



# User Manual



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# Symbols & Abbreviations

The following symbols and abbreviations are used in the product labeling and instructions for the MyCare Insite laboratory photometer.

Table 1: Product Labelling and User Manual Symbols
















Symbols	Explanation
	Conformity marking according to the directive 2014/30/EU of the European Parliament and of the European Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility
	Authorized Representative in the European Community
	Catalog number
	Batch Code
	Serial number
	Bluetooth
	Connection
	Power Supply / Device Status
	Use by
	Temperature limit
	Humidity Limitation
	Consult Instructions for Use
	Caution
	Contains sufficient for <n> tests
	Manufacturer

Table 1 continued: Product Labelling and User Manual Symbols






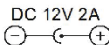

Symbols	Explanation
	<i>Production date</i>
	<i>Mark of electrical and electronic equipment in accordance with Article 14(4) of Directive 2012/19/EU (WEEE)</i>
	<i>Bluetooth</i>
	<i>Connection</i>
	<i>Power Supply / Device Readiness</i>
	<i>Electrical Symbol</i>

Table 2: Abbreviations and Definitions in the User Manual

Abbreviations and Definitions	Explanation
	<i>Operator's action</i>
Test Cartridge	<i>Cuvette sealed with Sample Collector containing a sample</i>
LED	<i>Light Emitting Diode</i>
PC	<i>Personal Computer</i>
ID	<i>Identification</i>
HIS / LIS	<i>Hospital Information System / Laboratory Information System</i>
AC	<i>Alternating Current</i>
DC	<i>Direct Current</i>
RFID	<i>Radio Frequency Identification</i>

# Table of Contents

- Symbols & Abbreviations.....2**
- Table of Contents ..... 4**
- Introduction.....7**
  - Welcome .....7
  - Serial number .....7
  - Firmware versions.....7
  - Notes.....7
  - Intended Use of the MyCare Insite ..... 8
  - About this User Manual..... 8
- System Description .....9**
  - Description of the MyCare Insite..... 9
  - MyCare Insite Analyser Interfaces ..... 9
  - Indicator lights.....10
  - How to Handle the MyCare Insite Analyser Laboratory Photometer .....10
  - How the MyCare Insite Analyser Laboratory Photometer Works .....10
  - Manufacturer’s Calibration..... 11
- Pictograms / Button Symbols .....12**
  - Touch Screen Symbols and their Functions.....12
- Getting Started .....13**
  - Inspecting the Package Contents .....13
  - MyCare Insite Packaging .....13
  - The Proper Placement of the MyCare Insite Analyser Laboratory Photometer.....14
  - Transport lock .....14
  - Connecting the Power Supply .....14
  - Proper Grounding.....15
  - The Touch Screen .....16
  - Starting & Operating the Touch Screen.....16
  - The MyCare Insite Launch Screen .....16

Changing the Language of the MyCare Insite Application .....	17
How to Switch the MyCare Insite Laboratory Photometer ON .....	17
The Automatic Start-Up and Warm-Up Processes .....	18
<b>Configuring the MyCare Insite .....</b>	<b>19</b>
Setting Normal Values/Range and Limits .....	19
Setting units .....	20
Configuring Inputs (Sex, Sample Type, Operator) .....	20
Configuring Interfaces .....	21
<b>Optional Equipment.....</b>	<b>22</b>
Printer, Barcode Scanner or PC .....	22
Using a Barcode Scanner to Scan Patient ID and/or Operator Information .....	23
How to Wake-Up the My Care Insite or Switch It OFF .....	23
<b>Test Procedures .....</b>	<b>24</b>
Overview of the Testing and Measuring Procedures .....	24
Operating Safety Precautions .....	25
Testing a Patient Sample .....	26
Viewing and Processing Test Results .....	28
<b>MyCare Online Services (MyCOS) .....</b>	<b>29</b>
MyCOS Synchronization.....	30
Synchronize all test results.....	30
MyCare Online Services Registration.....	32
MyCOS Web Access.....	33
Recommended web-browsers.....	33
Login Sceen .....	34
Result List .....	34
Export of Measurement Result List .....	35
Printing of Measurement Result list .....	36
Header User Interface Elements .....	36

<b>Quality Control (QC)</b>	<b>37</b>
QC materials	37
Handling QC Control Materials	37
Frequency of QC Testing	38
<b>Correlation</b>	<b>39</b>
Performing a Parameter Correlation Adjustment	39
<b>Cleaning Instructions</b>	<b>40</b>
Cleaning the Touch Screen display	40
Cleaning the Door & Chamber	40
Cleaning the Exterior	40
<b>External Interface Description</b>	<b>41</b>
Serial Interface	41
USB Interface	41
<b>Error Information and Troubleshooting</b>	<b>42</b>
Error Messages and Possible Causes	42
Service information	43
<b>Technical Specifications</b>	<b>44</b>
MyCare Insite Analyser	44
Power supply	44
Options	44
<b>Shutdown and Waste Management</b>	<b>45</b>
<b>Manufacturer Information</b>	<b>46</b>

# Introduction

## Welcome

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Congratulations on the purchase of your MyCare Insite.

Upon arrival of your MyCare Insite Analyser, we recommend that the serial number along with the firmware version be recorded in the table provided below. The additional rows in the table are for any firmware upgrades performed on your Analyzer. The recorded information is of value if technical support is needed.

## Serial number

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SN

For serial number (SN), see label on the back side of the analyzer or on the box

## Firmware versions

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	Date	Firmware version*
Upon receipt		
1. Firmware upgrade		
2. Firmware upgrade		
3. Firmware upgrade		

\* see "Connection Screen", page16

## Notes

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Technical Support:

Visit [MyCareInsite.com](http://MyCareInsite.com)

Email: [TechSupport@saladax.com](mailto:TechSupport@saladax.com)

## Intended Use of the MyCare Insite

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The MyCare Insite, consisting of the MyCare Insite Analyser laboratory photometer and the MyCare Insite Touch Screen, is intended as a general purpose laboratory instrument for the quantitative determination of clinical wet chemistry parameters.

The Insite is highly compact and is designed as a point of care measuring device for the MyCare Insite Tests.

## About this User Manual

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This user manual will guide you through the installation, operation and maintenance of your MyCare Insite. The user manual also explains how the photometer works, describes the quality assurance system and assists you in troubleshooting any errors or problems. When not used according to the User Manual the MyCare Insite may not perform properly or be damaged.

We recommend that you familiarize yourself with these instructions before operating the MyCare Insite. Some of the information in this user manual is marked with the following symbols:



Operator's action



Warnings and precautions; see accompanying documents



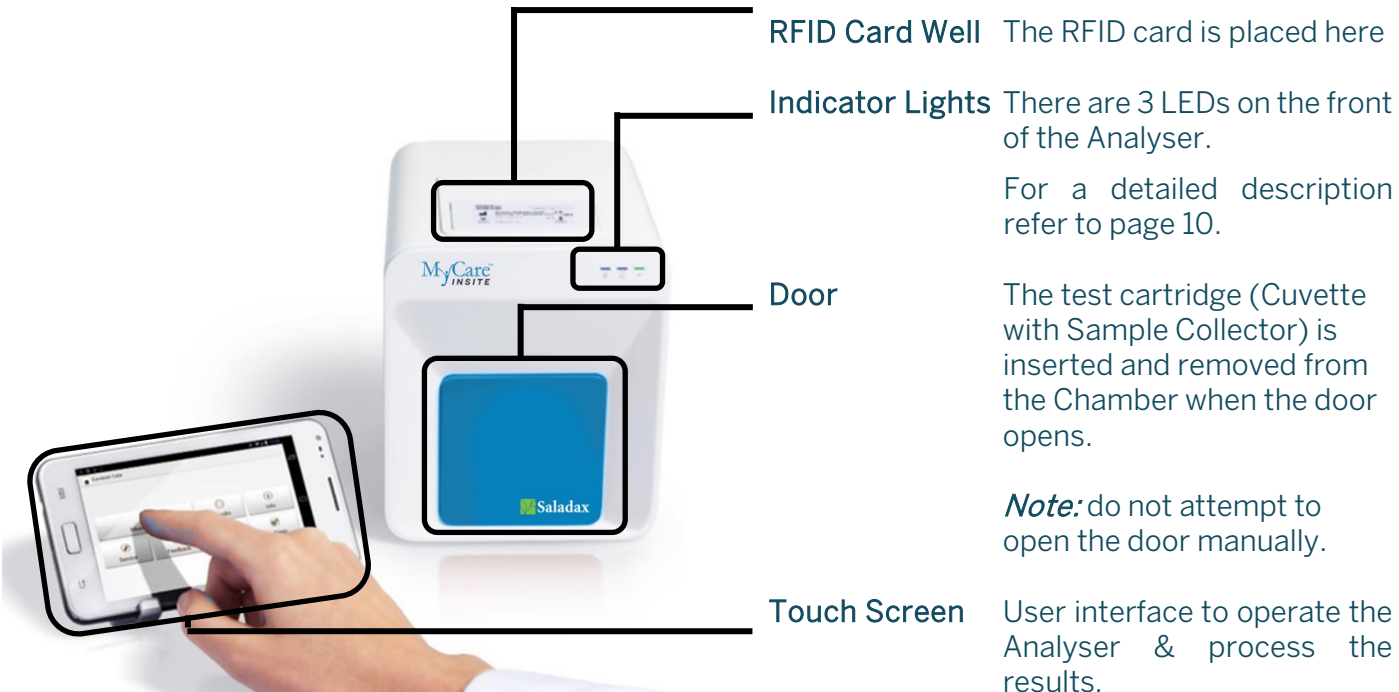
Refer to the user manual or test package insert and follow the instructions



