 7) changes from green to yellow and an acoustic alarm sounds. Patient samples requests remain in "**Stopped**" status (as shown in Figure 65).

Figure 65. Worksheet with Quality Control Warning Requirement (Example)

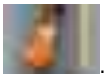
(1) The **Quality Control Warning** icon  .

(2) The **Missing Samples Warning** icon  .

(3) Patient samples request in "**Stopped**" status due to lack of QC sample tubes.

12.4.2 Resolving QC Warning

To solve the QC warning request and continuous processing patient samples proceed as follow:

1. Click the **Missing Sample Warning** icon  .

Missing Samples screen opens indicating the QC samples tubes that have to be loaded into the analyzer in order to solve the requirement, as well as the profile of the patient sample affected (Figure 66).

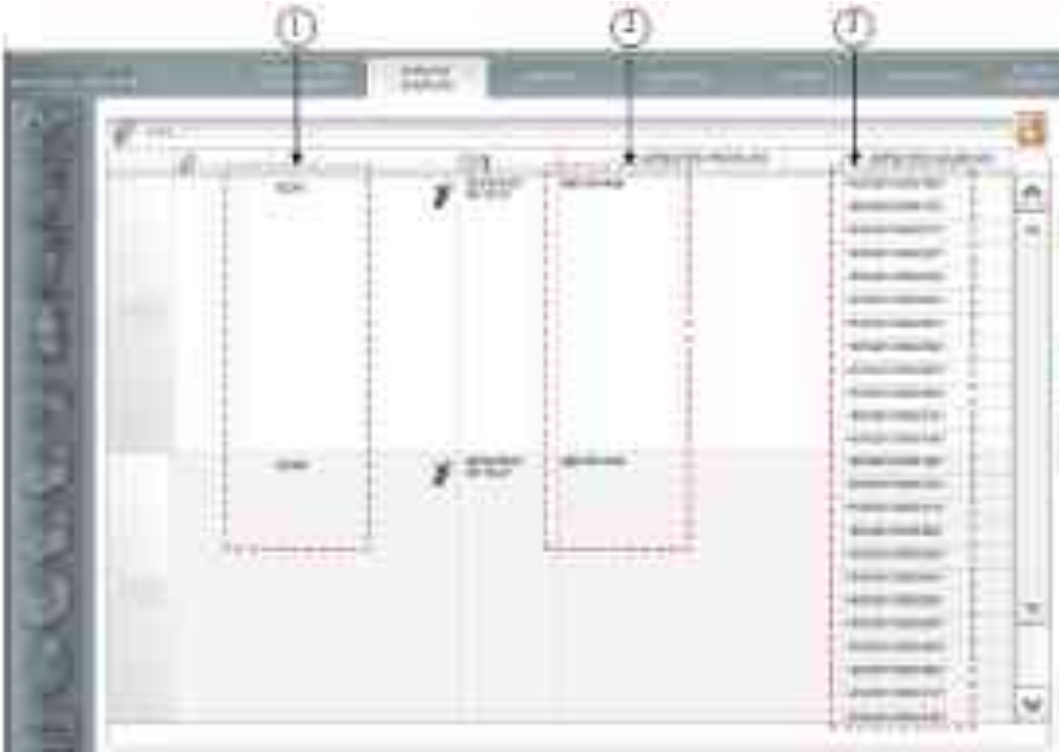


Figure 66. Quality Control Sample Requirement Information in Status > Missing Sample Screen (Example)

(1) QC sample tubes required by the analyzer.

(2) Profiles affected by lack of QC sample tubes.

(3) Patient samples affected by lack of QC sample tubes.

12.4.3 Manual Quality Control Programming

Despite the **Manager** software can automatically program the QC samples requests as described in previous section, QC samples requests can be programmed manually in the **Worksheet** before it is required by the frequency assigned. To do this, proceed as follow:

1. Load the **Quality Control** sample tubes as described in Section 7.3.3.
2. Go to **Manager** > **Worksheet** screen (Figure 42, no. 2).
3. Samples will appear after patient samples in the **Worksheet** screen.
4. Assign manually the test to be performed selecting in the corresponding box (see Section 9.2.2.2 for more information).

NOTE: It is also possible to request any of the profiles available on the **Worksheet** on QC samples tubes. The requests will be executed as a patient sample, without expected results associated. Given that these results are not part of the **Quality Control** protocol, the results will be displayed in the **Results** screen of **Manager** software instead of the **Results** screen of the **Quality Control** button.

12.4.4 Processing Quality Control Samples

Once programmed:

- The **Quality Control** samples requests are processed first in an independent incubator separate from the rest of the patient samples.
- If there is an associated requirement (reagents, gel card, sample, System Solution) to process the **Quality Control**, the Traffic light (Figure 15, no. 7) will change from green to yellow and the corresponding warning will be activated in **Warning Area** (Figure 43, no. 1), which will be accompanied by an acoustic alarm.
- The QC samples requests will be "**Stopped**" until the requirement is solve.
- If the QC samples are cancelled in the **Status > Missing Samples** screen (Figure 29) an error message will appear asking the user if the patient sample requests should be: Cancelled, remain pending or still be processed.
- If the analyzer detects that the QC kit is expired, the following options will be available:
  - **Open Drawer:** Opening the drawer to replace the expired QC kit for a current one.
  - **Continue:** Continue executing the profile to the samples of the expired QC kit.

    Once the results for the expired kit have been obtained, they will be accepted or rejected byt the **Manager** software according to the expected results but the **Expired Lot** icon will be displayed (Figure 67) for traceability purposes.

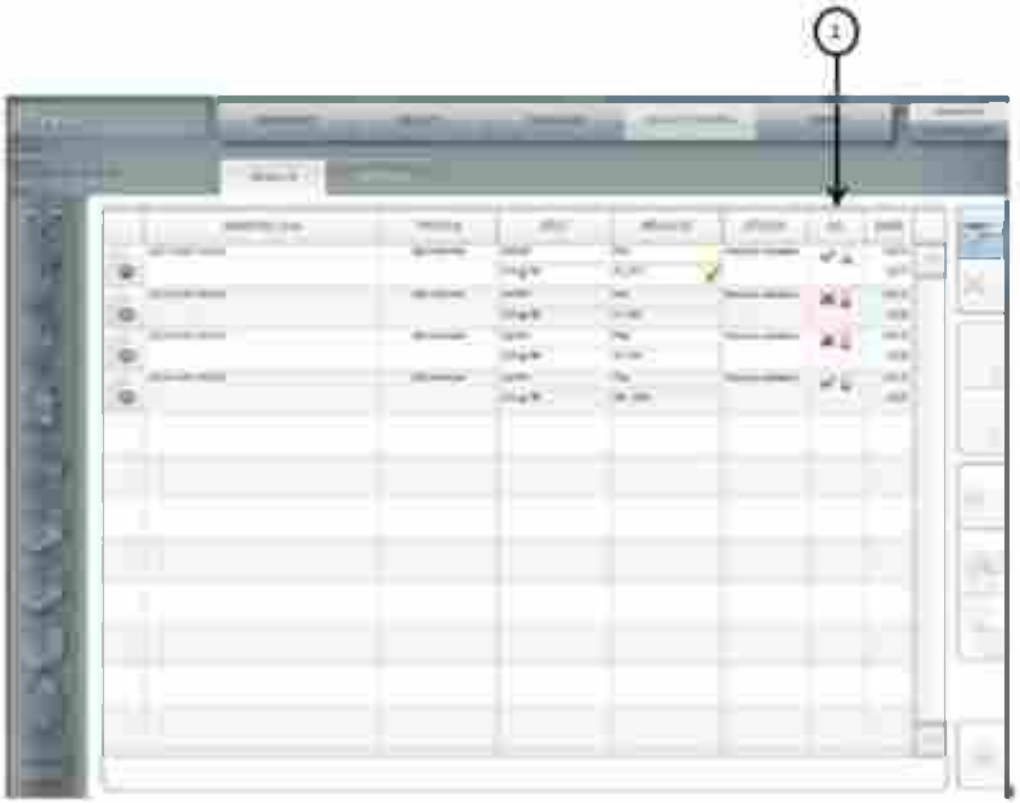


Figure 67. Results Associated to an Expired QC Kit (Example)

(1) Results associated of an expired QC lot.

12.4.5 Reviewing Quality Control Samples

Once the **Quality Control** samples have been processed for each profile, the results will appear in the **Results** screen of **Quality Control** module (Figure 68).

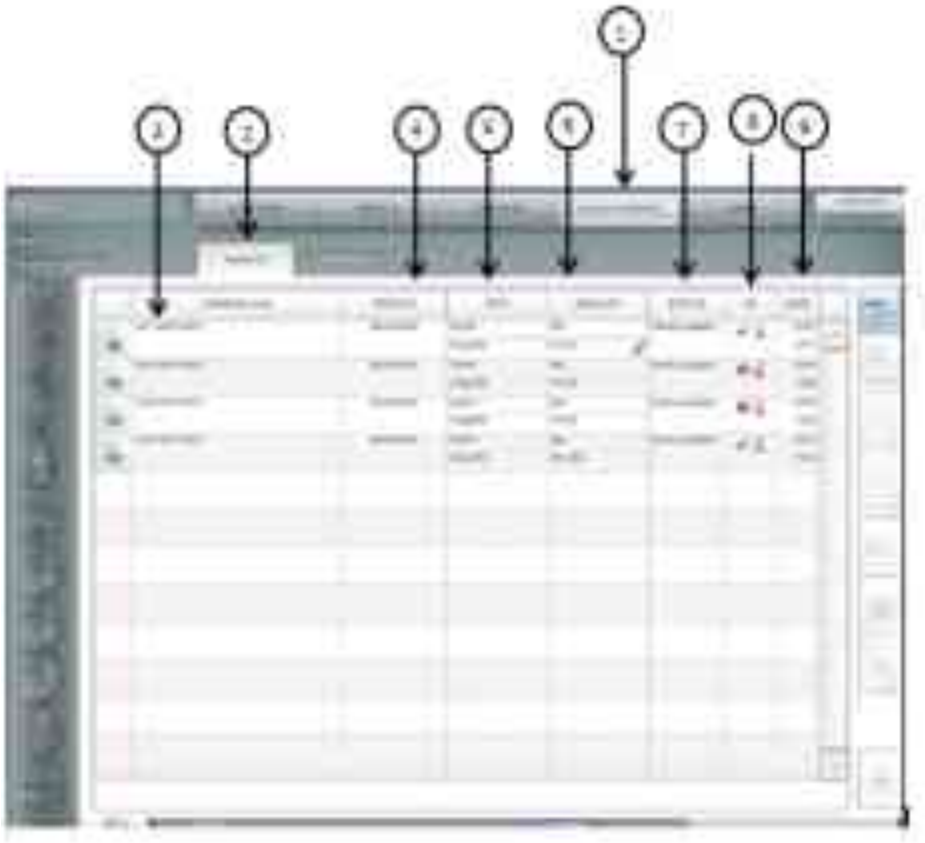


Figure 68. QC Results Screen in Quality Control Module (Example)

(1) **Quality Control** button to access to the **Quality Control** module.

(2) Button to access the **Profile Information Results.** For more information see Section 10.2.1. One of two icons are displayed:

Results without incidences which can be validated without a detailed review.

Results with an incidence or special result requiring review, acceptance and/or modification of the incidence or special result for its validation.

(3) **QC Sample Identification.**

(4) **Profile:** Set of tests executed on the QC samples.

(5) **Test:** Individual test which are part of the profile.

(6) **Results:** Results with clinical significance which are obtained by the combining of the reaction grade of the microtubes which form a part of the executed test.

(7) **Profile Status:** "**Pending Validation**" or "**Validated**" status. For more information see Section 10.2.

(8) **QC:** Concordance with the QC expected results:

The **Expected** icon indicates that the obtained results agree with the expected ones (in brackets in the **Results** column).

The **Unexpected** icon indicates that the obtained results disagree with the expected ones (in brackets in the **Results** column).

See more information about **Quality Control** in Section 12.

(9) **Date:** Date and time of the reading of the profile test.

12.4.6 Viewing Detailed QC Results Information

To view detailed results information of QC samples press  or  (Figure 68, no. 2)

The **Profile Information Results** screen opens showing all the information related to the profile tests, including the images of the microtubes associated with every test, the interpretation, the agreement with the expected results and the possible errors and associated incidences.

If the sample is the QC, new icons appear on the screen depending on the result of the QC.

The **QC Expected** icon indicates that this sample is a QC sample and its results agree with the expected result defined in the **Manager** software (in brackets in the **Results** column). See Figure 69 for more detailed information.

The **QC Unexpected** icon indicates that this sample is a QC samples and some of its results disagrees with the expected result defined in the **Manager** software.

The **QC Warning** icons activated in the **Warnings Area**. See Figure 70 for more detailed information.

Figure 69. Profile Information Result Screen for an Expected QC Result (Example)

(1) General information about the QC sample tube.

(2) Result interpretation of the test.

(3) **Result** of the test.

(4) Concordance of the Results ( **Expected** or  **Unexpected)** with the **Expected** in the **Manager** software.

(5) **Quality Control** acceptance criteria.

(6) The pass/fail information of the test interpretation segment.

(7) **Quality Control** status.

See general information in Section 10.2.1.

Figure 70. Profile Information Result Screen for an Unexpected QC Result (Example)

12.4.7 Validating Quality Control Results

To **Validate** the **Quality Control** result, follow the same procedure used to validate the results from patient samples (see Sections 10.3 and/or 10.3.2).

If the **Enable Autovalidation of QC PASS** option has been enabled in the **Quality Control** module (see Section 12.1).

- The QC results that do not have any exceptional results (see Section 10.3.2) and agree with the **Expected** result ( ) are automatically validated by the **Manager** software.
- The QC results that have an exceptional results (see Section 10.3.2) or/and have **Unexpected** results ( ) remain in "**Pending validation**" and must be validated by the Operator.

