

User's Guide

CE

1 Intended Use

3.3. ETI-MAX3000 analizatoriuje yra integruotas brūkšnių kodų skaitytuvas mėginiams bei reagentams, reikiamos purtyklės, reikiamos temperatūros inkubatoriai bei vieta kambario temperatūros inkubacijai. ETI-MAX3000 prietaisas automatiškai atlieka mėginio skiedimą, plovimą, inkubaciją ir rezultatų vertinimą.

The **ETI-Max 3000** system consists of the **ETI-Max 3000** instrument and the **ETI-Max 3000** software is a fully automated microplate analyser performing the complete sample processing (sample dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation.

For in Vitro Diagnostics only!

The **ETI-Max 3000** system has generally been designed and validated for the determination of infectious diseases by ELISA methods and evaluation by colorimetric and point determination.

Prior the use of the **ETI-Max 3000** system for IVD, any test methods (assays) and kits must be validated by the user in combination with the system according to common clinical laboratory practice, local legislations, and the state of the art.

1. Sistemą sudarys: 1 automatinis ETI-MAX3000 yra keturių plokštelių imunofermentinių tyrimų analizatoriai skirti 96 šulinėlių mikroplokštelių tyrimams atlikti.

2 System Basics

2.1 Overview

3.1. Be to, minėtieji analizatoriai atlieka visas tyrimo protokoluose išvardintas funkcijas, nuo mėginio išpilstymo iki rezultatų įvertinimo.

The **ETI-Max 3000** is a fully automated microtiter plate analyser performing the complete sample processing (sample pre-dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation. The instrument is controlled via the Windows PC software **ETI-Max 3000**. This software, which was specifically designed for this purpose, allows the user to process the pre-defined assays of DiaSorin as well as assays programmed by the user. The clear structure with intuitive user-guidance allows simple and quick operation of daily routine jobs as well as programming of user-specific assays.

2. ETI-MAX3000 yra atvira sistema, kuri užtikrins galimybę atlikti visus nurodytus specifikacijoje tyrimus. Taip pat yra galimybė papildyti atliekamų tyrimų spektrą.

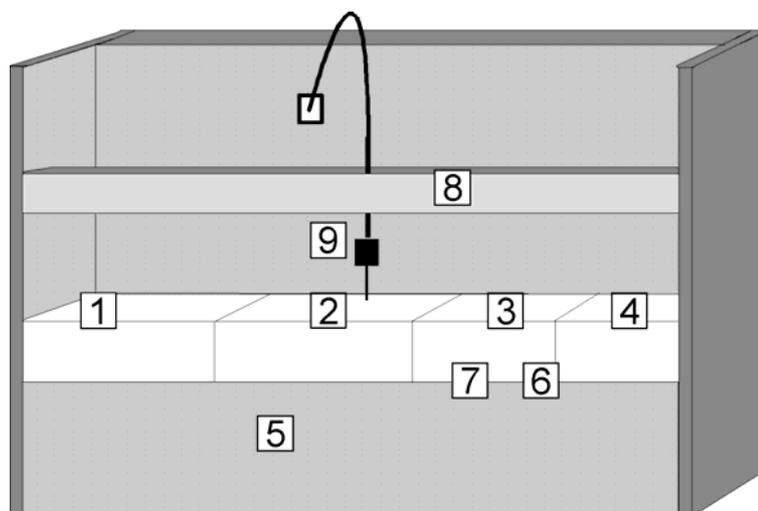


Figure 2-1: **ETI-Max 3000** - Instrument modules

- 1 Tray for tip racks and dilution tubes
- 2 Patient sample and reagent rack unit with bar code scanner
- 3 Tip eject station, pipettor wash station, pipetting station
- 4 Test plate compartment, plate transport unit
- 5 Drawer with wash unit and photometer
- 6 Position of incubators (below test plates), heated and for room temperature (dark)
- 7 Waste bag for tips
- 8 Guide rail for pipettor (X and Y movement)

3.3. BEP2000 ir ETI-MAX3000 analizatoriuose yra integruotas brūkšniinių kodų skaitytuvas mėginiams bei reagentams, reikiamos purtyklės, reikiamos temperatūros inkubatoriai bei vieta kambario temperatūros inkubacijai. BEP2000 bei ETI-MAX3000 prietaisai automatiškai atlieka mėginio skiedimą, plovimą, inkubaciją ir rezultatų vertinimą.

2.2 Top Level Instrument Modules

1. Sistemą sudarys: 1 automatinis ETI-MAX3000 bei 1 automatinis BEP2000 keturių plokštelių imunof fermentinių tyrimų analizatoriai skirti 96 šulinėlių mikroplokštelių tyrimams atlikti.

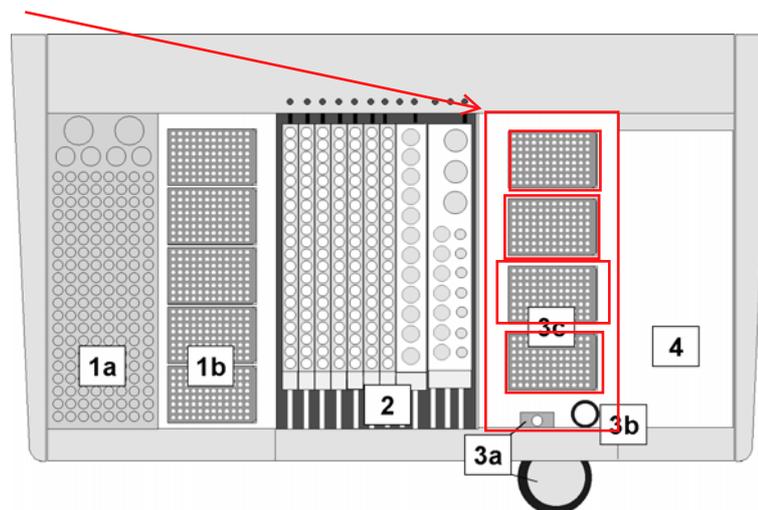


Figure 2-2: ETI-Max 3000 - View on top level

- 1a Dilution tubes (see chapter 2.2.1 on page 2-4)
- 1b Tip racks (see chapter 2.2.1 on page 2-4)
- 2 Patient sample and reagent unit (see chapter 2.2.2 on page 2-5)
- 3a Tip ejection station and waste bag (see chapter 2.2.3 on page 2-7)
- 3b Pipettor wash station (see chapter 2.2.3 on page 2-7)
- 3c Pipetting station (see chapter 2.2.3 on page 2-7)
- 4 Test plate compartment with plate transport unit (see chapter 2.2.4 on page 2-7)

