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Philips minicare analyzer

INSTRUCTIONS FOR USE

Release 1.0

English

PHILIPS

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1 Introduction

1.1 About the Philips minicare system

The Philips minicare system comprises a handheld analyzer, its docking station, and data manager software for the quantitative determination of the concentration of biomarkers in blood.



Figure 1.1 Philips minicare analyzer, with docking station (right)



Figure 1.2 Philips minicare analyzer, with cartridge loaded (right)

Philips minicare analyzer

The minicare analyzer receives blood cartridges and performs tests on the blood sample. It is intended for use in medical care settings, for example, operating theaters.

To perform a test with the minicare analyzer, a cartridge sample for a specific application is also required. These cartridges can be used only once.

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Philips minicare data manager

The minicare data manager software allows you to configure the minicare analyzer, and to exchange data from the minicare analyzer with an external information system, for example, LIS.

1.2 About these Instructions for Use

These Instructions for Use are intended to assist users in the safe and effective operation of the product described.

Before attempting to operate the product, you must read these Instructions for Use, noting and strictly observing all **WARNINGS** and **CAUTION** notices.

Pay special attention to all the information given and procedures described in the **SAFETY** section.

A **WARNING** alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

A **CAUTION** alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury, and/or cause environmental pollution.

Notes highlight unusual points as an aid to a user.

[NOTE TO REVIEWERS: If there are no options on the system, the following paragraph is can be removed. Please confirm.] These Instructions for Use describe the most extensive configuration of the product, with the maximum number of options and accessories. Not every function described may be available on your product.

1.3 Intended use

This Philips product is intended to be installed, used and operated only in accordance with the safety procedures and operating instructions given in this Instructions for Use for the purposes for which it is designed. The purposes for which this product is intended are given below. However, nothing stated in this Instructions for Use reduces user’s responsibilities for sound clinical judgment and best clinical procedure.

The intended use of the Philips minicare system is as a point of care device to measure the concentration of biomarkers in blood using Magnotech blood cartridges.

Installation, use, and operation of this product is subject to the law in the jurisdictions in which this product is being used. Operators must only install, use, and operate this product in such ways as do not conflict with applicable laws, or regulations, which have the force of law.

Uses of this product for purposes other than those intended and expressly stated by the manufacturer, as well as incorrect use or operation, may relieve the manufacturer (or his agent) from all or some responsibility for resultant non-compliance, damage, or injury.

Intended users

The intended users of the Philips minicare system are laboratory and non-laboratory medical professionals (for example, nurses).

Intended use environment

The Philips minicare system is used to perform tests in different care settings, for example, an emergency room or an operating theater.

1.4 Compatibility

The product described in this manual should not be used in combination with other products or components unless such other products or components are expressly recognized as compatible by Philips Electronics Nederland B.V. A list of such products and components is available from the manufacturer.

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Philips minicare analyzer identification	
Module no.	[To be defined]
Software version	[To be defined]

Changes and/or additions to the product should only be carried out by Philips Electronics Nederland B.V. or by third parties expressly authorized by Philips Electronics Nederland B.V. to do so. Such changes and/or additions must comply with all applicable laws and regulations that have the force of law within the jurisdiction(s) concerned, and with best engineering practice.



WARNING

Changes and/or additions to the product that are carried out by persons without the appropriate training and/or using unapproved spare parts may lead to the Philips Electronics Nederland B.V. warranty being voided. As with all complex technical products, maintenance by persons not appropriately qualified and/or using unapproved spare parts carries serious risks of damage to the product and of personal injury.

1.5 Compliance

The Philips minicare analyzer complies with relevant international and national standards and laws. Information on compliance will be supplied on request by your local Philips Electronics Nederland B.V. representative, or by the manufacturer.

1.6 European authorized representative



The European authorized representative is located at the following address:

Philips Electronics Nederland B.V, acting through Healthcare Incubator
High Tech Campus 5
5656AE, Eindhoven
The Netherlands.

1.7

Training

Users of this product must have received adequate training on its safe and effective use before attempting to operate the product described in these Instructions for Use. Training requirements for this type of device will vary from country to country. Users must make sure they receive adequate training in accordance with local laws or regulations.