If all samples of a QC kit have **Expected** results ( ) for a specific profile, the status of QC for this profile is **PASS**.

On the contrary, if any of the samples obtain an **Unexpected** results ( ) for any test, the overall QC result of this test will be **FAIL**.

12.4.8 Validating Unexpected Results

To have a **QC PASS** in the **Manager** software, all of the tubes in the QC kit must have **Expected** results ( ). If some of the results have **Unexpected** results ( ) proceed as follow:

1. Keep the **Expected** results ( ) in "**Validated"** status without exporting them.
2. Reject the **Unexpected** results ( ) of the corresponding QC sample tube (see more information in Section 10.5).
3. Repeat the profile programming it manually (see Section 12.4.3).
    - If the repeated profile obtain an **Expected** results ( ), the results will be validated automatically.
    - If the repeated profile obtain an **Unexpected** results ( ) again, a complete verification of:
        - QC sample tube.
        - Reagents, Diluent and gel cards.
        - Material used.

- Maintenance status of the analyzer.

If all the cause is not confirmed, contact to your local Grifols service representative.

12.4.9 The Quality Control Warning

The **Quality Control Warning**  icon is activated when:

- The QC has expired in accordance with the programmed frequency (see Section 12.1). The QC execution has been interrupted due to missing resources. For more information on resolving them, see Section 7.4.
- An **Unexpected** results () has been obtained for one of the tests executed on QC samples.

12.4.10 Exporting Quality Control Results

CAUTION: QC results must be exported before patient sample results can be validated.

CAUTION: Unexpected results () of QC samples cannot be exported. To repeat the test follow the instructions described in Section 12.4.8.

If some results have exceptional results, follow the instructions described in Section 10.3.2 to accept or modify them.

Once the results are validated (see Section 10.3) the results can be exported and sent to the Laboratory Information System (LIS), if it is configured.

To export results:

- From the **Results** screen in **Quality Control** module (Figure 63), select the results to export by pressing on each result or by pressing the **Select All** button to select all of the results on the **Results** screen.
- Press the **Export** button  .
- Press the **Confirm** button  to confirm.

  The selected results are sent to LIS (if configured) and removed to the **Result** screen.

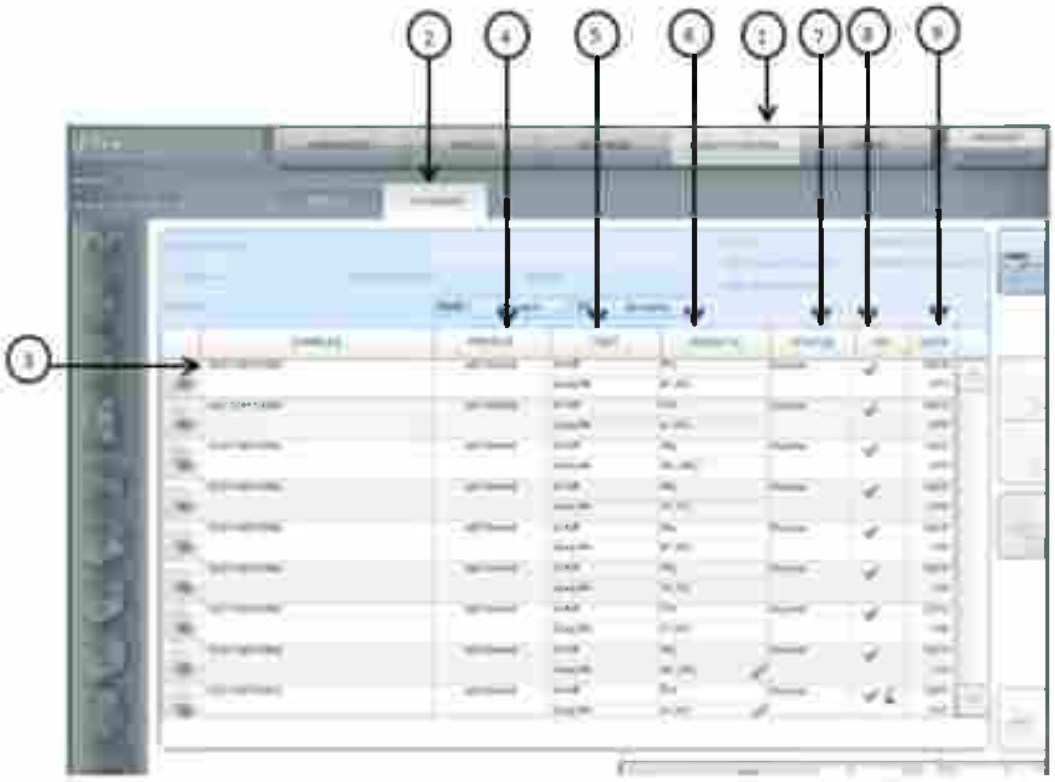


Figure 71. Exported QC Results in Database Screen of Quality Control Module (Example)

(1) **Quality Control** tab.
(2) The **Database** tab of the **Quality Control** screen.
(3) QC sample information.
(4) Profile associated with the QC sample.
(5) Test associated with the QC sample.
(6) Results obtained.
(7) QC sample status.
(8) Result of the **Quality Control** in accordance with the expected result.
(9) Execution date.

In the **Database** screen, the detail of any processed, validated or exported QC result can be recovered (Figure 72). To do this, the filter may be used, as explained in Section 12.4.12.

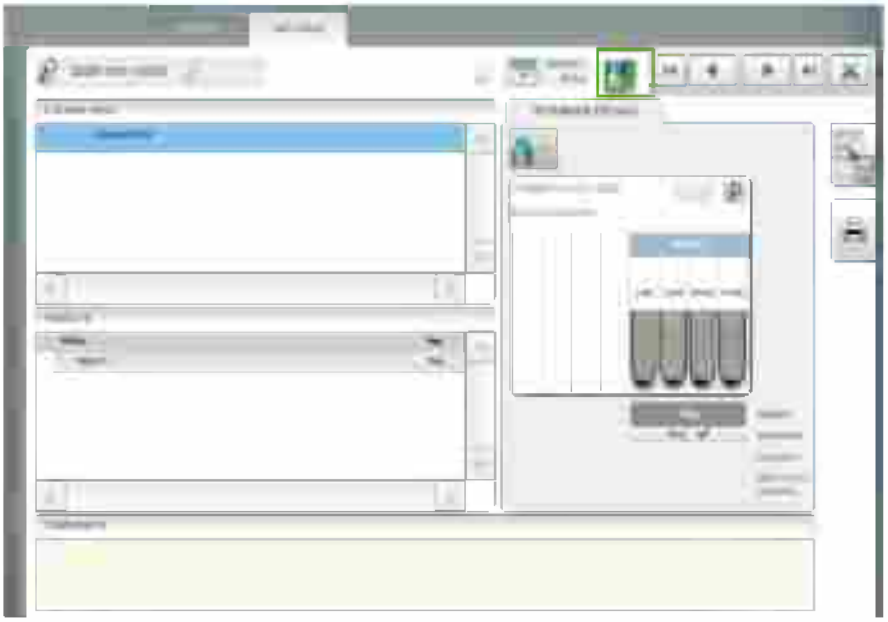


Figure 72. Profile Information Result Screen for an Exported QC Result (Example)

12.4.11 Printing and Saving QC Results Reports

The **Manager** software provides different reports, which can be viewed, and printed by the Operator at any stage after QC results have been generated. To print the results which appear on the **Results** screen of **Quality Control** module, follow the same procedure described in Section 10.7 for patient samples.

12.4.12 QC Database Searches

The **Quality Control** module of **Manager** software has a **Database** (independent from the **Database** in any connected LIS) where all QC results are stored, including the images. All of these results and images are accessible to the Operator at any time.

To search and view QC results that have been stored in the **Database** after exporting from the **Results** screen:

1. Press the **Database** button (Figure 63, no. 2).

   The **Search Filter** screen open.

2. Follow the procedure described in Section 11.1 for patient samples.

12.4.13 Executing Patient Samples Linked to QC

The patient samples loaded into the analyzer that are affected by a "**Pending QC**" status will remain in "**Stopped**" status meanwhile the QC result is processed according in Section 12.4. Once the QC result is obtained, two situations can occur, depending on the QC result:

- If QC status is **Pass,** patient samples starts to be automatically executed and their status change from "**Stopped**" to "**In process**".
- If QC status is **Fail:** A message will appear on screen giving three possible options:
  - **Continue:** The analyzer will continue processing the patient samples, despite the **Fail** QC result.

CAUTION: It is not recommended to process patient samples with a **Fail** QC result as the results for these samples cannot be exported.

NOTE: Continuing to process routine samples with a **Fail** QC result can only be done by an Operator with the appropriate rights.

- **Re-Run:** This option keeps the patient samples in "**Stopped**" status. This option allows **Quality Control** to be repeated.
- **Cancel:** This option keeps the patient samples in **Pending** status.

CAUTION: STAT samples will always be directly processed independently of the QC status.

However, they will also have an associated QC status, corresponding to the QC status at the time of execution.

Once the patient samples have been processed, they will appear on the **Results** screen (Figure 42, no. 3) and the QC Status column (Figure 73) will also indicate the result of the **Quality Control** protocol for those tests that have an associated QC.

In the case of profiles with more than one test, the analyzer will process the patient samples when the QC result for the corresponding test has obtained a **Pass** result.

Figure 73. QC Results Screen for Patient Samples

Button to access the **Profile Information Results**. For more information see Section 10.2.1. One of three icons are displayed:

Icon	Description
	Results without incidences which can be validated without a detailed review.
	Results with exceptional result. See more information in Section 10.3.2.
	Results affected by a not resolved QC status profiles See more information in Section 12.4.13.

NOTE: If there is a patient result with a QC status not resolved but with **Expectional Results** at the same time, this one overrides and the **Manager** software will display icon.

12.4.14 Viewing Patient Detailed Results Information

To view detailed results information press  or  (Figure 73). For more information see Section 10.2.1. The **Profile Information Results** screen will show one of the following QC statuses associated:

-  **QC Pass and Exported:** The QC results obtained are in accordance with the expected results and have been exported.

  This status enables validate patient samples results. The  icon is displayed in absence of incidences in **Results** screen (Figure 73).

-  **QC Pass and Not Exported:** The QC results obtained are in accordance with the expected results but they have not been exported.

  Patient samples results cannot be validated until the QC results will be exported. The  icon is displayed in absence of incidences in **Results** screen (Figure 73).

-  **QC Fail and Not Exported:** The QC results obtained are not in accordance with the expected results and therefore, they have not been exported.

  To validate patient sample results, the QC **Fail** status must be resolved by repeating the **Unexpected** result () (see Section 12.4.8 for more information).

  Patient samples results cannot be validated until the QC results will be **Pass** and **Exported**. The  icon is displayed if there is absence of incidences in **Results** screen (Figure 73).

-  **Omitted QC:** The QC kit has not been completely executed (due to a lack of resources or the cancellation of the protocol during its execution) but the QC status was **Pass** before its expiration.

  Patient samples results can be validated. The  icon is displayed in absence of incidences in **Results** screen (Figure 73).

12.4.15 Printing and Saving Patient Samples

The **Manager** software provides different reports, which can be viewed, and printed by the Operator at any stage after QC results have been generated.

To print the results which appear on the **Results** screen (Figure 51) follow the procedure described in Section 10.7.

The patient sample reports printed from the **Results** screen and the **Database** screen have a field in the header indicating the sample QC status (Figure 74):

Figure 74. Traceability Print Report with Exported Pass and Exported QC Status (Example).

13 Configuring User Access

This section provides a description of the user configuration and managment of the analyzer.

13.1 User Configuration Overview

The **Users** module (Figure 42, no. 6) allows the quickly and efficiently manage user groups and their access permissions across the analyzer interfase. Supervisor is the responsible to configure them.

Users must be configured to work with the analyzer.

NOTE: A part from the roles described in this section that are defined by the **Supervisor**, there are authorized personel who have access to the **Controller** and the **Manager** softwares with different rights of access. If you desire further information about the configuration programs, the authorized personal and their privileges contact your local Grifols service representative.

NOTE: To configure the frequency with which the system require users to change their passwords, as well as which specific actions require passwords to access, contact your local Grifols service representative.

13.2 User Groups and Access Permissions

There are four predefined users groups or roles with different access permissions:

- Operator Basic.
- Operator.
- Operator Plus.
- Supervisor.

The following table is a summary of the permitted actions within each group of users:

Table 13. Permited Actions for each Access Level

	OPERATOR BASIC	OPERATOR	OPERATOR PLUS	SUPERVISOR
Execute tests	Access	Access	Access	Access
Print results	Access	Access	Access	Access
Validate routine and QC results (no alarms)		Access + confirmation message	Access + confirmation message	Access + confirmation message
Export routine and QC results		Access + confirmation message	Access + confirmation message	Access + confirmation message
Modify results			Access + identification required (configurable) + confirmation message	Access + identification required (configurable) + confirmation message)
Cancel validated results			Access + confirmation message	Access + confirmation message
Reject results			Access + confirmation message	Access + confirmation message

Execute samples with QC pending			Access + identification required (configurable) + confirmation message	Access + identification required (configurable) + confirmation message
Validate samples with QC pending			Access + identification required (configurable) + confirmation message	Access + identification required (configurable) + confirmation message
Accept and validate special results or results with incidences			Access + identification required (configurable) + confirmation message	Access + identification required (configurable) + confirmation message
Accept inconsistencies			Access + confirmation message	Access + confirmation message
Activate and deactivate modules		Access	Access	Access
Backup Data			Access	Access
Access User management				Access
Probe replacement			Access	Access
Erytra Diagnostic			Acess	Access
Record Technical Service inspection				Access

13.3 Creating New Users

To create new users in **Users** module proceed as follow:

1. Go to **Users > User** screen (Figure 42, no. 6) of **Manager** software.

   The **User Management** screen appears (Figure 75).

