

CE



## User manual

Code: **ORG 300-00**

Name: **Alegria®**



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Further instructions:

- [Form FD4.27H Transport preparation](#)

For authorised service personnel:

- [Alegria® Installation Guide](#)
- [Alegria® Service Manual](#)

# 1. MANUFACTURER

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# 2. IDENTIFICATION

ORG 300-00 Alegria®

# 3. INTENDED USE AND PURPOSE

The Alegria® is an in vitro diagnostic medical device (IVD) CE marked in conformity with European IVDD 98/79/EC.

The Alegria® instrument is an automated random access analyser intended to process Alegria® IVD assays supplied by ORGENTEC: human samples are processed with the purpose of presenting analytical results. Results obtained with the Alegria® instrument shall be used only in conjunction with other medical evidence to diagnose conditions of the human body.

The Alegria® is to be used by trained personnel in medical laboratories.

The user interacts with the Alegria® instrument through an easy to understand user interface (touch display).

The Alegria® user interface is used for starting and viewing the processed Alegria® IVD assays and general tasks. It also displays the results from the analyses performed. The test data and results can be printed on paper, stored or transferred to other computers.

# 4. CONDITIONS FOR STORAGE AND HANDLING



**Consult Alegria® Installation Guide**

## Storage and transport conditions

	Temperature		Humidity
Metric	-40°C to +70°C		10% - 80% rh. non-condensation
US	-40°F to 158°F		10% - 80% rh. non-condensation

## Operating conditions

	Temperature	Humidity	Air pressure
Metric	20°C to 32°C	25% - 75%rh. non- condensation	Not critical, suitable up to 2300m above sea level
US	68°F to 89°F	25% - 75%rh. non- condensation	


## Measures and weights

	Height	Width	Depth	Weight
Metric	760 mm	685 mm	540 mm	52.4 kg
US	29.9 inches	26.9 inches	21.2 inches	132.3 Lbs.

## 5. WARNINGS AND PRECAUTIONS

Adhere to the following recommendations for safe and proper operation of the device:



- In all cases where the symbol for Warning or Biohazard appears on the instrument, the instructions in this manual have to be consulted in order to find out the nature of the potential hazard and any actions to avoid them
-  Follow the packaging/un-packaging procedure to avoid personal injuries, equipment damage or property damage.
- Never use the device near mobile telephones, CB radios or other forms of radio communication, and/or electromagnetic fields. These may affect the performance of the device. The analyser conforms to IEC/EN 61326 and shall not be exposed to higher levels of disturbance.

-  **Squeeze risk:**

Do not place any object or hand/fingers in the sample loading door mechanism. If the sample loading door, an Alegria® Test Strip or a SysTray has blocked the rotation plate call for service.

Do not attempt to force the plate or mechanics.

- Do not attempt to open the device sample loading door by hand.
- Do not attempt to open the device or any cover unless it is described within this manual.
- Do not refill the fluid container(s) while the container(s) are in the device or when in use.
- Do not run the device without having the fluid bottles connected (waste, System Fluid, Wash Buffers 1 and 2).
- Do not immerse the device in water or any other liquid (see the [Maintenance](#) section for specific details).
- Unplug the power connector from its power source before cleaning or servicing. Failure to do so could result in personal injuries or equipment damage.

- Ensure that the power cord is not pinched between mechanisms during normal operation. Failure to do so can result in personal injuries or equipment damage.
- Do not connect the power connector or anything other than the appropriate input on the device.
- The Alegria® instrument shall not be exposed to direct sunlight nor be placed in a draught environment.
- If the Alegria® instrument shall be transported and the transport conditions are to be less than 0 degrees Celsius (32 degrees Fahrenheit) the analyser's liquid system must be emptied to avoid equipment damage.
- Use only ORGENTEC spare parts, accessories and consumables.
- All service shall be performed by ORGENTEC authorised service personnel.
- Mains supply cord must be rated adequately. Use only adequate fuses. See Technical Specifications, page 8.
- During handling of all human specimen samples and Alegria® IVD reagents, observe the existing laboratory safety regulations and good laboratory practice:



#### Biohazard:

Handle human samples and Alegria® Test Strips and all material in contact with these as potentially infectious material.

For disposal of laboratory waste the national or regional legislation has to be observed.

Personal protection:

The samples, reagents and the instrument shall be handled with protective gloves.

First aid measures: In case of skin contact, immediately wash thoroughly with water and soap. Remove contaminated clothing and shoes and wash before reuse. If System Fluid comes into contact with skin, wash thoroughly with water. After contact with the eyes carefully rinse the opened eye with running water for at least 10 minutes. Get medical attention if necessary.

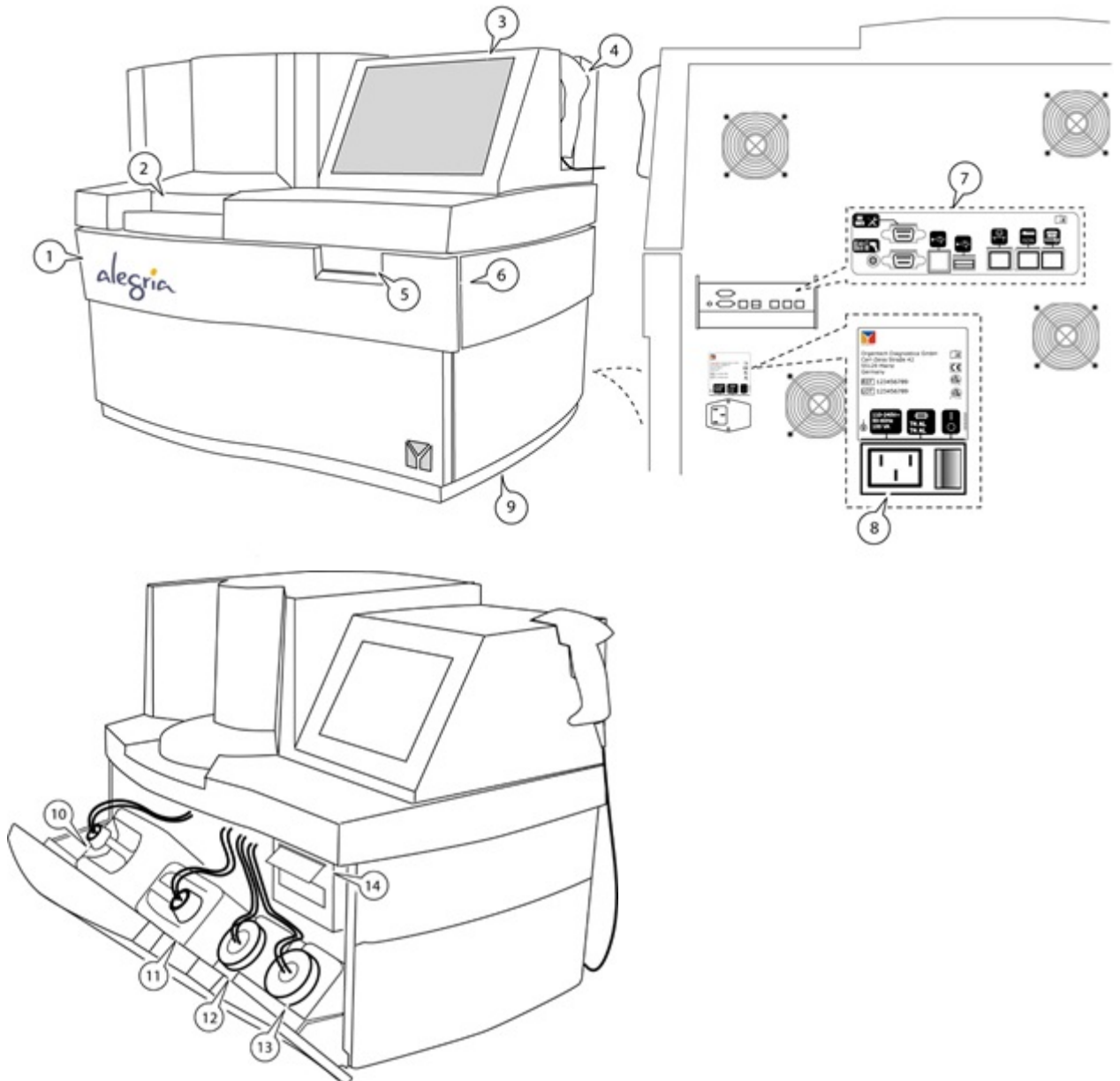
Personal precautions, protective equipment and emergency procedures:

Observe laboratory safety regulations. Avoid contact with skin and eyes. Do not swallow. Do not pipette by mouth. Do not eat, drink, smoke or apply makeup in areas where specimens or kit reagents are handled. When spilled, absorb with an inert material and put the spilled material in an appropriate waste disposal.

- Observe the guidelines for performing quality control in medical laboratories by assaying controls and/or pooled sera.




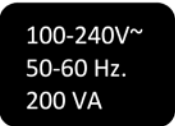








# 6. INSTRUMENT INSTALLATION













## 6.1. DESCRIPTION OF THE INSTRUMENT



1	Front cover door
2	Sample loading area
3	Touch screen
4	Barcode reader ext. (optional)
5	Printer paper output
6	Front cover opening handle (both sides of the analyser)
7	Input & output connection panel (rear of analyser)
8	Mains power input and on/off switch (rear of analyser)
9	Lifting handle (both sides of the analyser)
10	Waste container
11	System Fluid container
12	Wash Buffer 1 container
13	Wash Buffer 2 container
14	Printer

Explanations of the symbols found on the body of the device or on the transportation box:

Symbol	Description
	CE marked according to European Directive 98/79/EC
	In vitro diagnostic medical device
	Read the instructions
	Voltage Power consumption
	Warning or caution, precaution
	On Off
	Fuse
	Barcode scanner port
	Service PC port
	Universal Serial Bus
	Ethernet port
	ISDN port

Symbol	Description
	Serial number
	Order number
	Manufacturer
	Manufacturing date
	Biological hazard
	System Fluid
	Waste fluid
	Wash Buffer (1)
	Wash Buffer (2)
	Printer
	Modem port
	This way up, keep dry, fragile packaging



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## Technical specifications

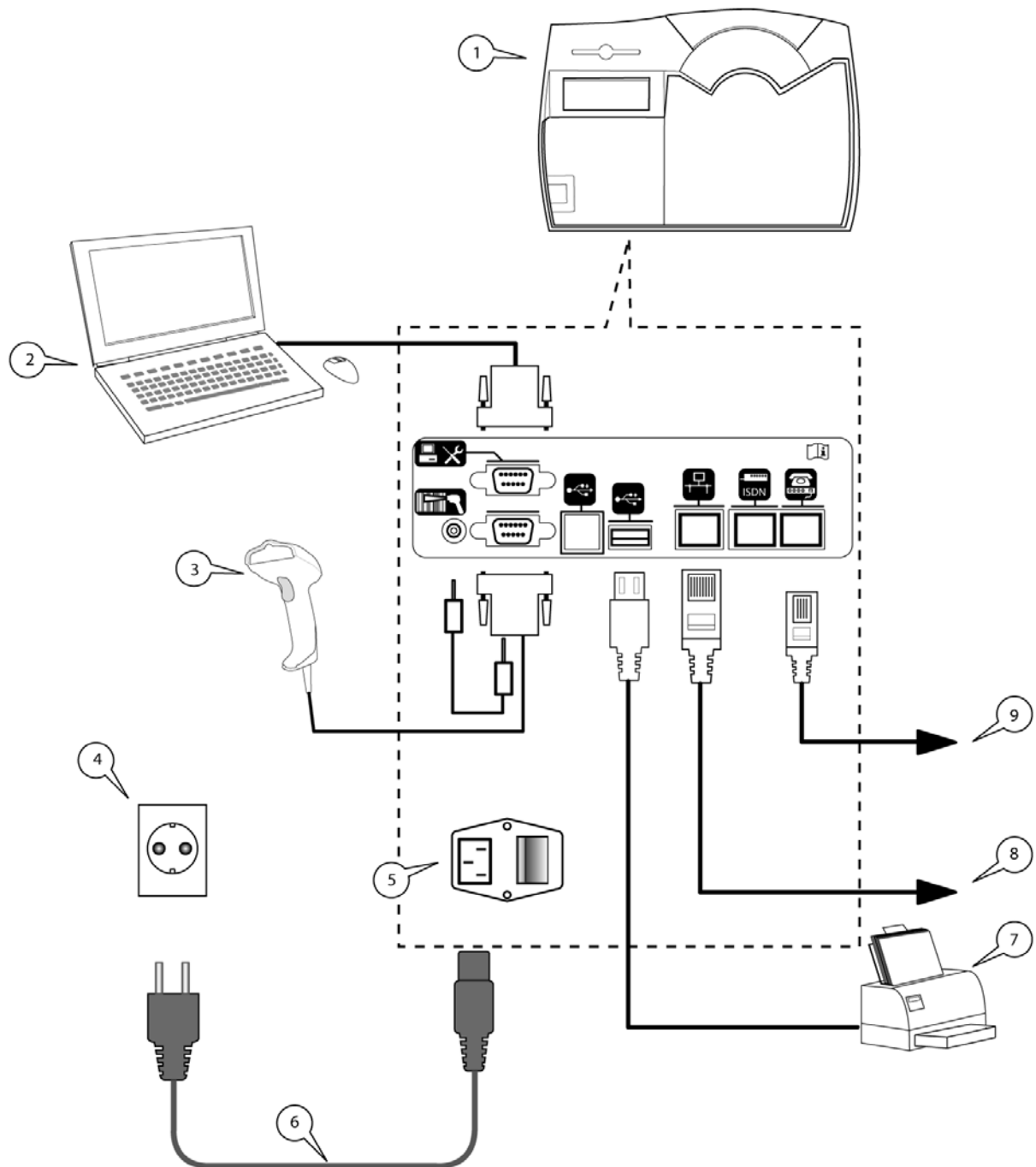
If there are additional questions please contact your ORGENTEC representative.  
Note that ORGENTEC Diagnostika GmbH reserves the right to make changes in the specifications without prior notice.