# System Description

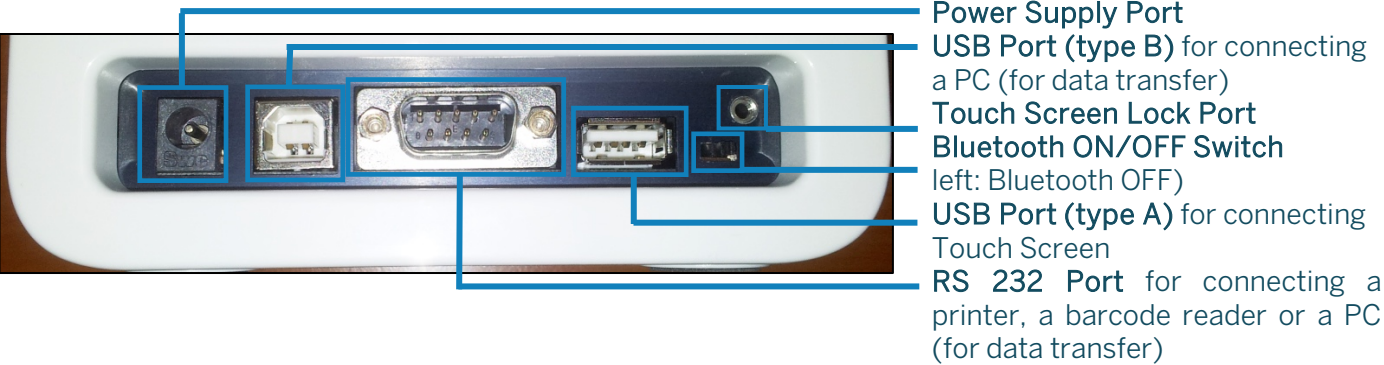
## Description of the MyCare Insite

This section introduces the general characteristics of the MyCare Insite Analyser and Touch Screen.



## MyCare Insite Analyser Interfaces

### Analyser Back



Do not use liquid cleaners on the Analyser or Touch Screen. Use a lint-free, slightly damp cloth only.

Do not attempt to open the Analyser door manually.




## Indicator lights

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MyCare Insite Analyser front



### LEDs on the MyCare Insite Analyser

-  This green LED indicates the Analyser status  
**Flashing:** the Analyser is warming up and testing cannot be started yet. (*Note:* warm-up takes approximately 10 min.)  
**On (green):** the Analyser is warmed up and ready for use  
**Off:** the Analyser is not plugged in
-  This blue LED indicates Touch Screen connection status  
**On (blue):** connection with Touch Screen is established  
**Off:** the Touch Screen is not connected
-  This blue LED indicates Bluetooth connection status  
**On (blue):** connection with Touch Screen is established  
**Flashing:** Analyser Bluetooth is activated but no Touch Screen is connected via Bluetooth  
**Off:** Bluetooth is switched off

**Note:** Use of the USB cable connection is recommended to keep the Touch Screen powered.


## How to Handle the MyCare Insite Analyser Laboratory Photometer

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The Analyser is operated solely by means of the Touch Screen. All the basic operating steps are displayed as symbols in *Table 1* (page 2), and *Table 2: Abbreviations and Definitions* in the User Manual (page 3).

To activate a symbol tap it with a finger.

In order to perform a test, the RFID card enclosed in the test kit must first be placed on the analyser. This card contains all the data needed to perform the tests. No analysis can be started without the RFID test card.

The door opens automatically when a test is initiated by pressing the  button. After entering all the requested data on the Touch Screen and inserting the test cartridge (Cuvette closed with Sample Collector) into the Chamber, close the door. The test starts automatically. After the test is completed, the door opens automatically and the test cartridge is removed.

The door prevents ambient light, dust, dirt and humidity from entering the Analyser during the testing process, and when the Analyser is not in use.

Please make sure the door is closed whenever the Analyser is not in use.

## How the MyCare Insite Analyser Laboratory Photometer Works

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The MyCare Insite Analyser laboratory photometer is a measuring device. To perform a test, the MyCare Insite Analyser is loaded with a test cartridge (Cuvette with Sample Collector containing a sample). The Analyser automatically processes the test when the door is closed. The latest LED

technology means maintenance-free operation.

The Analyser is equipped with an RFID card-reader module. RFID cards are necessary for performing all testing; they are included in the MyCare Insite Test kits and are specific to the kit. The Cuvette, Sample Collector and RFID card are color coded. Check that the RFID card, Cuvette, and Sample Collector are of the same color. RFID cards contain all the specific steps necessary for the Analyser to perform tests, as well as lot data, and calibration data. The Analyser performs all the tests automatically according to the information on the RFID card.

Test components are incubated and combined by the Analyser to generate a reaction that absorbs light according to the amount of drug in the sample. The photometer unit performs the analysis with a light diode. The absorption of light rays is measured during this process and the measured value is then mathematically converted into a test result. The result is displayed on the Touch Screen. Optionally, results can be exported to an external computer or an HIS/LIS and can also be printed out using an external printer.

After the test process is complete, the door opens automatically, and the test cartridge (Cuvette with Sample Collector) can be removed and discarded. After confirming the result on the Touch Screen and closing the Analyser door, the device is ready to perform the next test.

## **Manufacturer's Calibration**

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The MyCare Insite Analyser is manufactured according to the highest quality standards to produce safe and accurate test results. Every Analyser is inspected and calibrated during the manufacturing process.

# Pictograms / Button Symbols

## Touch Screen Symbols and Their Functions

Table 3: MyCare Insite Touch Screen symbols

Tap a symbol on the Touch Screen to activate the described function.

Symbol	Name	Function
	<i>MyCare Insite App</i>	<i>Starts the MyCare Insite app</i>
	<i>Browser</i>	<i>Opens the Web Browser on the Touch Screen</i>
	<i>Android Settings</i>	<i>Opens the Android settings menu</i>
	<i>Return arrow</i>	<i>Cancels an input OR returns to the previous screen or menu</i>
	<i>Return to main menu</i>	<i>Returns directly to the main menu</i>
	<i>Measurement</i>	<i>Opens the menu for test data entries</i>
	<i>Results</i>	<i>Opens the result list screen</i>
	<i>MyCare Insite Settings</i>	<i>Opens the Settings menu</i>
	<i>Edit</i>	<i>Opens an entry or value so it can be edited</i>
	<i>Confirm</i>	<i>Confirms the input</i>
	<i>Abort to main menu</i>	<i>Cancels an action and returns to the main menu</i>
	<i>Start analysis</i>	<i>Starts the test process</i>
	<i>Print</i>	<i>Opens the print / export / mail dialogue</i>
	<i>Filter</i>	<i>Opens the Filter Options</i>
	<i>Transmit</i>	<i>Opens the Export dialogue</i>
	<i>Analyser Data Button</i>	<i>Displays the photometric data of a test result</i>
	<i>Page forward</i>	<i>Displays the next page</i>
	<i>Page backward</i>	<i>Displays the previous page</i>
	<i>Recycle bin</i>	<i>Opens the delete dialogue</i>
	<i>Synchronize</i>	<i>Synchronises result(s) and Analyser status with the MyCare Insite servers</i>

# Getting Started

## Inspecting the Package Contents

For a quick overview of this section watch the MyCare Insite Getting Started Video at [MyCareInsite.com](http://MyCareInsite.com).

When unpacking the MyCare Insite, check the contents against the list below and examine the components for signs of shipping damage.

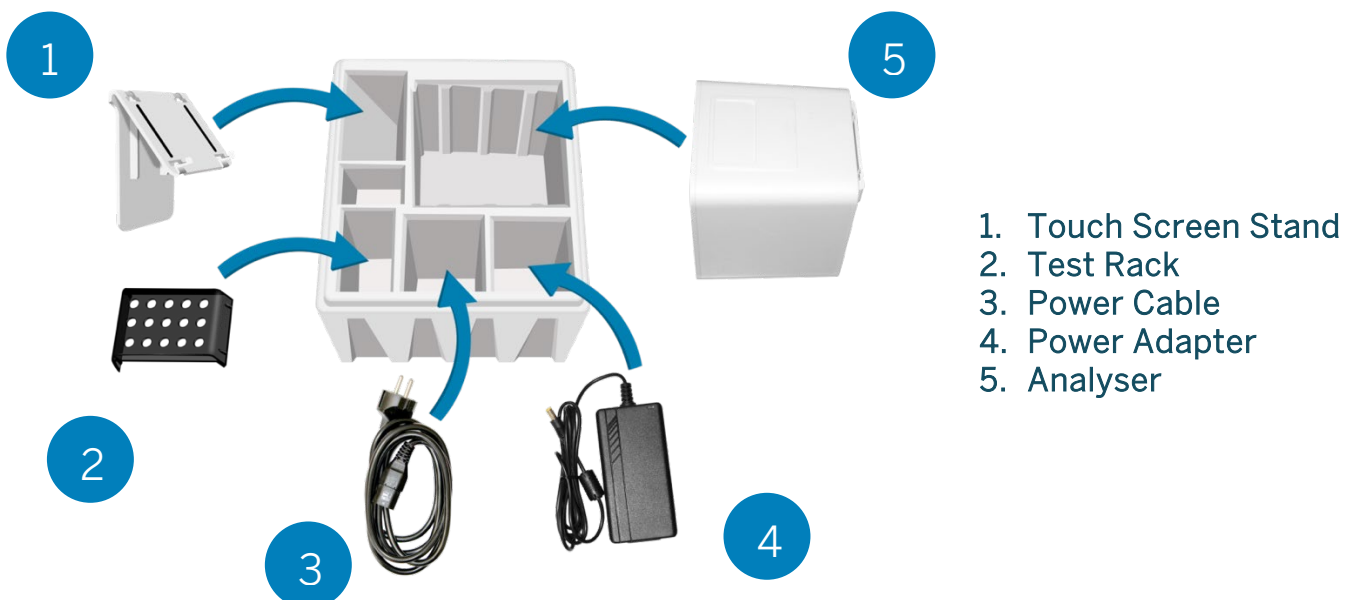
The MyCare Insite package contains:

- Touch Screen
- Touch Screen Starter Manual
- MyCare Insite Quick Reference
- MyCare Insite Analyser
- Power Adapter
- Power Cable
- Test Rack
- Touch Screen Stand
- Touch Screen Mounting Directions

If any part of the package is missing or damaged, please report this immediately to your Official Saladax Distributor. Keep the original packaging for transport and shipping.

## MyCare Insite Packaging

If the Analyzer must be returned to the manufacturer or before transport, please repack the Analyzer contents in the original packaging according to the following illustration:



**Note:** please remember to reinsert the transport lock (p. 11) into the Analyser door before repacking



**WARNING:** Incorrect packing and/or inappropriate packaging can cause severe damage to the Analyser

# The Proper Placement of the MyCare Insite Analyser Laboratory Photometer



Place the Analyser on a dry, clean, stable, and level surface. Make sure the Analyser has at least 10 cm of table surface and clearance on each side, and that the Analyser can be easily disconnected from the power source. Allow the Analyser to acclimate to the ambient room temperature before operation.

The Analyser can be damaged by:



Condensing humidity and water  
Heat and large temperature fluctuations  
Direct sunlight  
Vibrations (e.g. from centrifuges and dishwashers)  
Electromagnetic radiation  
Electrostatic discharge

## Transport lock



Before first use, remove the transport lock by pulling it up from the Chamber of the Analyser.

**Note:** keep both the transport lock and the original packaging in case of a the Analyser must be re-packaged for transport. Transporting in the original packaging with the transport lock installed will prevent damage in transport.

## Connecting the Power Supply

*MyCare Insite Analyser Interfaces*



Power Supply Port  
USB Port (type B) for connect-  
ing a PC (for data transfer)  
Touch Screen-Lock Port  
Bluetooth ON/OFF Switch  
left: Bluetooth OFF)  
USB Port (type A) for  
connecting a Touch Screen  
RS 232 Port for connecting a  
printer, a barcode reader or a PC  
(for data transfer)



- Connect the power cable to the power adapter.
- Insert the plug from the power adapter into the power supply port on the back of the Analyser.
- Plug the power cable into the wall socket.

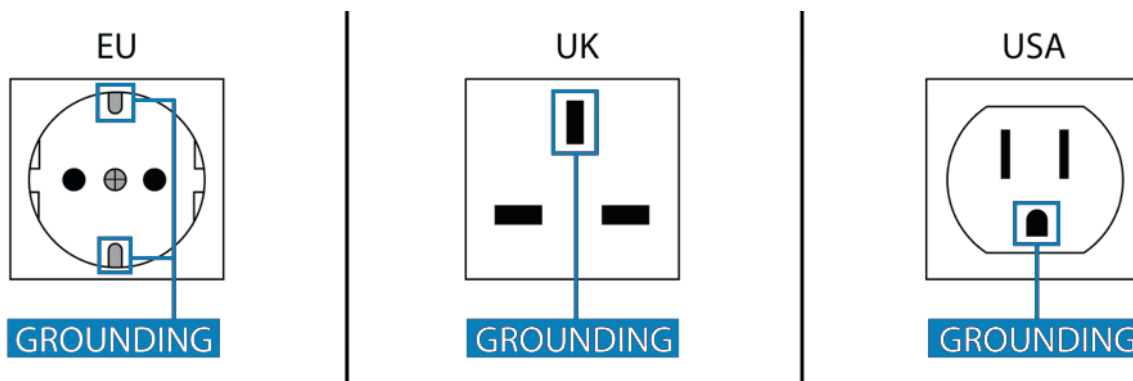


Always connect to the proper supply voltage. The power adapter voltage must comply with the regulations cited in the technical specifications on page 44. Ensure the electrical ground is correctly installed (page 15). Use only the power adapter provided to operate the Analyser.

## Proper Grounding

To ensure that the Analyser is properly grounded, use a 3-pole power outlet that includes neutral, hot and ground sockets. The MyCare Insite must be connected to a power outlet with a 3-pole plug.

Illustration of different power outlets with grounding



A certified electrician can confirm that the grounding meets requirements.

### EMC Related Caution:

This equipment and/or system complies with the International Standard EN61326-1 for electromagnetic compatibility for electrical equipment and/or system for measurement, control and laboratory use. However, an electromagnetic environment that exceeds the limits or levels stipulated in EN61326-1, can cause harmful interference to the equipment and/or device or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or device, if there is any undesired deviation from its intended operational performance, the electromagnetic interference must be identified and resolved before continuing to use the equipment and/or device. The following describes some common interference sources and remedial actions:

1. **Strong electromagnetic interference from a nearby emitter source such as an authorised radio station or cellular devices:**  
Install the equipment and/or system at another location if it is interfered with by an emitter source such as an authorised radio station. Keep the emitter source such as cellular devices away from the equipment and/or system.
2. **Radio-frequency interference from other equipment through the AC power supply of the equipment and/or system:**  
Identify the cause of this interference and if possible remove this interference source.
3. **Effect of direct or indirect electrostatic discharge:**  
Make sure all users and patients in contact with the equipment and / or system are free from direct or indirect electrostatic energy before using it. A humid room can help reduce this problem.



4. Electromagnetic interference with any radio wave receiver such as radio or television:  
If the equipment and / or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.

If the above suggested remedial actions do not solve the problem, consult your Distributor for additional suggestions.

## The Touch Screen

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The MyCare Insite Analyser is operated with a Touch Screen.

Insure the Analyser is plugged in. Connect the Touch Screen to the USB port (see page 9) of the Analyser and then turn on the Touch Screen.

An independent Touch Screen manual is included with the Touch Screen. It describes in detail the use of the Touch Screen, how to manage settings and establish a Bluetooth or USB connection between the Analyser and the Touch Screen.

## Starting & Operating the Touch Screen

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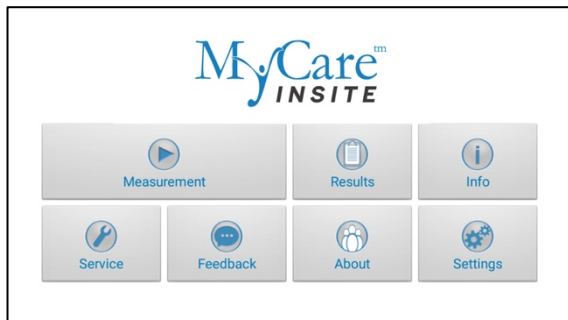
### 1. Connection Screen



The connection screen appears when the Touch Screen is connected to the MyCare Insite Analyser. The serial number, firmware version and wavelengths are displayed.

Tap *Next* to continue.

### 2. Main Menu



The MyCare Insite application starts and the main menu appears.

**Note:** while the MyCare Insite Analyser is warming up (indicated by the flashing green LED on the front, see page 10) the "Measurement" button is grey and inactive.

## The MyCare Insite Launch Screen

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### Launch Screen



The Launch Screen is shown when the Touch Screen is not connected to the Analyser or by pressing the Touch Screen home button.

Tap *Browser* to open the Android web browser.


Touch the MyCare Insite Logo to start the MyCare Insite app.

Touch *Settings* to open the Android setting menu.



## Changing the Language of the MyCare Insite Application

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The application language is automatically set to the language of the Touch Screen operating system. It can be changed by pressing the home button on the Touch Screen (the launch screen appears), then pressing  to open the settings. Swipe down and select *Advanced settings*, then *Language and input*, then *Language & region*, then *Language*, and choose a language. Press the home button to return to the launch screen.

**Note:** the MyCare Insite application supports several languages. If you choose a language in the system settings that is not supported by the MyCare Insite application, English will be used.

## How to Switch the MyCare Insite Laboratory Photometer ON

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The analyser is switched on by plugging the power cable into the socket. This launches the analyser's automatic start-up and warm-up processes. Please wait for these to be completed (approximately 10 minutes).

### When operating the Analyser:



The door protects the Analyser Chamber from dust, dirt and humidity. Empty the chamber after every test, and keep it closed when the Analyser is not in use.