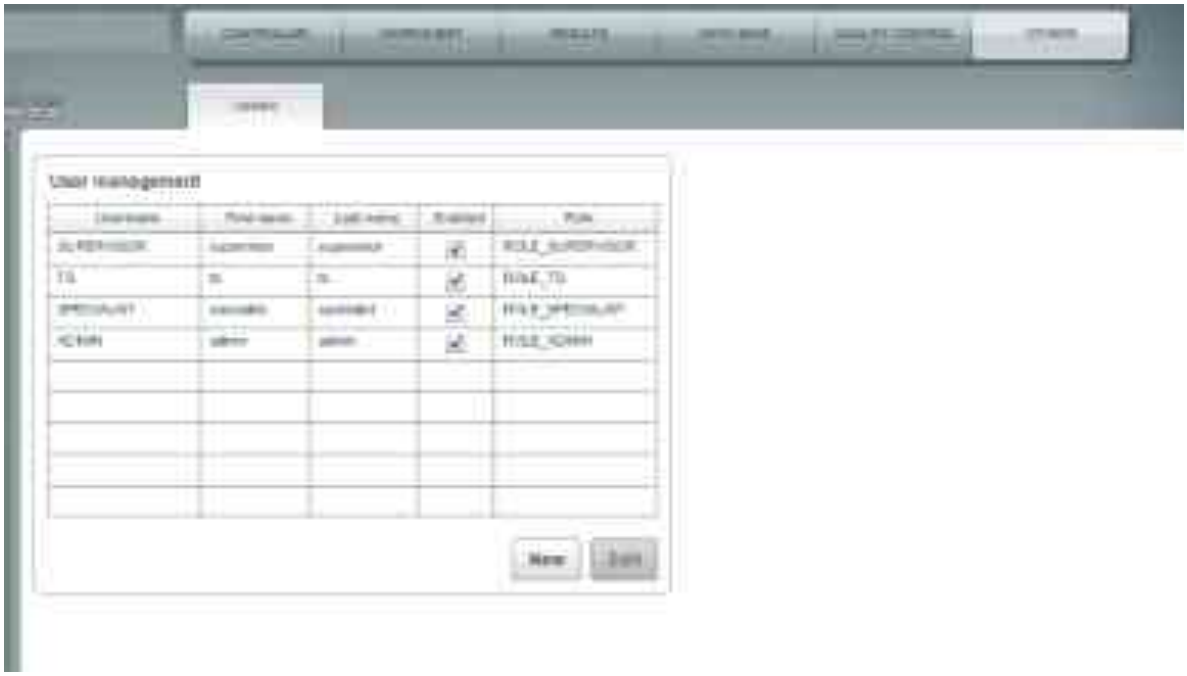


Figure 75. Users Screen (Example)

2. Click the **New** button.
3. Fill in the fields, keeping in mind the following restrictions:
    - **Username:** The unique numbers and/or letters that identify the user in the **Database** (between 4 and 10 characters in length). If you enter a **User** that is already in use, the system will display an error message requesting a new **User**.
    - **First Name:** User first name. This field cannot be left blank.
    - **Last Name:** User last name. This field cannot be left blank.
    - **Enabled User:** If this field is not checked, the user will not be able to access the application and this will be reflected on the software login screen when the user attempts to enter.
    - **Reset Password:** This option erases the password for a specified user.
    - **Role**: This option allows selecting from the various role types.

After a user is created, the software generates a temporary password that matches the user's username. The software then requests a new password, which must be entered twice to confirm.

CAUTION: After 3 incorrect attempts to enter the password, the system automatically disables the user. To reset password, see Section 13.4.

NOTE: When a new users log on to the software for the first time, they should use their username as a password.

NOTE: It is advisable to create at least 2 different Supervisor users to have a second one in case that the first one is also disabled for wrongly introducing the password.

13.4 Reset Password

To enable a user that has been disabled by the **Manager** software due to repetitive wrong identification, proceed as follow:

NOTE: Option available for the Supervisor users group only.

1. Go to **Users > Users** screen.
2. Select in the table the User whose password are to be erased.
3. Press **Edit** button.

   The **User Information** screen displays.
4. Click the **Reset Password** button.

   The software will erase the password and generates the temporary one that matches the user's username. This user must then enter a new password the next login.

13.5 Modifying User Data

To modify **User** data in the **Manager** software proceed as follow:

1. Go to the **Users > Users** screen to view the **User** List.
2. Select the user whose data are to be modified.
3. On the **User Information** screen, press the **Edit** button.
4. Modify the data to be changed.

NOTE: The **User** field cannot be changed.

5. After completing the changes, press  to confirm the changes (or  to cancel the changes).

13.6 Changing Passwords

Users can change their password from the analyzer software interfase. To change a password proceed as follow:

1. Press the **Password Change** button  on the main screen of the software analyzer.
2. Fill in the **Current Password** field with the current password.
3. Fill in the **New Password** field with a new password.
4. Re-enter the same password again in the **Confirm Password** field.
5. Press  to confirm the changes (or  to cancel the changes).

NOTE: If the data entered is not correct (the **New Password** does not match its confirmation, the password does not meet the system requirements, etc.) the **Manager** software will notify the user on screen and will not save the changes that were made.

14 Maintenance

This section provides a description of the Maintenance of the analyzer, **Database** backups, daily Maintenance, weekly Maintenance, monthly Maintenance, preventive Maintenance, replacing a probe and activating and deactivating modules.

14.1 Maintenance Plan

The maintenance plan is a set of operations carried out at regular intervals to preserve the function of the Erytra Eflexis®. As a general rule, follow the maintenance plan listed in the table below to ensure the proper functioning of the analyzer.

It is possible to maintain the instrument always primed, so it is ready to process samples at any moment. To configure this option, please contact with your local Grifols service representative.

Table 14. Maintenance Plan

PERIOD	ACTIVITY	DONE BY
When drops of samples or of other substances are spilled inside the analyzer	Clean the affected area (see Section 14.1.12)	Supervisor/Operator
After each session (daily minimum)	• Check for liquid leaks (see Section 14.1.10). • Check for the growth of microorganisms (see Section 14.1.11).	Supervisor/Operator
Every week	Clean the surfaces, if necessary (see Section 14.1.12)	Supervisor/Operator
Every week	Re-start the analyzer	Supervisor/Operator
Every month	Decontaminate the instruments and its components (see Section 14.1.16)	Supervisor/Operator
Every month	Decontaminate the liquid containers	Supervisor/Operator
Every year	Review the general status of the Erytra Eflexis® analyzer (see Section 14.1.24)	Qualified Technician

If working continuously with the analyzer, it is recommended to turn it off and on every seven days for the Windows operating system to work correctly.

The maintenance operations done on the instrument must be recorded in Section 20.

The technical assistance can be provided by your local Grifols representative.

⚠ **CAUTION:** Do not use the instrument if the Maintenance Plan has not been followed.

14.1.1 Maintenance Screen Overview

The **Controller** software of analyzer contains a dedicated **Maintenance** module to perform and record all the relative maintenance actions. To access to this **Maintenance** module, go to **Others > Analyzer** (Figure 26). The main screen displays (Figure 76).

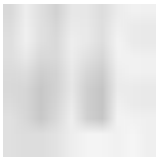
Figure 76. Overview of the Maintenance (Example)

(1) **Maintenance Summary** tab.
(2) **Decontamination** tab.
(3) **Probe Replacement** tab.
(4) **System Solution Registry** tab.
(5) **Technical Service Operations Registry** tab.
(6) **Activate/Deactivate Modules** tab.
(7) **Backup** tab.

The following table describes the meaning of the tabs related to instrument satus and maintenance:

The **Maintenance Summary** tab (Figure 76, no. 1) provides information about the general status of the instrument, including the expiration dates of the decontamination procedures and of Technical Service inspections, the next required restart of the system and whether any modules are disabled.

The **Decontamination** tab (Figure 76, no. 2) provides information about the expiration dates of previous decontamination procedures, as well as a button to perform a fluidic system decontamination.



The **Probe Replacement** tab (Figure 76, no. 3) provides information on when probe was replaced, as well as button to facilitate replacing the probe.

The **System Solution Registry** tab (Figure 76, no. 4) provides information about when the System Solution containers have been refilled, as well as a button to facilitate recording the refilling of the System Solution.

The **Technical Service Operations Registry** tab (Figure 76, no. 5) provides information about when Technical Service inspections have been performed and when the current Technical Service inspection expires. This tab also contains a button to facilitate recording Technical Service inspections.

The **Activate/Deactivate Modules** tab (Figure 76, no. 6) provides information about the current status of the modules, as well as information about previous module activation and deactivation actions. This tab also contains a button to facilitate activating and deactivating modules.

The **Backup** tab (Figure 76, no. 7) provides information about the last backup performed, as well as a button to facilitate running a manual backup of certain stored data.

The above tabs are connected to the **Maintenance Warning** icon  (Figure 22). This warning is activated under the following conditions:

- When there are one or more disabled modules.
- When there are one or more actions (decontamination procedure, Technical Service inspection, system restart, etc.) that have expired (these appear in red in the **Maintenance Summary** screen).
- When there is an action that is about to expire (these appear in orange in the **Maintenance Summary** screen).

The warning is fully activated when the cause that provokes this warning activation occurs for the first time. This warning appears with the background and outline highlighted.

The warning is partially activated when the user has accessed this section of the **Others > Analyzer** screen before. This warning appears with only the outline highlighted.

14.1.2 The Maintenance Summary Tab

Use the **Maintenance Summary** tab (Figure 76, no. 1) to check the general status of the instrument. Pressing in that tab the **Maintenance Summary** screen displays (Figure 77):

Figure 77. Maintenance Summary Screen (Example)

(1) **Decontamination** status: Including the expiration date of the decontamination of the following areas:

- Fluidic system.
- Probe.
- Dilution Station.
- Surfaces.
- Sample racks and holders.
- Reagent racks.

(2) **Technical Service Inspection** including:

- Expiration date of the latest Technical Service inspection (based on yearly inspections).
- Expiration date of the next required system restart (based on weekly system restarts).

(3) **Modules** status: The activated modules appear in green and the deactivated modules appear in red.

(4) **Analyzer Restart status.**

The information for the areas in no. 2 and 3 appears with the following color code:

- Green: If they are within the expiration date period.
- Orange: If they are close to the expiration date.
- Red: If they are expired.

14.1.3 The Decontamination Tab

Use the **Decontamination** tab (Figure 76, no. 2) to:

- Obtain information about the expiration date of each of the current decontamination procedures.
- Obtain a track record of the maintenance actions.
- Record manual decontamination actions.
- Perform the fluidic system decontamination listed in the Maintenance Plan. See procedure in Section 14.1.18.

Pressing in that tab, the **Decontamination** screen displays (Figure 78):

Figure 78. Decontamination Screen (Example)

(1) **Register** of the current decontamination actions and their validity period.
(2) The **Filter** button.
(3) **Remove Filter** button.
(4) The **Manual Decontamination Record** button.
(5) The **Fluidic System Decontamination** button.
(6) **Print** button.
(7) Register of previous decontamination procedures.

14.1.3.1 Obtaining a Track Record of Decontamination Actions

To obtain a track record of the maintenance actions proceed to apply a filter:

1. Press the **Filter** button  (Figure 78, no. 2).
   The **Filter** screen displays (Figure 79).

2. Select the filter according the desired criteria:
   - A period of time (from **From** to **To**).
   - A specific decontamination procedure.

   Multiselection is permitted.

Figure 79. Decontamination Filter Screen

NOTE: Press to erase the information entered in the differents fields of the **Filter** screen.

3. Press to confirm (or to cancel).

   A table displays information about the decontamination actions performed during the selected period of time.
4. Press **Print** to obtain a print this information.

14.1.3.2 Recording Manual Decontamination Actions

To record a manual decontamination action, proceed as follow:

1. Press the **Manual Decontamination Record** button (Figure 78, no. 4) to open the **Manual Decontamination Register** window (Figure 80).
2. Record the decontamination procedures performed manually:
   - Select the action in the corresponding.
   - Enter the date.

Figure 80. Manual Decontamination Registry Window

14.1.3.3 Performing Fluidic System Decontamination

To run fluidic system decontamination, proceed as follow:

1. Press the **Fluidic System Decontamination** button (Figure 78, no. 5).
2. Click the **Confirm** button on the message that appears (or to cancel the decontamination).
3. Follow the instructions shown on the screen.

14.1.4 Probe Replacement Tab

Use the **Probe Replacement** tab (Figure 76, no. 3) to:

- Check information on previous probe replacements.
- Replace the probe. For the probe replacement procedure, see Section 14.1.4.2.

Pressing in that tab, the **Probe Replacement** screen displays (Figure 81):

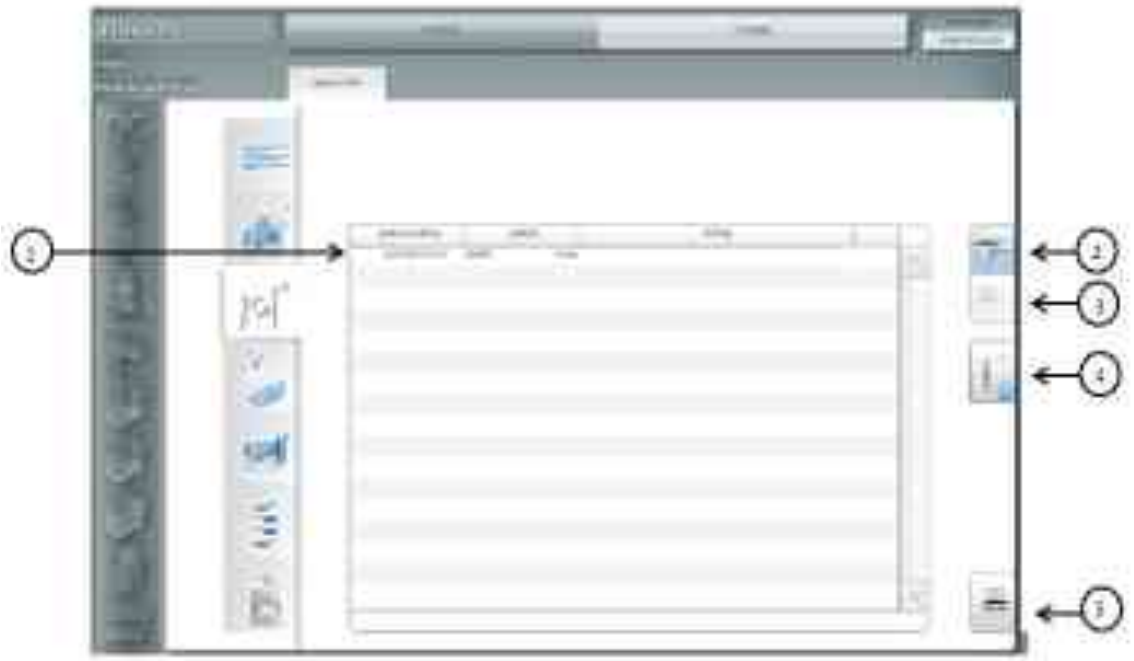


Figure 81. Probe Replacement Screen

(1) **Registry** of previous probe replacements actions.

