1.2   Principle of Operation

The DG Reader Net is a workstation especially designed to read the reactions and give the results according to the grading scales as defined in the Instructions for Use of the Grifols gel cards, allowing laboratories to:

- Increase process safety and traceability by reducing possible identification and eliminating transcription errors.
- Increase analytical reliability interpreting results with objective criteria.

The DG Reader Net reads and interprets the following gel immunohematology tests:

- ABO Red Cell and Serum Grouping.
- Rh(D) Typing.
- Antibody detection.
- Antibody identification.
- Extensive phenotypes.
- 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 system 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 instrument is only designed to read immunohematology tests described in Section 1.2 and should not be used for any other type of test.

3.2 Functional Specifications

Table 2. Functional Specifications

MODULE	SPECIFICATION
GRIFOLS GEL CARD READING HOLDER	
Grifols gel card loading capacity	1 Grifols gel card
Grifols gel card loading system	Manual
Number of different Grifols gel card types	Unlimited
READING MODULE	
Reading system	High-resolution color reading using a color CCD camera
OTHERS	
LIS connectivity	Yes, unidirectional
Useful life	7 years
Disposal material	No
Connectivity	Standard interfaces: • 3 RS 232 connections. • 4 USB ports. • 2 LAN connections. • Wi-Fi. • 1 Microphone in. • 1 Headphones out. • 1 VGA. • HDMI. • 1 Mouse PS2. • 1 Keyboard PS2. **Note**: Only peripherals aimed to be connected to the described connector types are allowed.

3 SPECIFICATIONS OF THE CENTRIFUGE

3.1   Technical specifications

MODEL	*DG SPIN*	
LOAD CAPACITY	24 *DG Gel cards*	
DG SPIN HEAD	Removable and interchangeable	
CENTRIFUGATION CONDITIONS	Pre-programmed. Those required for *DG Gel cards*	
CENTRIFUGATION SPEED	990 rpm ± 10 rpm (128.1 g ± 1.0 %)	
CENTRIFUGATION UNITS	Programmable, rpm or g	
CENTRIFUGATION TIME	9 minutes	
ACOUSTIC ALARM	Yes, to indicate end of centrifugation and error situations	
VOLUME OF ACOUSTIC ALARM	Programmable, 3 levels.	
SAFETY SYSTEMS	• Out-of-balance control • Detection of door opening • Safety closure	
INTERFACE	LCD screen and Buttons	
SUPPLY	Voltage:	100–240 V ~
	Frequency:	50-60 Hz
	Input power:	50 W
	Fuses	2x T2AL 250 V, 5x20 mm
PROTECTION AGAINST ELECTRIC SHOCK	Class:	I
INSTALLATION CATEGORY	Overvoltage category II (local level, appliances, portal equipment, etc.)	
DIMENSIONS (mm)	525 (depth) x 410 (width) x 180 (height)	

3 SPECIFICATIONS OF THE INCUBATOR

3.1   Technical specifications

MODEL	DG THERM	
LOAD CAPACITY	• 24 *DG Gel cards* • 24 sample tubes	
INCUBATION BATCHES	2 batches with independent timer	
INCUBATION TEMPERATURE	37 °C ± 1°C	
TEMPERATURE UNITS	Programmable, °C or °F	
INCUBATION TIME	15 minutes, modifiable	
PREHEATING TIME	Approximately 6 minutes	
ALARM SYSTEMS	Yes, two independent sensors to measure and control temperature	
ACOUSTIC ALARM	Yes, to indicate end of incubation and error situations	
VOLUME OF ACOUSTIC ALARM	Programmable, 3 levels	
INTERFACE	LCD screen and Buttons	
SUPPLY	Voltage:	100–240 V ~
	Frequency:	50-60 Hz
	Input power:	270 W
PROTECTION AGAINST ELECTRIC SHOCK	Class:	I
INSTALLATION CATEGORY	Overvoltage category II (local level, appliances, portal equipment, etc.)	
DIMENSIONS (mm)	325 (depth) x 295 (width) x 95 (height)	
WEIGHT (Kg)	Approximately 4 kg.	

Diamedica | Kristina Gaidelionienė

From:	Dobaj, Katarzyna <katarzyna.dobaj@grifols.com>
Sent:	ketvirtadienis 2022 m. gegužė 5 14:50
To:	Diamedica	к⁣⁣⁣⁣⁣⁣⁣⁣⁣⁣lionienė
Subject:	FW: DG Reader Net reading time
Signed By:	katarzyna.dobaj@grifols.com

Dear Kristina
Please find explanation from Javier
Kind regards
Kasia

From: Gomez, Javier <javier.gomez@grifols.com>
Sent: środa, 4 maja 2022 14:52
To: Dobaj, Katarzyna <katarzyna.dobaj@grifols.com>
Subject: RE: DG Reader Net reading time

Hi Kasia,

The Reading time is very low about 2 seconds but you must add the time of transport to the reading area about 3 seconds to enter and 3 seconds to exist. In total less than 10 seconds.