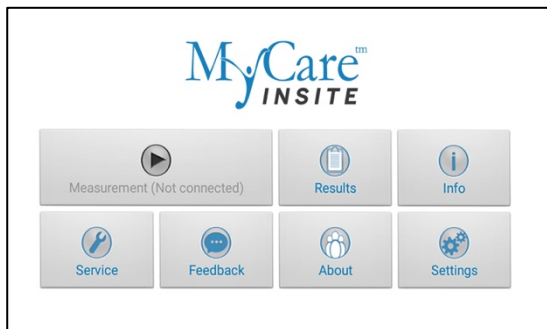
The door opens automatically. Do not attempt to open the door manually!

If an error message appears during an analysis, please consult the "Error information and troubleshooting" section on page 42.

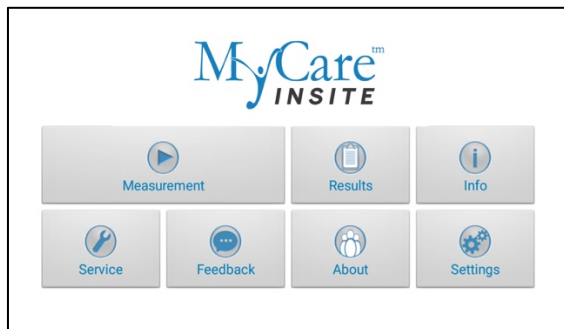
# The Automatic Start-Up and Warm-Up Processes

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## 1. Warm-up menu



## 2. Main Menu



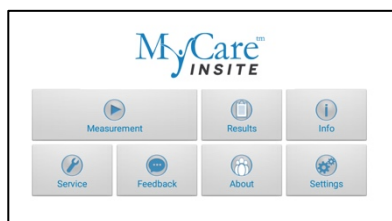
The automatic start-up procedure (indicated by the flashing green LED) starts as soon as the Analyser is connected to the power supply. It takes approximately 10 minutes for the Analyser to warm up to its proper working temperature. In colder environments it may take longer for the Analyser to reach operating temperature.


As soon as the initialization of the optical unit is completed, the  button turns from gray (locked) to blue and may be used. The Analyser is now operational.

# Configuring the MyCare Insite

You can configure your MyCare Insite laboratory photometer according to your needs before using it. To access the settings menu follow these steps:

## 1. Start-up menu



Tap  to open the Settings menu.

## 2. Settings menu



Tap the setting you want to configure. Swipe down to view all available options.



The following descriptions are examples. The configuration of the MyCare Insite may vary depending on the tests used.

**Note:** The Normal values/Range, units and sample types for a test can only be displayed if the RFID card for the test has been placed on the Analyser and read.

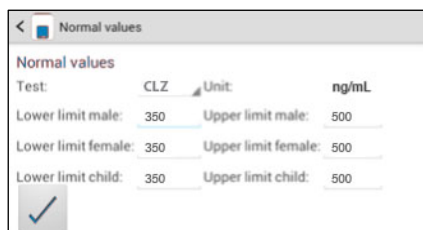
## Setting Normal Values/Range and Limits

### 1. Settings menu




Tap *Normal Values* to open the Normal values / Limits menu.

### 2. Normal values/limits menu, e.g. CLZ

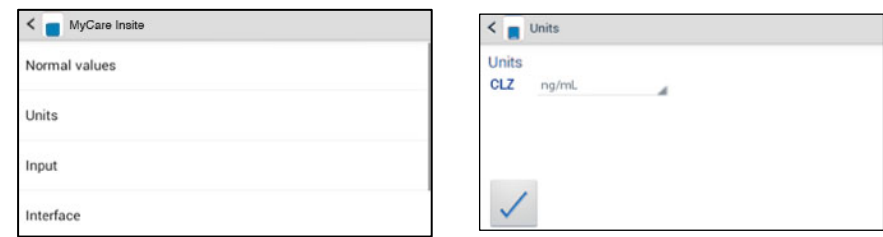


To change a limit, tap the value and change it using the Touch Screen keyboard that appears.

To change the test for which the normal values are displayed, tap  and select a test from the drop-down menu.

# Setting Units

1. Settings menu
2. Unit selection menu



Tap *Units* to open the Unit selection menu.

If alternate units are available, tap and select a unit in the drop-down menu. Confirm the change(s) with .

# Configuring Inputs (Sex, Sample Type, Operator)

1. Settings menu
2. Input menu
- 3.1 Default sex menu

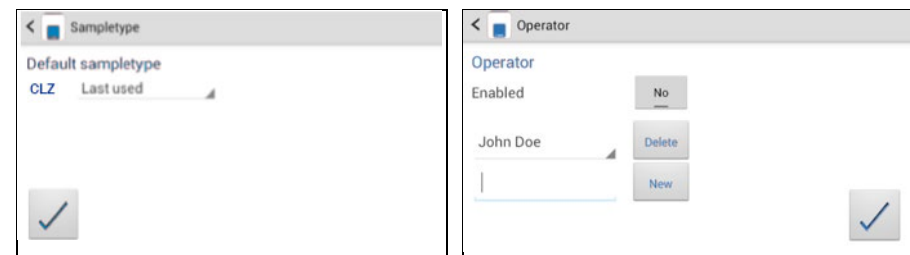


Tap *Input* to open the Input menu.

Tap a parameter and the respective menu will open. The following descriptions are provided in the order of the parameters in the Input menu.

Tapping opens a drop-down menu. Select which gender is to be used as the standard default. *Last used* means that the gender last used will always be selected. Control may be selected when a control is tested.

- 3.2 Sample Type menu
- 3.3 Operator menu



Tap and a drop-down menu opens, select which type of sample should be selected by default. *Last used* means the sample type last used will be selected. Confirm with . Press to cancel.

Enable the operator mode by tapping the button. To create a new operator, type the name in the box blank and then tap . To delete an operator, tap and select a name in the drop down menu, then tap .

# Configuring Interfaces

## 1. Setting menu



Tap *Interface* in the Settings menu. The Interface menu appears.

## 2. Interface menu



Tap an interface to configure. The respective configuration menu appears.

The following descriptions are in the order of the interfaces in the Interface menu.

## 3.1a Printer configuration menu

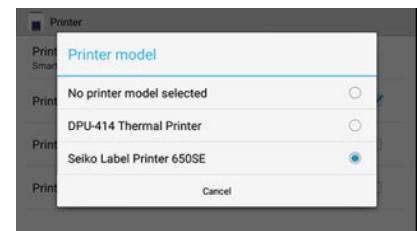


Tap on *Printer model* to select the standard printer model (see 3.1b)

*Print operator ID*, *lot number* and *serial number* are additional information that can be added to the printout. Tap a checkbox next to an option to select or de-select it.

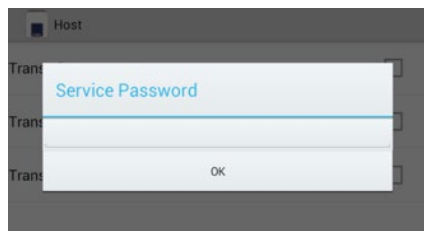
**Note:** the screenshot above is for demonstration purposes only. By default, all boxes are unchecked.

## 3.1b Standard printer model selection



Tap on the corresponding printer model to select your default printer. If *No printer model selected* is chosen you will be prompted to choose the desired printer model directly before the first printout.

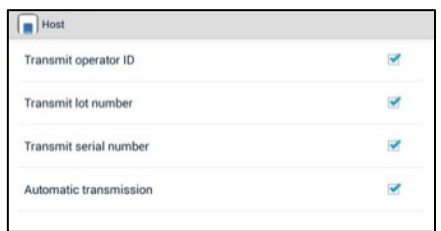
## 3.2a Host configuration password screen



The service password is required to change interface host options. Tapping on the input field opens the Touch Screen keyboard and the password can be typed. After pressing OK on the password screen, the host configuration menu opens.

If you do not know the Service Password, please contact your Official Saladax Distributor.

## 3.2b Host configuration menu



Tap a checkbox next to an option to select or de-select it. Check *Automatic transmission* for automatic transmission of the standard result information after the measurement is done via USB or serial port. Operator ID, lot number and serial number are additional information that can be added to the *Automatic transmission* or standard manual transmission format.

**Note:** the screenshot above is for demonstration purposes only. By default, all boxes are unchecked.

# Optional Equipment

## Printer, Barcode Scanner or PC

The following optional devices (not included in the standard delivery package) can be connected to the Analyser:

- An external printer – for optional test result printouts
- An external barcode scanner
- A PC – for the transfer of test data into a hospital or laboratory Information system (HIS/LIS)



Connect optional equipment only when the Analyser is switched off. Please note that attaching optional equipment (e.g. a printer) can increase the amount of leakage current.



To ensure safe operation, always use the MyCare Insite according to the instructions in the User Manual.

To install a printer or barcode reader (see “Technical specifications” section on page 44) please connect the RS232 cable to the RS232 port on the Analyser (see illustration below).

An adapter (Serial Splitter – Db-9 (F) to Db-9 (M)) is required to use a printer and barcode reader simultaneously.

For selection of a default printer model please refer to *Printer configuration under Configuring interfaces* (page 21).