3.3. ETI-MAX3000 analizatoriuje yra integruotas brūkšnių kodų skaitytuvas mėginiams bei reagentams, reikiamos purtyklės, reikiamos temperatūros inkubatoriai bei vieta kambario temperatūros inkubacijai. ETI-MAX3000 prietaisas automatiškai atlieka mėginio skiedimą, plovimą, inkubaciją ir rezultatų vertinimą.

2.2.2 Patient Sample and Reagents Unit with Bar Code Reader

(See figure 2-2: position 2)



CAUTION: Laser radiation - do not stare into beam!

The bar code scanner is located on the right side at the front of the patient sample and reagent unit.

The patient sample and reagent unit, accessible via a flap, includes 12 tracks for sample and reagent racks.

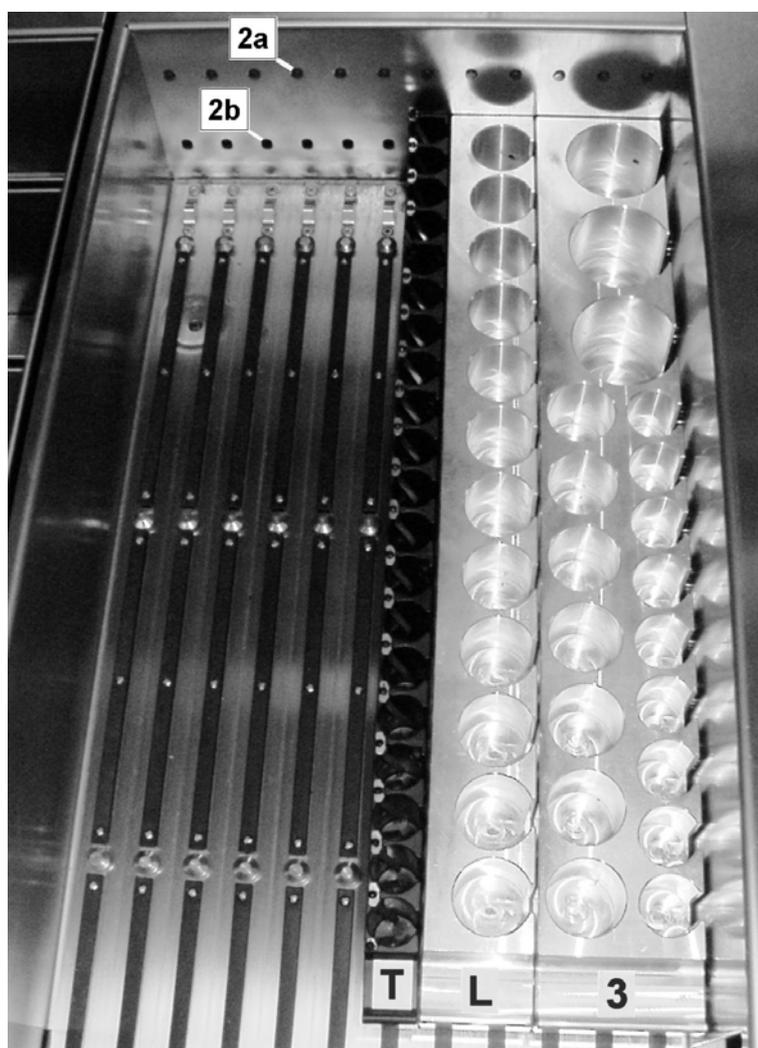


Figure 2-4: Sample and reagent unit

- 2a LED
- 2b Contact pin hole

The following racks are supplied by DiaSorin:

- T, U, V, W,** Sample racks for 20 patient samples (occupies one track).
- Y:**
- O:** Reagent rack for 15 controls (occupies 2 track).
- L:** Reagent rack for 12 bottles (occupies 2 tracks).
- R:** Reagent rack for 18 bottles for auto immune (occupies 1 tracks).
- Z:** Sample racks for 20 secondary tubes used for archiving (occupies one track).
- 2:** Reagent rack for 20 bottles (occupies one track).
- 3:** Reagent rack for 12 bottles with bar codes and 7 bottles without barcode (occupies 3 tracks).

4.1. ETI-MAX3000 analizatoriuoje
tinka tiek pirminiai,
tiek antriniai mėgintuvėliai.



Figure 2-5: Reagent rack types

- 2c Contact pin

Each rack includes a contact pin; on racks occupying one track, this pin is located at the top centre, and on the broader racks at the top right.

The software specifies which track is to be used for the respective rack. This is indicated by a red LED. A reagent rack occupying 3 tracks must be inserted such that the contact tappet is in contact with the lit up LED.

Each rack has to be inserted up to the limit stop. The respective LED on the rear panel goes off (Loading/Unloading see chapter 5 on page 5-1).

Reloading of patient and reagent racks is possible when the instrument is in the incubation mode.



Keep the flap of this unit closed during a run. It may be opened only for re-loading (see chapter 5.2 on page 5-6). Opening the flap while transfer steps are being performed results in an immediate stop of the pipettor and entry in the event log.

2.2.3 Tip Ejection Station, Pipettor Wash Station, Pipetting Station

Tip ejection station and waste bag (see figure 2-2: position 3a)

The opening serves as ejection station for disposable tips. The ejected tip is transported into the waste bag via a slide which is attached to the front side of the instrument. The ejection station is closed by a cover plate which can be pulled off by hand. With the cover plate removed, the waste bag can be taken out of the holding device and replaced (Disposal see chapter 5.3 on page 5-7).