If you require further information about training in the use of this product, please contact your local Philips Electronics Nederland B.V. representative. Alternatively, contact the manufacturer.

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Training

Introduction

2.1 Important safety directions

WARNING



Maintenance and faults

- Do not use the product for any application until you are sure that the user routine-checks have been satisfactorily completed, and that the periodic maintenance of the product is up to date. If any part of the product is known (or suspected) to be defective or wrongly adjusted, **DO NOT USE** the product until a repair has been made. Operation of the product with defective or wrongly adjusted components could expose the user or the patient to safety hazards. This could lead to fatal or other serious personal injury, or to clinical misdiagnosis.

WARNING



Safety awareness

- Do not use the product for any application until you have read, understood and know all the safety information, safety procedures and emergency procedures contained in this SAFETY section. Operation of the product without a proper awareness of how to use it safely could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis.

WARNING



Adequate training

- Do not use the product for any application until you have received adequate and proper training in its safe and effective operation. If you are unsure of your ability to operate this product safely and effectively **DO NOT USE IT**. Operation of this product without proper and adequate training could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis.
- Do not operate the product with patients unless you have an adequate understanding of its capabilities and functions. Using this product without such an understanding may compromise its effectiveness and/or reduce the safety of the patient, you and others.

WARNING



Safety devices

- Never attempt to remove, modify, or over-ride or frustrate any safety device on the product. Interfering with safety devices could lead to fatal or other serious personal injury.
- [NOTE TO REVIEWERS — during review 1, a defect was raised indicating this warning (above) is too vague. In your review, please indicate one of the following: (A) that there are no safety devices on the analyzer (not required through good design), in which case we can remove this warning altogether, or (B) there are specific safety devices on the analyzer that require more in-depth explanation, in which case we need to expand this warning with more detail. Thank you.]

WARNING



Intended use and compatibility

- Do not use the product for any purpose other than those for which it is intended. Do not use the product with any product other than that which Philips Medical Systems recognizes as compatible. Operation of the product for unintended purposes, or with incompatible product, could lead to fatal or other serious injury. It could also lead to clinical misdiagnosis.

2.2 Emergency procedures

There are no emergency procedures for the minicare analyzer.

2.3 Explosion safety

WARNING



[NOTE TO REVIEWERS - During review 1, the following defect was raised: “Do we need a 'battery exploding warning' ? These types of batteries (used in remote controlled cars e.g., sometimes self combust. Are our batteries safeguarded against that?” In your review, please could you indicate whether or not there is a risk of the battery exploding that requires mitigation in the IfU. Normally, this will be driven by the Risk Management Report (not available at the time of writing).

2.4 Electromagnetic Compatibility (EMC)

This Philips product complies with relevant international and national law and standards on EMC (electro-magnetic compatibility) for this type of product when used as intended. Such laws and standards define both the permissible electromagnetic emission levels from product and its required immunity to electromagnetic interference from external sources.

Other electronic products exceeding the limits defined in such EMC standards could, under unusual circumstances, affect the operation of the product.

Medical electrical products needs special precautions regarding EMC, and needs to be installed and put into service according to EMC information provided in the accompanying documents.

The use of accessories and cables other than those specified, may result in increased emission or decreased immunity levels.

The product should not be used adjacent to or stacked with other products and that if adjacent or stacked use is necessary, it should be observed to verify normal operation.

Portable and Mobile Phones

CAUTION

Portable and mobile RF communications can affect medical electrical equipment. Use caution when using such communication devices within the specified range of medical electrical devices.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

This device complies with Part 15 of the FCC Rules and with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

2.5 Labels and symbols

2.5.1 minicare analyzer label

The following label is located on the rear side of the minicare analyzer.