### MyCare Insite Analyser Interfaces



Power Supply Port

USB Port (type B) for connecting a PC (for data transfer)

Touch Screen-Lock Port

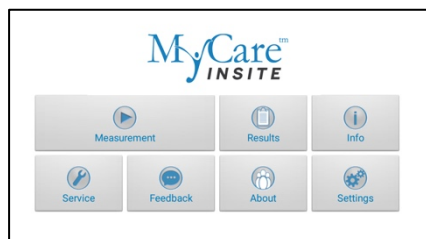
Bluetooth ON/OFF Switch  
(left: Bluetooth OFF)


USB Port (type A) for connecting a Touch Screen

RS 232 Port for connecting a printer, a barcode reader or a PC (for data transfer)

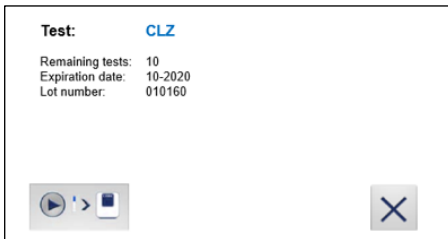
## Using a Barcode Scanner to Scan Patient ID and/or Operator Information

### 1. Main menu





Start a test by tapping . Make sure that RFID card is placed on the Analyser.

### 2. Test screen




The MyCare Insite displays the type of test and number of tests remaining on the RFID card.

Tap  to proceed to the input menu or  to exit to the main menu.

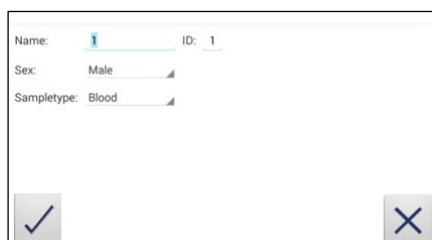
### 3. Select operator screen\*





On this screen an operator can now be selected by scanning the operator barcode and tapping  to continue.

If new information is scanned (i.e. the operator has not been created in the operator menu yet) a new operator will be created automatically.

### 4. Input menu



Scan patient information with the barcode scanner. It will automatically be set as "ID" value.

Tap  to confirm the input or  to exit to the main menu.

### 5. Insert test cartridge and close door



The door opens automatically. Insert the test cartridge (Cuvette with Sample Collector) and close the door. The test procedure starts automatically.

\* This screen only appears when operator input is enabled (page 20).

## How to Wake-Up the My Care Insite or Switch it OFF



When the Touch Screen displays the main menu, the "power safe" function dims the screen. Pressing the Lock Switch will re-illuminate the display. It is not necessary to switch the Analyser off every day. Switching the Analyser off completely can only be done by disconnecting it from the power supply.

## Overview of the Testing and Measuring Procedures

---

Allow the Cuvette and Sample Collector for each sample to reach room temperature before use. If the MyCare Insite Analyser has been disconnected from the power supply, reconnect to reach operating temperature before testing.

### To analyse a patient sample:

- Prepare Sample Collector and Cuvette - allow at least 10 minutes to come to room temperature
- Place the RFID card provided in the test kit package in the RFID card well on top of the Analyser.
- Enter the required patient data.
- Prepare a patient sample according to the instructions in the MyCare Insite Test kit package insert
- Insert the cartridge into the Analyser and start the test measurement by closing the door.
- The result will be displayed on the Touch Screen.
- The result will be saved in the Touch Screen's memory.
- If desired, export the result to an (optional) external computer, print the result with an (optional) external printer (see page 21) or send it via email (see page 28)

Be sure to follow the detailed instructions for the test that are provided in the following sections and to comply with the information provided in the package insert enclosed with each MyCare Insite Test kit.



# Operating Safety Precautions

## When Operating the MyCare Insite Analyser:

Use only your fingertips to operate the Touch Screen! Do not use pens or other objects that may scratch or damage the screen



If an error message appears on the screen, please consult the “Error information and troubleshooting” section



The door protects the Analyser Chamber from dust, dirt and humidity. Remove the test cartridge from the Chamber after every test. Keep it closed when the Analyser is not in use

The door opens automatically. Do not attempt to open the door manually

## When Handling a Test (Cuvettes and Sample Collectors):

Do not use tests after their expiration date

Do not use tests that have not been stored properly according to the package insert/IFU for the test



Do not use the test if the packaging is damaged or if fluids have leaked

Do not use the test directly from the refrigerator; the test must reach room temperature (20 - 28°C; 68 - 82.5 °F) before use

Use gloves when handling and disposing of Cuvettes, patient samples and sample collection equipment that pose a potential biohazard risk



Please refer to package insert provided with the MyCare Insite Test and follow all instructions including:

- The proper temperature of a test before it can be used
- Test preparation
- The proper storage of the tests

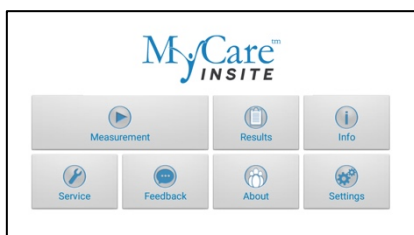
# Testing a Patient Sample

## 1. RFID card placement



Take the provided RFID card out of the test kit package and place it on the RFID card well on top of the Analyser. The RFID and test are color coded – confirm and correct.

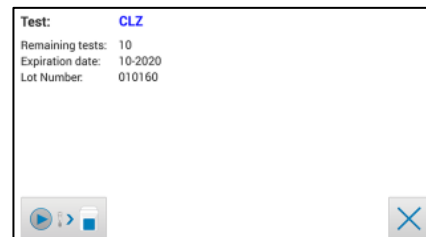
## 2. Main menu



Tap  in the main menu to start a measurement.


The MyCare Insite automatically reads the RFID card and the Test Menu appears.

## 3. Test screen





The MyCare Insite displays the test name and number of tests remaining on the RFID card. Compare the test name to the kit color coding.

Tap  to proceed.

Tap  to return to the main menu.


## 4. Select operator screen\*



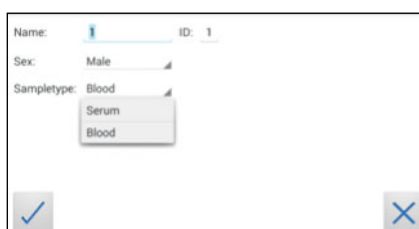
All saved operators will be shown in the drop-down list. Tap  and select an operator or tap  to create a new operator (see 3.4 on p. 20 for details).

Tap  to confirm the input.


**Note:** when testing for the first time, you will be prompted to create an operator.

Tap  to open the operator menu (see 3.4 on p. 20 for details).

## 5. Input menu



Tap the desired input field (e.g. "Name"), the Touch Screen keyboard appears. Enter the information and confirm with "Done".

Next, tap  and select an entry from the drop down-menu.

## 6. Insert cartridge and close door

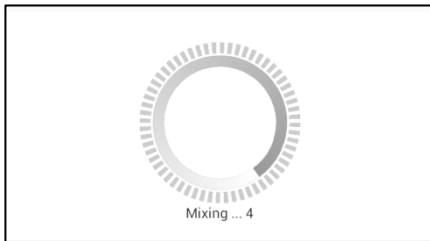


The door opens automatically. Insert the test cartridge (Cuvette with Sample Collector) and close the door. The test procedure starts automatically.

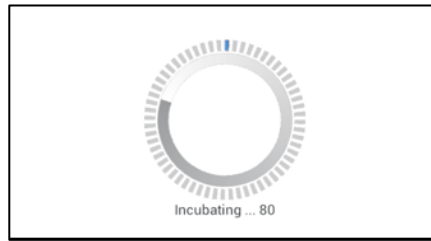
\* This screen only appears when operator input is enabled (page 20).

The Touch Screen displays the following information during the testing process (varies by test):

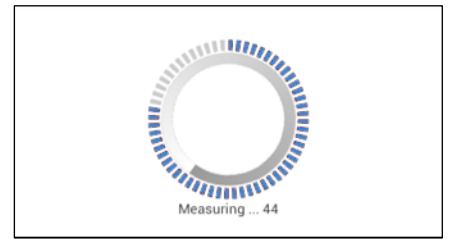
*Mixing*



*Incubating*



*Measuring*



Be sure to handle the tests according to the instructions in the package insert.

Be sure the test cartridge (Cuvette with Sample Collector) is properly sealed before inserting into the Analyser.



Be sure the test cartridge (Cuvette sealed with Sample Collector) is fully inserted into the proper opening in the Analyser.

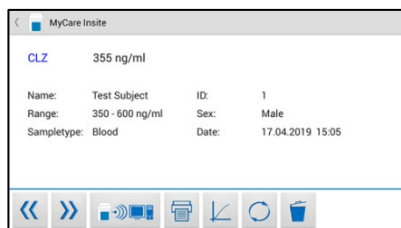
Use ONLY manufacturer-approved tests. Otherwise serious damage to the Analyser and/or inaccurate test results may occur.

Do not attempt to open the door manually.

# Viewing and Processing Test Results

After processing a test, the result screen appears on the Touch Screen:

## 1. Result Screen

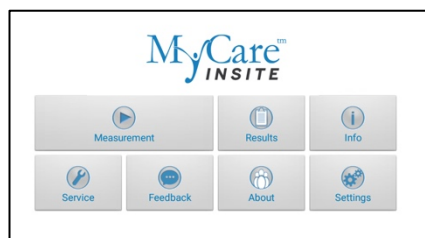


The test result is displayed on the Touch Screen. Use « and » to scroll back and forth within the results. Tap to export to a HIS/LIS or PC or send as Email.

Tap to print. Tap to open the photometric data curve. Tap to delete the result. Tap to exit to the main menu.