Pipettor wash station (see figure 2-2: position 3b)

The pipettor wash station is located next to the tip ejection station.

1. Sistemą sudarys: 1 automatinis ETI-MAX3000 yra keturių plokštelių imunofermentinių tyrimų analizatoriai skirti 96 šulinėlių mikroplokštelių tyrimams atlikti.

Pipetting station (see figure 2-2: position 3c)

The test plates are positioned by the system. Up to 4 plates can be positioned in this station. A transport unit automatically moves them from the plate compartment to the correct position where they are processed further (Loading/Unloading see chapter 5 on page 5-1).

2.2.4 Test Plate Compartment with Bar Code Scanner

(See figure 2-2: position 4 or figure 2-7: position 4)



CAUTION: Laser radiation - do not stare into beam!

The bar code scanner is located on the left side at the front of the test plate compartment.

The test plate compartment can be opened only on request by the software. The LED indicator LD lights up green.

Open the door and place the respective (bar coded) test plate with the holding frame onto the transport unit so that both pins of the holding frame sit in the openings of the slide. Position A1 is at the top left (see figure 2-6:). The plate is moved to the pipetting station following the respective command on the screen.

1. Sistemą sudarys: 1 automatinis ETI-MAX3000 yra keturių plokštelių imunofermenčių tyrimų analizatoriai skirti 96 šulinėlių mikroplokštelių tyrimams atlikti.

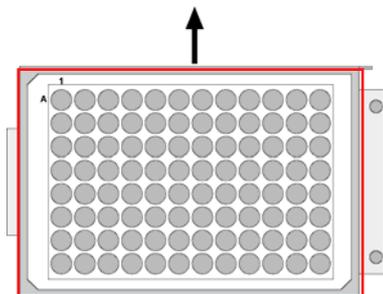


Figure 2-6: Inserting a test plate with holding frame

From there the plate is transported - depending on the defined assay - to the various instrument modules and then back again to the plate loading position (Loading/Unloading see chapter 5 on page 5-1).

2.3 Drawer Instrument Modules

The drawer is automatically locked during a run. The green LED INSTR goes off.

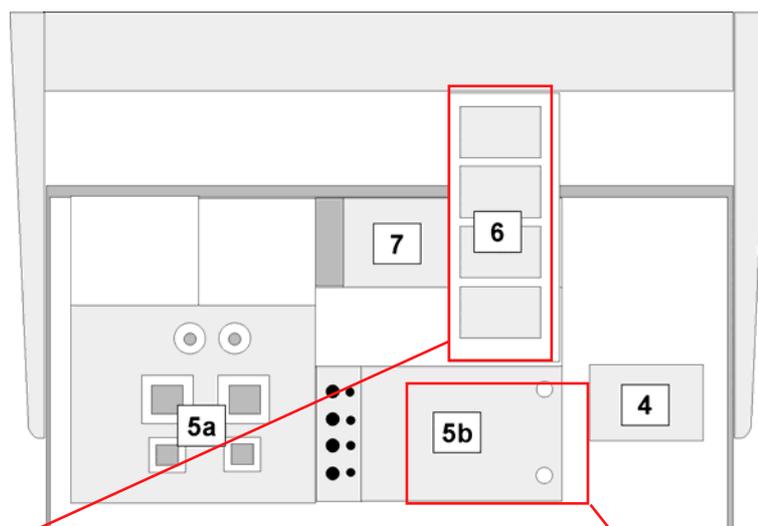


Figure 2-7: ETI-Max 3000 - Bottom drawer pulled out

3.8. ETI-MAX3000 analizatoriuje yra po 4 inkubavimo pozicijas, kameros.

- 4 Test plate compartment with plate transport unit (see chapter 2.2.4 on page 2-7)
- 5a Wash buffer container (square) and waste bottles (round) (see chapter 2.3.1 on page 2-9)
- 5b Wash unit for test plates (see chapter 2.3.2 on page 2-10)
- 6 Incubators (see chapter 2.3.3 on page 2-10)
- 7 Photometer (see chapter 2.3.4 on page 2-10)

2.3.1 Wash Buffer Container and Waste Bottles

(See figure 2-7: position 5a)

A maximum of 3 bottles (1 x 1 litre, 2 x 2 litres) can be used for various wash buffers; another position has to be reserved for the cleaning fluid (distilled water) to clean the washer head.

The connection fitting consists of 4 colour-coded connection pairs: one tubing and one level sensor each per bottle (Loading see chapter 5.1 on page 5-1).

Two waste bottles are available for the wash unit. One waste bottle contains the liquid waste which is pumped to the waste container which is positioned below the instrument. The second bottle serves as overflow protection.

3.5. BEP2000 ir ETI-MAX3000 analizatoriuose yra integruota plovimo stotelė ir skaitytuvas su pagrindiniais integruotais filtrais: 405, 450, 492, 550, 620 nm. Taip pat analizatoriuose yra galimybė padidinti filtrų skaičių.

3.9. ETI-MAX3000 analizatorius turi atliekų ir plovimo sistemos skysčio talpas su skysčio lygio atpažinimo davikliu (indo užpildymo kontrolei).

2.3.2 Wash Unit for Test Plates with Window

(See figure 2-7: position 5b)

The test plates are moved into the wash unit by the system. The wash process and the height adjustment of the washer head can be checked via the window.

2.3.3 Incubator Unit

3.8. ETI-MAX3000 analizatoriuje yra po 4 inkubavimo pozicijas, kameros.

(See figure 2-7: position 6)

Below the pipetting area for the test plates there are four independent heatable and shakeable incubator chambers; the test plates are automatically transported into these incubators and out again according to the assay protocol.

The instrument is equipped with a light-protected storage magazine accommodating four plates for room temperature incubation. It is located below the incubators in front of the photometer.

2.3.4 Photometer (Back of Bottom Drawer)

(See figure 2-7: position 7)

The photometer (400 - 700 nm) is installed at the back of the bottom drawer. The photometer can be equipped with up to 8 filters (end point or kinetic evaluation possible). The photometer is moved out with the bottom drawer.