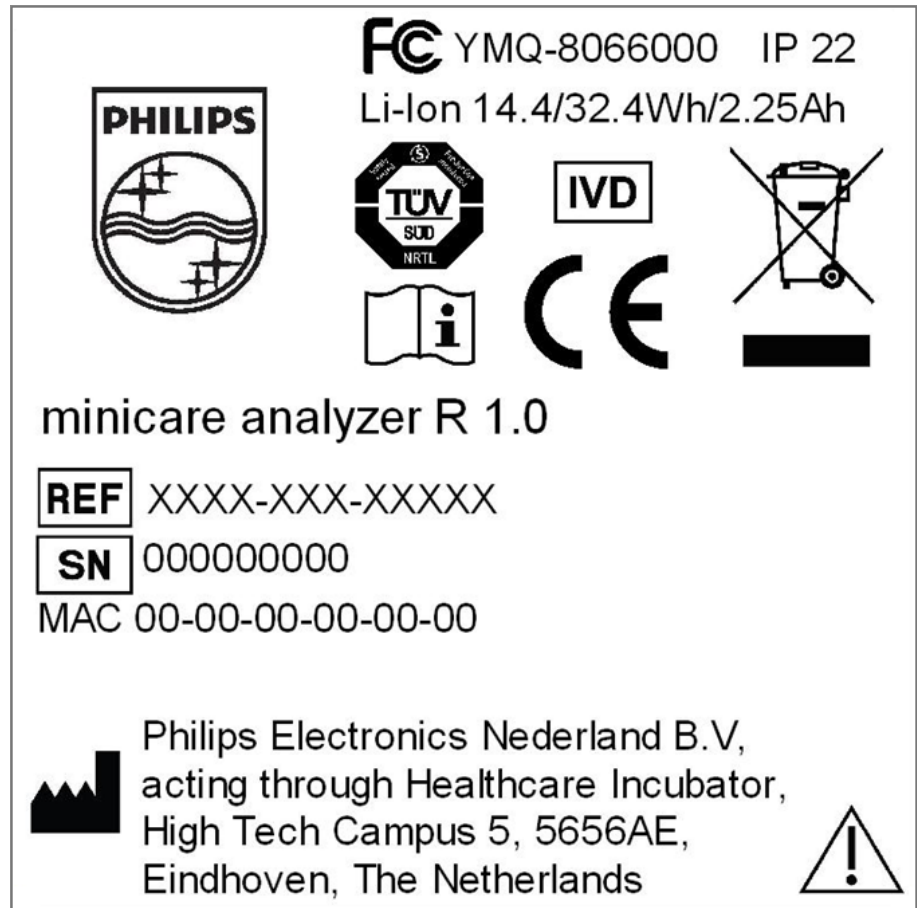


Figure 2.1 minicare analyzer label

2.5.2 minicare docking station label

The following label is located on the rear side of the minicare docking station.