REF	Specification
Product name	Alegria®
Operating system	Microsoft, Windows CE
Operating system version	4.1
Voltage	100-240V~ 50-60 Hz.
Power consumption	200 VA
Fuses	100-240V~ 2x T4 A L250V (5 x 20 mm) CSA and UL approved
Principle	ELISA analyser
Assays (min-max)	1-30 assays per run (analysis dependant)
Assays per TEST STRIP	1
Sample volume per assay	10µL (analysis dependant)
Calibration	Automatic (dispensing volume calibration)
Measuring time	Analysis type and sample amount dependant
Throughput time/ test run	67-94 minutes, see measuring time
Detector type	Optical
Light source	LED
Wavelength(s)	650 nm
Dispense pump (range)	19-162 µL
Battery back-up	Lithium backup battery (used for real time clock time keeping)
Noise level	55 dBA
System Fluid container volume	2.5L
Waste container volume	5L
Wash Buffer container volume	1L
Printer type	Thermal printer
Printer paper type	Thermal paper

## Classification

- Degree of protection against electric shock:  
Equipment providing particular degree of protection against electric shock, particularly regarding allowable leakage current.
- Degree of protection against harmful ingress of water: IP20
- Mode of operation: Continuous operation.

## Scope of package delivery



1	Alegria® analyser
2	PC (optional, Patient Archive Loader, LIMS)
3	Barcode reader ext. (optional)
4	Mains outlet with protective earth
5	Mains input and on/off switch (Alegria®)
6	Mains power cable (supplied only in Germany, see Installation Guide)
7	USB cable to optional external printer
8	LAN (Ethernet port) not supported
9	Modem cable (option for remote service and data transfer)

## Consumables and spare parts

The Alegria® instrument has several consumables, which are installed, delivered or sold separately. These are described in the table below.


Authorised service personnel must install these spare parts (see back cover for representatives).


REF	Description	Qty.	Supplied in Package	Consumable	Option	Spare Part
86000003	System Fluid container	2.5L	▪			▪
86000002	Wash (Buffer A) container	1 L	▪			▪
86000002	Wash (Buffer B) container	1 L	▪			▪
86000004	Waste container	5 L	▪			▪
86000008	Wash Buffer level sensors	2	▪			▪
86000007	System Fluid level sensor	1	▪			▪
86000075	Waste level sensor	1	▪			▪
86000017	Set of frames (A, B, C)	Pack of 3	▪			▪
on request	Pointing device	1 pcs	▪			▪
ID0122 ID0146	Printer paper	1 x 1 x	(1x) (1x)	▪		(5x) (5x)
86000043	Barcode reader external	1 pcs	▪		▪	▪
86000034	Dispense needle	1 pcs			▪	▪
86000032	Wash needle front	1 pcs			▪	▪
86000033	Wash needle back	1 pcs			▪	▪
on request	PC cable (serial cable)	2 m			▪	
on request	ISDN cable	1 m			▪	
on request	Modem cable	2 m			▪	
on request	USB cable A-B (external printer)	2 m			▪	
on request	USB cable A-A (extension)	2 m			▪	


## 6.2. SPECIFICATIONS FOR THE INSTALLATION SITE

- Refer to technical specifications
- Prepare an appropriate shelf or table to place the Alegria® analyser on. This place must be capable of carrying the analyser load (~60 kg including all liquids). Make sure there is clearance around the device, ensuring access to the main switch and inputs.

## 6.3. PROCEDURE FOR UNPACKING AND INSTALLATION

 Detailed information is given in the **Alegria® Installation Guide** for service personnel. It is mandatory that authorised service personnel will unpack and install the instrument and carry out a test run.

 **WARNING:** Use proper lifting methods when moving or lifting the package. Failure to do so can result in personal injury, equipment damage and property damage. Have minimum two persons lifting the device to its location and use the lifting handles (see: [Alegria® Analyser overview picture, p. 7](#)).

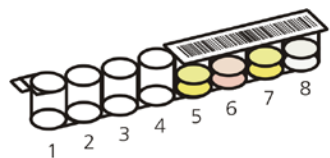
 **WARNING:** Do not use any sharp tools when removing protection wrapping from the device. Failure to do so can result in equipment damage.

- Inspect the package for transport damage.  
If damaged contact your ORGENTEC representative.
- Inspect the transport problem indicators TILTWATCH™ and SHOCKWATCH® for activation.
- Remove all the exterior packaging.
- Remove interior packaging material.
- Remove protective wrapping.
- Remove any disconnected accessories.
- Remove the transport secure locking (see: [How to remove transport locking](#))
- Inspect the parts for damage and verify completeness against Packing List. If damages or missing parts found, fill out the Installation Report form and send it to your ORGENTEC representative.
- Make sure that all parts ordered are included, if not contact your ORGENTEC representative.

## 7. FUNCTIONAL PRINCIPLE OF THE DEVICE

The Alegria® instrument processes Alegria® IVD assays supplied by ORGENTEC. The Alegria® IVD assay is based on ELISA technology and features barcoded 8-well-microstrips, called Alegria® Test Strips.

The Alegria® Test Strip holds a complete set of reagents and is designed for a single determination of one patient sample:



Wells 1 + 2: empty (wells for sample dilution)

Wells 3 + 4: **two coated wells** (reaction wells for one control and one patient sample)

Well 5: **Control**; yellow

Well 6: **Enzyme Conjugate**; light red

Well 7: **Sample Buffer**; yellow

Well 8: **TMB Substrate**: clear

Example: A typical test procedure

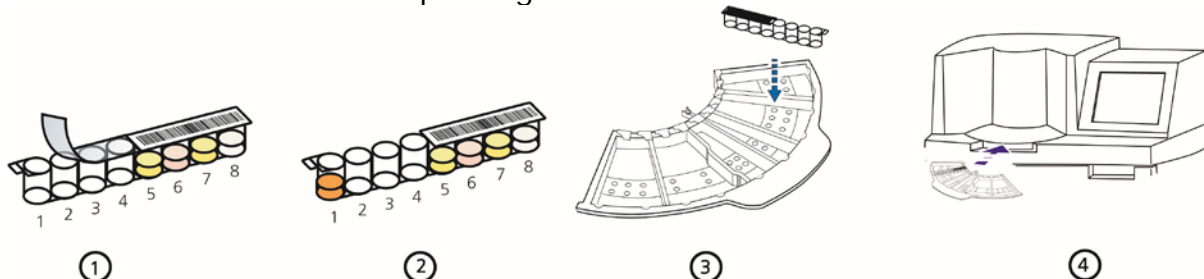
(1) Remove the foil from the empty wells 1 to 4 of the Alegria® Test Strip.

Do not remove foil with printed barcode, covering wells 5 to 8.

(2) Pipette 10 µl of sample at the bottom of well 1.

(3) Insert the strip into the SysTray.

(4) Place loaded SysTrays into the correct position in the Alegria® instrument and start run. All further steps will be done automatically. The test run is completed when the instrument starts printing the results.



Three SysTrays can hold up to 30 Alegria® Test Strips.

The Alegria® can process up to 30 different Alegria® IVD assays in one run.

### **Proprietary SMC®-Technology (Sensotronic Memorised Calibration):**

Information about the assay, analysis and evaluation, and the lot-specific expiry date are contained on the **barcode** printed on each Alegria® Test Strip.

Data encoded on the barcode are transferred from the Alegria® Test Strip to the Alegria® instrument and the assay is automatically processed and evaluated.

The instrument reads the date of expiry and rejects further processing if the Alegria® Test Strip is outdated.

### **Example for the SMC®-Technology**

Barcode: 215 1 702 4 37 53 1111

Product code: 215 coding for: ORG 215

Conjugate type: 1 coding for: Conjugate type

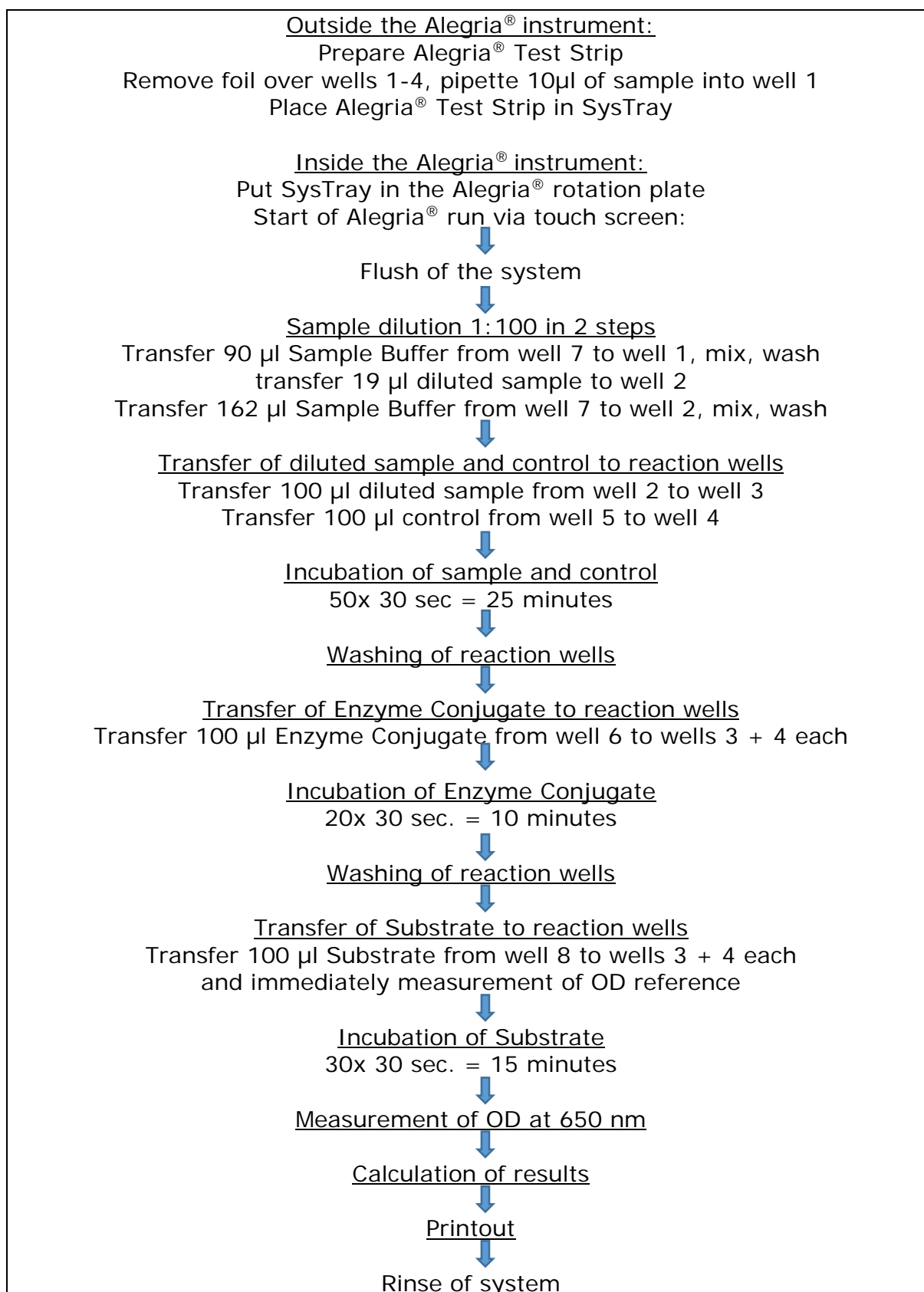
Expiry date: 702 coding for: 2017-02-28

Calibration curve: 4 37 53 coding data for 4 points of calibration

Strip number: 1111 singular continuous number of Test Strip

Calculation of results: First an index is calculated from OD reading from internal control and patient sample and then this index is read from the virtual calibration curve defined in the barcode.

## Example: Flow chart of a typical Alegria® application



[Quality check and presentation of results see chapter 12 and 13](#)

## 8. FUNCTIONS AND PERFORMANCE DATA

- Barcode reader (internal and external)
- Dispensing module
- Optical module
- Analytical system

Evaluation of precision and exactitude is done for every Alegria® instrument.

### • Barcode reader

Evaluation of the ability of the barcode reader to read the barcode on Alegria® Test Strips accurately: Thirty Alegria® Test Strips were put into SysTrays of the Alegria® instrument and read via internal barcode reader. Eleven Alegria® instruments were used.

Interpretation:

The internal barcode reader is able to read all Alegria® Test Strips accurately.

### • Dispensing module

Evaluation of the ability of the pipetting unit (consisting of calibrator needle and conjugate needle) to dispense defined volumes (19 µl, 100 µl, 162 µl) accurately.

#### Precision

Mean dispensation [mg], 1 µl = 1 mg, standard deviation and coefficient of variation was calculated from values of eleven instruments with three dispensations of each volume.

#### Exactitude

Deviation was calculated:  $\text{target dispensation} - \text{mean dispensation}$

% deviation was calculated:  $(\text{deviation} * 100) / \text{target dispensation}$

		Precision [mg]	Target [mg]	Deviation [mg]	Exactitude % deviation
Calibrator needle	mean	19.00	19.00	0.00	0 %
	sd	0.20			
	% CV	1.06			
Calibrator needle	mean	99.65	100.00	0.35	0.35 %
	sd	0.72			
	% CV	0.72			
Calibrator needle	mean	160.16	162.00	1.13	0.69 %
	sd	0.60			
	% CV	0.38			
Conjugate needle	mean	99.91	100.00	0.09	0.09 %
	sd	0.63			
	% CV	0.63			

#### Interpretation

The acceptance range for the exactitude of the dispensing needles was set to be ≤ 2.5 % deviation from dispensing target for target volumes 19 µl, 162 µl and 100 µl.