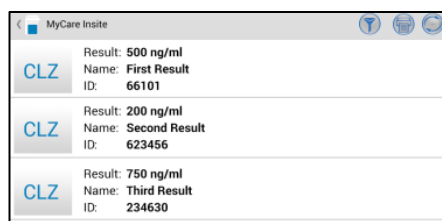
*All test results are stored on the Touch Screen. They can be accessed as follows:*

## 1. Main Menu



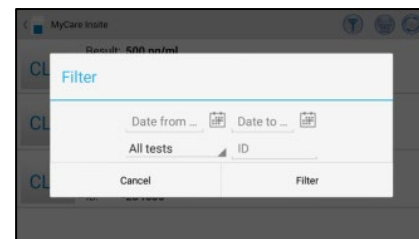
Tap in the main menu to open the Result List.

## 2. Result List Screen



The stored results can be browsed by swiping up and down. Tap a result to open the result screen (see above), to return to the result list from a result screen press the *Return Arrow* . Tap to open the filter options. Tap to print, mail or export.

## 2.1 Filter Options



Results can be filtered by date, test and Patient ID.

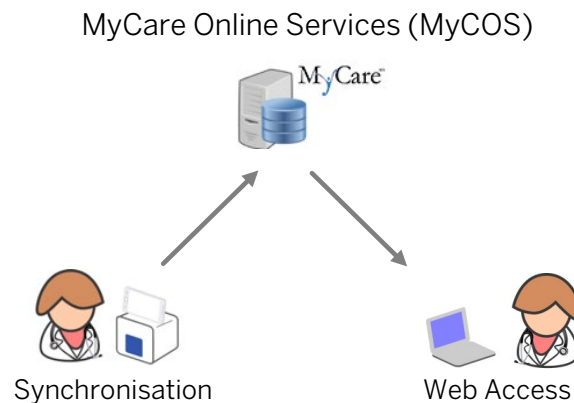
Tap to set the desired start date, to set the desired end date. Tap to select a test name in the drop-down menu (e.g. CLZ). Tap to filter by patient ID.



Whenever the transmission of the operator ID, lot number and serial number is activated in the appropriate settings menu (see p. 20) the appropriate data will be transferred to the printer or host system automatically and will appear on the printouts and/or the computer or host system.

# MyCare Online Services (MyCOS)

The MyCare Insite offers the possibility to store test results on the encrypted MyCare Online Services (MyCOS) servers. No test results are stored until the MyCOS registration is completed.



The feature to synchronize data from the MyCare Insite application into the MyCOS account can be used according to the steps described on page 30, *MyCOS Synchronization*.

The synchronized data can be viewed by using a web-browser e.g. on a PC or tablet. A description of the *MyCOS Web Access* and an explanation of the user interface can be found on page 33, *MyCOS Web Access*.

Sensitive data is encrypted by the Insite using industry standard cryptographic algorithms (following ENISA recommendations) before transmitting data.



Data decryption is done on the web-browser. Saladax has no access to personal passwords and cannot retrieve them in case of a loss.

Do Not Lose Password.

# MyCOS Synchronization

Once registered and logged in with a MyCOS account Insite result synchronization is enabled


There are three ways to synchronize data:

- Synchronize all currently stored measurement results at once
- Synchronize a single measurement result
- Synchronize a filtered measurement result list

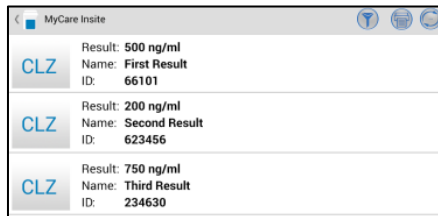
## Synchronize all Test Results


### 1. Main Menu



Tap  in the main menu to open the Result List.

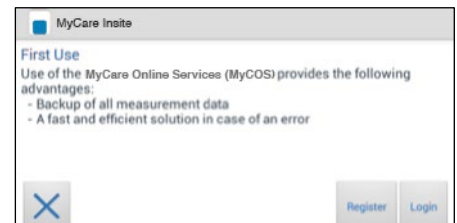
### 2. Result List Screen





Tap  in the upper right corner to synchronize all test results.

When not logged in with a MyCOS account, the registration or login screen will appear.

### 3. MyCOS Registration & Login Screen

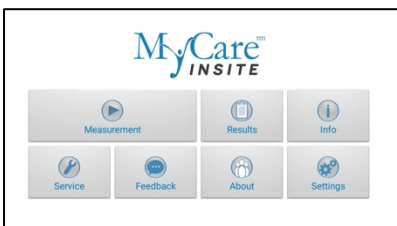



Use  to register a new MyCOS account (see page 32) or  to log in with an already existing MyCOS registration (see page 33).

**After registration or login, the results will be synchronized.**

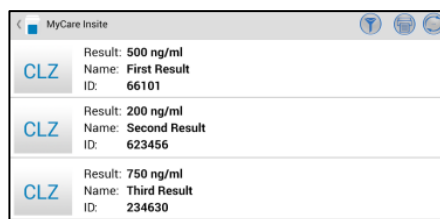
## Synchronize a single result

### 1. Main Menu



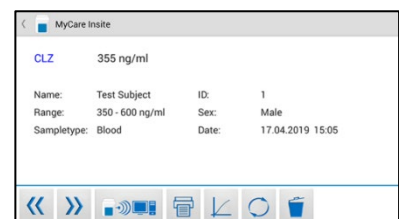
Tap  in the main menu to open the Result List.

### 2. Result List Screen



Tap a result to open the result detail screen.

### 3. Result Detail Screen




Tap  to synchronize the result currently viewed.

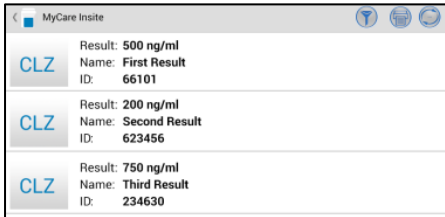
# Synchronizing a filtered result list


## 1. Main Menu



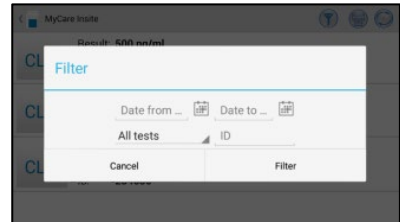
Tap  in the main menu to open the Result List.

## 2. Login Screen



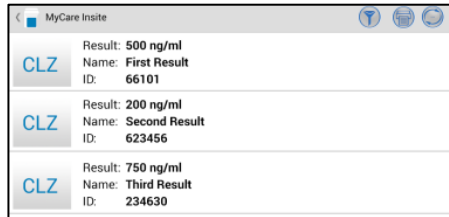
Tap  to open the filter options.


## 3. Filter Options



Set a filter according to 2.1 Filter Options on page 28.

## 4. Filtered Result List (e.g. CLZ)

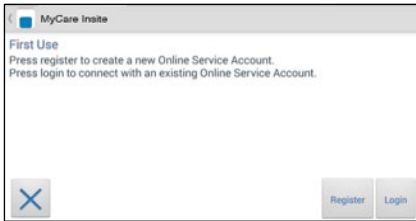



Tap  in the upper right corner to synchronize the filtered test results.

# MyCare Online Services Registration

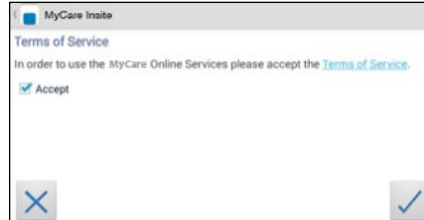
The MyCare Insite application asks the user to register or login to the MyCOS once before synchronizing. The following steps describe the registration process.



## 1. MyCOS Registration & Login Screen



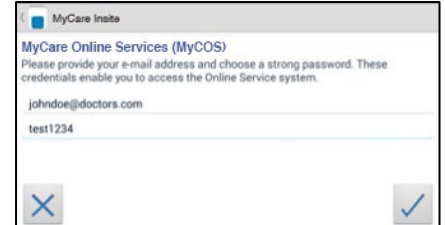
Tap  to open the registration screen.


## 2. Terms of Services



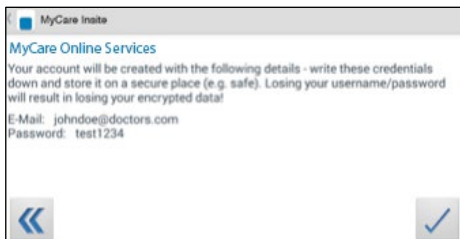
Before registering with the MyCOS system, the terms of services need to be read and accepted. Please read through the terms of service thoroughly. The terms of service are accepted by ticking the "Accept" checkbox  and pressing .


## 3. Registration



Register with the MyCOS system by providing an e-mail address and a strong and secret password. Accept the account information by pressing . The registration confirmation appears.

## 4. Registration Confirmation



Please double check the registration details and accept by pressing . After successfully registering with the MyCOS system, the login is done automatically at each synchronization request.



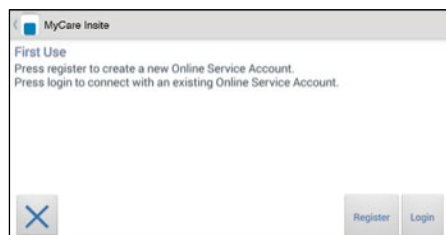
Do not lose your password; Saladax Biomedical has no way to retrieve or reset passwords.