(2) The **Filter** button.

(3) **Remove Filter** button.

(4) **Replace Probe** button.

(5) **Print** button to print the probe replacement registry.

14.1.4.1 Obtaining a Track Record of Probe Replacements

To obtain a track record of the replacements that have been taken place during a certain periode of time, apply a filter:

1. Press the **Filter** button (Figure 81, no. 2).

   The **Filter** screen appears (Figure 82).

Figure 82. Probe Replacement Filter Screen

2. Enter the period of time of the search (from **From** to **To**).

NOTE: Press to erase the information entered in the differents fields of the **Filter** screen.

3. Press to confirm (or to cancel).

   A table displays information about the replacement probe actions performed during the selected period of time.

4. Press **Print** to obtain a print this information.

14.1.4.2 Replacing Probe

In the case of breakage, bending or persistent obstructions, the probe can be replaced without the need for Technical Service. The analyzer has been designed to allow user to replace probe.

To change the probe:

1. In the **Probe Replacement** tab  (Figure 76, no. 3), press the **Replace Probe** button  .

   Follow the program instructions.

2. Remove the rack when the analyzer opens it.
3. Press **Continue**.

   The Pipetting Transport arm moves to the front in the rack position and it lowers its head so that the probe is made more accessible.

4. The upper door is automatically opened.
5. Replace the probe by unscrewing the hex nut that holds the probe on the robotic arm, turning it counter-clockwise until it comes free.
6. Carefully remove the probe from the Washing Station. Keep the fluidics fitting and discard the probe.
7. Wash off the remains of the saline solution that may be on the upper part of the Washing Station.
8. Place the fluidics fitting over the new probe.
9. Pass it down over the lower end though the Washing Station.
10. Align they key of the probe with the groove in the support of the robotic arm.
11. With one finger, hold the fluidics fitting and, with the other finger, screw it onto the arm support, making sure that the probe is securely fastened to the arm.

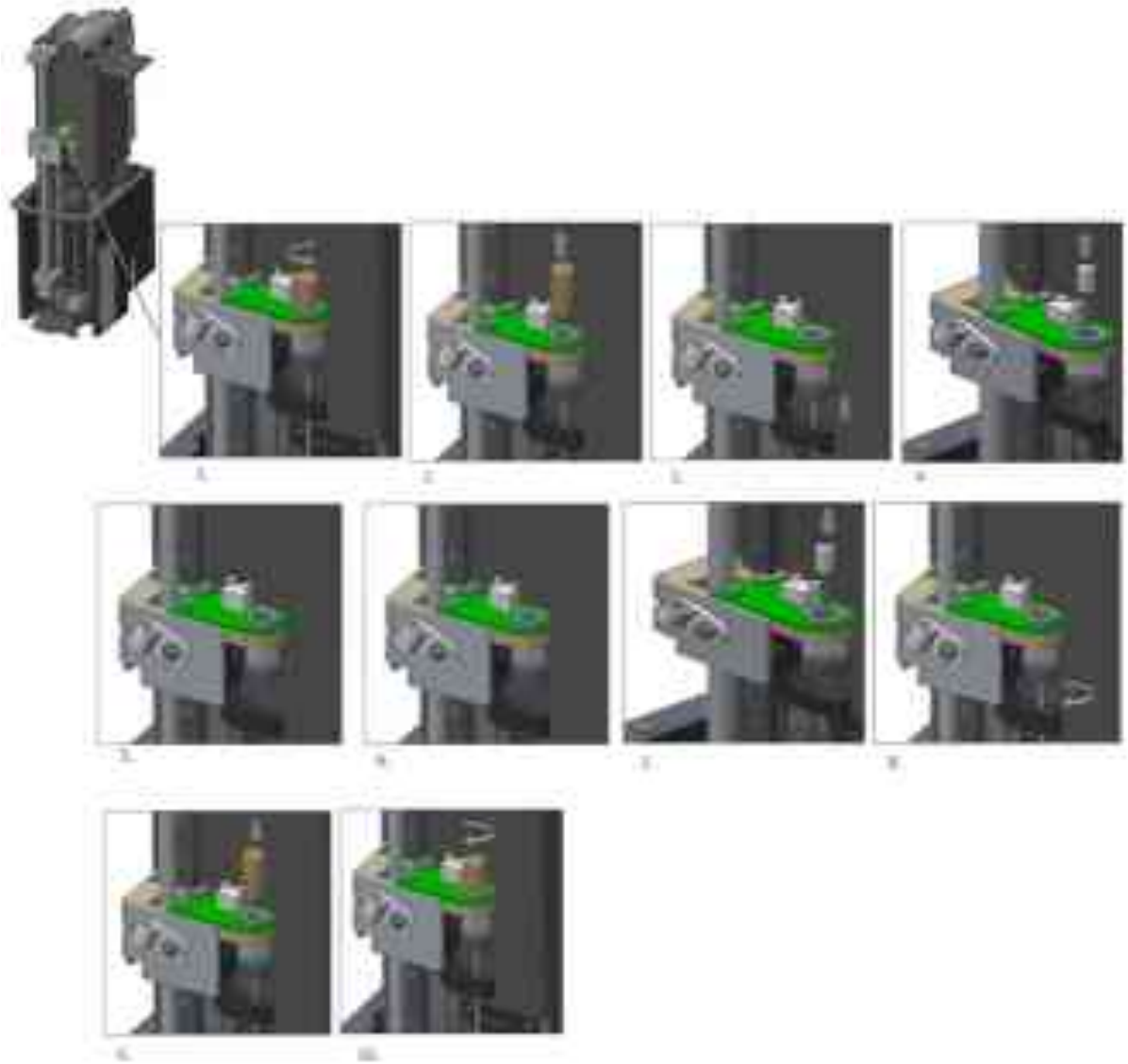


Figure 83. Probe Replacement Process

12. Close the upper door and press **OK** to continue.

NOTE: The replacement probe action is recorded automatically in Probe replacement actions registry.

13. The **Probe Replacement Registry** window opens (Figure 84) to record this action. Enter a comment (if it is necessary).

Figure 84. Probe Replacement Registry Window

14. Press to confirm. The software restarts the robotic arm and leaves it prepared for test processing.

14.1.5 The System Solution Registry Tab

Use the **System Solution Registry** tab (Figure 76, no. 4) to:

- Check traceability information of System Solution lots used in the analyzer during a certain period of time.
- Record traceability information (lot number and date) in each refilling container action.

Pressing in that tab, the **System Solution Registry** screen displays (Figure 85).

Figure 85. System Solution Registry Screen

(1) **Registry** of the previous refillings of the System Solution containers.

(2) **Filter** button.

(3) **Remove Filter** button.

(4) **System Solution Record** button.

(5) **Print** button to print the probe replacement registry.

14.1.5.1 Obtaining a Track Record of System Solution Use

To obtain a track record of the System Solutions used in the analyzers for a certain period of time, apply a filter:

1. Press the **Filter** button (Figure 85, no. 2).

   The **Filter** screen appears (Figure 86).

Figure 86. System Solution Filter Screen

2. Enter the period of time of the search (from **From** to **To**).
3. Select the System Solution origin of the search in the **Select Solution** field:
   - System Solution A.
   - System Solution B.

NOTE: Press to erase the information entered in the differents fields of the **Filter** screen.

4. Press to confirm (or to cancel).

   A table displays information about the refilling actions performed and the System Solutions used during the selected period of time.
5. Press **Print** to obtain a print this information.

14.1.5.2 Recording System Solution Traceability Information

To keep the traceability of the System Solutions used in the analyzer, every time that refill the System Solution containers proceed as follow to record them:

1. Press the **System Solution Record** button (Figure 85, no. 4) to open the **System Solution Registry** window (Figure 87).
2. Record each refilling action including:
   - Type of System Solution.
   - Lot number.
   - Expiration date.

- Total diluted volume.

3. Add comments in the **Comments** field (if necessary).
4. Press **Print** button to obtain a Traceability report of this refilling.

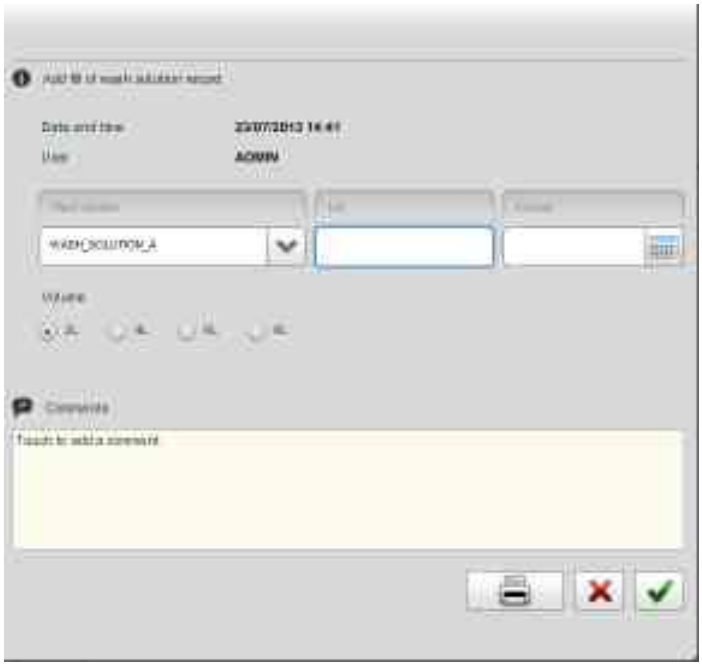


Figure 87. System Solution Registry Window

14.1.6 Technical Service Operations Registry Tab

Use the **Technical Service Operations Registry** tab (Figure 76, no. 5) to:

- Check traceability information of Technical Service operations during a certain period of time.
- Record Technical Service operations.

Pressing in that tab, the **Technical Service Operations Registry** screen displays (Figure 88).

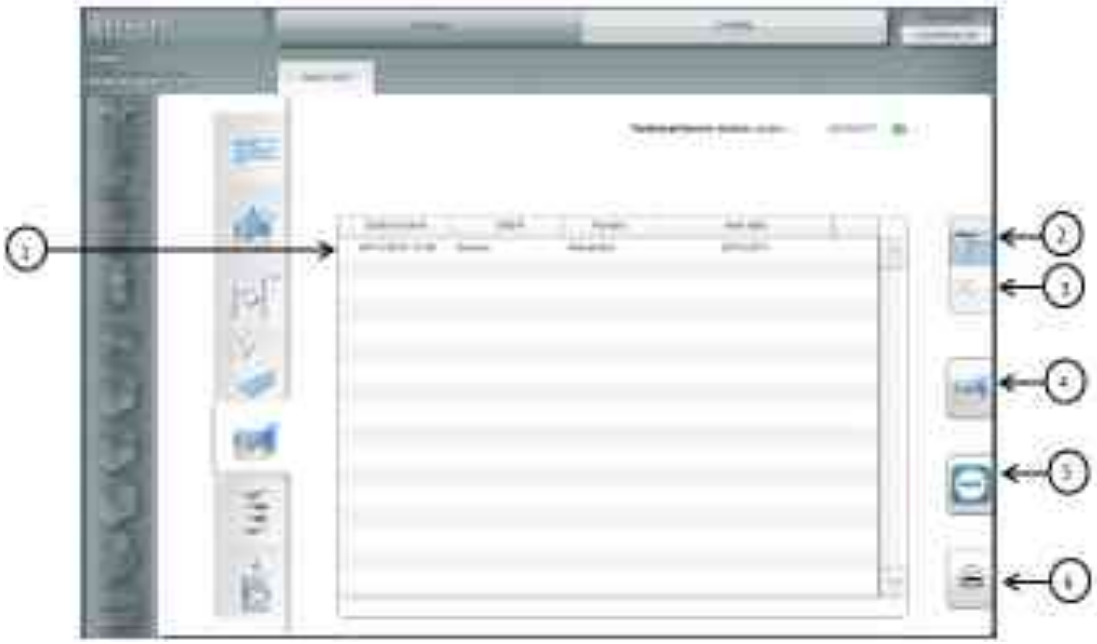


Figure 88. Technical Service Operation Registry Screen

(1) **Registry** of the previous Technical Service operations.

(2) **Filter** button.

(3) **Remove Filter** button.

(4) **Technical Service Operation Record** button.

(5) **Remote Connection** button.

(6) **Print** button to print the Technical Service inspection registry.

14.1.6.1 Obtaining a Track Record of Technical Service Operations

To obtain a track record of the Technical Service operations in the analyzers for a certain period of time, apply a filter:

1. Press the **Filter** button (Figure 88, no. 2).

   The **Filter** screen appears (Figure 89).