- **Optical Module**

Evaluation of the ability of the optical unit to give equivalent optical density (OD) in well 3 and well 4 of an Alegria® Test Strip.

Calculation: Index value = OD well 3 / OD well 4

Target: Index value 1.0 for equivalent optical densities in well 3 and 4

Eleven instruments with twenty-nine determinations each were evaluated:

	OD Well 3	OD Well 4	Index
mean	1.128	1.130	0.997
sd	0.037	0.032	0.014
% CV	3.3	2.8	1.5

Interpretation

The acceptance range for the index (OD well 3 / OD well 4) was set to be < 2.5 % CV.

- **Analytical system**

Evaluation of the ability of the analytical system to give accurate and exact results with Alegria® Test Strips by using all functions of the instrument (barcode reader, dispensing needle, dispensing pump, optical module, software).

Product ORG 310 is intended for functional control of the Alegria® instrument.

Twelve ORG 310 Alegria® Test Strips were assayed in one run.

Ten Alegria® instruments were used.

Index was calculated as follows: OD well 3 / OD well 4 = Index

Intra-instrument reproducibility

Coefficient of variation (CV) was calculated for one instrument for each of twelve Alegria® Test Strips from the results of index.

Inter-instrument reproducibility

Coefficient of variation (CV) was calculated for each of 10 instruments with a total of 120 Alegria® Test Strips from the results of index.

Exactitude

Deviation was calculated: target index – mean index observed

% deviation was calculated: (deviation \* 100) / target index

Instrument	Precision (Intra-instrument reproducibility)				Exactitude		
	well 3 OD mean	well 4 OD mean	Index mean	Index % CV	Target index	Index deviation	Deviation from target %
SN310685	0.893	0.379	2.354	<b>1.9</b>	2.340	0.018	<b>0.8</b>
SN310686	0.905	0.391	2.320	<b>4.3</b>	2.340	0.016	<b>0.7</b>
SN310687	0.859	0.362	2.375	<b>2.1</b>	2.340	0.039	<b>1.7</b>
SN310688	0.918	0.386	2.377	<b>1.1</b>	2.340	0.041	<b>1.8</b>
SN310689	0.851	0.351	2.426	<b>2.8</b>	2.340	0.090	<b>3.8</b>
SN310690	0.872	0.367	2.381	<b>3.5</b>	2.340	0.045	<b>1.9</b>
SN310691	0.917	0.383	2.398	<b>2.2</b>	2.340	0.062	<b>2.6</b>
SN310692	0.880	0.379	2.323	<b>1.6</b>	2.340	0.013	<b>0.6</b>
SN310693	0.876	0.366	2.394	<b>2.3</b>	2.340	0.058	<b>2.5</b>
SN310694	0.890	0.373	2.390	<b>3.3</b>	2.340	0.054	<b>2.3</b>



Instrument	Precision (Inter-instrument reproducibility)				Exactitude		
	well 3 OD mean	well 4 OD mean	Index mean	Index % CV	Target index	Index deviation	Deviation from target %
10 instruments	0.886	0.374	2.374	<b>2.9</b>	2.340	0.038	<b>1.6</b>

Interpretation

The acceptance range was set to be

< 7.5% CV for precision

< 7.5% for exactitude (deviation from target)

## 9. ***LIMITATIONS OF USE***

The content of this manual is the property of ORGENTEC Diagnostika GmbH. Any reproduction in whole or in part is strictly prohibited.

At the time of printing, this manual correctly described the device and its functions. However, as modifications may have been carried out since the production of this manual, the system package contains this manual and may contain one or more amendments to the manuals. This manual including any amendments must be thoroughly read, before using the device.

ORGENTEC Diagnostika GmbH is only responsible for the reliability and performance of the device if the following points are strictly observed:

- Authorised personnel (see back of manual for authorised service centres) carries out all service, repairs and modifications.
- The device must be used in accordance with the intended use and the instructions put forth in the Warnings and Precautions section.
- If the instrument is used in a manner not specified by the manufacturer, the protection provided by the instrument may be impaired.
- ORGENTEC Diagnostika GmbH offers one-year warranty, from the day of purchase, on defective material and assembly.
- The warranty does not cover damage resulting from incorrect use, incorrect user maintenance or from non-authorised software modification.
- ORGENTEC Diagnostika GmbH is only responsible for replacement of defective parts, not wear of parts.
- ORGENTEC Diagnostika GmbH is not responsible for any personal injury or any damage resulting from incorrect use of the analyser.

If the above points are not strictly observed, the warranty will be considered invalid.

# 10. OPERATING THE ALEGRIA®

## 10.1. START-UP PROCEDURE

- Connect the fluid bottles (Waste, System Fluid, Wash Buffer 1 or 2).
- Connect the mains cable to a wall socket (protective earth type).
- (Optional) Connect barcode scanner.
- (Optional) Connect cables such serial for LIMS connection or USB for external printer.

## 10.2. POWER ON PROCEDURE

- Check that there is Wash Buffer(s) and System Fluid in the respective container and that the waste container is empty (see [How to empty waste fluid and load reagent fluids](#)).
- Turn on the mains switch on the back of the device.
- Wait for the Alegria® software to start. [Automatic calibration see chapter 12.](#)
- Wait for the system to flush the fluid system.
- After the power on procedure is finished the Alegria® instrument is ready to be used.

## 10.3. POWER OFF PROCEDURE

- The operator returns to the main screen.
- The operator presses the **Shut Down** button (the system is rinsed with System Fluid).
- Wait for the "Safe to turn off" message to appear and confirm by pressing **OK**.
- Turn off the mains switch on the back side of the device.

## 10.4. USER INTERACTION

The user interacts with the Alegria® instrument through the user interface which is a **touch display**:

You interact by touching the computer screen with your finger.

Touching the screen is like clicking with a mouse (touch to select).

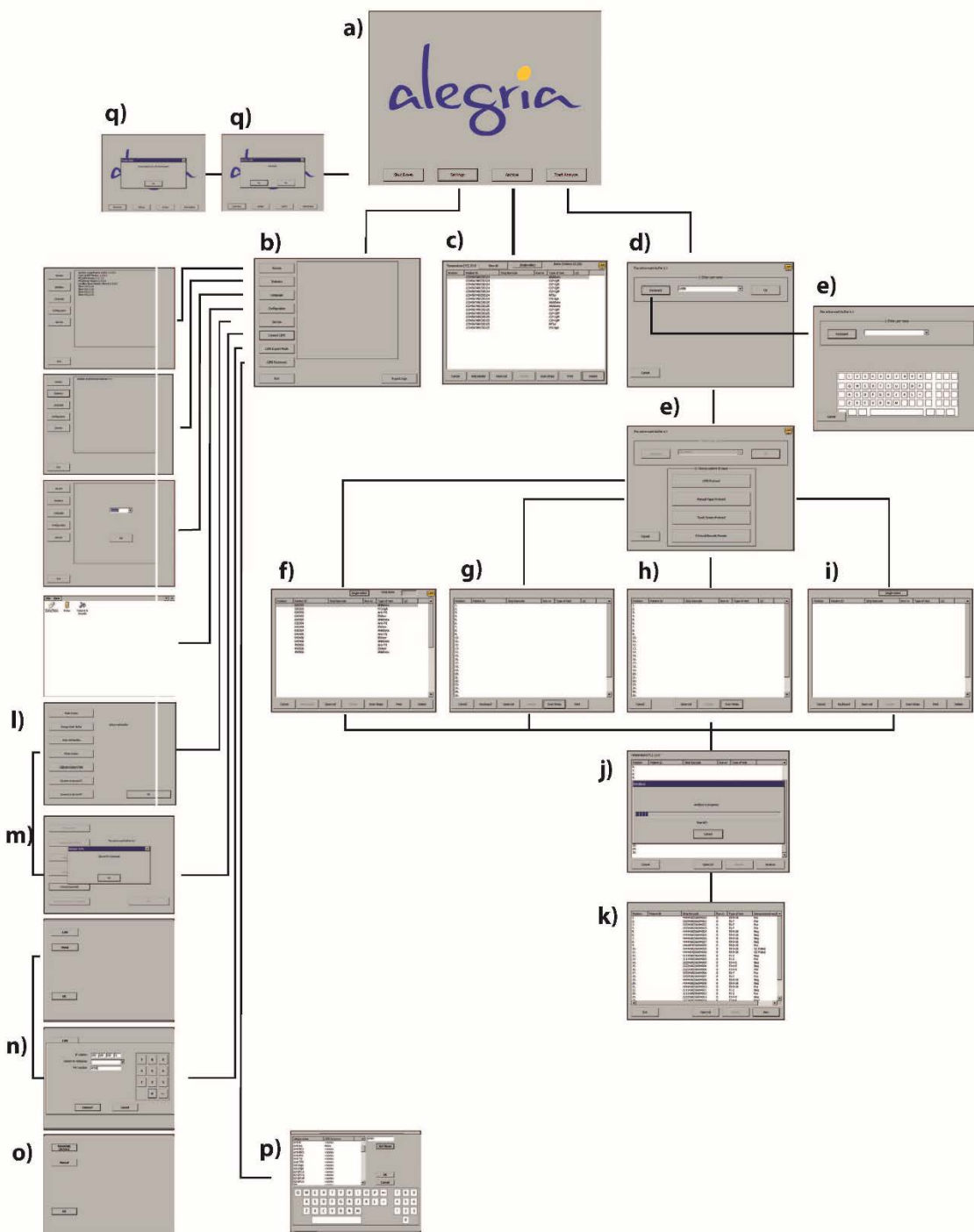
You can then touch the buttons to start the analysis or change settings, enter data and examine the analysis results. Screens will open other screens where you can enter information and display data.

Note: There is no external keyboard,  
However where it is required to type in text or numbers touch the button  
Labelled **Keyboard** and a keyboard appears on the touch screen:

*Touch the specific field, enter your text / number,  
Then touch next field and enter next text / number  
Touch the **Keyboard** button again and the keyboard will disappear.*

The following tutorial shows how the screens relate to each other and how to operate the Alegria® instrument by these screens:

- a) Main screen
- b) Settings screen
- c) Archive screen
- d) Analyse screen
- e) Analyse, enter username and select protocol
- f) Run list (LIMS protocol)
- g) Run list (touch screen protocol)
- h) Run list (manual protocol)
- i) Run list (external barcode reader)
- j) Analyse (run)
- k) Results
- l) Service screen
- m) Connect LIMS screen
- n) LAN configuration screen
- o) LIMS Export Mode
- p) LIMS Synonyms screen
- q) Shut down



## Main screen



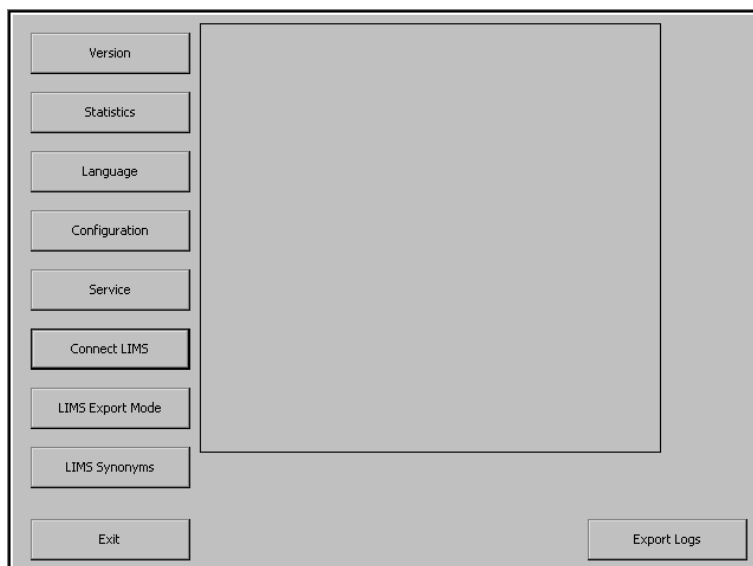
Tapping any of these buttons will take you to the next screen.


Button	Explanation
<b>Shut Down</b>	The <b>Shut Down</b> button will take you through the steps for safely turning off the Alegria® instrument.
<b>Settings</b>	The <b>Settings</b> button will take you to the settings options / information: Version Statistics Language Configuration Service Connect LIMS * Lims Export Mode * LIMS Synonyms * Export Logs These different topics and information is displayed or editable. * Just available in LIS software
<b>Archive</b>	The <b>Archive</b> button will take you to the test archive. The archive displays test results and other information of the latest 2000 processed tests.
<b>Start Analyze</b>	The <b>Start Analyze</b> button will take you to the analysis process start.

	<p>By pressing the <b>Yes</b> button you can recover that unfinished working list.</p>	<p>By pressing the <b>No</b> button the recovered list will be erased.</p>
--	--	--

All input to the run list is saved in a file in case there is a problem encountered or an aborted analysis, this screen would appear in front of the main screen if so. The user can reload the list if desired.