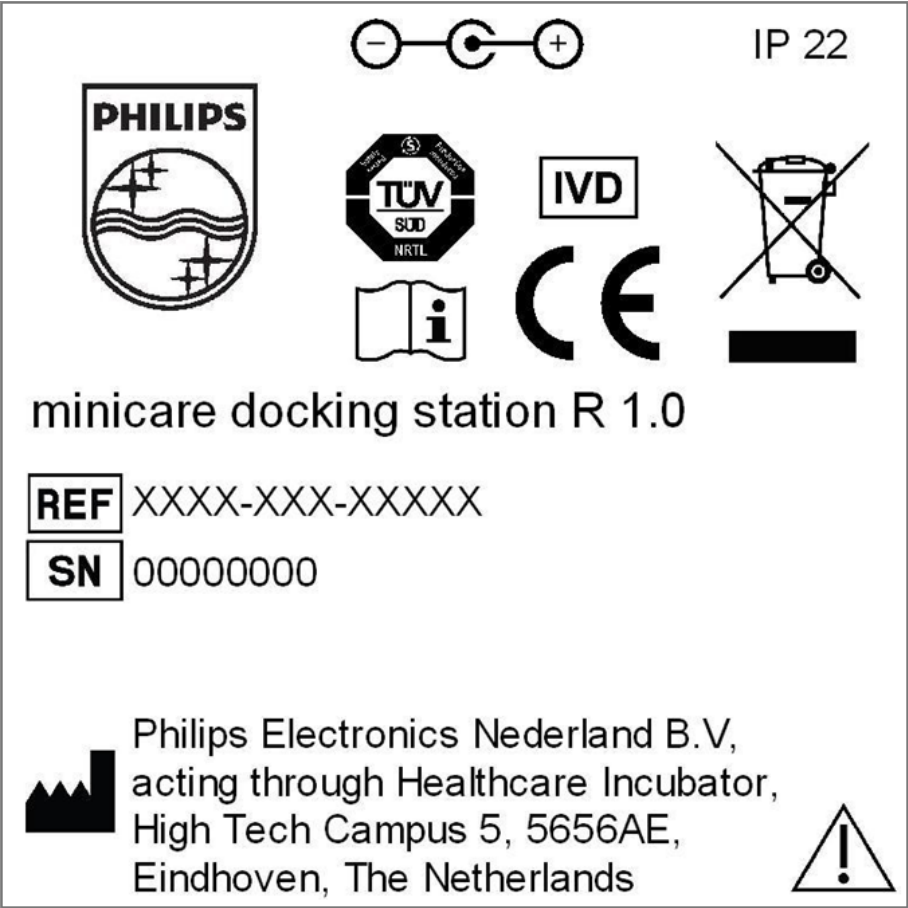
















Figure 2.2 minicare docking station

2.5.3 Symbols









The following symbols are used on the equipment and on equipment labels.

	Authorized Representative in the European Community
	Batch code
	Catalogue number
	Caution, consult accompanying documents
	CE mark
	Consult Instructions for Use
	Contains sufficient for (specified number of) tests
	Contents <ul style="list-style-type: none">The contents of the package are listed below this symbol
	Do not use if package damaged
	Docking status <ul style="list-style-type: none">Illuminated: dockedNot illuminated: undocked
	In Vitro Diagnostic Medical Device
	Mains connection status <ul style="list-style-type: none">White: connectedRed: not connected
	Manufacturer
	Network connection port

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	On / Off button
	Polarity
	Power supply adapter connection port
	Printer connection port
	<p>Product disposal</p> <p>This symbol indicates that the equipment contains materials that are harmful to the environment if disposed of incorrectly. See section “Product disposal” on page 9-1 for details.</p>
	Serial number
	<p>Temperature limitation</p> <p>This symbol indicates the lower and upper limit of the acceptable temperature range for storage or transportation.</p>
	Use By

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Labels and symbols

Safety

3

3.1

- analyzer
- docking station
- cables, power adapter
- CDs

with a legend key to each item]

Figure 3.1 Equipment inventory

Legend	
1	minicare analyzer
2	Docking station
3	Docking station AC adapter
4	AC adapter power cord
5	Ethernet cable
6	Data manager installation CD
7	[Other items as appropriate]

3.1.1 Equipment connections

minicare analyzer



Figure 3.2 Network connection port

- Specification: Ethernet
- An Ethernet cable is supplied with the minicare analyzer



Figure 3.3 Docking station connector

Docking station



Figure 3.4 Docking station connection ports




Symbol	Description	Specification
1 	Printer connection port	<ul style="list-style-type: none">• Specification: Mini USB• [To be confirmed — Cable supplied?]
2 	Network connection port	<ul style="list-style-type: none">• Specification: Ethernet• An Ethernet cable is supplied with the minicare analyzer
3 	Power supply adapter connection port	<ul style="list-style-type: none">• Input: 100–240 V AC, 47–63 Hz, 700 mA• Output: 24 V DC, 1250 mA• A power supply adapter and power cord are supplied with the minicare analyzer



Figure 3.5 Docking station connector for the minicare analyzer

3.2 Action upon delivery

The minicare analyzer is installed and configured by a Philips Service engineer as part of delivery. If you require information about suitable location, preparation, and connection of the system, contact your local Philips Service organization.

3.3 Site preparation

Conditions

- A PC is required for installation of the data manager software.
- The docking station requires a power connection.
- To transfer data to the data manager PC, the docking station requires a connection to the local network or directly to the PC.

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- 1 Unpack the minicare start pack.
- 2 Connect one end of the Ethernet cable to the docking station, and the other end either to a port on the local network or directly to the PC.

[NOTE TO REVIEWERS: Does direct connection to the PC require an Ethernet crossover cable? If so, is this also provided?]
- 3 Connect the AC power adapter to the docking station and connect the AC power adapter to the power source using the power cord.
- 4 Place the battery in the minicare analyzer.