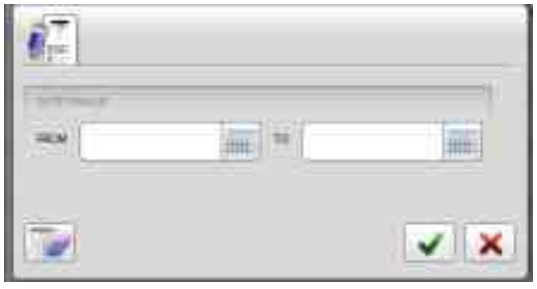


Figure 89. Technical Service Operations Filter Window

2. Enter the period of time of the search (from **From** to **To**).

NOTE: Press  to erase the information entered in the differents fields of the **Filter** screen.

3. Press to confirm (or to cancel).

   A table displays information about the operations carried out by the Technical Service performed during the selected period of time.

4. Press **Print** to obtain a print this information.

14.1.6.2 Recording Technical Service Operations

To keep the traceability of the Technical Service operations, record each service as follow:

1. Press the **Technical Service Operations Record** button  (Figure 88, no. 4) to open the **Technical Service Operations Record** window (Figure 90).
2. Record each Technical Service operation in **Comments** field.

   If the operation is a Preventive maintenance, click on **Preventive Radio** button.

3. Press **Print** button to obtain a Traceability report of this refilling.

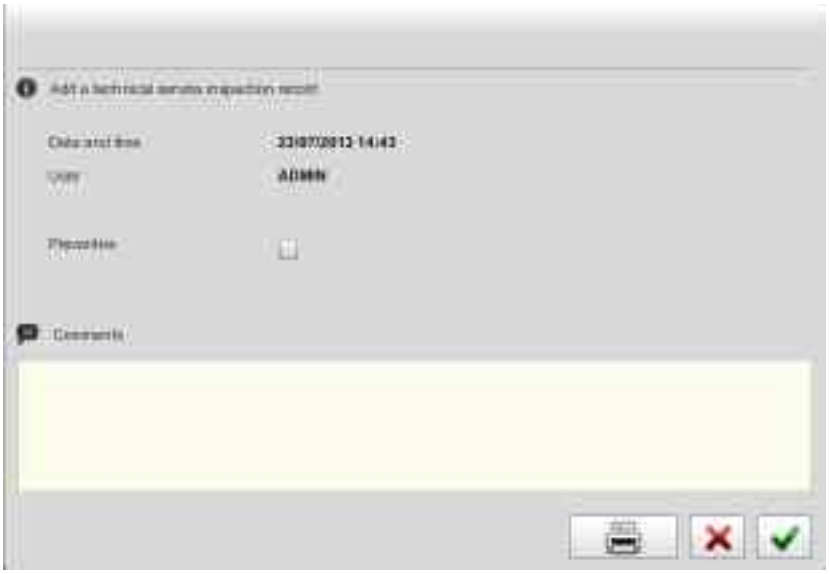


Figure 90. Technical Service Inspection Registry Window

14.1.7 The Activation/Deactivation Modules Tab

Use the **Activation/Deactivation Modules** tab (Figure 76, no. 6) to:

- Check the current activation status of the modules.
- Check traceability information of previous module activation or deactivation.
- Activate or deactivate modules.

Pressing in that tab, the **Activation/Deactivation Modules** screen displays (Figure 91).

Figure 91. Activate/Deactivate Modules Tab

(1) **Registry** of previous modules activation and deactivation.

(2) **Current status** of the different modules of the instrument:

- Incubators.
- Centrifuges.
- Probe.
- Fluidic system.
- Card Transport arm.

If the module is enabled, it appears in green. If it is disabled, it appears in red.

(3) **Filter** button.

(4) **Remove Filter** button.

(5) **Activate/Deactivate** modules button.

(6) **Print** button to print the module activation/deactivation events registry.

14.1.7.1 Obtaining a Track Record of Module Activation/Deactivation Events

To obtain a track record of the module activation/deactivation events for a certain period of time, apply a filter:

1. Press the **Filter** button (Figure 91, no. 3).

   The **Filter** screen appears (Figure 92.

Figure 92. Module Activation/Deactivation Filter Window

2. Enter the period of time of the search (from **From** to **To**).

NOTE: Press to erase the information entered in the differents fields of the **Filter** screen.

3. Press to confirm (or to cancel).

   A table displays information about the activation and desactivation modules events carried out during the selected period of time.

4. Press **Print** to print this information.

14.1.7.2 Activating/Deactivating Modules

The analyzer has been designed to allow user to activated and deactivated modules from the interfase. To activate or deactivate a module:

1. In the **Activate/Deactivate Modules** tab (Figure 76, no. 6), press the **Activate/Deactivate Modules** button .

   A **Modules Availability** window opens (Figure 93).

   The active modules are shown in green and the inactive ones in red.

Figure 93. Modules Availability Window

2. Select the module to change.
3. Press  to confirm (or  to cancel).

NOTE: Module activation is only possible when the instrument is idle.

NOTE: The Activation/Deactivation action is recorded automatically in Activation/Deactivation actions registry.

4. The **Activation/Deactivation Actions Registry** window opens (Figure 94) to record this action. Enter a comment (if it is necessary).

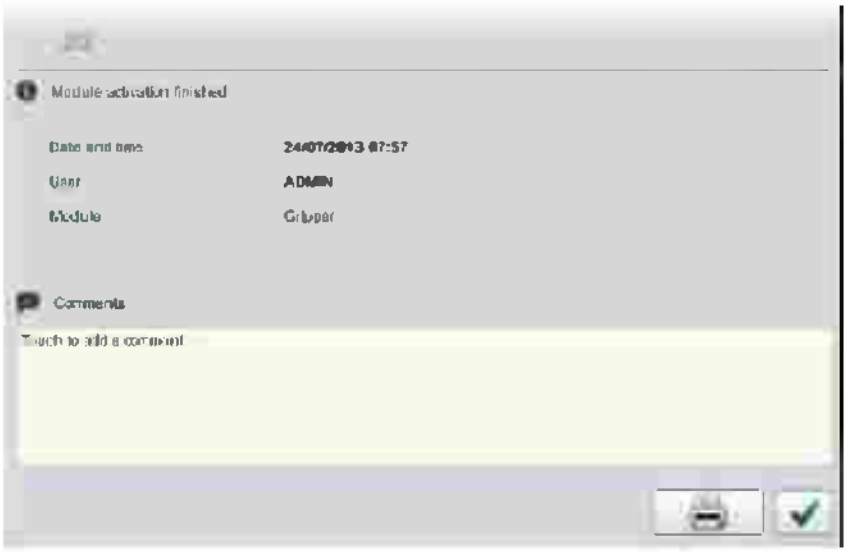


Figure 94. Activate/Deactivate Modules Registry Window

Figure 95. Probe Replacement Registry Window

5. Press to confirm.

NOTE: The fluidic modules is always automatically activated when restarting the analyzer. The Activation action is recorded automatically in Activation/Deactivation actions registry.

14.1.8 The Backup Tab

Use the **Backup** tab (Figure 76, no. 7) to:

- View information on previous backups.
- Perform a back.

Pressing in that tab, the **Backup** screen displays (Figure 96).

Figure 96. Backup Tab

(1) **Registry** of the last backup performed, showing information about:
- User.
- Date.
- Time.
- Comments associated to that backup.

(2) **Backup** button.

(3) **Print** button to print a report with information about the last backup performed.

A backup contains the following zipped information:
- Configuration files.
- Results' Data.
- Log files.
- **Database** backups.

For the full **Database** backup procedure, see Section 14.1.25.

14.1.9 Daily Maintenance

The following maintenance tasks should be performed daily (see Section 14.1).

14.1.10 Checking for Spills

1. Check for any liquids that have leaked or been spilled in the following areas:
   - Sample and Reagent Station.
   - Dilution Station.
   - On the seal of the cards in the incubator.
   - On the incubator.

- System and Waste containers.
- Floor of the analyzer.

2. If spills or leakages are detected, clean them carefully with a dampened cloth, as described in Section 14.1.13.
3. If you observe spills in areas that are not accessible or if the issue occurs again, contact your local Grifols representative.

14.1.11 Check for the Growth of Microorganisms

The growth of microorganisms must be avoided with systematic cleaning of the analyzer. It is recommended to check the following areas daily:

- The System Solution and Waste Solution containers and their lids.
- The connecting tubes of the Washing and Dilution Station.
- The surface of the Sample, Reagent, Gel card and Dilution Stations.
- The probe washer.
- In general, all of the interior surfaces of the instrument.

14.1.12 Weekly Maintenance: Cleaning the Analyzer Surfaces

WARNING: Cleaning process of the analyzer surfaces, the Dilution Station, the Washing Station of the probe must be done with the equipment unplugged from the power supply.

WARNING: Do not dismantle the instrument under any circumstances. If liquid has penetrated into its interior, unplug it from the power supply and wipe up the liquid. If liquid has spilled into an area of the analyzer that is inaccessible, contact your local Grifols representative.

WARNING: Waste materials should be disposed of according to local regulations.

WARNING: During cleaning and decontamination processes, suitable personal protection equipment must be used by the Operator.

CAUTION: Before starting the cleaning and decontamination procedures, all of the samples and reagents must be removed from the inside of the instrument.

14.1.13 Cleaning the External Surfaces

Biological samples, saline solutions, acid or alkaline solvents can cause damage to the exterior surface of the analyzer and should be removed immediately. Periodically wipe the exterior surfaces with a cloth dampened with a mild detergent.

WARNING: Solutions containing alcohol should not be used to clean the acrylic plastic of the front doors or side panels of the analyzer.

NOTE: Before cleaning the exterior surfaces of the analyzer, unplug the analyzer from the power supply.

NOTE: The cleaning of the front and side plastic must be done with mild products that are non-abrasive, to avoid scratching the plastic.

14.1.14 Cleaning the Touch Screen

Clean regularly the touch screen with a cloth that does not leave behind lint and that has been dampened with a solution of 50% ethyl alcohol (v/v).

WARNING: Do not scrub the touch screen directly with cleaning agents as there is a danger that they will leak inside and result in an electric shock to the Operator, as well as cause the deterioration of the touch screen.

WARNING: Ethyl alcohol is highly flammable and irritating. Read the Safety Data Sheet (SDS) before use and follow appropriate precautions.

CAUTION: Do not use caustic chemical agents to clean the touch screen.

14.1.15 Cleaning the Internal Surfaces

1. Clean the internal surfaces (once the racks have been removed) with a cloth which has been dampened with soap and water.
2. Clean the upper part of the Washing Station of the probe and the Dilution Station with a swab dampened with purified water by inserting the swab into the openings in the robotic arm.

WARNING: Take care to not spill liquids into the equipment openings.

3. Remove the system and waste containers from the instrument to be emptied and cleaned.
4. Wash the outside of these containers with soap and water.

WARNING: The contents of the waste drawers must be transferred to containers designated for waste disposal and disposed of in accordance with regulatory requirements.

14.1.16 Monthly Maintenance: Decontaminating the Analyzer

To avoid health risk, decontaminate the analyzer on a month basis or in the following situations:

- After spills, leaks, etc. of potentially contaminating liquids.
- Preparation of the instrument for its transport or storage.
- Before the intervention of the Technical Service.
- Before disposing the instrument.

The fluid circuit and the surfaces in contact with potentially contaminating liquids must be decontaminated.

WARNING: Waste materials should be disposed of according to local regulations.

NOTE: It is recommended to record decontamination activities after they are performed by using one of this options:

- Software interfase: For more information, see Section 14.1.3.

- Fill in Section 20 record which is attached to these Instructions for Use.

WARNING: The analyzer must be decontaminated before performing any preventative and/or corrective maintenance operations.

14.1.17 Decontamination Material Required

To decontaminate the Erytra Eflexis® analyzer, gather the following supplies:

- 2000 mL of 0.5% sodium hypochlorite solution (v/v).
- 3000 mL of purified water when the instrument is not draining the waste into an external drain (mono mode).
- A decontamination container.

CAUTION: Before using any means of cleaning or decontamination that are different from those recommended by the manufacturer, the Supervisor must verify with the manufacturer that the proposed methods are not going to damage the instrument.

WARNING: During the use of the decontamination liquids, adhere to the following recommendations:

- The corresponding Instructions for Use.
- Laboratory security rules.
- Current local risk prevention legislation.

WARNING: Some cleaning or decontamination products, such as sodium hypochlorite solution, may be corrosive, irritating for the skin or eyes, or toxic if by inhaled, absorbed, or ingested. Read the Safety Data Sheet (SDS) before use and follow appropriate precautions.

14.1.18 Decontaminating the Fluidic System

To decontaminate the fluidic system of the analyzer:

1. From the **Others > Analyzer** screen (Figure 26) press the **Decontamination** tab (Figure 76, no. 2).

   The **Decontamination** screen displays (Figure 78).

2. Press the **Fluidic System Decontamination** button  (Figure 78, no. 5) to run the fluidic system decontamination procedure.
3. Click the **Confirm** button on the message that appears on screen to start the procedure and follow the instructions shown on screen.
4. When the analyzer has indicated, remove all the System Solution A and B containers from the analyzer.
5. Connect the decontamination solution container filled with 2000 mL of decontamination solution in the position of the System Solution A container.
6. Press **Continue**. The fluidic system starts priming.
7. When the analyzer has indicated, remove the System Solution A container and place the decontamination solution container in the position of the System Solution B container.

CAUTION: Make sure that decontamination solution container is filled with 1000 mL of decontamination solution.

8. Press **Continue**. The fluidic system starts priming.

9. When priming is completed and when the analyzer has indicated, remove the decontamination solution container.
10. Place the System Solution A and B containers filled with 3000 mL of purified water in the position of the System Solution A and B containers, respectively.
11. Press **Continue**. The fluidic system starts rinsing with purified water.
12. When rinsing is completed, remove the System Solution A and B containers.
13. Empty the purified water from the containers.
14. Refill the containers with the corresponding diluted System Solutions A and B.
15. Open any reagent rack to automatically initiate the priming of the fluidic system.

    Once this priming finishes, the analyzer will be ready to perform analysis.