3.5. BEP2000 ir ETI-MAX3000 analizatoriuose yra integruota plovimo stotelė ir skaitytuvas su pagrindiniais integruotais filtrais: 405, 450, 492, 550, 620 nm. Taip pat analizatoriuose yra galimybė padidinti filtrų skaičių.

3.3. ETI-MAX3000 analizatoriuje yra integruotas brūkšinių kodų skaitytuvas mėginiams bei reagentams, reikiamos purtyklės, reikiamos temperatūros inkubatoriai bei vieta kambario temperatūros inkubacijai. ETI-MAX3000 prietaisas automatiškai atlieka mėginio skiedimą, plovimą, inkubaciją ir rezultatų vertinimą.

2.5 Connections

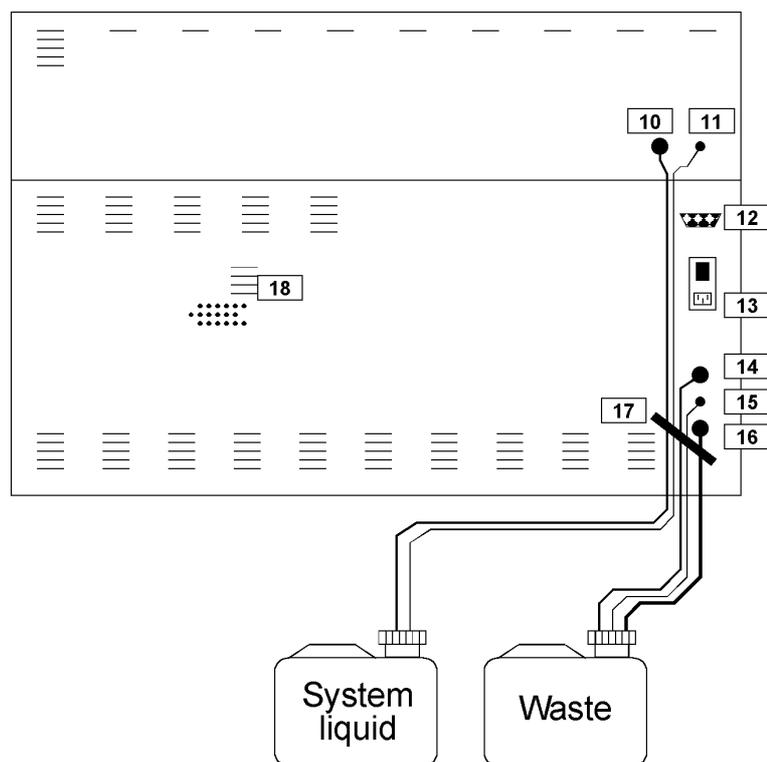


Figure 2-8: ETI-Max 3000 - Instrument rear panel with connections

- 10 Tubing connection for system liquid
- 11 Electrical connection for system liquid level sensor
- 12 PC port (RS232, 9-pole)
- 13 Mains fuses, mains switch and mains connection
- 14 Liquid waste outlet
- 15 Electrical connection of waste container level sensor
- 16 Waste from pipettor wash station
- 17 To protect tubing's and cables
- 18 Ventilation channels

3.9. ETI-MAX3000 analizatorius turi atliekų ir plovimo sistemos skysčio talpas su skysčio lygio atpažinimo davikliu (indo užpildymo kontrolei).



Pass tubing's and cables through below the bow.

3.3 File Types

6. ETI-MAX3000 analizatoriaus programinės įrangos atmintyje saugoma visa informacija apie atliktą tyrimą: naudotų reagentų informacija, interpretacija, paciento informacija

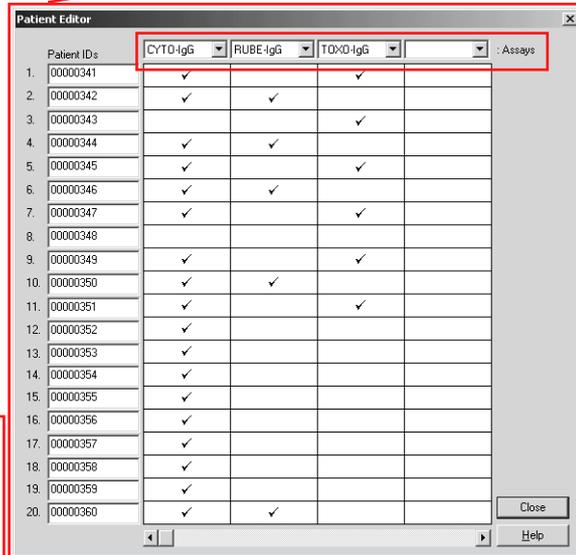
File	Extension	Path
File polling format setting of the import file for host systems. For detailed information see ETI-Max 3000 'Connectivity Manual'.	*.apm	C:\ETI-Max 3000\System
Archive files	*.arc	C:\ETI-Max 3000\Serotec
Assay protocol files	*.asy	C:\ETI-Max 3000\Assays
System information files (e. g. saving maintenance tasks)	*.bin	C:\ETI-Max 3000\System
Files documenting daily data communication between PC and ETI-Max 3000 instrument as well as error messages.	*.log	C:\ETI-Max 3000\Logfiles
Coordinate files for e.g. pre-dilution plates	*.mpc	C:\ETI-Max 3000\System
Coordinate files for the racks	*.rac	C:\ETI-Max 3000\System
Result files	*.res	C:\ETI-Max 3000\Results
Spectrum files (contain data of a spectrum acquisition)	*.spe	C:\ETI-Max 3000\System
Self test files with information about the self tests that were performed.	*.tst	C:\ETI-Max 3000\System
Export files in ASCII format	*.txt	C:\ETI-Max 3000\Export
ASCII patient data import files can be downloaded from a host computer to the ETI-Max 3000 software (patient with associated assays).	*.txt	For host connection
Verification report files	*.ver	C:\ETI-Max 3000\System
Worklist files	*.wor	C:\ETI-Max 3000\System

Table 3-4: File types

4.2.2 Input of Bar Coded Patient Samples

3.6. Analizatoriuose BEP2000 ir ETI-MAX 3000 yra garsinė ir vaizdinė aliarmo sistema įvykus klaidai (pasibaigus reagentui, nenuskaitant mėginio ar reagento brūkšninio kodo ir pan.). Analizatoriai leidžia ištaisyti klaidą ir tęsti darbą toliau.