# MyCare Online Service Login

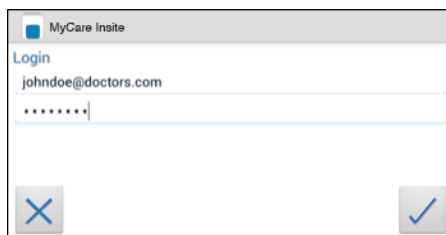
---

## 1. MyCOS Registration & Login Screen



Press  to open the login screen.

## 2. Login Screen



Provide your MyCOS account information and tap  to log in.

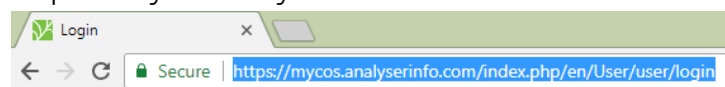
# MyCOS Web Access

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Once results have been synchronized with the user's MyCOS account they can be viewed independently with a web-browser using a personal computer, tablet or smartphone.

The web application can be accessed by navigating to the following URL:

<https://mycos.analyserinfo.com>



## Recommended web-browsers


---

Web browsers that are recommended to use for accessing the MyCOS Web Access are shown in the table below. Other browsers are not recommended.

Windows	<ul style="list-style-type: none"><li>• Internet Explorer 10 or higher</li><li>• Mozilla Firefox 24 or higher</li><li>• Google Chrome 33 or higher</li></ul>
Linux	<ul style="list-style-type: none"><li>• Mozilla Firefox 24 or higher</li></ul>
Mac	<ul style="list-style-type: none"><li>• M3w[ ]sls;21</li></ul>


Always use the most recent version of a browser to make sure that the latest security updates are applied. Older browsers might not provide all functions and features correctly for the MyCOS Web Access.

## Login Screen


MyCare™ Online Services 4 

### Login

E-Mail address

 E-Mail address 1

Password

 Password 2

Login 3

- (1) Email address which has been used for registration on the App
- (2) Password which has been used for registration on the App
- (3) Button to perform login after entering email address and password
- (4) Change Language

## Result List

### Measurement results

Test: All ... 1

Instrument: All ... 2

Result-Type: All ... 3

Patient ID: 4

Patient Name: 4

Date from: 5

Date to: 5

Filter 6 Reset 7

Export 12

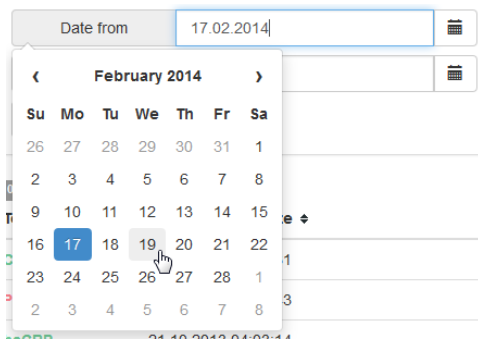
100 / 165 8

Test <span>9</span>	Measurement Date <span>9</span>	Measurement Value <span>9</span>	Patient Name <span>9</span>	Patient ID <span>9</span>
CLZ	24.04.2017 09:59:37	288 ng/mL	Huber	4
CLZ	24.04.2017 09:52:11	723 ng/mL	Mayer	3
CLZ <span>10</span>	18.04.2017 17:31:35	457 ng/mL	Lessing	2
CLZ	13.04.2017 17:13:04	913 ng/mL	Eder	26
CLZ	16.11.2016 09:28:34	602 ng/mL	Rapp	33
CLZ	03.11.2016 09:44:05	339 ng/mL	Pichler	26
CLZ	03.11.2016 09:30:23	540 ng/mL	Kleinfirchner	25
CLZ	03.11.2016 09:18:04	313 ng/mL	Gruber	24

100 11 more results ...

### Filtering:

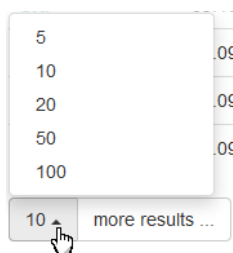
- (1) Test: Choose which test should be displayed
- (2) Analyser: Choose an Analyser that is connected to the MyCOS account
- (3) Result-Type: Choose if sample or controls should be displayed
- (4) Patient ID/Patient Name: Choose which Patient IDs/Names should be displayed
- (5) Date(s): Select a time frame



- (6) Button to apply the chosen filter(s)
- (7) Button to reset the filter

#### Result list:

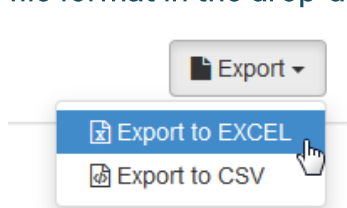
- (8) Displays the number results in the current view and the total number of results connected to the MyCOS account
- (9) The MyCOS result list in the current view can be sorted by pressing the titles in the table
- (10) Measurement result list (filtered). Click on the entries to toggle detail information
- (11) Button to display 'x' more results up to the maximum of all stored results connected to the MyCOS account:



Tap the “more results” button to add the chosen number of results to the result view:



- (12) Button to export currently shown results as Excel or CSV file. Choose the desired file format in the drop-down menu:



## Export of Measurement Result List

Before being exported, the results can be filtered with the filter button in the result screen. Only the results currently shown on the screen are exported (the “more results” button may be pressed to display more results).

## Printing of Measurement Result List

The measurement results can be printed out through the browser (depending on the type of browser) usually through the browser's menu, or by pushing CTRL+P simultaneously. Only the results currently shown on the screen are printed (including details for a single measurement, if shown).

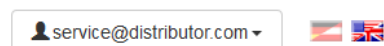
### Measurement results

100 / 570

Test	Measurement Date	Measurement Value	Patient Name	Patient ID
CLZ	24.03.2015 11:33:00	275 ng/mL	David Gerber	ID 6
CLZ	24.03.2015 11:33:00	390 ng/mL	Malene Kjeldsen	ID 40

**Instrument SN:** Ca10001  
**Unit 1:** 390 ng/mL  
**Gender:** female  
**Operatorname:** Blood  
**Type:** Sample  
**Sampletype:** Control Plasma  
**Lotnumber:** L85552

## Header User Interface Elements



This shows the currently logged in user as well a language option.

# Quality Control (QC)

A quality control program should be performed on a regular basis to verify the MyCare Insite Analyser is working properly and providing reliable results. Data integrity can only be assured when controls and Good Clinical Laboratory Practice are used routinely. The frequency of performing QC differs from laboratory to laboratory; please comply with your national quality control regulations.

## QC materials

---

Quality control material is defined in the MyCare Insite Test package inserts.

### To run QC:

- Prepare Sample Collector and Cuvette - allow at least 10 minutes to come to room temperature.
- Place the provided RFID card from the test kit package in the RFID card well on top of the Analyser.
- Prepare the control according to the instructions in the control package insert.
- Enter the control level and control lot number instead of the patient data.
- Prepare the test like a patient sample according to the instructions in the control package insert and start the measurement.
- The result is displayed on the Touch Screen.
- Record the result according to your laboratory's quality guidelines.
- The result will be saved in the device's memory – just like a patient's result.
- If desired, export the result(s) to an (optional) external computer, print the result with an (optional) external printer or send it via Email (see p. 28).
- Verify that the result is within the mandatory limits for the control material (according to the control package insert).

Be sure to follow the detailed instructions for the test that are provided in the operation sections (page 25) and comply with the information provided in the package insert enclosed with each MyCare Insite Test kit.

## Handling QC control materials

---



**Please refer to the package insert provided with each control kit for detailed instructions on storage and handling of control materials.**

Follow the instructions in the “Testing a Patient Sample” sections (starting on p. 26) on how to properly perform a control test. The measured values must be within the range of target values specified in the control package insert. If the control results fall within the specified range, the testing of patient samples may begin.

If one or more controls tested are outside the specified control range:

- Verify that the control materials have been stored according to the directions and that the open vial stability claim and expiration date have not been exceeded.

- Verify that the handling and testing procedures were performed according to the directions in the package insert.
- Repeat the control test, using a new control from the same lot.

If one or more control results are still outside the specified range:

- Perform a test using a new lot of control.



If all instructions have been followed but control results are still not within range, please contact your Official Saladax Distributor for assistance before testing any patient samples.

## Frequency of QC Testing

---

**Control testing is recommended when:**

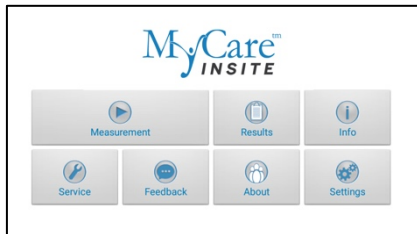
All quality control requirements and testing should be performed in accordance with local, state and/or federal regulations or accreditation requirements.

QC testing is recommended when:

- The Analyser is installed
- A new kit shipment or lot is used
- There is an unexpected patient result
- New users are trained

## Performing a Parameter Correlation Adjustment

### 1. Start-up Menu



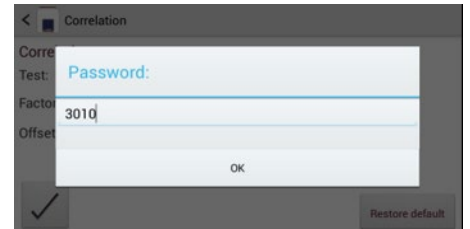
Tap *Settings* to open the settings menu.

### 2. Settings menu



Tap *Correlation* to open the correlation menu.