Javier

De: Dobaj, Katarzyna <katarzyna.dobaj@grifols.com>
Enviado el: miércoles, 4 de mayo de 2022 14:04
Para: Gomez, Javier <javier.gomez@grifols.com>
Asunto: FW: DG Reader Net reading time
Importancia: Alta

Dear Javier
Do you have any details aboutreading yime in our DG Reader net?
I need this information up to the end of this week because on Monday morning is tender submission date.
Thank you in advance

Kasia

Dear All,

We have tender for manual system. In the tender is requirements for Reader reading time. Do you have any document where can be show reading time?

Looking forward to get your answer

Jūsų tiltas į geresnę diagnostiką

Best regards

Product and sales manager

UAB Diamedica
Geliu g. 2, Avizieniai,
LT- 14184, Vilniaus r., Lithuania
Phone: +370 52790080
Fax. +370 52107286
Mobile
e-mail: k

8   Grifols Gel Card Assignment

This section provides a description of the profile, sample ID and reagents ID assignment process to a Grifols gel card.

8.1   Profile Assignment

When introducing a Grifols gel card in the DG Reader Net to initiate the reading process (see Section 7.2), the DG Reader Net identifies the Grifols gel card with its barcode, reads the agglutination grade of each microtube, and places the Grifols gel card to Assignment position (Figure 13).

Figure 13. Assignment Position of the Reading Holder

📄   **NOTE:** When a Grifols gel card is in Assignment position, it can not be removed, as it indicates that there are pending steps to complete its test assignment.

9.6 Exporting Results to LIS

Once the Results are validated (see Section 9.3) the results can be sent to the Laboratory Information System (LIS), if it is configured.

To export results:

1. From the **Pending Results** screen (Figure 19), 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 **Pending Results** screen.

2. Press the **Export button** .

3. Press **Continue** button to confirm.

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

It is possible to configure that normal results are automatically validated and exported. See Section 11.2.2.2 for further information.

9.7 Printing and Saving Results Reports

9.7.1 Printing Report

The DG Reader Net 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 **Pending Results** screen (Figure 19):

1. From the **Pending 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 **Result Report** button 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 **Results List** button 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 **Result Traceability Report** 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.

Sample : 987654321

First name:	-	Last name:	-		
Gender:	-	Date of Birth:	-	Hospital Id:	-

Profile : 3 Screen (AHG)

Execution date:	03/10/2018 09:07:47	Status:	Exported		
Executed by:	ADMIN	Modified by:	-	Reviewed by:	GB
Analyser (SN):	0000562	Analyser (name):	TAS Train		

Profile interpretation

AbScr C:Pos

Comment

DG Gel Coombs   713004190770114258

LOT *077.01   ⧗ 2019-04

3 Screen (AHG) 7130

AbScr C:Pos

1	2	3	4	5	6	7	8
			-	-	3+		
			I.IAC	II.IAC	III.IAC		

Incidences

Traceability

Interpretation has not been modified.

Reagents

Name	ID	Lot	Expiry date
I	023082830259	*025	10/10/2018
II	023182830258	*025	10/10/2018
III	023282830257	*025	10/10/2018

10 Searching Results in Database

The DG Reader Net 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.

10.1 Searching and Viewing Results in the Database

To search and view results that have been stored in the Database:

1. Press the **Search Results** button (Figure 11, no. 3).

   The **Search Results** screen opens (Figure 25). It allows viewing results present in the Database.
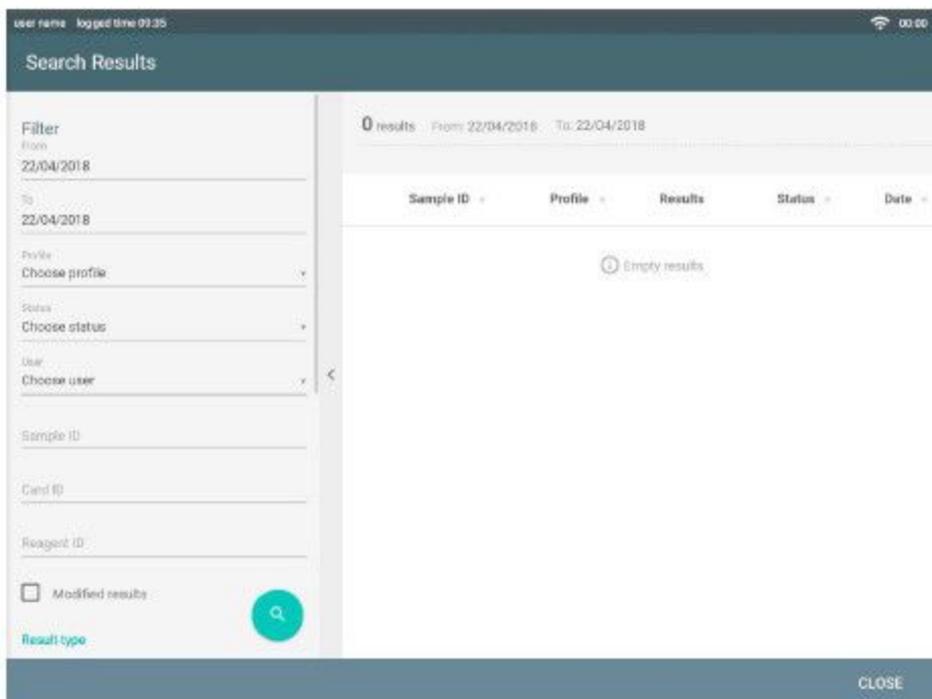

Figure 25. Search Results Screen

9.6   Exporting Results to LIS

Once the Results are validated (see Section 9.3) the results can be sent to the Laboratory Information System (LIS), if it is configured.

To export results:

1. From the **Pending Results** screen (Figure 19), 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 **Pending Results** screen.

2. Press the **Export** button   .

3. Press **Continue** button to confirm.

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

It is possible to configure that normal results are automatically validated and exported. See Section 11.2.2.2 for further information.

9.7   Printing and Saving Results Reports

9.7.1   Printing Report

The DG Reader Net 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 **Pending Results** screen (Figure 19):

1. From the **Pending 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 **Result Report** button 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 **Results List** button 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 **Result Traceability Report** 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.

1   Introduction

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

These Instructions for Use are intended for the users of the DG Reader Net and contain all the information necessary to safely and adequately work with the instrument.

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 instrument.

1.1   Intended Use

The DG Reader Net is a device designed to read, interpret, and report the results of the processed Grifols gel cards. The instrument also identifies Grifols gel cards by reading their barcodes.

As a stand-alone or interfaced to the customer's Laboratory Information System (LIS), the instrument automates data management requirements using Grifols gel cards and digital image processing.

1.2   Principle of Operation

The DG Reader Net is a workstation especially designed to read the reactions and give the results according to the grading scales as defined in the Instructions for Use of the Grifols gel cards, allowing laboratories to:

- Increase process safety and traceability by reducing possible identification and eliminating transcription errors.
- Increase analytical reliability interpreting results with objective criteria.

The DG Reader Net reads and interprets the following gel immunohematology tests:

- ABO Red Cell and Serum Grouping.
- Rh(D) Typing.
- Antibody detection.
- Antibody identification.
- Extensive phenotypes.
- Direct Antiglobulin test.
- Compatibility Tests (Crossmatching).

GRIFOLS

Diagnostic Grifols, S.A.
Passeig Fluvial, 24
08150 Parets del Vallès
Barcelona - ESPAÑA
Tel. [34] 935 710 400
Fax [34] 935 710 373
diagnostic@grifols.com

Declaración CE de Conformidad

EC Declaration of Conformity

Fabricante:
Manufacturer:

DIAGNOSTIC GRIFOLS, S.A.
Passeig Fluvial, 24
08150 - Parets del Vallès
Barcelona. ESPAÑA

Producto y referencia:
Product and reference:

DG Reader Net   210700

Clasificación de acuerdo con la Directiva 98/79/CE:
Classification according to Directive 98/79/EC:

No listado en Anexo II de la Directiva 98/79/CE /
Non-listed in Annex II of Directive 98/79/EC

Primera fecha emisión:
First issue date:

20 de Diciembre de 2018
20 December 2018

DIAGNOSTIC GRIFOLS, S.A. declara bajo su propia responsabilidad que el producto indicado anteriormente cumple los requisitos esenciales de la Directiva sobre Productos Sanitarios para Diagnóstico In Vitro 98/79/CE, habiéndose seguido el procedimiento de evaluación de conformidad del Anexo III.

DIAGNOSTIC GRIFOLS, S.A. declares under sole responsibility that the product specified above complies with the essential requirements of the Directive on In Vitro Diagnostic Medical Devices 98/79/EC and Annex III is used as the conformity assessment procedure.

$$C\,E$$

Parets del Vallès, 20 de Diciembre de 2018
Parets del Vallès, 20th December 2018

Albert Hernández Botey
Director Técnico
Technical Director