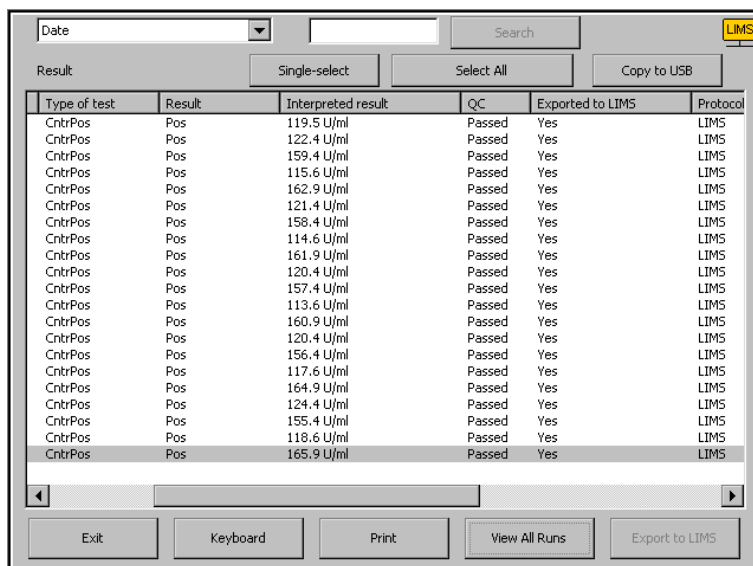
## Settings screen



Button	Explanation
<b>Version</b>	By tapping the <b>Version</b> button the instrument will present the software versions of the instrument.
<b>Statistics</b>	By tapping the <b>Statistics</b> button the instrument will present the current statistics (amount of runs performed).
<b>Language</b>	By tapping the <b>Language</b> button the instrument will present the current language. To change the language press the down arrow, select the language from the drop down list and confirm by pressing <b>Set</b> .
<b>Configuration</b>	By tapping the <b>Configuration</b> button the instrument will request the password to present the configuration files: Time Touch screen calibration After changes are done press the <b>Set</b> button.  Changing the setup file can have serious effect on the instrument and its performance.
<b>Service</b>	By tapping the <b>Service</b> button the instrument will present the service menu.
<b>Connect LIMS</b>	By tapping the <b>Connect LIMS</b> button the instrument will present the two different options for connecting to a LIMS: Serial LAN (not supported) The activated LIMS connection will be displayed through the LIMS icon in the top right corner.
<b>LIMS Export Mode</b>	By tapping the <b>LIMS Export Mode</b> button the instrument will present the two different options for exporting results to LIMS. Automatic is the default option. In automatic mode all results are automatically exported to LIMS as soon as they are available, but only if the user is working in the LIMS protocol. In manual mode the operator must manually export results from the archive screen. Automatic (default) Manual

<b>LIMS Synonyms</b>	By tapping the <b>LIMS Synonyms</b> button the instrument will present the dialog for linking test names to synonyms used by LIMS.
<b>Export Logs</b>	By first inserting an USB memory stick and then tapping the <b>Export Logs</b> button the instrument will copy error- and other important logs to the root directory of the memory stick in a file called LogData.org. This file is encrypted and can be sent to your local ORGENTEC representative for further assistance in the investigation of problems or malfunction of the instrument.

## Archive screen



Tapping the **Keyboard** button will bring up a keyboard on the screen that can be used for entering text. Pressing **Exit** will take you to the previous menu.

The archive menu has a drop down list (Date / Run no / Strip Barcode / Patient Id) that selects the way the test results are displayed.

Press the down arrow to select for example **Date**, enter a valid information in the text field and then press the **Search** button. The instrument will search for the results. Example given choose Date from the drop down list, enter a valid date (YYYY-MM-DD) and press the **Search** button. The instrument will search for the tests performed on that date.

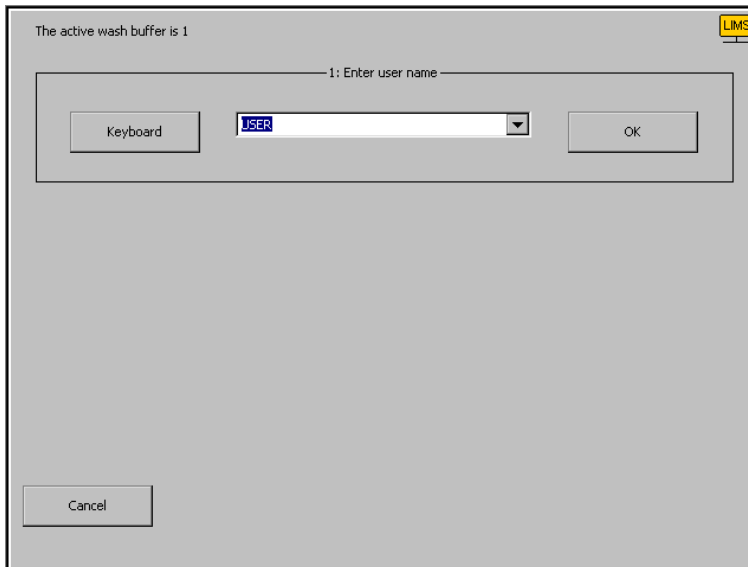
The text field can hold a maximum of 16 characters. It is possible to use "\*" for incomplete information. Example given enter a date 2015-03-\*\* to search for the tests of an entire month.

Button	Explanation
<b>Exit</b>	By tapping the <b>Exit</b> button you will be taken back to the previous menu.
<b>Keyboard</b>	By tapping the <b>Keyboard</b> button the instrument will display the hidden keyboard. Select the search field and tap the keyboard buttons like a normal keyboard. Press the <b>Search</b> button to start the search.
<b>Print</b>	By tapping the <b>Print</b> button the instrument will print the results displayed.
<b>View All Runs</b>	By tapping the <b>View All Runs</b> button the instrument will display all tests performed and stored in the instrument. <b>NOTE:</b> <i>The instrument can store a maximum of 2000 test results. When the memory is full the oldest test result will be overwritten.</i>
<b>Export to LIMS</b>	By tapping the <b>Export to LIMS</b> button all selected entries will be exported to the LIMS if LIMS connection has been established. This can be determined by looking for the LIMS symbol icon on in the top right corner of the screen.
<b>Select All</b>	By tapping the <b>Select All</b> button all displayed entries will be selected.
<b>Copy to USB</b>	By tapping The <b>Copy to USB</b> button the entire archive is copied to the USB memory.



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## Analyse screen



The analyses process is divided into several steps depending on choices, first you need to enter your user name.  
Select the text field and type with the keyboard or select your name from the drop down list (name entered earlier) then press the **OK** button.

Tapping any of the buttons such as the **Keyboard** button will bring up a keyboard on the screen that can be used for entering text.  
Pressing the **Cancel** button will take you to the previous menu.

Button	Explanation
<b>Keyboard</b>	By tapping the <b>Keyboard</b> button the instrument will display the hidden keyboard.
<b>Cancel</b>	By tapping the <b>Cancel</b> button you will be taken back to the previous menu.
<b>OK</b>	By tapping the <b>OK</b> button you confirm the chosen user name. <b>NOTE:</b> Confirmation only possible when Keyboard is hidden again.

## Analyse, enter username and select protocol

The screenshot shows a software window titled 'The active wash buffer is 1' with a 'LIMS' logo in the top right corner. The interface is divided into two main sections:

- 1: Enter user name:** This section contains a 'Keyboard' button on the left, a text input field with 'USER' and a dropdown arrow in the center, and an 'OK' button on the right.
- 2: Choose patient ID input:** This section is a vertical stack of four buttons: 'LIMS Protocol', 'Manual Paper Protocol', 'Touch Screen Protocol', and 'External Barcode Reader'.

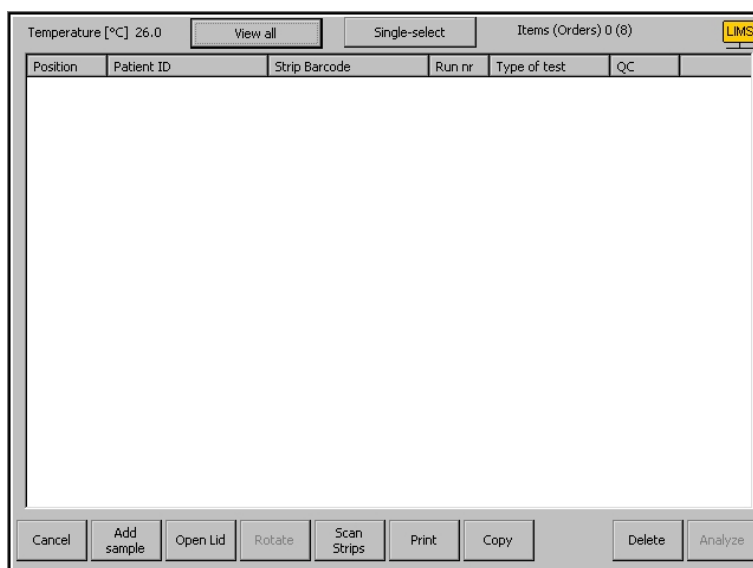
A 'Cancel' button is located at the bottom left of the window.

Select the type of test protocol you like to use.

**Note:** For more detailed information and step by step instruction of how to start the analyses in the different protocols have a look into the section 10.4 Alegria® protocols.

Button	Explanation
<b>LIMS Protocol*</b>	<p>This protocol requires that test orders have been received from the LIMS. When a Patient ID is scanned the corresponding test orders are displayed. The matching of Patient ID to Strip ID is done by selecting a row with wanted test and scanning the Strip ID with the external barcode scanner. The test orders contains:</p> <p>Patient ID Type of test</p> <p><b>NOTE:</b> <i>The instrument will keep track of the strip positions in the instrument.</i></p> <p>* Only available in LIS software.</p>
<b>Manual Paper Protocol</b>	<p>This protocol requires that you record the:</p> <p>Patient ID Strip ID Strip position</p>
<b>Touch Screen Protocol</b>	<p>This protocol requires that you type/tap on the patient ID on the correct strip position (in the instrument) with the test. You can also use the barcode reader or the keyboard to enter the patient id, select a row and scan the barcode or enter it with the keyboard.</p>
<b>External Barcode Reader</b>	<p>This protocol requires that you use the Barcode scanner and scan the Patient ID barcode and then scan the respective strip ID barcode.</p> <p><b>NOTE:</b> <i>The instrument will keep track of the strip positions in the instrument.</i></p>

## Run list (LIMS protocol)

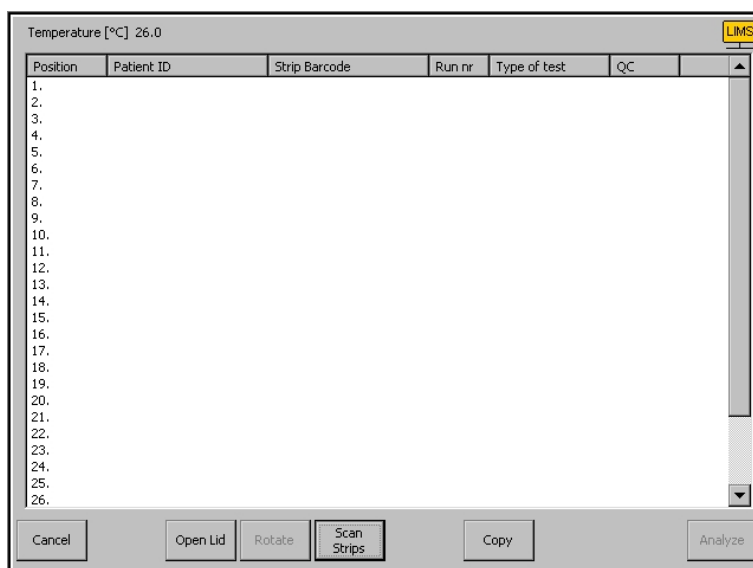


In the run list the test orders are displayed when a patient ID is scanned. The instrument displays all test orders received for that Patient ID. The analyses process consists of matching each selected row (Patient ID, type of test) with corresponding Strip ID by scanning the strip barcode with the external barcode scanner and confirming this linkage. The position of the test strips will be displayed once **Scan Strips** is performed. Pressing **Single-select/Multi-select** button will toggle row select mode and allow selecting more than one row. Counters **Items** and **(Orders)** show number of tests in run list and total number of test orders received from LIMS. Pressing **Cancel** will take you to the previous menu.

Button	Explanation
<b>Add sample</b>	By pressing <b>Add sample</b> a patient ID input dialog is opened. Enter patient ID and close dialog by pressing <b>Add sample</b> again.
<b>Open Lid / Close Lid</b>	By pressing <b>Open Lid</b> or <b>Close Lid</b> the loading sample area is opened or closed.
<b>Rotate</b>	By pressing <b>Rotate</b> the instrument will rotate the loading area to the next sample loading area and give you the option to insert a new Sys-Tray or remove a SysTray.
<b>Scan Strips</b>	Press <b>Scan Strips</b> when you have loaded all required samples. The instrument will scan the barcodes on the test strips. After the <b>Scan Strips</b> button is pressed and at least one strip barcode is recognized it will change to <b>Rescan</b> .
<b>Temperature</b>	This is the status information of the current temperature inside the climate chamber [°C]. <b>NOTE:</b> <i>Temperature has to be stable at 26°C before starting the analyses. The acceptance range is ± 2°C.</i>

<b>Analyse</b>	Press <b>Analyse</b> to start the run. <b>Analyse</b> button will be activated after at least one strip barcode is read.
<b>View all</b>	Pressing <b>View all</b> will display all test orders received from LIMS in the run list.
<b>Rescan</b>	<b>Rescan</b> enables the user to scan all 30 positions for another time without losing the already scanned barcodes of previous scans.
<b>Print</b>	By pressing <b>Print</b> the instrument will print the run list.
<b>Delete</b>	Row(s) can be deleted by selecting the row(s) and then pressing <b>Delete</b> button. A popup dialog prompts user if he/she is sure and a second popup dialog prompts user if he/she wants to delete the LIMS order as well, if not, the LIMS order(s) will remain in the instrument and can be run later.