### 3.1 Password screen



Enter the password. The default setting is 3010.

### 4. Correlation menu



Tap  to open a drop-down menu. Select which parameter is to be adjusted. Enter the factor and the offset accordingly and tap  to accept the new correlation settings.

### 5. Test Screen



An active correlation adjustment is marked by *Correlated* as seen in the test screen when starting a measurement process.

# Cleaning Instructions

## Cleaning the Touch Screen Display

---

Clean the Touch Screen display with a clean, lint-free cloth moistened with water.



**Do not use any liquid other than water when cleaning the Touch Screen!**

**To avoid damage avoid excess water on the Touch Screen!**

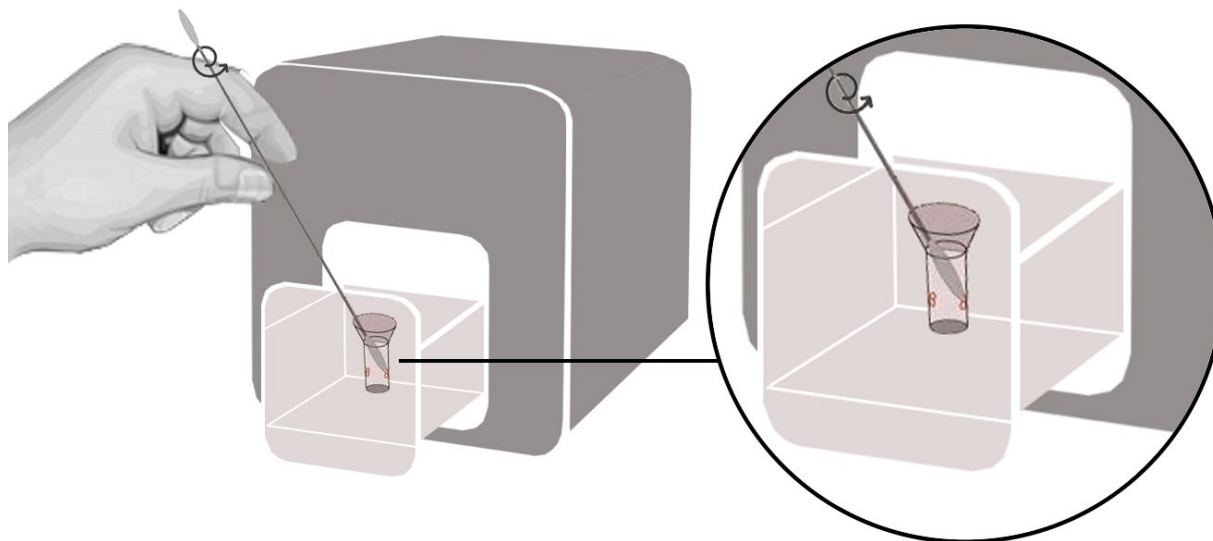
**Never use isopropyl alcohol on the Touch Screen**

## Cleaning the Door & Chamber

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Clean the door with a clean, lint-free cloth moistened with isopropyl alcohol. Wipe down the surface.

The cartridge area may be cleaned with a cotton swab moistened with isopropyl alcohol.



## Cleaning the Exterior

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The surface of the MyCare Insite Analyser should be cleaned with a clean, lint-free cloth only moistened with isopropyl alcohol. Wipe down the exposed surfaces.



**Do not clean the surface of the Touch Screen with isopropyl alcohol!**



# External Interface Description

## Serial Interface

### Interface signals

Pin	Signal
1	
2	TxD
3	RxD
4	
5	GND
6	
7	
8	
9	

### Interface parameters

Parameter	Value
Baud rate	9600
Data bits	8
Parity	None
Stop bits	1

### Data format

*Data is transmitted in blocks of data sets.*

*One data set contains the data from one analysis.*

*Data sets consist of data fields.*

*A data field consists of an identifier (7 characters) and its respective value or text.*

*Data fields are concluded with one carriage return and line feed.*

*Data sets are concluded with three carriage returns and line feeds.*

### Data Fields

Identifier	Format	Example	Remarks
Name:	Text	Name: John Doe	
ID:	Text	ID: 1234	
Sex:	Male/Female/Child/Control	Sex: Male	
Sample:	Blood	Sample:Blood	Optional
HCT:	Value	HCT: 40	Optional
Testname:	Value and unit	CLZ: 248 ng/mL	
Calculatedname:	Value and unit		Optional
Range:	Value – Value	Range: 350 – 600	Optional
Time:	hh:mm	Time: 14:44	
Date:	dd-mm-yyyy	Date: 08-02-2007	
Operat:	Text	Operat:Max Muster	Optional
Lot No:	Value	Lot No:4111	Optional
Ser No:	Value	Ser No:Ba00001	Optional

## USB Interface

The USB interface emulates the serial interface.

# Error Information and Troubleshooting

## Error Messages and Possible Causes



Door opening during a measurement indicates an error. Consult the following error messages. Conduct a self test before performing a measurement.

Error message	Cause	Correction
Invalid card	A wrong, defective or expired RFID card A defective RFID module	Use a new test. Contact Official Saladax Distributor.
Tests expired	The test has passed its expiration date.	Use a new test that has not expired.
Wrong date set	The date set on the Touch Screen is wrong.	Change the date to "today" as described in the Touch Screen Starter Manual.
Door blocked	The test Cuvette is blocking the door because the Cuvette has not been inserted completely or the Sample Collector does not cap the Cuvette firmly enough.	Reposition the test Cuvette or tighten the Sample Collector on top of the Cuvette.
Wrong cap   Missing cap   Missing cartridge	The wrong Sample Collector is being used or the Sample Collector is missing or the cartridge is missing or an already used cartridge is inserted.	Use the correct Cuvette and Sample Collector.
Bolt blocked	The test Cuvette blocks the bolt (that locks the Chamber) because the wrong Sample Collector is being used.	Use the correct Cuvette and Sample Collector.
Measurement overflow	The photometric measurement value lies outside the measuring range (e.g. a cold Cuvette and Sample Collector have been used).	Repeat the test using a new Cuvette and Sample Collector.
Blank error	The photometric measurement value is outside the measuring range (without the cartridge).	Repeat the test after restarting the Analyser.
Temperature error	The temperature is outside the range.	Repeat the test after restarting the Analyser.
Wrong samplotype?	The wrong sample type has possibly been selected.	Select the correct sample type.
Mix error	Analyser fails to perform test due to possible hardware error.	Please contact your Official Saladax Distributor.
Sample volume error	The provided sample volume is not correct (e.g. pipetting error).	Repeat the test using a new Cuvette and Sample Collector. with correct sample volume.
Cuvette temperature error	The completed Cuvette' temperature is too low for a proper test.	Repeat the test and refer to the package insert for proper Cuvette use.

## Service Information

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If a problem persists after the corrective actions are taken, contact your Official Saladax Distributor for technical assistance.

Before requesting assistance, please have the following information ready:

- the serial number of your Insite Analyser
- the test
- the test lot number
- the control lot number
- the control results obtained so far
- a description of the problem, including any of the Insite Analyser's error messages

# Technical Specifications

## MyCare Insite Analyser

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Photometer resolution	0.0001 ABS
Reproducibility	< 1.5% CV at 1 OD
Linearity	0.1000 – 3.0000 OD better than ffl 1.5% and ffl 0.01 OD
Temperature control	Electrical temperature control of the photometer unit to 37°C ffl 2°C
Fuse	2.5 A, self-healing
Dimensions	160 x 135 x 145 mm (H x W x D)
Weight	2.2 kg (unpackaged)
Communications interface	RS232, USB, Bluetooth
Tolerance conditions:	Work space: 20 - 28°C; relative humidity: 10 – 85% Transport/Storage: 0 - 50°C; relative humidity: 5 – 85%
Work surface:	A dry, clean, level surface. Avoid direct sunlight.
Power usage:	12V DC, 2A


## Power Supply

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<i>Manufacturer</i>	<i>Globtek</i>
<i>Type</i>	<i>GTM21097-5012</i>
<i>Mains adapter</i>	<i>A separate AC to DC mains adapter with double insulation</i>
<i>Input</i>	<i>90 - 264V AC, 47 - 63 Hz</i>
<i>Output</i>	<i>12V DC, 4.17A</i>
<i>Power usage</i>	<i>Max. 30 VA</i>

## Options

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<b>Thermo printer</b>	Seiko DPU-414	Seiko Label Printer 650SE
Interface	Serial	 <b>Compatible starting with Touch Screen Software Version 3.6!</b>
Mains adapter	100 - 240 VAC	Serial 100 - 240 VAC
<b>Barcode reader (scanner)</b>	Datalogic Heron D130	Honeywell Voyager 1200g
Reading area	2 ~ 27 cm (20 mils)	3.8 ~ 13.2 cm (5 mils)
Max. resolution	0.10 mm ( 4 mils)	0.09 mm ( 3.5 mils)
Mains adapter	100 - 240 VAC	100 - 240 VAC

# Shutdown and Waste Management

Before shutting down the MyCare Insite for repair or disposal ensure that there is no Cuvette left within the Analyser Chamber. To protect the Analyser in shipping the original packaging must be used.

For proper waste management according to the Directive 2012/19/EU please contact your Official Saladax Distributor. Used cartridges need to be disposed of with laboratory waste and according to the corresponding regulations.

# Manufacturer Information



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