NOTE: The decontamination procedure takes into account the configuration of the fluidic system (*i.e.* whether or not the instrument is set up to drain to a lab drain or not).

14.1.19 Decontaminating the Probe

Decontaminate the probe periodically, and whenever they get dirty, to keep the exterior of the probe clean and to ensure that the probe level detection system performs properly.

To do this, proceed as follows:

1. Go to the **Others > Analyzer** screen (Figure 26) and press the **Probe Replacement** tab (Figure 76, no. 3).
2. Press the **Replace Probe** button  (Figure 81, no. 4) to move probe to an accessible position.
3. Clean the exterior of the probe with a cloth dampened with 0.5% sodium hypochlorite solution.
4. Wipe the exterior of the probe with a cloth dampened with purified water.
5. Once finished.
6. Open any reagent rack to automatically initiate the priming of the fluidic system.

   Once this priming finishes, the analyzer will be ready to perform analysis.

14.1.20 Decontaminating the Dilution Station

1. Open the top door of the analyzer.
2. With a pipette, add 2.5 mL of 0.5% sodium hypochlorite to the **Dilution Station**.
3. Close the upper door.
4. Let the decontamination solution stand for 15 minutes.
5. Remove the sodium hypochlorite solution from the **Dilution Station** with a pipette.

   The previous steps are automatically performed during the monthly decontamination of the fluidic system. If the decontamination of the fluidic circuit has been performed recently, start with step 5 of the procedure to decontaminate the Dilution Station.
6. Open the upper door and wipe the interior of the Dilution Station using a cotton swab dampened with purified water.
7. Close the top door.
8. Open any reagent rack to automatically initiate the priming of the fluidic system.

   Once this priming finishes, the analyzer will be ready to perform analysis.

14.1.21 Decontaminating the Analyzer Surfaces

To decontaminate the analyzer, proceed as follows:

1. With the instrument plugged in, take out the racks from the Sample and Reagent Station.
2. Open the upper door.
3. Remove all the containers on the lower level.
4. Turn off the instrument and unplug it from the power supply.
5. In the case of a spill, wipe up the liquid with an absorbent material (*i.e.* paper towels or a bunch of gauzes or tissues).
6. Decontaminate the surfaces with a solution of 0.5% sodium hypochlorite (v/v). To do this, clean the surfaces with disposable swabs or wipes soaked in disinfectant so they are completely wet.
7. Wipe up the disinfecting solution with a disposable material.
8. Wipe the surface with a mild detergent mixed with water in order to remove the residual harmful chemical components.
9. Dry the surface.
10. Discard all of the contaminated material that was used during the decontamination process into a container for biological waste.

14.1.22 Decontaminating Racks and Samples Holders

To decontaminate the sample and reagent racks and sample holders:

1. Remove the sample and reagent racks and sample holders from the analyzer.
2. Soak them for half an hour in soap and water mixed with a small amount of 5% sodium hypochlorite (v/v).
3. Rinse completely.
4. Allow the racks to dry, taking care not to force the straps or the flaps and making sure that they are completely dry before reloading them into the analyzer.

14.1.23 Decontaminating the Liquid Containers

1. Clean the outside of the liquid containers with a cloth dampened with soap and water.
2. Clean the inside of the containers by rinsing them with an aqueous solution of 0.5% sodium hypochlorite (v/v).

WARNING: If the liquid containers are cleaned with sodium hypochlorite, intensive rinses with purified water should be performed in order to remove all traces of the sodium hypochlorite before using the container again.

14.1.24 Preventive Maintenance

Preventive maintenance of the Erytra Eflexis® analyzer must be performed on a year basis by a Qualified Technician.

NOTE: Contact to your local Grifols representative to schedule the preventive maintenance.

CAUTION: Before the Qualified Technician performs any preventive and/or corrective maintenance operations, remove all the samples and reagents from the instrument.

NOTE: It is recommended to record decontamination activities after they are performed by using one of this options:

- Software interfase: For more information, see Section 14.1.3.
- Fill in Section 20 record which is attached to these Instructions for Use.

This preventive maintenance includes, among others:

- Mechanical review.
- Fluidic system review.
- Review of the status of the probe washers and the probes.
- Review of the reader and its components.
- Review of the IT system.

14.1.25 Database Backups

To perform back-ups of the system data:

1. Go to the **Other > Analyzer** screen and select the **Backup** tab (Figure 76, no. 7). For more information, see Section 14.1.8.
2. Click the **Backup** button (Figure 96, no. 2).

CAUTION: To avoid the loss of data due to a temporary corruption of the system, make a backup copy of the results stored in the Erytra Eflexis® analyzer **Database** on a regular basis.

CAUTION: If an error occurs during the execution of a backup, an error message will appear on the screen. If the problem persists, contact your local Grifols service representative.

NOTE: Backing up the **Database** is only possible when the instrument is idle.

By default, the information that has been backed up will be stored in the D:\Backup folder. To configure another folder to store the backup, contact your Grifols service representative.

14.1.25.1 Restoring the Database

To restore the **Database**, contact your local Grifols service representative.

CAUTION: Backup the **Database** before restoring it. To do this, follow the instructions described in Section 14.1.25.

14.1.25.2 Restoring the User Database

To restore the user **Database** (containing user configuration information), contact your local Grifols service representative.

15 Erytra Diagnostic

The Erytra Diagnostic program performs a series of tests that check for the correct functioning of the different modules of the instrument.

To run it, press the **Diagnostic** icon  from the initial loading window (Figure 97).

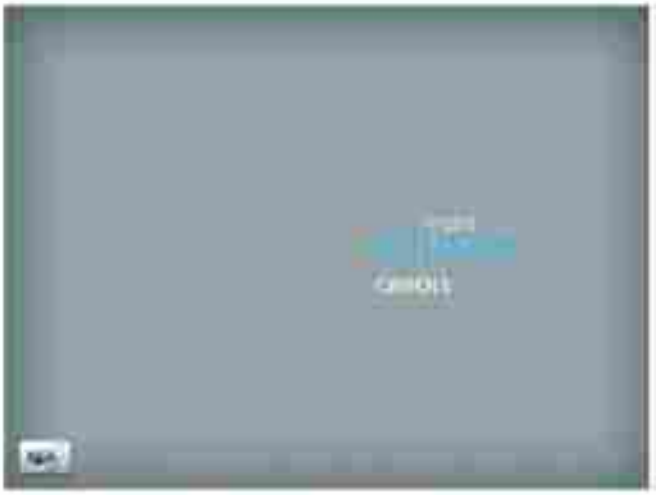


Figure 97. Erytra Diagnostic Program Loading Window

NOTE: The **Diagnostic** icon is only available to press during the initial loading window.

When pressed the **Diagnostic** icon, a menu tab opens. Select the option Erytra Diagnostic in the **Diagnostic menu** tab (Figure 98) to run the Erytra Diagnostic program.

Figure 98. Diagnostic Menu Tab

Once the **Diagnostic** window opens (Figure 99), select the modules to be checked and press the **Green Arrow** button  to start the diagnostic.

Figure 99. Erytra Diagnostic Window

To run the diagnostic on all of the analyzer modules, the following requirements must be met, as shown in the message that appears on the screen:

- Reagents/Samples Level:
  - There must be no samples in holder 1 of racks 3 and 4.
  - Holder 2 in sample rack 3 must contain barcode labelled tubes filled with 0.9% saline solution:
    - 10 mm diameter tubes in positions 1 to 4.
    - 12 mm diameter tubes in positions 5 to 8.
    - 15 mm in diameter in positions 9 to 12.
  - Place reagent racks in positions 1 and 2.
  - There must be in reagent rack 1:
    - 1 diluent in position 1.
    - 2 reagent vials filled with reagent erythrocytes or 0.9% saline solution in position 3, 5, 7, 12, 17 and 23.
- Cards Level:
  - No card in the Card Transport arm.
  - There must not be any Grifols gel cards in rack 2, or in the incubators or centrifuges.
  - There must be empty card racks in positions 1 of drawer 1 and positions 3 and 4 of drawer 2.
  - There must be a Grifols gel card rack with lower floor only (12 cards) in drawer 1, position 4.
- Solution and Waste level:
  - A full wash solution container must be available.
  - System Solution containers A and B must each contain a minimum of 4 L of the appropriate System Solution.

- A 0,5 Kg weight must be available.
- An empty System Solution container must be available.
- A minimum capacity of 6 L in the two waste containers must be available.

• General:

- All drawers and racks must be closed.

To open drawers/racks for the requirements above, use the buttons on the front of the analyzer.

Follow the instructions that appear on the screen while the diagnostic is running.

WARNING: Do not open the upper door while the Erytra Diagnostic program is running, as the Lower Robotic arm may be moving.

After the diagnostic program is complete, the **Print** icon will become active so that an execution report containing the results of the different modules checked by the program (Figure 100) can be printed.

Figure 100. Execution Report

The Execution Report shows the results of the Erytra Diagnostic grouped by module, by the result of the diagnostic wether a status of "PASS" or "FAIL", and by whether the diagnostic has been executed on that module or not. These results may be saved and/or printed from the tool bar:

Figure 101. Erytra Diagnostic Tool Bar

To close the Erytra Diagnostic program and initialize the analyzer, press  and Erytra Eflexis® program loading window opens. Then press **Start Eflexis** option from the menu.

If any modules do not pass, contact your local Grifols service representative.

16 Transport and Storage

16.1 Storing the Instrument

If the Erytra Eflexis® analyzer must be stored for a long period of time, it is recommended that it is packaged as if it were to be transported.

The environmental conditions of storage must be those specified in Section 3.1.

The requirements for storing the instrument are:

- Size: Width 1200 mm by depth 800 mm by height 2000 mm.
- Weight: 350 kg.

CAUTION: Only use the original packaging for the transport of the instrument.

WARNING: The instrument must be decontaminated before being transported.

16.2 Unpacking the Instrument

To unpack the instrument, remove the packaging by following the instructions:

1. Remove the wooden box keeping in mind the screws of the pallet.
2. Remove the foam covers that protect the instrument.

When the Erytra Eflexis® is received, check that it includes all the items specified in the packing list attached and follow the instructions for unpacking.

16.3 Placing the Instrument in Its Location Place of Operation

Unpack the Erytra Eflexis® analyzer as close as possible to its installation location.

Here it will be unpacked as explained in the previous section and it will be placed in the chosen location.

WARNING: The weight of the instrument is considerable, and therefore it is advised to strictly follow these installation instructions.

16.4 Installation Procedure

The installation procedure is described in the Technical Service manual.

17 Equipment Disposal

At the end of its useful life or in the case of wanting to dispose the instrument, remove all remains of samples and reagents, and then clean and decontaminate it. Upon completion, dispose of the analyzer as electronic waste, according to local and state regulations and sent it to an authorised centre for the disposal of this type of waste.

WARNING: This instrument must only be dismantled by authorized specialists.

CAUTION: When an instrument has reached the end of its useful life, keep in mind that all current local legislation must be complied with during disposal.

The Erytra Eflexis® analyzer is considered to be electronic waste. Electronics can contain hazardous materials. Dispose of all electronics in accordance with local and state regulations.

If you have any question about the disposal of the analyzer, contact your local Grifols service representative.

18 Warranty

The warranty conditions are established in a separate document. For more information, contact your local Grifols service representative.

The following parts are excluded from the guarantee:

- RS 232 Cable and network cable.
- The tubing and connectors.
- The syringe.
- The containers.
- The probe.
- Any part that has been used improperly.

⚠ **CAUTION:** Repairs should be carried out only by authorized personnel.

⚠ **CAUTION:** The use of analyzer for any procedure other than those procedures specified by the manufacturer shall automatically invalidate any type of warrancy.

19 Troubleshooting

19.1 Incident List

During the normal working of the Erytra Eflexis® analyzer some error messages and incidences may appear that can be resolved by the Operator.

Lower-level incidences can affect the working of the analyzer without stopping test execution completely.

Intermediate level incidences related to the lack of a resource (reagent, Grifols gel card, sample, System Solutions, etc.) appear in the **Warning Area** of the Erytra Eflexis® software and do not require immediate intervention. To obtain detailed information about how to solve these types of incidences, see Section 7.4.

High-level incidences require immediate intervention to correct the situation. High-level incidences are accompanied by an acoustic alarm.

Incidents are shown on the screen as error messages, along with a red ten-digit codeassociated with it in the top right portion of the error message. These digits are used in the following way:

- The first 2 digits identify the module that has produced an error.
- The next 2 digits identify the device that has produced an error in the module.
- The next 3 digits indicate the type of error.
- The last 3 digits indicate wether the error is a fluidic error. If the last 3 digits are zeros (“000”), the error is a non-fluidic error. For fluidic errors, the last three digits identify the type of fluidic error.

Figure 102. Incident Error Message

This information should be given to contact your local Grifols service representative if the incidence requires contacting them.

19.2 Low-Level Incidences

Low-level incidences appear on the **Erytra Eflexis® Software** screen in the form of error messages. The following table shows a list of messages that are shown by the Erytra Eflexis® software, grouped by the type of error.