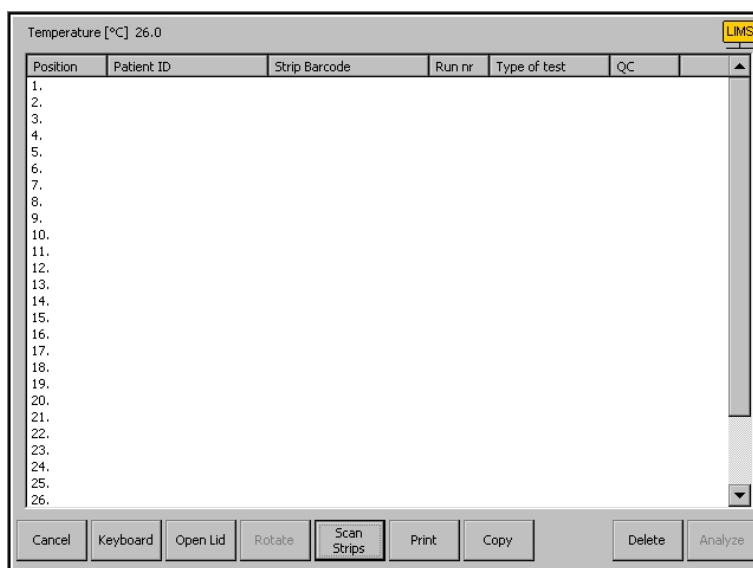
## Run list (manual protocol)



The analyses process is divided into several steps depending on choices. The third step is to insert the strips (with the protocol setting taking into account). Pressing **Cancel** will take you to the previous menu.

Button	Explanation
<b>Open Lid / Close Lid</b>	By pressing <b>Open Lid</b> or <b>Close Lid</b> to open or close the loading sample area.
<b>Rotate</b>	By pressing <b>Rotate</b> the instrument will rotate the loading area to the next sample loading area and gives the option to insert a new or remove a SysTray.
<b>Scan Strips</b>	Press <b>Scan Strips</b> when you have loaded all required samples. The instrument will scan the barcodes on the test strips. After the <b>Scan Strips</b> button is pressed and at least one strip barcode is recognised it will change to <b>Rescan</b> .
<b>Rescan</b>	<b>Rescan</b> enables the user to scan all 30 positions for another time without losing the already scanned barcodes of previous scans.
<b>Analyse</b>	Press <b>Analyse</b> to start the run. <b>Analyse</b> button will be activated after at least one strip barcode is read.
<b>Temperature</b>	This is the status information of the current temperature inside the climate chamber [°C]. <b>NOTE:</b> <i>Temperature has to be stable at 26°C before starting the analyses. The acceptance range is ± 2°C.</i>

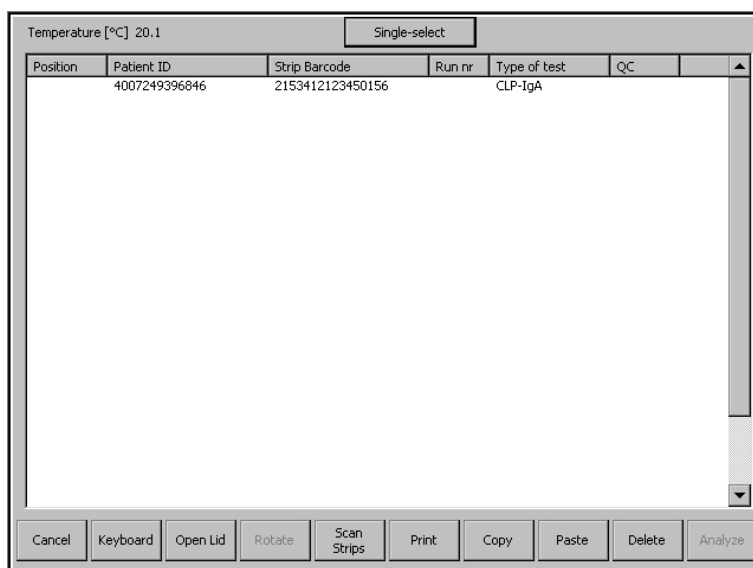
## Run list (touch screen protocol)



The analyses process is divided into several steps depending on choices. The third step is to insert the strips (with the protocol setting taking into account). Pressing **Cancel** will take you to the previous menu.

Button	Explanation
<b>Keyboard</b>	By pressing <b>Keyboard</b> a patient ID input dialog is opened. Enter patient ID and close dialog by pressing <b>Keyboard</b> again.
<b>Open Lid / Close Lid</b>	By pressing <b>Open Lid</b> or <b>Close Lid</b> to open or close the loading sample area.
<b>Rotate</b>	By pressing <b>Rotate</b> the instrument will rotate the loading area to the next sample loading area and gives the option to insert a new or remove a SysTray.
<b>Scan Strips</b>	Press <b>Scan Strips</b> when you have loaded all required samples. The instrument will scan the barcodes on the test strips. After the <b>Scan Strips</b> button is pressed and at least one strip barcode is recognized it will change to <b>Rescan</b> .
<b>Rescan</b>	<b>Rescan</b> enables the user to scan all 30 positions for another time without losing the already scanned barcodes of previous scans.
<b>Print</b>	By pressing <b>Print</b> the instrument will print the run list.
<b>Analyse</b>	Press <b>Analyse</b> to start the run. <b>Analyse</b> button will be activated after at least one strip barcode is read.
<b>Temperature</b>	This is the status information of the current temperature inside the climate chamber [°C]. <b>NOTE:</b> <i>Temperature has to be stable at 26°C before starting the analyses. The acceptance range is ± 2°C.</i>

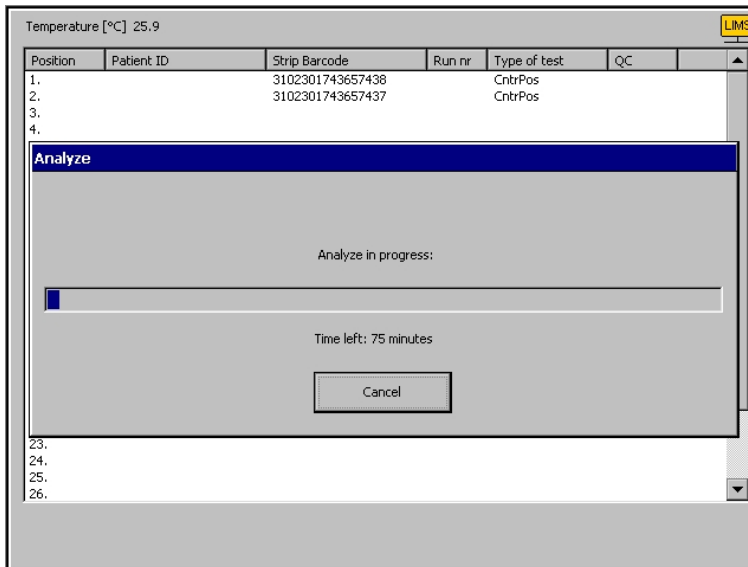
## Run list (external barcode reader)



The analyses process is divided into several steps depending on choices. The third step is to insert the strips (with the protocol setting taking into account). Pressing **Cancel** will take you to the previous menu.

Button	Explanation
<b>Keyboard</b>	By pressing <b>Keyboard</b> a patient ID input dialog is opened. Enter patient ID and close dialog by pressing <b>Keyboard</b> again.
<b>Open Lid / Close Lid</b>	By pressing <b>Open Lid</b> or <b>Close Lid</b> to open or close the loading sample area.
<b>Rotate</b>	By pressing <b>Rotate</b> the instrument will rotate the loading area to the next sample loading area and gives the option to insert a new or remove a SysTray.
<b>Scan Strips</b>	Press <b>Scan Strips</b> when you have loaded all required samples. The instrument will scan the barcodes on the test strips. After the <b>Scan Strips</b> button is pressed and at least one strip barcode is recognized it will change to <b>Rescan</b> .
<b>Rescan</b>	Rescan enables the user to scan all 30 positions for another time without losing the already scanned barcodes of previous scans.
<b>Print</b>	By pressing Print the instrument will print the run list.
<b>Delete</b>	Row(s) can be deleted by selecting the row(s) then pressing Delete button.
<b>Temperature</b>	This is the status information of the current temperature inside the climate chamber [°C]. <b>NOTE:</b> <i>Temperature has to be stable at 26°C before starting the analyses. The acceptance range is ± 2°C.</i>
<b>Analyse</b>	Press <b>Analyse</b> to start the run. <b>Analyse</b> button will be activated after at least one strip barcode is read.

## Analyse (run)



The analyse dialog shows the status of the analyse.



**WARNING:** Pressing **Cancel** will terminate the analysis and all its data.

If **Cancel** is pressed the analysis will be terminated and the device will return to the main screen.



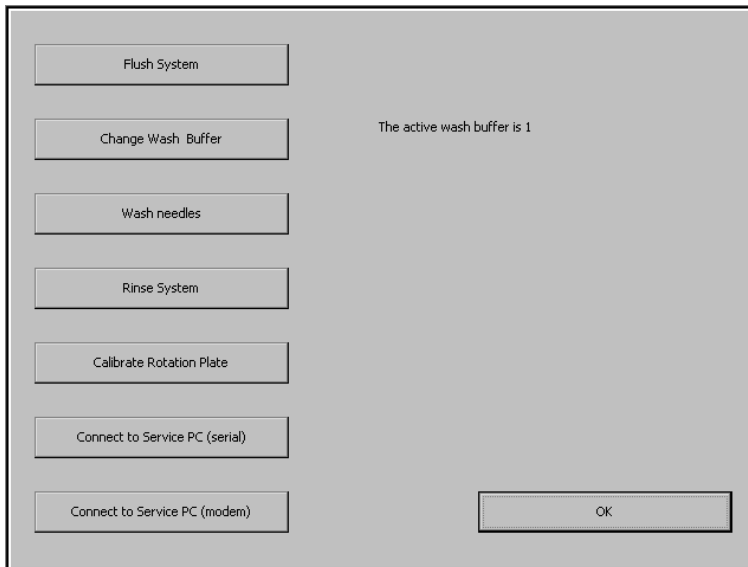
## Results

Temperature [°C] 26.0							LIMS
Position	Patient ID	Strip Barcode	Run nr	Type of test	QC	Result	
1.		3102301743657438	14	CntrPos	Passed	Pos	
2.		3102301743657437	14	CntrPos	Passed	Pos	
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							
11.							
12.							
13.							
14.							
15.							
16.							
17.							
18.							
19.							
20.							
21.							
22.							
23.							
24.							
25.							

Exit    Open Lid    Rotate    Rescan    Print    Copy    Paste    Delete    New

Button	Explanation
<b>Exit</b>	By pressing <b>Exit</b> the instrument will return to the main screen.
<b>Open Lid / Close Lid</b>	By pressing <b>Open Lid</b> or <b>Close Lid</b> to open or close the loading sample area.
<b>New</b>	By pressing <b>New</b> the analysis process will be restarted.
<b>Temperature</b>	This is the status information of the current temperature inside the climate chamber [°C]. <b>NOTE:</b> <i>Temperature has to be stable at 26°C before starting the analyses. The acceptance range is ± 2°C.</i>

## Service screen

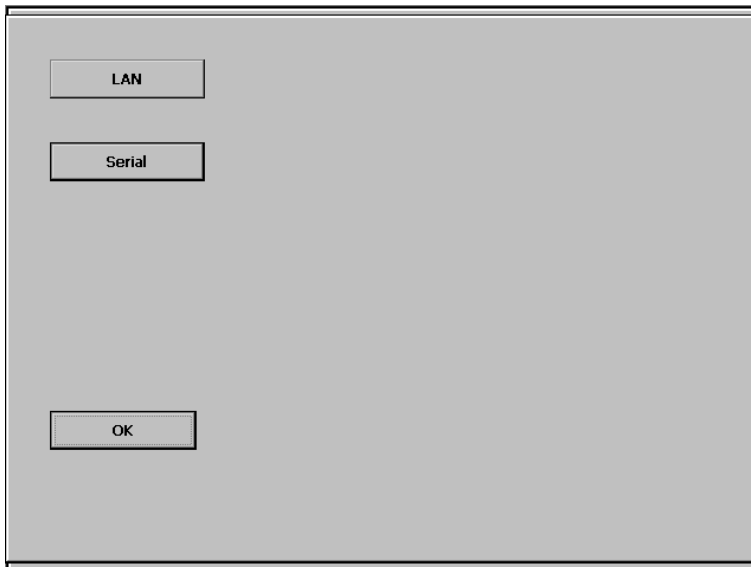


Tapping any of the buttons such as the **Flush System** button will initiate the flushing sequence. Pressing **Exit** will take you to the previous menu.

Button	Explanation
<b>Flush system</b>	The entire system is flushed. Wash station 1 and 2 is flushed with pre-defined Wash Buffer. The dispensing station is flushed with System Fluid.
<b>Change Wash Buffer</b>	The wash stations 1 and 2 is flushed with the other Wash Buffer.
<b>Wash needles</b>	The needles of dryer stations 1, 2 and 3 are flushed with Wash Buffer and held in Wash Buffer for 30 seconds. The dispensing station needles are flushed with System Fluid and held for 3 seconds.
<b>Rinse System</b>	The needles of wash stations 1 and 2 are flushed with System Fluid and thereafter flushed with Wash Buffer. The dispensing station is flushed with System Fluid.
<b>Calibrate Rotation Plate</b>	The rotation plate will be calibrated.
<b>Connect to Service PC (serial or modem)</b>	By selecting connect to pc and the type (serial or modem) the instrument is made ready for connection and communication with the service PC.

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## Connect LIMS screen



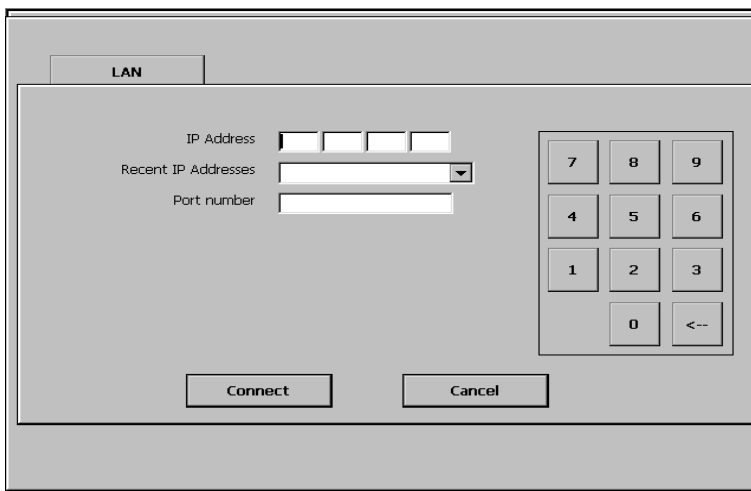
In the connect LIMS screen there is a choice of LAN or Serial connection. Tapping the **Serial** button will connect to LIMS using serial port on instrument. Tapping **LAN** button will display the LAN configuration screen.