1. Insert samples into the **ETI-Max 3000** with the worklist closed.
The patient bar codes are read.
The dialogue box depicted to the right appears on the screen, showing the identified bar codes.
2. From the respective list box (with all available assays), select the respective assay by clicking on the column header.
3. Then assign the samples by clicking on the field in the respective assay column.
4. Click on the **Close** to accept the selection.
5. Proceed accordingly for each further sample rack.



In case the patient informations are imported via ASTM-Query mode, the dialogue box appears after inserting the sample rack. If one or more patient bar-codes are not read, the user has the possibility to enter them manually. Confirming the dialog box with **OK**, the patient information data are collected from the host and the dialogue box appears again showing all requested assays for each patient sample.

3.2. BEP2000 ir ETI-MAX3000 analizatoriuose tyrimai yra užsakomi iš sudaryto sąrašo, pasirenkant norimą tyrimą kompiuterio ekrane. Programinė įranga suteikia galimybę tuo pačiu metu derinti keletą skirtingų tyrimų atlikimą



The patient editor only accepts letters and numbers as patient ID. The use of any special characters such as "%", "-", "\$", "€", "", "\", "/", "\\", ",", ";", " or "." when creating a patient ID or receiving from the host computer is forbidden.



Maximum length of data fields: 20 characters for the plate ID, Patient ID and 50 characters for the assay name, patient name and comments.



As an alternative, patients may be entered via host. In this case, you may start directly with creating a worklist (see chapter 4.3.1 on page 4-5).



You will find further information to the tests in the manual of the respective test.

4.4.3 Loading Samples and Reagents



CAUTION: Laser radiation - do not stare into beam!



Allocate the vials only into suitable locations. An incorrect allocation may cause errors in dispensing.



Samples having particulate matter, turbidity, lipaemia, foam, or erythrocyte debris may require clarification by filtration or centrifugation before testing.



The use of primary tubes with gel separator requires a careful check of the sample volume above the gel to avoid any possible errors in dispensing.



When refilling a reagent bottle, never exceed the bottle shoulder. An over-filling may lead to an incorrect dispensing.

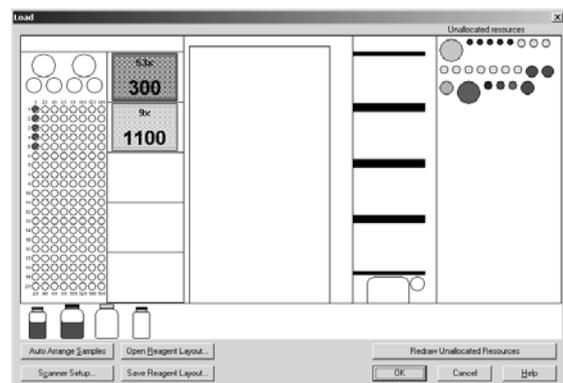
4.1. ETI-MAX3000 analizatoriuje tinka tiek pirminiai, tiek antriniai mėgintuvėliai.

4.4.3.1 Loading Bar Coded Patient Samples and Reagents

The sample and reagent area on the screen are empty.

The dilution tubes are arranged automatically.

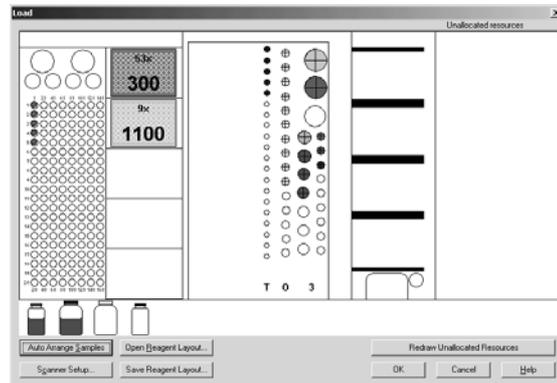
The required resources are displayed as circles in different colours in the top right corner of the screen. You can view the respective name by moving the cursor over these circles. An inserted rack is depicted graphically and the loaded resources are automatically allocated.



3.6. Analizatoriuje ETI-MAX3000 yra garsinė ir vaizdinė aliarmo sistema įvykus klaidai (pasibaigus reagentui, nenuskaitant mėginio ar reagento brūkšninio kodo ir pan.). Analizatoriai leidžia ištaisyti klaidą ir tęsti darbą toliau.

Performing a Test Run

1. Right LED lights up red.
2. Insert first rack into the right track.
3. The bar codes are read and the rack and the available reagents are identified.
4. If the rack has been inserted properly up to the limit stop, the LED goes off. On the screen, the loaded resources from the pool of unallocated resources are allocated to the inserted rack (marked with a cross in the rack position), since they are bar coded and are therefore identified.
5. The next empty track is marked by a red LED. Proceed as described in the preceding step (see chapter 5 on page 5-1).



Always load racks from right to left.

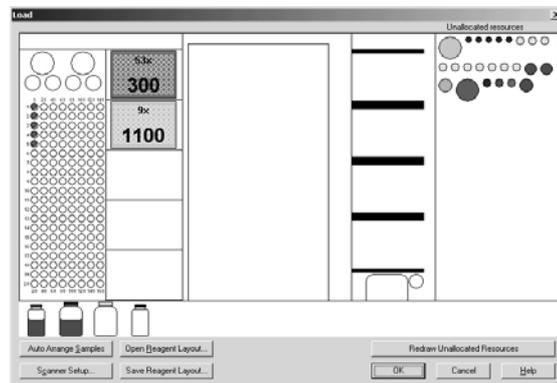
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4.4.3.2 Allocation on Non-bar Coded Reagents and Samples

The sample and reagent area on the screen is empty.

The dilution tubes are arranged automatically.