19.2.1 Controller

Table 15. Low-level Incidences Controller Descriptions

MESSAGE	DESCRIPTION
IDENTIFICATION	
One or more tubes have not been identified. Please, go to SAMPLES in order to repair the problem.	The identification process has found one or more tubes not detected or with a problematic barcode number. Go to the **Samples** screen to locate the tube that is responsible for the incidence. Open the drawer, face the tube’s

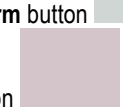
MESSAGE	DESCRIPTION
	barcode toward the identification window, and close the drawer. If the problem persists, identify the tube manually.
Identification process has found one or more vials not detected or with a wrong identifier. Please, go to REAGENTS in order to repair the problem.	Identification process has found one or more vials not detected or with a wrong identifier. Go to the **Reagent** screen to locate the vial that is responsible for the incidence. Open the drawer, correctly face the vial's barcode and close the drawer.
The system has detected tubes manually identified. Please, select YES to confirm that tubes have not been substituted by new ones and to confirm that the sample racks have been introduced in the same orientation as when those tubes were manually identified.	The process has detected tubes that have been previously identified manually. If you select YES, the system will assume that the tubes have not been replaced with new tubes and will maintain the manual identification.
The system has detected more than one tube with the same barcode.	The system has detected more than one tube with the same barcode. Go to the **Samples** screen to locate the tubes that are responsible for the incidence. Open the rack and check the tubes that are responsible for the incidence.
Samples holder identifier does not match with the configured ones.	The rack barcode identified by the system does not match with any of the configured ones.
Samples holder identifier has not been detected. Please ensure that the holder is properly labelled and try again.	The holder barcode has not been detected by the Card Transport arm. Open the drawer and check that the holder is labeled with the proper barcode.
EXECUTION	
One or more process incidences have been detected in tubes. Go to the **Samples** screen to resolve the problem.	One or more process incidences have been detected in tubes. Go to the **Samples** screen to check the type of incidence as well as the affected tube and take the necessary actions.
The requested action is already in process. Please wait.	The analyzer has been requested to perform an action that cannot be executed immediately. Wait a few seconds until the analyzer executes the requested action.
There is no empty position to insert new samples. Select Open immediately in order to replace an existing tube or Open after works to wait until a position becomes available.	If the **STAT** button on the front of the instrument is used to insert a STAT sample and there are no positions available, the system immediately unlocks a rack and gives the user the choice of replacing an existing tube or closing the rack and waiting until a loaded sample has been pipetted so that it can be replaced with the STAT sample.
QUALITY CONTROL MANAGEMENT	
The identification process has found one or more expired QC tubes. Please, open drawer in order to repair the problem.	During the identification process, the system has detected that the expiry date has passed for one or more of the **Quality Control** samples. Please, open the rack in order to repair the problem.
QC protocol {0} is wrong or	The system has registered a **Quality Control** result that is incorrect or

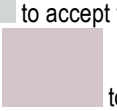
MESSAGE	DESCRIPTION
cancelled and some samples are stopped by QC. Please, press CONTINUE if you want to queue with QC protocol omission, RE-RUN if you want to maintain them stopped until QC is passed or CANCEL works if you want to cancel that works.	cancelled and there are samples pending processing. In this case, the system offers the following options: Continue: Processing them and omit the QC protocol Re-run: If you wish to maintain them on hold until the correct QC result is obtained Cancel works: If you wish to cancel all the jobs.
PROBES	
Probe has been disabled.	The probe has been disabled. If the problem persists after restarting the Erytra Eflexis® software, contact your local Grifols service representative.
Probes cannot be changed whilst there is pending work.	Probes cannot be changed whilst there is pending work. Wait until the assigned workload is finished before changing the probes.
CENTRIFUGES	
Centrifuge X has been disabled.	One of the centrifuges has been disabled by the system. Click Accept. The error message will indicate if the deactivated centrifuge is number 1 or 2. If the problem persists after restarting the Erytra Eflexis® software, contact your local Grifols service representative.
INCUBATORS	
Incubator X has been disabled.	One of the incubators has been disabled. The error message will indicate if the deactivated incubator is number 1, 2 or 3. If the problem still persists after restarting the Erytra Eflexis® software, your local Grifols service representative.
Temperature out of margins in incubator. Incubator has been disabled and tests (if any) cancelled.	The incubator temperature is outside the optimum range to perform the test and therefore will not be used. The error message will indicate if the deactivated incubator is number 1, 2 or 3. If the problem still exists after restarting the Erytra Eflexis® software, your local Grifols service representative.
DECONTAMINATION	
Decontamination is disabled because there is pending work or fluidic actions in process.	The decontamination process cannot be started while there are pending tasks. Wait until the pending task is finished before proceeding with decontamination.
Decontamination process cannot be executed if waste capacity is smaller than 3 L.	The decontamination process has been cancelled as the total capacity of the waste drawer is less than 3 L. The container must be emptied before proceeding with the decontamination of the analyzer.

19.2.2 Manager

Table 16. Low-level Incidences Manager Descriptions

MESSAGE	DESCRIPTION
USER MANAGEMENT	

MESSAGE	DESCRIPTION
Access level insufficient for this action.	The identified user does not have permission to access the action requested, Only a user with sufficient permission for this action can access it.
Error creating New User.	There has been an error creating a New User. Close the window and try again.
Error updating User.	There was an error when updating the user. Close the window and try again.
Some form required fields have not been filled in.	Some fields have not been filled. Complete the information to finish the process.
Error loading **User Management** screen.	There was an error on loading the **User Management** screen. Close the window and try again.
This is a required field!	There is still one field that has not been filled in. Complete the information to finish the process.
Username exist in **Database**.	A new user is being created, assigning an already existing username.
VALIDATION	
Are you sure that you want to validate selected results? Pending tests will be cancelled.	Press the **Confirm** button to continue validating the result or press the **Cancel** button  to cancel the validation.
Are you sure that you want to Cancel the Validation for the selected results?	Press the **Confirm** button to cancel the validation or press the **Cancel** button to continue without cancelling the validation**.**
Are you sure that you want to Export the selected results?	Press the **Confirm** button to continue exporting the selected results or press the **Cancel** button to cancel the export.
Are you sure that you want to Reject the selected results?	Press the **Confirm** button to reject the selected results or press the **Cancel** button to cancel the rejecting of the selected results.
Samples with modified results are being validated. Are you sure you want to continue?	Press the **Confirm** button to continue validating results that have been modified or press the **Cancel** button to cancel the validation of results that have been modified.

MESSAGE	DESCRIPTION
Are you sure you want to modify this well result?	Press the **Confirm** button to accept the modification made on the results or press the **Cancel** button  to not save the modification made on results.
There are no selected results.	There are no selected results, so no action can be performed on them.

19.3 High-Level Incidences

High-level incidences require immediate Operator intervention. All incidences are accompanied by an error message with the option to "**Retry**" in the situations where this is possible. This option allows you to repeat execution of the process that generated the incidence.

Some of these high-level incidences can only be resolved by re the Erytra Eflexis® System. In these cases, you must accept the only option available that appears on the error message.

Table 17. High-level Incidences Descriptions

MESSAGE	DESCRIPTION
GENERAL	
There is an initialization problem. Please, RESTART the system.	The system has detected an initialization problem. Press "Restart the system".
Server is not available.	The system has detected a problem. If the problem persists after restarting the Erytra Eflexis® software, contact your local Grifols service representative.
Virtual keyboard is not available.	The system has detected that the virtual keyboard is not available. If the problem persists after restarting the Erytra Eflexis® software, contact your local Grifols service representative.
Error during Reader initialization. Please, RESTART the instrument.	The system has been unable to start the viewer module. If the problem persists after restarting the Erytra Eflexis® software, contact your local Grifols service representative.
Error setting security data.	The system has detected an error while setting security data. If the problem persists after restarting the Erytra Eflexis® software, contact your local Grifols service representative.
Error opening Erytra Eflexis® program.	The system has detected an error while opening the software. If the problem persists after restarting the Erytra Eflexis® software, contact your local Grifols service representative.
HARDWARE	
Unrecoverable error. Please press OK to RESTART.	The system has detected an unreparable hardware error. Press "OK" to restart the program.
The system has a significant error.	The system has detected an irreparable error. It is necessary to restart the

MESSAGE	DESCRIPTION
Please RESTART the instrument before requesting any further test.	Erytra Eflexis® software.
FLUIDIC SYSTEM	
Fast prime error.	The system has detected an error when priming or rinsing. Press OK to Continue.
The fluidic system has been marked as not usable. Please RESTART the instrument as soon as possible.	The fluidic system is not usable and the instrument should be restarted whenever possible.
There are one or more instrument fluidic incidences.	The system has detected one or more incidences related with the fluidics. Please choose one of the options: "**Retry**" or "**Cancel Works**".
Pressure error on Solution A circuit. Please check: • Containers are properly connected. • Check that there is no spilling in the upper level.	The system has detected a pressure error in the Solution A circuit. Please ensure that containers are properly connected and that there is no spilling in the upper level.
Pressure error on Solution B circuit. Please check: • Containers are properly connected. • There is no spilling in the upper level.	The system has detected a pressure error in the Solution B circuit. Please ensure that containers are properly connected and that there is no spilling in the upper level.
Vacuum error. Please check: • Lab drain tube and connection. • There is no spilling in the upper level.	The system has detected a vaccum error. Please check the lab drain tube and connection and that there is no spilling in the upper level.
TRANSPORT	
Error in the Card Transport arm when taking a card. Select RETRY or CANCEL.	There has been an error in the Card Transport arm when taking a card. Select Retry or Cancel.
Error in the Card Transport arm when releasing a card. Please inspect cards zone for lost card. Select RETRY, CANCEL or RELEASE CARD.	There has been an error in the Card Transport arm when releasing a card. Please inspect the cards zone for lost card.
Error during card drawer presence detection. Please choose one of the following options: RETRY or CANCEL.	The system has detected an error during a card drawer presence detection performed by the Card Transport arm. Please choose Retry or Cancel works.
An error in a barcode reader has	The system has detected an error during the reading of a barcode

MESSAGE	DESCRIPTION
been detected. Please, restart the system.	performed by the Card Transport arm. If the problem persists after restarting, contact your local Grifols service representative.
Card lost while reading. Select RETRY or CANCEL.	A card has been lost during the reading process. Select Retry or Cancel.
Error in the Card Transport arm while transporting a card. Please inspect cards zone for lost card. Select RETRY or CANCEL.	A card has been lost during the transport process. Select Retry or Cancel. Moreover, ensure that the lost card does not affect the card transport and remove it as soon as possible.
Error in the Card Transport arm while transporting a card. Please inspect card drawer zone for lost card and open drawer if needed. Select OPEN, RETRY or CANCEL.	A card has been lost in a card drawer during the transport process. Select Open, Retry or Cancel. Moreover, ensure that the lost card does not affect the card transport, open the drawer and remove it as soon as possible.
A card has been lost while transporting to the Service Rack. Ensure that the lost card does not affect the card transport and remove it as soon as possible.	A card has been lost during the transport to a Service Rack process. Select Retry or Cancel. Moreover, ensure that the lost card does not affect the card transport and remove it as soon as possible.
Card barcode not expected. Card will be discarded and samples cancelled. Press OK.	The system has detecte dan unexpected barcode of a Grifols gel card. Press Ok to Continue discarding the sample of the associated card.
Service Rack is full. Please empty one Service Rack holder in order to resume cards reading.	Service Rack is full. It is necessary to empty one Service Rack holder to continue with the cards reading.
PIPETTING	
Obstruction detected during pipetting sample(s) X located in position(s) Y. Please Open the drawer and remove the obstruction.	The system has detected an error during the pipetting due to the detection of a clot in sample X located in position Y. Please Open the rack and remove the obstruction.
Level detection error during pipetting. Please check there is enough volume and the absence of bubbles.	The system has detected an error during the pipetting. Please check there is enough volume and the absence of bubbles.
Error during reagents stirring process. Please choose one of the following options: RETRY or CANCEL.	The system has detected an error during reagents stirring process. Please choose one of the following options: **Retry** or **Cancel Works**.
Error during homogenization in dilution cup. Please choose one of the following options: RETRY or CANCEL.	The system has detected an error during reagents stirring process or homogenization in dilution cup. Please choose one of the following options: **Retry** or **Cancel Works**.
Probe of Pipetting arm has found and obstacle. Please check: • Samples and reagents	The probe of Pipetting arm has found and obstacle. Please check: Samples and reagents suitability and samples and reagents racks positioning.

MESSAGE	DESCRIPTION
suitability. • Samples and reagents racks positioning.	
PROBES	
It is not possible to process samples as there is no probe available.	The probe is not available, so it is not possible to process samples.
The system was not able to complete the probe replacement process.	The process of replacing the probe has not been successful. Close the software and try again. If the problem persists, contact your local Grifols service representative.
INCUBATORS	
It is not possible to process samples as there is no incubator available.	None of the incubators are available, so it is not possible to process samples.
CENTRIFUGES	
There is no balance card to allow centrifuging. Open a card drawer to introduce it and then press RETRY.	There is no Grifols gel card available in the Erytra Eflexis® analyzer that can be used as a balance card for the centrifuge. To continue with the process open any drawer and insert a Grifols gel card. Press Retry.
It is not possible to process samples as there is no centrifuge available.	None of the centrifuges are available, so it is not possible to process samples.
Error during centrifuge positioning. Please choose one of the following options: RETRY or CANCEL.	The system has detected an error during the movement of any of the centrifuges. Please choose one of the following options: **Retry** or **Cancel Works**.
CONTAINERS	
There is an opened Waste drawer. Please, close it and then press Retry fluidic operation.	The system has detected an open waste drawer. Close the waste drawer that is open and press "Retry" to continue with the fluidic operation.
Required fluidic container is not present. Please, insert it.	The system requires a fluidic container that is not present. Insert it and select OK to continue.
Card waste container is full. Please empty it.	The system requires the waste containers and has detected that they are full. Remove the container, empty it and load the empty container into the analyzer. Then select OK to continue.
Card waste container is not present. Please insert it and press OK.	The system requires a fluidic container that is currently not present. To continue, insert the container.
DRAWERS AND RACKS	
Reagent drawer has been disabled. Please RESTART the system as soon as possible.	The system has disabled a reagent rack. It is necessary to restart the system as soon as possible.