**NOTE: LAN** is not supported by the Alegria® software for the moment.

Pressing **OK** will take you to the previous menu.

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## LAN configuration screen

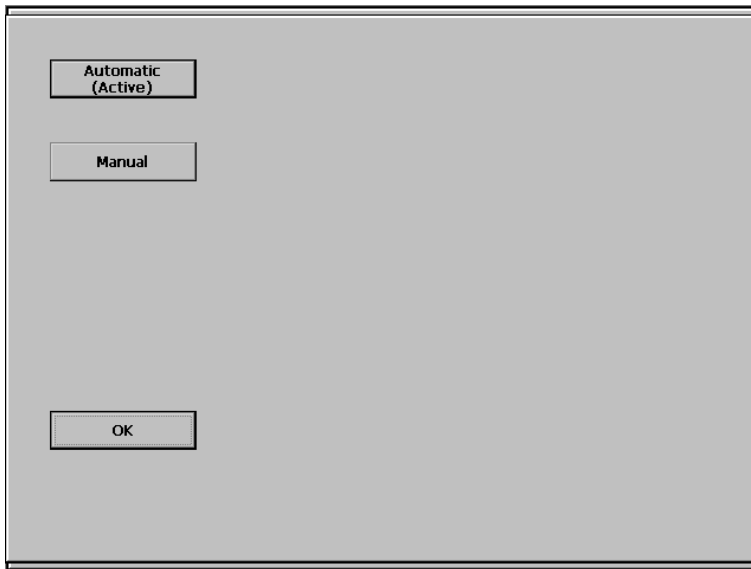


To connect enter the IP address of the LIMS host and the port number of the LIMS application using the digit key pad. Tapping the **Connect** button will initiate the connection.

To go back to the previous screen, tap the **Cancel** button. For information on IP-address and port number please contact your network administrator.

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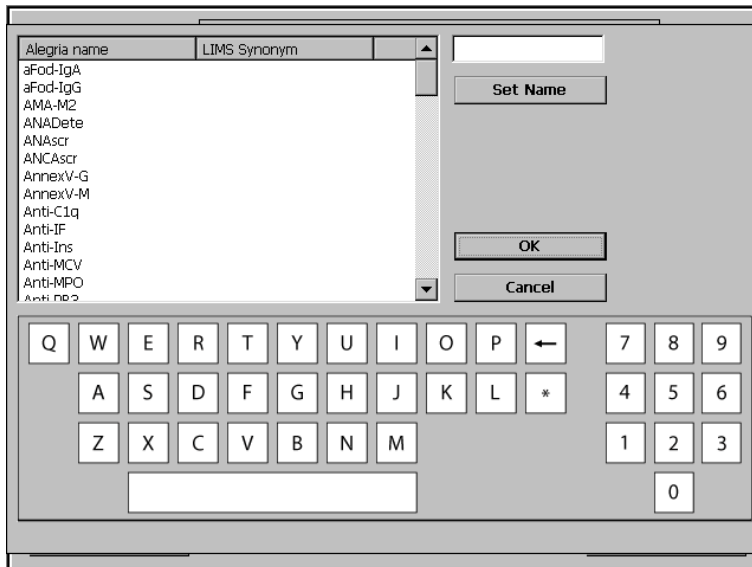
## LIMS Export Mode



The LIMS Export Mode screen has two different options for exporting test results to a LIMS. Automatic is the default option. In **Automatic** mode all results are automatically exported to LIMS as soon as they are available after an analyse, but only if the user is working in LIMS protocol. Otherwise in **Manual** mode the operator must manually export results from the archive.

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## LIMS Synonyms screen



The LIMS Synonyms screen lets you associate the test names with a corresponding LIMS synonym. These synonyms are only used in LIMS mode. If no synonym is entered for a specific test name, the Alegria® test name will be used under LIMS operation. If a synonym exists for a test name, it can be used as Test ID when sending test orders from a LIMS to the instrument. When the result is sent from the instrument to the LIMS, it is the synonym of the Test ID that is used.

The first time you enter LIMS Synonyms screen, there will be no synonyms set for any of the test IDs. To create a LIMS test ID synonym, tap on the desired test ID and write the synonym in the textbox. This can be done either with the on-screen keyboard, or by plugging in an external USB keyboard. The name must be at least one character, and no more than 20 characters long. Tapping **Set Name** button applies the change. When you are finished editing synonyms, tap the **OK** button to save your changes or **Cancel** to return to previous screen without saving.

**NOTE:** Each synonym must be unique which is checked by the instrument and if the synonym is not unique a warning is displayed.

## 10.5. ALEGRIA® PROTOCOLS

Start the instrument:

- Press "Start Analyse" button
- Enter a user name by using touch screen keyboard
- Press "Ok" button
- Press the respective protocol button and follow instructions below

After having started the instrument different protocols will be visible depending on the device configuration (with or without Laboratory Information Management System (LIMS)):

- a) LIMS Protocol: requests sorted by patient ID
- b) LIMS Protocol: view all requests
- c) Manual Paper Protocol
- d) Touch Screen Protocol: entering patient ID before scanning
- e) Touch Screen Protocol: entering patient ID after scanning
- f) External Barcode Reader Protocol

---

### a) LIMS Protocol: Requests sorted by patient ID

- By using the external barcode reader, scan first the patient ID and the appropriate test requests are shown in the run list
- Insert the corresponding test strips into the SysTray
- Highlight the test request on the display by tapping the corresponding line showing the patient ID and the test name;  
scan the corresponding test strip barcode with the external barcode reader; a message appears that prompts if the two scanned IDs are to be linked together; push the "OK" or "Cancel" button; repeat for every test request.
- A list can be printed by pressing "Print" button, this can be helpful when pipetting the samples
- Pipette the samples into the strips and ensure to pipette into the correct strip position in the SysTray
- Press "Open Lid" button
- Insert SysTray into instrument
- To insert more than one SysTray press the "Rotate" button to rotate to the next free SysTray position
- Press "Close Lid" button
- Press "Scan Strips" button
- Note: After scanning of the test strips with the internal barcode reader inside the instrument, the position of the test request on the display is set according to the position of the test strip inserted to the SysTray
- Press "Analyze" button
- Results will be transferred after the test run depending on the chosen LIMS export mode either automatically to the LIMS, or can be exported manually from the archive
- Printing is done automatically
- Remove SysTray
- To remove more than one SysTray, press the "Rotate" button to rotate to the next SysTray
- Press "New" button to start a new test or press "Exit" button to end analyse session

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## b) LIMS Protocol: View all requests

- Press "View all" button to call up all test requests stored on the Alegria® to the display
- Insert the corresponding test strips into the SysTray
- Highlight the test request on the display by tapping the corresponding line showing the patient ID and the test name; scan the corresponding test strip barcode with the external barcode reader; a message appears that prompts if the two scanned IDs are to be linked together, press the "OK" or "Cancel" button; repeat for each test request.
- A list can be printed by pressing "Print" button, this can be helpful when pipetting the samples
- Pipette the samples into the strips and ensure to pipette into the correct strip position in the SysTray
- Press "Open Lid" button
- Insert SysTray into instrument
- To insert more than one SysTray press the "Rotate" button to rotate to the next free SysTray position
- Press "Close Lid" button
- Press "Scan Strips" button
- Note: After scanning of the test strips with the internal barcode reader inside the instrument, the position of the test request on the display is set according to the position of the test strip inserted to the SysTray.
- Press "Analyze" button
- Results will be transferred after the test run depending on the chosen LIMS export mode either automatically to the LIMS, or can be exported manually from the archive
- Printing is done automatically
- Remove SysTray
- To remove more than one SysTray, press the "Rotate" button to rotate to the next SysTray
- Press "New" button to start a new test or press "Exit" button to end analyse session

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## c) Manual Paper Protocol

- Insert strips into SysTray
- ⇒ Note on paper protocol on which position the strips are entered in the SysTray.
- Pipette the samples into the strip and ensure to pipette into the correct strip position in the SysTray
- ⇒ Note on paper protocol in which strip the sample is filled
- Press "Open Lid" button
- Insert SysTray into instrument
- To insert more than one SysTray press the "Rotate" button to rotate to the next free SysTray position
- Press "Close Lid" button
- Press "Scan Strips" button
- Press "Analyze" button
- Printing is done automatically
- Remove SysTray
- To remove more than one SysTray, press the "Rotate" button to rotate to the next SysTray
- Press "New" button to start a new test or press "Exit" button to end analyse session

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## d) Touch Screen Protocol: Entering patient ID before scanning

- Insert strips into SysTray
- Press "Keyboard" button and enter patient ID by using the touch screen, or use the external barcode reader and note in which position the patient ID is entered
- Pipette sample into strip and ensure to pipette into the correct strip position in the SysTray according to entered patient ID on the touch screen
- Press "Open Lid" button
- Insert SysTray into instrument
- To insert more than one SysTray press the "Rotate" button to rotate to the next free SysTray position
- Press "Close Lid" button
- Press "Scan Strips" button
- Press "Analyze" button
- Printing is done automatically
- Remove SysTray
- To remove more than one SysTray, press the "Rotate" button to rotate to the next SysTray
- Press "New" button to start a new test or press "Exit" button to end analyse session

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## e) Touch Screen Protocol: Entering patient ID after scanning

- Insert strips into SysTray
- Press "Open Lid" button
- Insert SysTray into instrument
- To insert more than one SysTray press the "Rotate" button to rotate to the next free SysTray position
- Press "Close Lid" button
- Press "Scan Strips" button
- Press "Keyboard" button and enter patient ID by using the touch screen, note in which position the patient ID is entered
- A list can be printed by pressing "Print" button, this can be helpful when pipetting the samples
- Press "Open Lid" button
- Remove SysTray
- To remove more than one SysTray, press the "Rotate" button to rotate to the next SysTray
- Press "Close Lid" button
- Pipette sample into strip and ensure to pipette into the correct strip position in the SysTray according to entered patient ID on the touch screen
- Press "Open Lid" button
- Insert SysTray into instrument
- Press "Close Lid" button
- Press "Scan Strips" button
- Press "Analyse" button
- Printing is done automatically
- Remove SysTray
- To remove more than one SysTray, press the "Rotate" button to rotate to the next SysTray
- Press "New" button to start a new test or press "Exit" button to end analyse session



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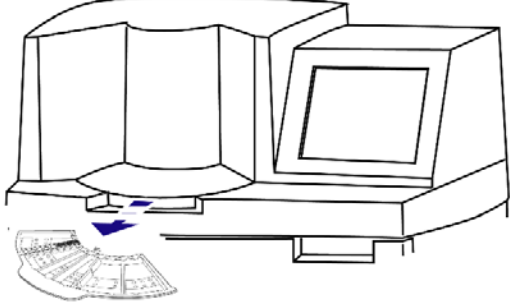
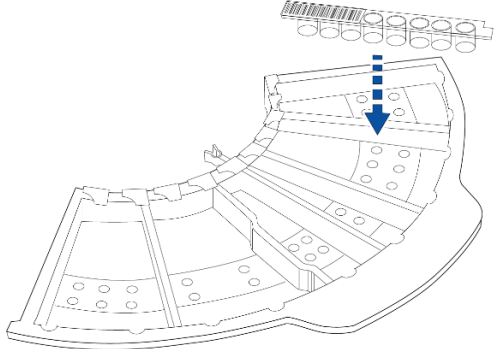
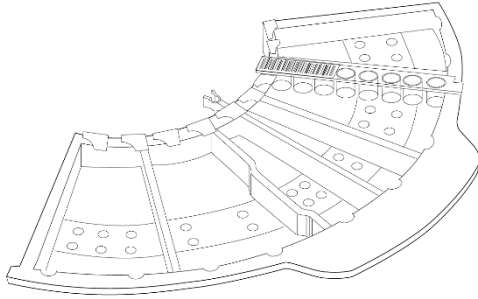
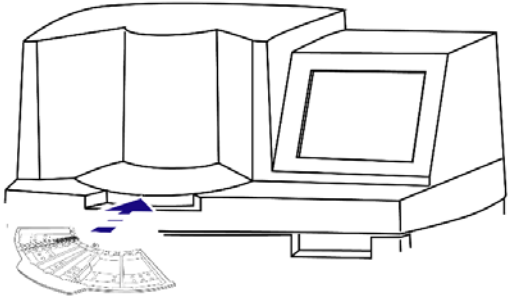
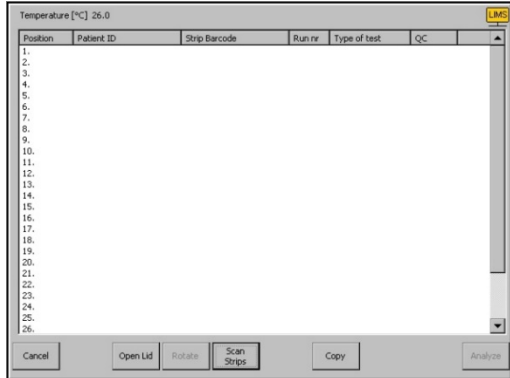
## a) External Barcode Reader Protocol

- Insert strips into SysTray
- By using external barcode reader scan first the patient ID and then the strip ID; a message appears that prompts if the two scanned IDs are to be linked together, press the OK or Cancel button
- A list can be printed by pressing "Print" button, this can be helpful when pipetting the samples
- Pipette sample into strip and ensure to pipette into the correct strip position in the SysTray
- Press "Open Lid" button
- Insert SysTray into instrument
- To insert more than one SysTray press the "Rotate" button to rotate to the correct SysTray position
- Press "Close Lid" button
- Press "Scan Strips" button
- Note: After scanning of the test strips with the internal barcode reader inside the instrument, the position of the test request on the display is set according to the position of the test strip inserted to the SysTray
- Press "Analyze" button
- Printing is done automatically
- Remove SysTray
- To remove more than one SysTray, press the "Rotate" button to rotate to the next SysTray
- Press "New" button to start a new test or press "Exit" button to end analyse session

# 11. REPLACEMENT PROCEDURES

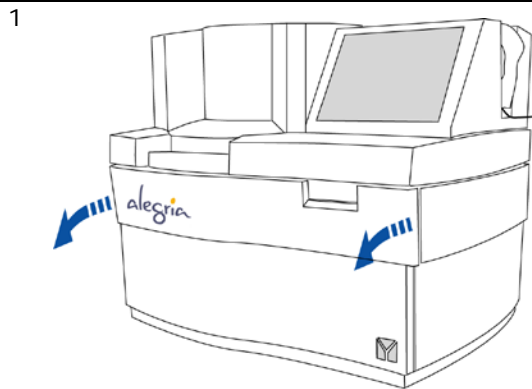
The following section shows how to replace or how to conduct normal use tasks.