After insertion of the racks **only the rack types** with empty positions are depicted. Unallocated but required resources are displayed as circles in different colours in the top right corner of the screen. You can view the respective name by moving the cursor over these circles.



4.4.5 Reagent Volume Check

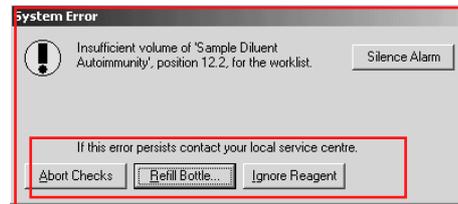
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After loading and allocation of all required resources, press on the Ok button. A volume check of all reagents is carried out automatically.

If the reagent check shows, that the volume of one reagent is low, a System Error dialogue box appears alerting you about any insufficient volume.

To refill the respective reagent or to replace it by a new bottle, the respective reagent rack has to be moved out, reagent has to be refilled or the bottle replaced, respectively and the rack has to be inserted again.

- If you press on the Refill Bottle... button, the volume is checked once more.
If the reagent was identified manually, the position in the rack has to be allocated once more (see above).
- If the reagent cannot be supplied, press on the Abort Worklist button.
This will abort any further volume check.
- The Ignore button skips the reagent check for this specific reagent (the insufficient volume is logged) and continues with the reagent check for the next one.



Do not change any reagent positions!

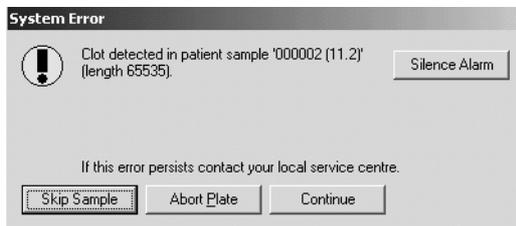
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4.4.7.1 Error Handling for “Clot detection” and “No liquid detected”

Dependent on the attitude in the test definition (“Raise alarm and stop”, “Log and continue” or “Manual pipette at end of step”) the error handling is different at a “Clot detection” or “No liquid detected”..

Action on error “Raise alarm and stop”

“Clot detection”



If a clot is detected, the system stops and shows a message with the following buttons:

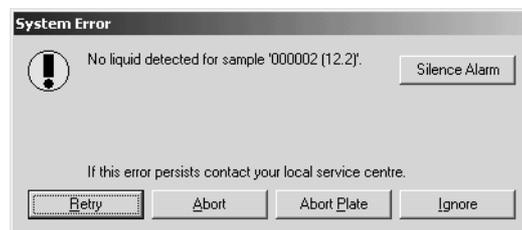
Skip Sample:

- The pipettor moves to the eject position to remove the tip.
- Entry in the Eventlog.
- The next sample will be pipetted.
- The result file flags all samples with “Clot detected” where a clot was detected.

Abort Plate:

- An additional message comes up to confirm the plate abort process.
- The pipettor moves to the Eject position to remove the tip.
- Entry in the Eventlog.

“No liquid detected”



If no liquid is detected, the system stops and shows a message with the following buttons:

Retry:

1. The pipettor repeats the level detection and in case the liquid is detected, it is aspirated and pipetted into the appropriate well of the micro plate.
 - Entry in the Eventlog.
 - The result file does not flag the sample.
2. The pipettor repeats the level detection and in case the liquid is not detected, the message appears again.
 - Entry in the Eventlog.

Abort:

- The pipettor moves to the Eject position to remove the tip.
- If available, the next sample of the next plate will be pipetted.
- Entry in the Eventlog.
- The result file flags the sample(s) with 'No liquid detected’

Continue:

- The sample is pipetted in the appropriate well of the micro plate.
- The result file flags all samples with "Clot detected" where a clot was detected.
- Entry in the Eventlog.

Abort Plate:

- An additional message comes up to confirm the plate abort process.
- The pipettor moves to the Eject position to remove the tip.
- Entry in the Eventlog.

Ignore:

- The pipettor repeats the level detection and in case no liquid is detected, the pipettor moves to the Zmax position and aspirates an undefined amount of liquid. The aspirated liquid is pipetted into the appropriate well of the micro plate.
- Entry in the Eventlog.
- The result file flags the sample(s) with "No liquid detected"

Action on error "Log and continue"**"Clot detection"**

If a clot is detected, the system does not show a message and continues with:

- The pipettor moves to the eject position to remove the tip.
- Entry in the Eventlog.
- The next sample will be pipetted.
- The result file flags all samples with "Clot detected" where a clot was detected.

"No liquid detected"

If no liquid is detected, the system does not show a message and continues with:

- The pipettor moves to the eject position to remove the tip.
- Entry in the Eventlog.
- The next sample will be pipetted.
- The result file flags the sample(s) with "No liquid detected"

Action on error "Manual pipette at end of step":**"Clot detection"**

If a clot is detected, the system does not show a message and continues with:

- The pipettor moves to the eject position to remove the tip.
- Entry in the Eventlog.
- The next sample will be pipetted.
- At the end of the pipetting step, a message comes up and shows you all samples which were not pipetted or were a clot was detected.
- The result file flags all samples with "MP" where a clot was detected.

"No liquid detected"

If no liquid is detected, the system does not show a message and continues with:

- The pipettor moves to the eject position to remove the tip.
- Entry in the Eventlog.
- The next sample will be pipetted.
- At the end of the pipetting step, a message comes up and shows you all samples which were not pipetted or were a clot was detected.
- The result file flags the sample(s) with "No liquid detected"

3.6. Analizatoriuje ETI-MAX3000 yra garsinė ir vaizdinė aliarmo sistema įvykus klaidai (pasibaigus reagentui, nuskaitant mėginio ar reagento brūkšninio kodo ir pan.). Analizatoriai leidžia ištaisyti klaidą ir tęsti darbą toliau.

4.5 Results of a Run

6. ETI-MAX3000 analizatoriaus programinės įrangos atmintyje saugoma visa informacija apie atliktą tyrimą: naudotų reagentų informacija, interpretacija, paciento informacija

Upon complete processing of a plate, the results are saved to a result file and displayed on the screen, which can be printed in individual parts or as a whole.