MESSAGE	DESCRIPTION
The rack could not be opened. Ensure the rack is properly located and try to open again.	The system could not open the required rack. Try again. If the problem persists, contact your local Grifols service representative.
The rack is being accessed by probe, try it again later.	The system can not open the rack because it is being used by the system. Wait for some seconds and try again. If the problem persists, contact your local Grifols service representative.
DECONTAMINATION	
The instrument is disabled because the decontamination process was not executed correctly. Please execute the decontamination process again in order to enable sample testing.	The decontamination process has not been done successfully. Ensure that the container placed in the System Solution B drawer is full and that the waste drawers are empty before repeating the procedure. If the problem persists, contact your local Grifols service representative.
The instrument did not complete the decontamination process. The system will not allow executing any workload until decontamination procedure is successfully completed.	The instrument has not finished the decontamination process. It is necessary to perform a successful decontamination procedure to continue executing any workload.
During decontamination process, the system has detected that a container is not present. Please, close it and press RETRY.	The system has detected a container is not present during the decontamination. Please close it and press Retry.
Decontamination process could not be performed correctly. Please ensure that container placed in Solution B position is full and Waste bottles are empty and repeat the decontamination process.	The system has detected that there is not enough volume in the container placed in Solution B or that there is not enough capacity in the liquid waste container to perform the decontamination process Check it and repeat the decontamination process.
DOORS	
Upper door is open. Please, close it to continue.	The system has detected that the general door is open. The door must be closed in order to continue processing samples.
ARM MOVEMENTS	
Error during the Pipetting arm movement. Please, inspect the instrument pipetting area. Please choose one of the following options: RETRY or CANCEL Works.	The analyzer has detected that the Pipetting arm was not able to complete its movement. Press Retry or Cancel Works to continue.
Error during the Card Transport arm movement. Please, inspect the instrument middle level. Please choose one of the following options: RETRY or CANCEL	There has been an error during the Card Transport arm movement. Please, inspect the instrument middle level. And choose one of the following options: **Retry** or **Cancel Works**.

MESSAGE	DESCRIPTION
Works.	
STAT SAMPLES	
Missing cards affect one or more STAT samples. The workload will not be processed until these cards are introduced. Please, go to MISSING CARDS and REAGENTS to obtain more information.	The Grifols gel card(s) required by the analyzer affect one or more of the STAT samples. Go to the **Missing Cards & Reagents** screen of the analyzer and load the required Grifols gel cards.
Missing container affects one or more STAT samples. The workload will not be processed until this container is introduced. Please, go to CONTAINERS to obtain more information.	The container required by the analyzer affects one or more of the STAT samples. Please go to the **Containers** screen of the analyzer to identify the container that is needed.
Missing reagent kit X affects one or more STAT samples. The workload will not be processed until these reagents are introduced. Please, go to MISSING CARDS and REAGENTS to obtain more information.	The reagent required by the analyzer affects one or more of the STAT samples. Go to the **Missing Cards & Reagents** screen and load the required reagent.
Missing sample X affect one or more STAT samples. The petitions will not be processed until these samples are introduced. Please, go to MISSING SAMPLES to obtain more information.	The sample required by the analyzer affects one or more of the STAT samples. Go to the **Missing Samples** screen of the analyzer and load the sample required.
CLOSING PROGRAM	
There are some unsaved changes. Are you sure to CANCEL them?	The system has detected that there are some unsaved changed. Confirm if you want to cancel them.
There are tests in process. Are you sure you want to shutdown the instrument? Before switching off, please ensure that all reagents, diluent and cards that require storage conditions between 2-8 ºC are removed from the instrument.	The system has detected that there are tests in process. Confirm if you want to shutdown the instrument. Before switching off, please ensure that all reagents, diluent and cards that require storage conditions between 2-8 ºC are removed from the instrument.
There are tests pending. Are you sure you want to shutdown the instrument? Before switching off, please ensure that all reagents, diluent and cards that require storage conditions between 2-8 ºC are removed from the instrument.	The system has detected that there are pending tests. Confirm if you want to shutdown the instrument. Before switching off, please ensure that all reagents, diluent and cards that require storage conditions between 2-8 ºC are removed from the instrument.
There are tests waiting. Are you sure you want to shutdown the instrument? Before switching off,	The system has detected that there are tests waiting. Confirm if you want to shutdown the instrument. Before switching off, please ensure that all reagents, diluent and cards that require storage conditions between 2-8 ºC

MESSAGE	DESCRIPTION
please ensure that all reagents, diluent and cards that require storage conditions between 2-8 ºC are removed from the instrument.	are removed from the instrument.
Are you sure you want to shutdown the instrument? Before switching off, please ensure that all reagents, diluent and cards that require storage conditions between 2-8 ºC are removed from the instrument.	Confirm if you want to shutdown the instrument. Before switching off, please ensure that all reagents, diluent and cards that require storage conditions between 2-8 ºC are removed from the instrument.
Movement error during shutdown. Due to this error, the system could not be rinsed and emptied. Please choose one of the following options. CANCEL option will continue with shutdown procedures without rinsing and emptying the fluidic system.	The system has detected a movement error during shutdown. Due to this error, the system could not be rinsed and emptied. Please choose one of the following options. CANCEL option will continue with shutdown procedures without rinsing and emptying the fluidic system.
BACKUP AND ARCHIVE PROCEDURES	
Error on Backup process.	The system has detected an error during the Backup process. If problem persist after restarting the analyzer, contact your local Grifols service representative.
Error on Archive process.	The system has detected an error during the Archive process. If problem persist after restarting the analyzer, contact your local Grifols service representative.
It is not possible to start the backup process because there are pending works.	It is not possible to start the backup process because there are pending works. Wait until the workload has finished and try to start the backup again. If problem persists, contact your local Grifols service representative.

19.3.1 Manager

Table 18. High-level Incidences Manager Descriptions

MESSAGE	DESCRIPTION
PROGRAMMING	
Due to a compatibility problem, only a subset of the request analysis will be programmed. Do you want to continue?	The system has detected compatibility issues and only some of the selected requests can be programmed. Press "Yes" or "No" to continue.
The selected combination of Recipient/Donor already exists. Press OK if you want to edit the existing assignment or press CANCEL to create a new one.	The system has detected that the Donor/Recipient combination selected already exists. Press "OK" to modify this assignment or "Cancel" to create a new assignment.
This sample is not inside the analyzer.	The system has detected that the sample is not inside the analyzer.

MESSAGE	DESCRIPTION
LIS	
LIS error: Unable to initialize Host **Database**. Please contact your local Grifols service representative.	The system was not able to initialize the Host **Database**. You should contact your local Grifols service representative.
LIS error: Unable to initialize file “Pocillos.def”. Please contact your local Grifols service representative.	The system was unable to initialize the files “Pocillos.def”. You should contact your local Grifols service representative.
LIS error: Unable to initialize file “Interp.def”. Please contact your local Grifols service representative.	The system was unable to initialize the files “Interp.def”. You should contact your local Grifols service representative.
LIS error: Unable to initalize file “Alias.def”. Please contact your local Grifols service representative.	The system was unable to initialize the file “Alias.def”. You should contact your local Grifols service representative.
LIS error: Unable to initialize file “Idioma_I.def”. Please contact your local Grifols service representative.	The system was unable to initialize the file “Idioma_I.def”. You should contact your local Grifols service representative.
LIS error: Unable to initialize file “DSC.def”. Please contact your local Grifols service representative.	The system was unable to initialize the file “WadianaConnection.def”. You should contact your local Grifols service representative.
LIS error: Unable to find “erytra_data” environment variable. Please contact your local Grifols service representative.	The system could not find the “erytra_data” environment variable. You should contact your local Grifols service representative.
LIS error: Timeout exceeded during a request to DianaServer. Please contact your local Grifols service representative.	The system has detected that the time limit in communicating with the DianaServer has been exceeded. You should contact your local Grifols service representative.
DianaServer request error. Please contact your local Grifols service representative.	The system has detected a communication error with the DianaServer. You should contact your local Grifols service representative.
LIS error: DLL has not been initialized. Please contact your local Grifols service representative.	The system has detected that the DLL has been not initialized. You should contact your local Grifols service representative.
LIS error: Gru X not found in “DSC.def”. Please contact your local Grifols service representative.	The system has detected that the Gru has not been found in “DSC.def”. You should contact your local Grifols service representative.
LIS error: Error loading template X. Please contact your local Grifols service representative.	The system has detected an error while loading the template. You should contact your local Grifols service representative.
LIS error: Error loading XML. Please contact your local Grifols service representative.	The system has detected an error while loading XML. You should contact your local Grifols service representative.
LIS error: Result of segment X not found in “DSC.def”. Please contact your local	The system has detected that the result of the segment is not found in “DSC.def”. You should contact your local Grifols service

MESSAGE	DESCRIPTION
Grifols service representative.	representative.
LIS error: Well X not found in “DSC.def”. Please contact your local Grifols service representative.	The system has detected that the well has not been found in “DSC.def”. You should contact your local Grifols service representative.
LIS error: Result of well X not found in “DSC.def”. Please contact your local Grifols service representative.	The system has detected that the well result has not been found in “DSC.def”. You should contact your local Grifols service representative.
Program error: Error in DSC_Custom.def. Please contact your local Grifols service representative.	The system has detected an error in the DSC_custom.def. Contact Technical Service.
Program error: Error deleting batch. Please contact your local Grifols service representative.	The system has detected an error deleting the batch. Contact Technical Service.
Error when Exporting to LIS.	The system has detected an error exporting from LIS. Contact Technical Service.
Error when Importing from LIS.	The system has detected an error importing from LIS. Contact Technical Service.
LIS connection failed. LIS will not be available until the system is restarted. If problem persists, please contact your Technical Service.	The system has detected a failure in the LIS connection. If problem persists after restarting the Erytra Eflexis® software, contact your local Grifols service representative.
Program error: Well image not found. Please contact your local Grifols service representative.	The system has detected that the well image has not been found. Contact Technical Service.
REPORTS	
The report could not be shown due to other notifications. Please close all notifications and create the report again.	The report could not be shown due to other notifications. It is necessary to close all notifications and create the report again. If problem persists, contact your local Grifols service representative.
Please select a maximum of X entries.	The report could not be shown. It is necessary to select a lower number of fields and then create the report again. If problem persists, contact your local Grifols service representative.
The resulting Activity report will only show the first X entries.	The Activity report displayed will show the first X entries selected. For the non shown results, select them in a second time and create the report again.
The resulting Report will only show the first X entries.	The report displayed does not show all the results selected. It only displays the first X entries. Select the rest of results not shown in a second time and create the report again.
An error was occurred while attempting to print a report.	
RESULTS FILTERING	
Some fields are required or wrong.	Some fields are required or wrong. Select the fields correctly in the

MESSAGE	DESCRIPTION
	filter and press OK to Confirm your selection.
Final date must be greater than initial.	The final date must be higher than the initial one in the calendar field of the filter. Select the range date appropriately.
MAINTENANCE	
Module activation is not allowed because there are pending works.	It is not possible to access the module **Activation** tab because there are pending works. Wait until the workload has finished and then access it. If problem persists, contact your local Grifols service representative.
Probe activation is not allowed because fluidic system is disabled.	Probe activation is not allowed because fluidic system is disabled. If problem persists after restarting the system, contact your local Grifols service representative.

20 Maintenance Services

Model:

Serial number:

Installation date:

MAINTENANCE SERVICES DONE			
DATE	TASK PERFORMED	PERFORMED BY AND DATE	SUPERVISOR AND REVIEW DATE

20.1 Adjusting the Screen Position

To adjust the touch screen position and block the monitor arm, a key (Figure 103, no. 1) can be used.

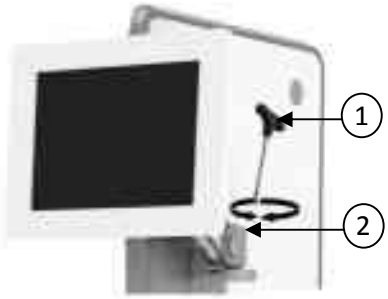


Figure 103. Adjustment of the Tension of the Articulated Arm of the Touch Screen

(1) Key.

(2) Screw.

To modify the tension of the articulated arm, proceed as follows:

1. Introduce the key into the screw.
2. Turn the arm nut clockwise until the monitor arm moves.
3. Adjust the position of the touch screen by moving the articulated arm (Figure 104):
   - On the vertical axis until obtaining the desired height.
   - Moving it to the left or the right to set the screen to the desired horizontal position.
   - To achieve the desired inclined position of the touch screen, tilt the screen forwards or backwards.

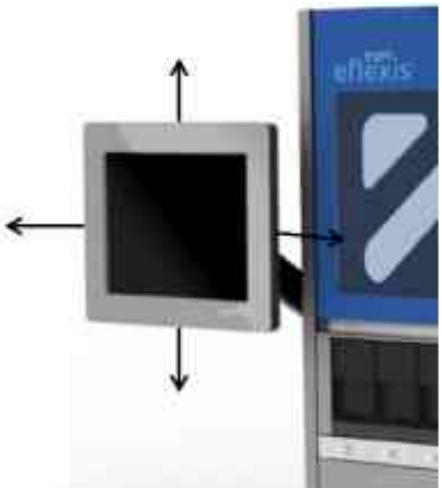


Figure 104. Adjustment of the Position of the Screen

4. Turn the arm nut counter-clockwise to bloc the monitor arm in the desired position.

20.2 Manual Opening of the Upper Door

In the case of emergency, for cleaning purposes or if the software does not respond, the analyzer has a manual opening system for the upper door. Proceed as follows:

1. Locate the safety lock of the analyzer that is placed at the top, central and external part of the analyzer.

2. Insert a resistant, long, thin tool with a maximum width of 5 mm and a minimum length of 10 cm into the safety lock opening (Figure 105).

Figure 105. Location for the Manual Opening of the Upper Door

3. Using the tool, press the internal latch to open the door.
4. Remove the tool.
5. To close the door, push it in the normal way.

20.3 Decontamination Certificate

The following Decontamination Certificate must be filled in every time that the instrument is decontaminated. This Decontamination Certificate must be given to Grifols service representative before any intervention takes place.

DECONTAMINATION CERTIFICATE OF THE ERYTRA EFLEXIS® ANALYZER	
Serial number	
Centre	
Decontamination was successfully completed according to the procedure described in Section 14.1.16	☐ PASS ☐ FAIL Comments:
Date	
Name and position	
Signature	
E-mail address	