## How to load and exchange SysTrays / sample strips

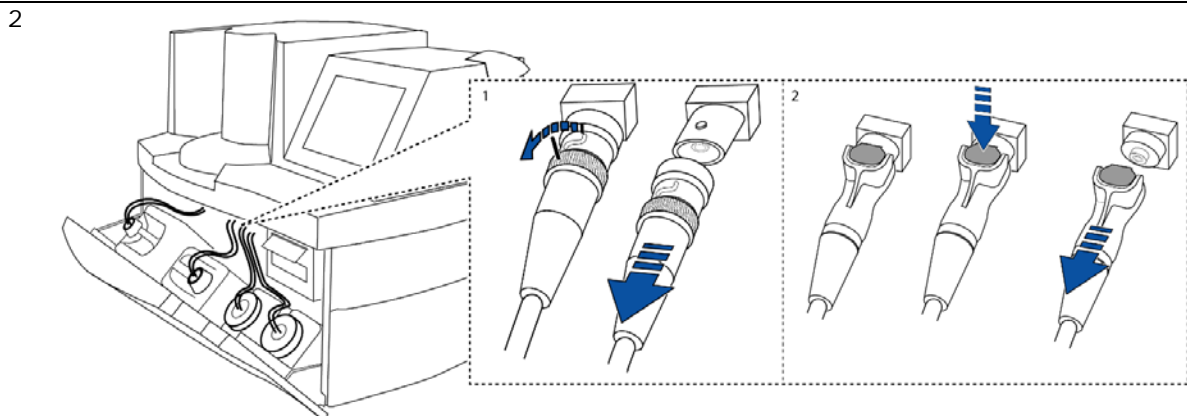
<p>1</p>  <p>Open the sample loading door by pressing the button <b>Open Lid</b>.</p>	<p>2</p>  <p>Remove SysTray from the analyser (lift out).</p>
<p>3</p>  <p>Remove or add sample strips, by lowering or raising the sample strip(s) into the SysTray.</p>	<p>4</p>  <p><b>NOTE:</b> Orientation of the barcode is towards the center of the carousel.</p>
<p>5</p> 	 <p>Load the SysTray into the analyser and press the button <b>Rotate</b> to load next SysTray or <b>Close Lid</b>, press <b>Scan Strips</b> and finally press <b>Analyse</b>.</p>

## How to empty waste fluid and load reagent fluids

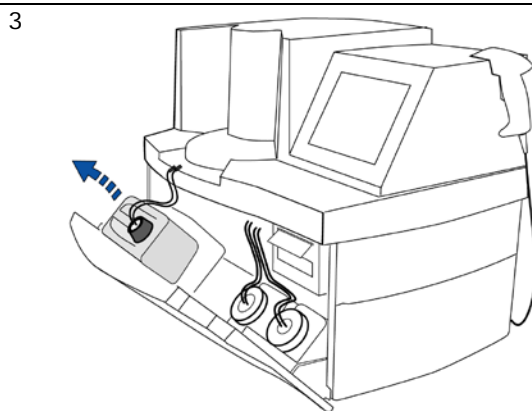
**!** **WARNING:** Do not refill or empty containers in or near the device!



Open the door to the fluid compartment.



Disconnect the level sensor (1) and fluid coupling (2) from the device (turn the level sensor connector and pull it gently out). The Fluid coupling, press the button on top and pull gently out.

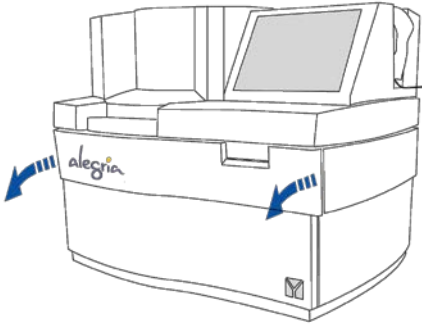
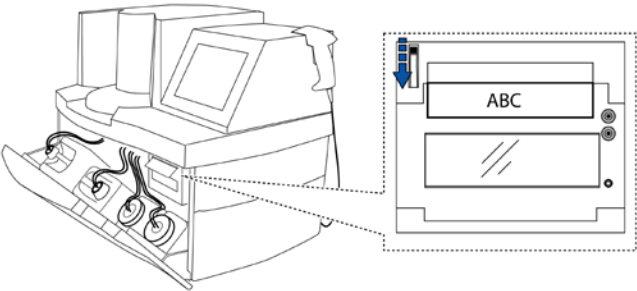
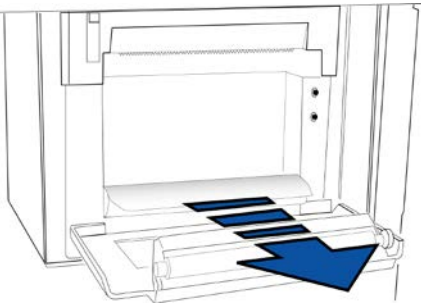
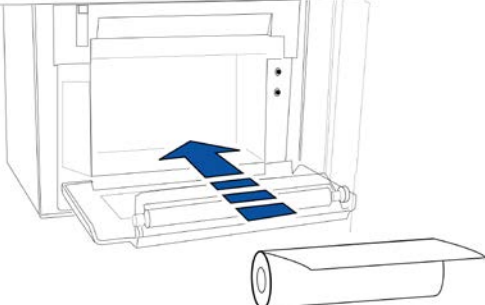
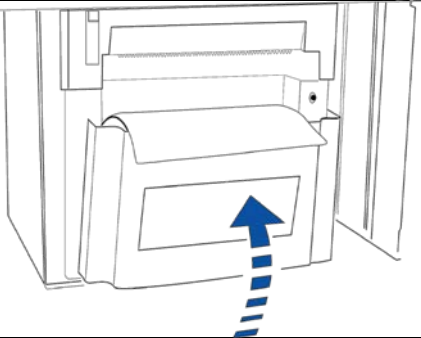
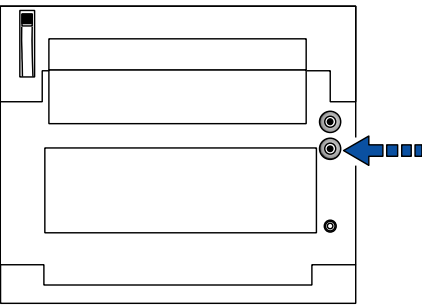
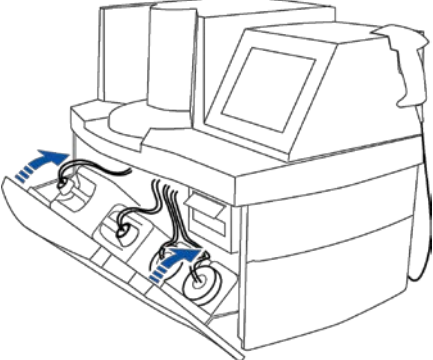


Remove the fluid container, refill or empty the container at appointed cleaning or fluid handling station or according to hospital/laboratory requirements.

Reverse order to install container.

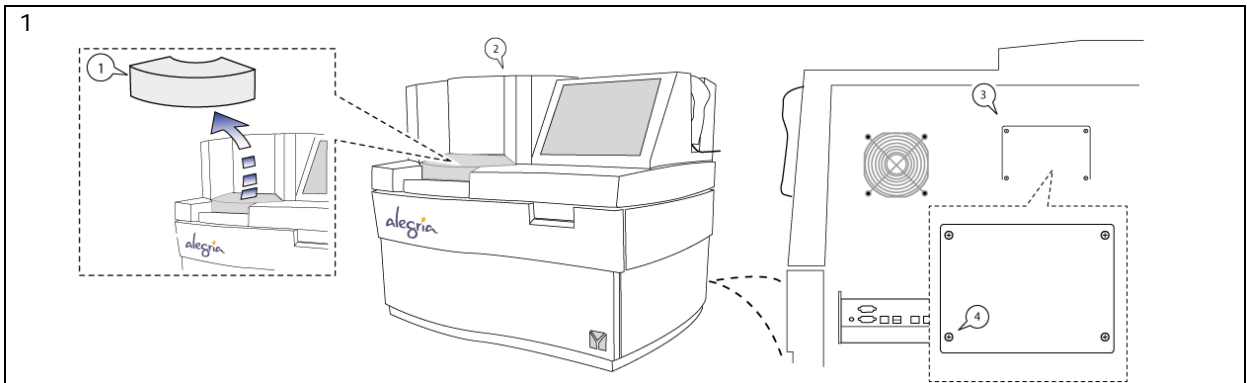
**NOTE:** Connect the containers to respective connector (colour coded).

## How to load printer paper

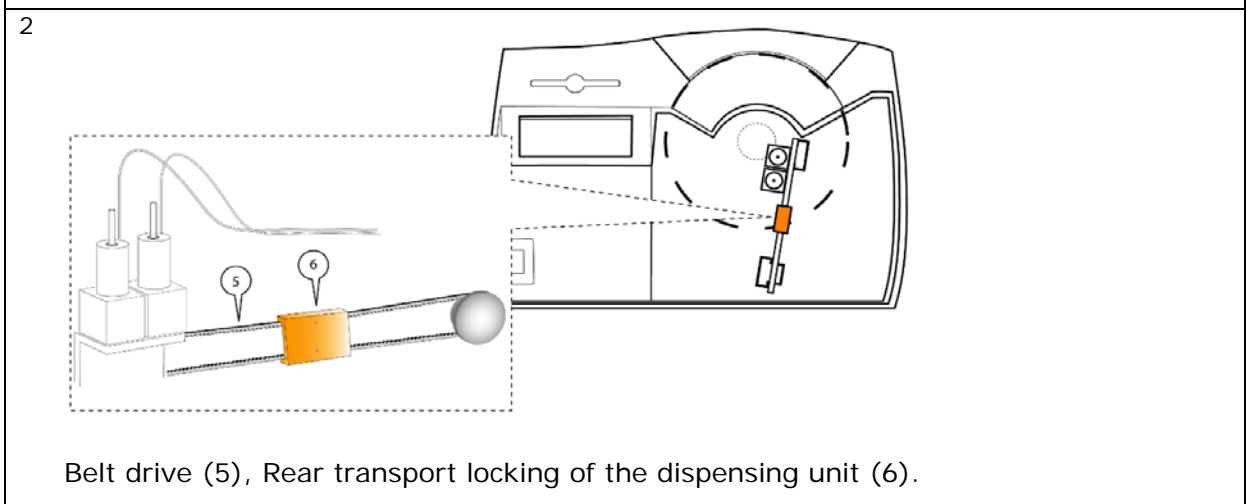
<p>1</p> 	<p>2</p> 
<p>Open the door to the fluid compartment.</p>	<p>Open printer compartment door by pushing the lever down (door opens).</p>
<p>3</p> 	<p>4</p> 
<p>Remove the old paper roll.</p>	<p>Replace the paper roll, note down the paper orientation.</p>
<p>5</p> 	<p>6</p> 
<p>Close the printer compartment door by gently pushing the door back.</p>	<p>Press the Form Feed button so there is approximately 5 cm paper on the outside of the printer (makes it easier to feed the paper through the front cover door).</p>
<p>7</p> 	
<p>Close the door to the fluid compartment.</p>	

## How to remove transport locking

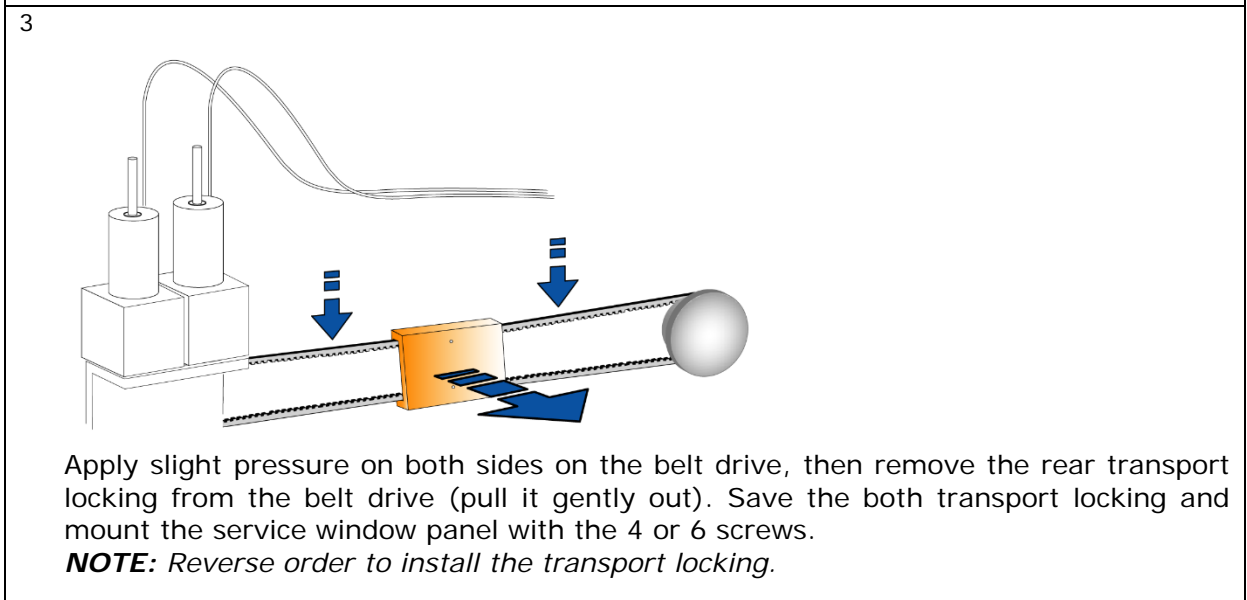
**⚠ WARNING:** Remove the power cord from the device and wall outlet! It is mandatory that authorised service personnel carry out this procedure.