- Click on the plus sign in front of file name to open the folder tree of the result file.
- Click on the individual symbol of the folder to display its contents in the right window.



Don't approve results without reviewing the original results printout and the events of the run!

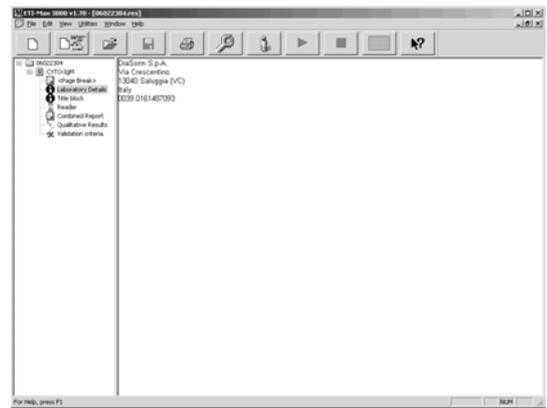
4.5.1 Results Report

4.5.1.1 Laboratory Details

6. ETI-MAX3000 analizatoriaus programinės įrangos atmintyje saugoma visa informacija apie atliktą tyrimą: naudotų reagentų informacija, interpretacija, paciento informacija

Select the item Laboratory Details to open the window depicted to the right, showing information about the laboratory (e.g. name, address, etc.)

This information can be entered and edited via the menu items Utilities | Options | Laboratory (see chapter 3.2.1 on page 3-2).



4.5.1.2 Title Block

6. ETI-MAX3000 analizatoriaus programinės įrangos atmintyje saugoma visa informacija apie atliktą tyrimą: naudotų reagentų informacija, interpretacija, paciento informacija

The Title Block identifies the assay respective assay definition file the results have been generated with. It provides information on the plate ID and the person responsible for running the test, specifies the assay used, saves date and time the test has been finished and shows certain default settings of the photometric measurement such as the overflow limit and the wavelength as well as the reference wavelength. Furthermore, important error messages that came up in the course of processing the assay respective the worklist are already displayed at this point.



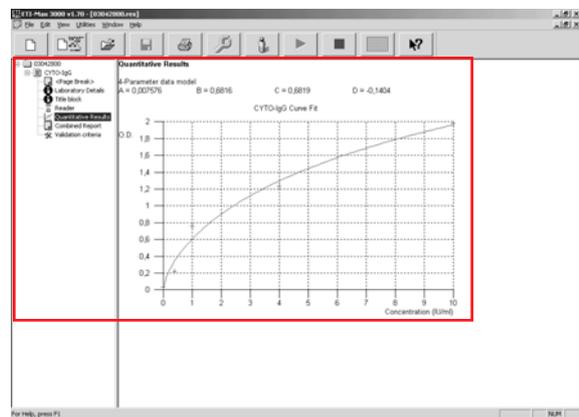
4.5.1.3 Reader

The blank value is displayed in the Reader result section. This section can also be used to show the raw data.



4.5.1.4 Quantitative Results

The window Quantitative Results shows the graph which is created with the standards defined in the assay.



4.5.1.5 Combined Report

6. ETI-MAX3000 analizatoriaus programinės įrangos atmintyje saugoma visa informacija apie atliktą tyrimą: naudotų reagentų informacija, interpretacija, paciento informacija

The Combined Report shows all patient IDs, results, flags etc. in one table. It gives a short overview about all relevant data.

The samples are identified by the patient ID. The individual wells are identified (alphanumerically), evaluated, calculated and, if necessary, flagged.

Combined Report

Patient ID	Patient	O.D.	Result
E1	S1	0.006	0.007
C1	S1	0.200	0.193
D1	S2	0.755	1.466
E1	S3	1.239	3.632
F1	S4	1.977	10.307

Patient ID	Patient	O.D.	Result
G1	318261	0.422	0.260
H1	318262	0.066	-0.4
A2	318263	1.221	3.262
B2	318264	0.616	1.039
C2	318265	1.146	3.143
D2	318266	1.112	2.911
E2	318267	1.114	2.982
F2	318268	1.500	3.012
G2	318269	1.640	6.741
H2	318270	1.523	3.028

Performing a Test Run

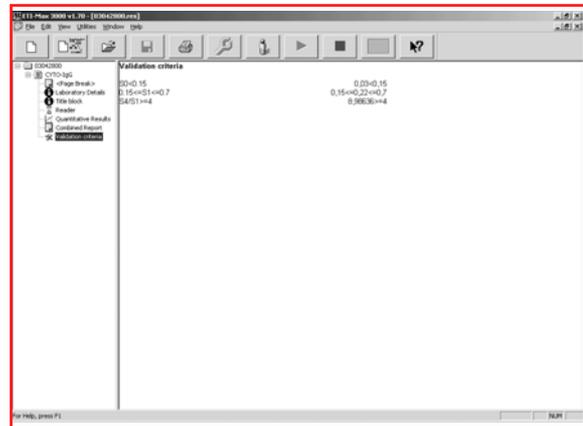
6. ETI-MAX3000 analizatoriaus programinės įrangos atmintyje saugoma visa informacija apie atliktą tyrimą: naudotų reagentų informacija, interpretacija, paciento informacija

4.5.1.6 Validation Criteria

The window Validation Criteria indicates if the control values of the test meet the defaulted criteria.

If the values of the control well are within the limits specified by the formula in this field, the test is considered valid and can therefore be evaluated.

If one of the criterias is failed, the test will not be evaluated.

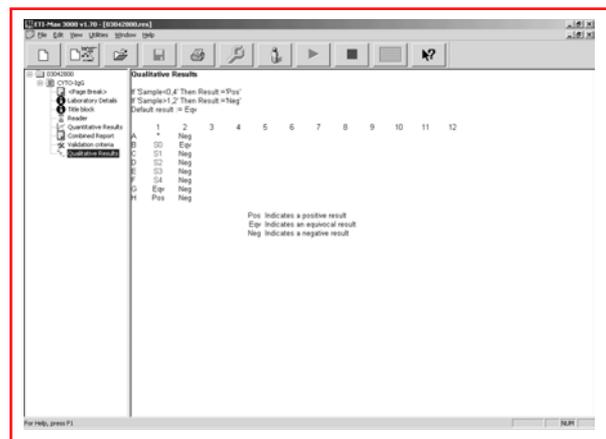


4.5.1.7 Qualitative Results

The window Qualitative Results provides information regarding the cut-off value of the test.

Three options are available:

- Pos: positive result
- Neg: negative result
- Eqv: result in the gray range.



4.5.1.8 Events

The Events window shows information on important actions performed by the analyser and subsequent reactions by the user.

- Important actions in this context are warning and error messages; they are displayed in red.
- Reactions by the user on these actions are displayed in green.
- User actions such as manual definition of reagents are also displayed in red.

4.5.1.9 Lot Specific Values

6. ETI-MAX3000 analizatoriaus programinės įrangos atmintyje saugoma visa informacija apie atliktą tyrimą: naudotų reagentų informacija, interpretacija, paciento informacija

The window Lot Specific Values, if selected in the assay-protocol, includes the lot data entered before the start of the worklist, the reagents used and the test kits.

4.5.2 Flags in the Result Report

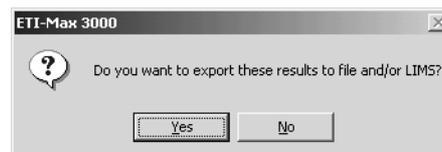
Reason:	Flag:
No liquid detected	NoLiq
Clot detected	Clot
Manually Pipetted	MP
Manual ID	ManID
Verification failed	VDFail
Rack removed	Removed

Table 4-1: Available result flags

4.5.3 Close the Results Report

By closing the results report the user can decide if the results should be send to a host computer.

Before sending results to the host computer, individual results can be modified by the user (all modifications are flagged).



8 Technical Data

4.2. ETI-MAX3000 analizatoriaus mėginio stovė yra galimybė dėti skirtingo tipo mėgintuvėlius, kurie išpildytų žemiau nurodytas išmatavimų ribas.

3.3. ETI-MAX3000 analizatoriuje yra integruotas brūkšninių kodų skaitytuvas mėginiams bei reagentams, reikiamos purtyklės, reikiamos temperatūros inkubatoriai bei vieta kambario temperatūros inkubacijai. ETI-MAX3000 prietaisai automatiškai atlieka mėginio skiedimą, plovimą, inkubaciją ir rezultatų vertinimą.

System Overview

Number of plates	4 positions for assay plates plus 3 positions in optional room temperature stacker
Number of samples	Max. 100 tubes, up to max. ϕ 16 mm, length up to 200 mm
Number of reagents	Special racks for DiaSorin reagents
Dilution positions	Positions for up to 160 dilution tubes
Number of tips	Up to 5 tip racks for 300 μ l or 1100 μ l disposable tips
Loading	Continuous loading of plates, samples, reagents and tips

Photometer

Spectral range	400 - 700 nm
Dynamic range	-0.100 to 3.000 O.D.
Accuracy	+/- 0.005 or 2.5 %
Linearity	0 - 2.000 O.D. +/- 1 %
Detection	Photo diode
Reading time	< 15 seconds
Read modes	OD and Kinetic mode
Filters	Up to 8 positions

3.7. ETI-MAX3000 analizatorių adata turi skysčio lygio aptikimo funkciją.

↑

Pipetting System	
Pipettor	Liquid pipettor for disposable tips
Liquid level detection	Standard
Accuracy and reproducibility of pipetting	+/- 5 %, 10 µl, CV < 8 % +/- 1 % at 100 µl, CV < 2.5 %
Conditions	<ul style="list-style-type: none"> Liquid used: distilled water Temperature constant: 21 °C +/- 2 °C (including reagents and samples) Valid for use of "Test protocol"
Features	Tip detection, mixing, multi-dispensing mode

Incubation

Capacity	4 independent chambers
Temperature range	Minimum temperature = RT + 5 °C Maximum temperature = 50 °C
Accuracy	+/- 1 °C mean of plate
Uniformity	+/- 0.7 °C across plate

Washing

Capacity	Max. 3 positions wash buffer + 1 distilled water
Wash head	1 x 8 with verify option
Dispense volume	200 - 2500 µl/well
Precision	+/- 5 % CV at 300 µl
Residual volume	< 2.5 µl in U-shaped bottom < 4 µl in flat bottom

Fluid alarms	Low reagent, waste full
Features	Sweeps, soak, purge, top and bottom wash, variable pump speeds

↓

3.6. Analizatoriuje ETI-MAX3000 yra garsinė ir vaizdinė aliarmo sistema įvykus klaidai (pasibaigus reagentui, nenuskaitant mėginio ar reagento brūkšninio kodo ir pan.). Analizatoriai leidžia ištaisyti klaidą ir tęsti darbą toliau.

PC requirements

PC	IBM compatible Pentium PC
RAM	At least 64 MB
Ports	1 serial ports 1 parallel port
Hard disk	Hard disk with min. 150 MB free hard disk space
Accessories	Colour monitor Keyboard and mouse Printer

7. Yra galimybė integruoti ETI-MAX3000 analizatorių į laboratorinę informacinę sistemą per ASTM ir ASCII.

Software features

Operating system	Microsoft Windows® 95 or Microsoft Windows® 2000
Interfaces	ASTM interface Flexible ASCII import of worklist sample ID's
Time Scheduling	Schedules 4 plates with user options
Multiple assays per plate	Up to 12 assays per plate (dependent on the possibilities of the assay combinations)
Export options	Flexible ASCII export and report
Qualitative	User definable result classes
Quantitative	Linear to quadratic regression, sigmoidal, and many more
Language support	Multiple languages possible
QA analysis	Mean, SD, CV, Standard Error and Levey-Jennings

Mains voltage and fuses

Universal a.c. input	100 - 260 VAC, 47 - 63 Hz Typically max. 500 VA
Main fuses	4 A T
Computer, monitor and printer	For electrical details of the PC equipment please refer to the technical documentation of the OEM manufacturer.