First remove the front transport locking of the rotation plate (1). On the backside of the Alegria® instrument (2) locate the service window panel (3) and remove the panel by unscrewing the 4 or 6 screws (4).



Belt drive (5), Rear transport locking of the dispensing unit (6).



Apply slight pressure on both sides on the belt drive, then remove the rear transport locking from the belt drive (pull it gently out). Save the both transport locking and mount the service window panel with the 4 or 6 screws.

**NOTE:** Reverse order to install the transport locking.

## 12. QUALITY CONTROL

### 12.1 CALIBRATION

The analyser is factory-calibrated (dispensing volume calibration) and during start-up the mechanical parts (*rotation plate, dispense needle and wash stations*) are automatically calibrated for position with the help of optical sensor.

### 12.2 VALIDITY OF ASSAY RUN

Good laboratory practice requires that quality control samples should be included in every run to check assay performance.

#### Internal quality check

Each Alegria® Test Strip contains a control in well 5 (see page 12).

*If the internal quality check for this control fails, the result of this particular Alegria® Test Strip is invalid and the user will be notified on the display and on the printout.*

*Performance of the Alegria® instrument can be monitored by running special Alegria® IVD assays available from ORGENTEC Diagnostika GmbH:*

ORG 310 Alegria® Positive Control

ORG 311 Alegria® Negative Control

## 13. ASSAY RESULTS

The Alegria® Test Strip is based on the proprietary SMC®-Technology (Sensotronic Memorised Calibration): *explanation of the SMC technology see chapter 7, p.13.*

The Alegria® Instrument reports results for each sample analysed per a specific assay protocol. The results for each specific assay type are reported as semiquantitative or quantitative numeric values and a qualitative result (positive or negative).

Data reported on screen or printout:

- Date + time
- Assay ID: abbreviation of product name
- Patient ID
- Assay result: numeric value + qualitative result / invalid (quality check failed)
- Strip ID: complete barcode read from the Alegria® Test Strip

#### Example of printout:

```
2017-04-20 13:39 User: ORGENTEC Test: RFIgA
Pat ID: SB11370A      Res: 161.8 U/ml      Pos
StripId: 2223806350660892
```

## 14. SPECIAL FUNCTIONS

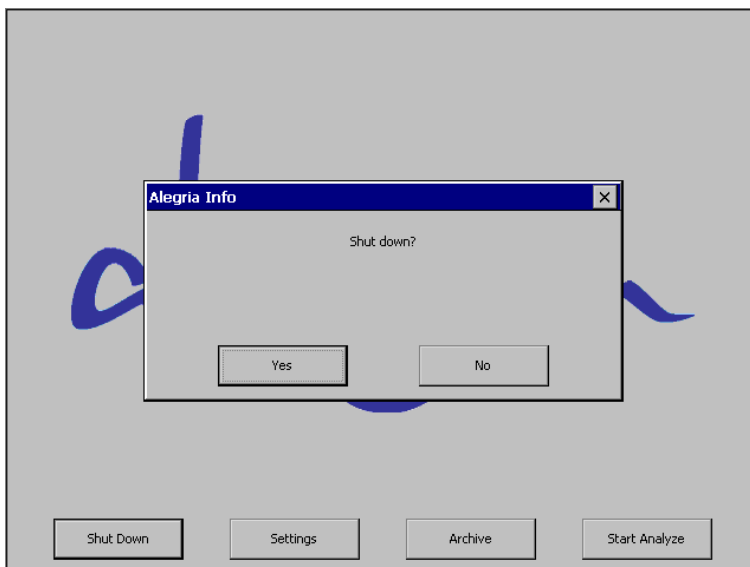
Not applicable

## 15. EMERGENCY SAMPLES

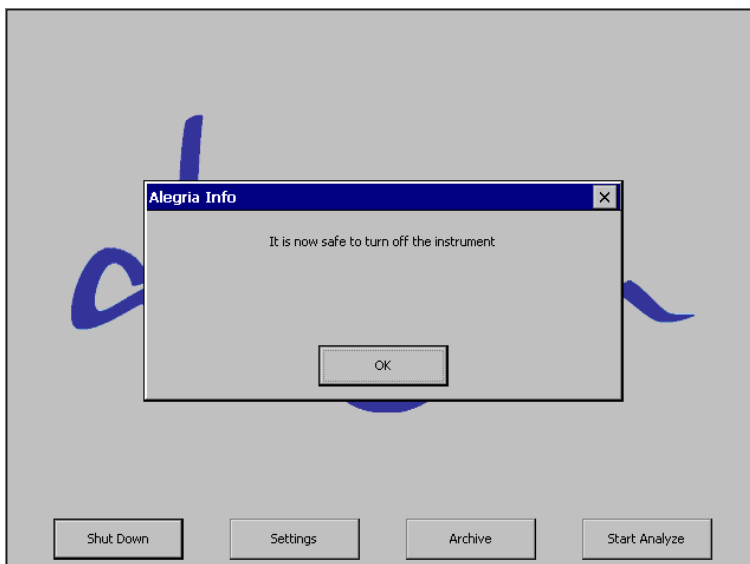
Not applicable

## 16. PROCEDURE FOR SHUT DOWN

The shut down process is divided into two steps, the instrument will guide you through the steps required:



First: Press **Shut Down** button and confirm by pressing **Yes**. The system is rinsing with System Fluid, no user interaction required.



Second: Press **OK** and turn off the power switch, see Power off procedure, [p. 19](#), for reference.

## 17. DISPOSAL

For disposal of the analyser or parts thereof, contact your local representative or see below for general disposal recommendations.

Fill in form FD4.27H transport preparation before transporting the instrument.

# 18. CLEANING, MAINTENANCE AND SERVICE



## CLEANING

- Instrument: Clean the outside of the instrument regularly with a soft cloth dampened with water and a mild detergent or if needed a disinfectant.
- SysTrays: SysTrays can be cleaned with normal household cleaning detergents or soap and water (wipe them dry with a cloth before use). Do not clean the SysTrays with alcohol or similar cleaning detergents. Do not autoclave the SysTrays.

### WARNING

- Do not immerse the device or any input in any liquid or cleaning detergent.
- Do not pour any liquid or cleaning detergent into any device opening.
- Do not use strong solvents to clean the device.
- Do not clean any input or communication ports with any liquid or cleaning detergents unless an ORGENTEC representative or authorised personnel has approved that procedure.

## WASTE DISPOSAL

- Printer paper is not recyclable and should be disposed of as residual waste.
- System Fluid and diluted Wash Buffer can be drained.
-  Waste should be considered potentially infectious and shall be disposed of according to the local laboratory procedure for biohazard material.
-  Alegria® Test Strips shall be disposed of according to local laboratory procedure for biohazard material.

We recommend autoclaving for potentially infectious biological material (human specimen samples) or waste that might be contaminated with potentially infectious biological material.

## MAINTENANCE

Maintenance between regular services can be done by the user.

- **Daily maintenance**  
At least once a day restart the instrument in order to rinse the tubing system with System Fluid to avoid blockages.
- **Weekly maintenance**  
Once a week thoroughly clean all reagent containers (System Fluid, Wash Buffer, waste) using a brush and a commercially available laboratory detergent. After cleaning the reagent containers rinse thoroughly with deionised water.
- **Monthly maintenance**  
Perform Monthly Flush Routine to clean the internal tubing system of the instrument using **ORG 305 Flush Routine Solution** according to package insert.



## SERVICE

Service personnel authorised by ORGENTEC will install the Alegria® instrument and perform the annual instrument service (interval 12 months ±2 months).

### Service software

The device has the capability of computer diagnosis tools; authorised personnel perform the service software according to Service Software Manual.

 **Service Software Manual for Service personnel.**

### Software upgrade

For the processing of new Alegria® assays, it is necessary to update the software. The latest software version contains the latest Alegria® assays. Software up-dates are announced by the ORGENTEC marketing department to the authorised service personnel via Newsletter.

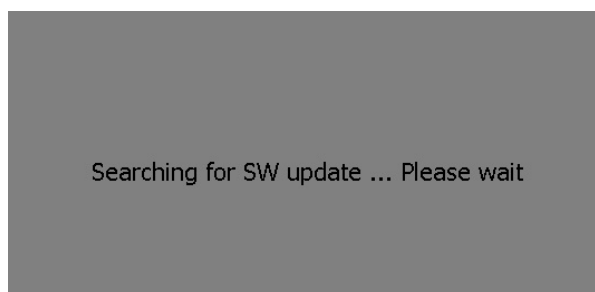
#### **WARNING**

- Only authorised personnel should upgrade the instrument software or be assisted by such person.
- Unauthorised upgrade or attempt to manipulate the instrument could result in personal injury, equipment damage or property damage.

#### **Software upgrade procedure**

- Shut down the instrument (see [Shut down procedure, p. 47](#)).
- Power up the instrument (see [Power on procedure, p. 19](#)) and wait for the beep.  
Now insert the USB stick prepared with the Alegria® software into the USB port at the rear panel (see [Scope of package delivery: point 7, p. 10](#)).

There will be a grey screen on the display with a message "Searching for SW update ... Please wait".



- Wait for the Alegria® software to start automatically after successful update of the software and remove the USB stick.  
If the Alegria® software should not start automatically after maximum 15 minutes please perform the software update procedure again after leaving the Alegria® turned off for at least 1 minute.

 *For more information on how to upgrade the Alegria® software see the latest Technical Bulletin.*

## 19. TROUBLE SHOOTING

This section describes the most anticipated errors related to consumables and user. The system has an error handling system that will display error messages when the system detects an error.

Symptom	Verify	Action	Ref.
Wash Buffer is empty	Check fluid level and sensor connected.	Refill if required and/or connect the sensor cable to the appropriate connector (colour coded).	See <a href="#">How to empty waste fluid and load reagent fluids</a> , p. 43.
System Fluid is empty	Check fluid level and sensor connected.	Refill if required and/or connect the sensor cable to the appropriate connector (colour coded).	See <a href="#">How to empty waste fluid and load reagent fluids</a> , p.43.
Waste container is full	Check fluid level and sensor connected.	Empty and connect the level sensor cable to the appropriate connector (colour coded).	See <a href="#">How to empty waste fluid and load reagent fluids</a> p.43.
Out of printer paper	Check printer.	Load new paper.	See <a href="#">How to load printer paper</a> , p. 44.
External barcode scanner not working	Check that the connection to the 5V (output) and barcode scanner is connected.	Connect if disconnected, if connected and not working then contact your representative.	See <a href="#">Scope of package delivery</a> p. 10 or <a href="#">Service Centers</a> , p. 51.
Temperature failure	Verify if the instrument is operated within the Operating conditions, p.5 and if the temperature was stable at 26°C during the analyses was started by the user.	Check the temperature before and during the analyse and contact your representative. The acceptance range during the analyses is 26 ± 2°C.	See <a href="#">Service centers</a> , p. 51.
Error message is displayed on the display	Note down the error message.	Contact your representative.	See <a href="#">Service centers</a> , p.51.
LIMS Connection Failed, please contact local IT-support	Check cables for LIMS connection. Verify that LIMS connection is enabled.	Contact local IT-support.	See <a href="#">Connect LIMS screen</a> screen, p. 35

## WARNING

- Only authorised personnel should troubleshoot / service the Alegria® instrument. Start by gathering information about the problem. Ask the operator about the issue and verify the problem.
- Troubleshooting by unauthorised personnel could result in personal injury, equipment damage or property damage.
- The user can handle replacement of consumables and corrections described in the symptoms list. If in doubt on how to perform these basic replacements and corrections then contact your local ORGENTEC representative.
- Follow the symptoms list and its actions if replacing any part or correction of a problem that the user is allowed to correct without special training.  
**NOTE:** *If the problem persists contact your local ORGENTEC representative for assistance.*

### **NOTE:**

*After any corrective action or service the Basic Function Test (see Service Manual for reference) shall be performed.*

*Exchange of consumables does not require Basic Function Test.*

## **20. SERVICE CENTERS**

### Germany

**ORGENTEC Diagnostika GmbH**

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D-55129 Mainz

Germany

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Fax +49 - (0)6131 / 92 58 58

Internet: <http://www.orgentec.com>

Authorised Service Representative:

### **Change Control:**

Version 3 replaces version 2 dated 2011-10

Reason for revision: Up-date to new labelling requirements and addition of functional principle of the Alegria® IVD assay.