For details, see section “Fitting, removing and disposing of batteries” on page 9-2.
- 5 Put the analyzer in docking station to charge the battery.

For details, see section “Docking the minicare analyzer” on page 4-5.

3.4 Storage and handling

3.4.1 Environmental conditions

Storage
The minicare analyzer can be stored and transported in the following conditions. These conditions are valid while the minicare analyzer is still in its original packaging.

Condition	Range
Ambient temperature	-25°C–70°C
Relative humidity (non-condensing)	5%–95%
Air pressure	70–110 kPa

Handling
The minicare analyzer can be used in the following conditions.

Condition	Range
Ambient temperature	2°C–27°C
Relative humidity	20%–80%

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Storage and handling

3.4.2 Battery care

During long periods of storage, you should remove the battery from the minicare analyzer. If the battery is left in the analyzer during storage, it will discharge slowly over time. Damage to the battery may result if it is allowed to completely discharge while in storage.

3.4.3 Dust

The minicare analyzer cap should be closed while not in use to avoid dust entering the device at the cartridge entrance.

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4 System overview

This product allows you to quickly and easily analyze the levels of certain bio markers in small blood samples taken from a patient. The system is designed for medical applications in various point of care settings, such as operation theatres and hospital emergency rooms. The system allows you to see and upload results to your information system for further analysis.

The system consists of the following main parts.

Cartridges

Blood samples are dispensed into cartridges for analysis.

The minicare analyzer

A handheld device in which you insert the cartridge containing the blood sample. The minicare analyzer executes the test and displays test results.

Docking station

The minicare analyzer can be docked in the docking station to charge the battery and to transfer test result data to the data manager software.

Data manager software

The data manager software allows you to configure the system and to exchange information with a hospital information system, for example, an LIS.

This section provides an overview of the system functions. The following sections provide details of the specific functions you use and the tasks you perform when operating the minicare analyzer and data manager software.

4.1 Theory of operation

The minicare analyzer uses Philips Magnotech technology. Magnotech is a type of biosensor technology that uses magnetic nanoparticles to measure picomolar concentrations of target substances in blood or saliva in a matter of minutes.

Integrated into a disposable biosensor cartridge that inserts into a handheld analyzer, it automatically fills itself from a single drop of blood or saliva. Once filled, no other fluid movement is required. The entire assay process within the cartridge is executed by controlled movement of the magnetic nanoparticles within the cartridge using external magnetic fields.

The cartridge, constructed entirely from plastic components, has no moving parts or embedded electronics, and is disposable. The analyzer unit contains the electromagnets, optical detection system, control electronics, software and the read-out display.

Magnotech process

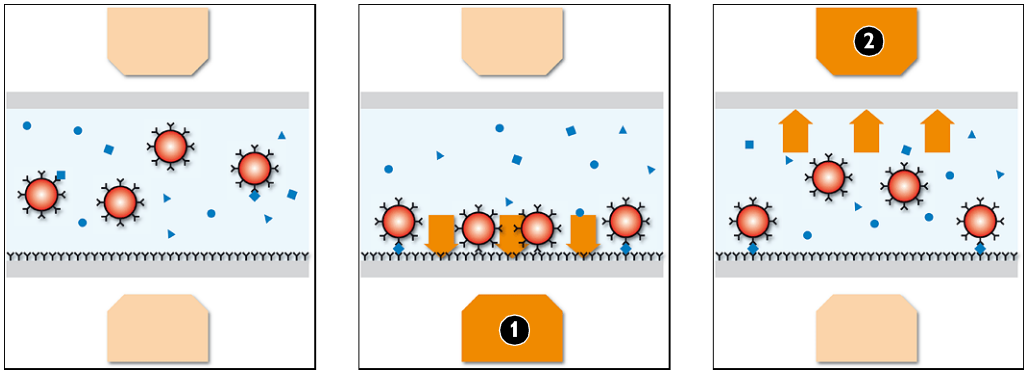


Figure 4.1 Magnotech process

Coated with appropriate ligand molecules, the magnetic nanoparticles bind to the target protein molecules in the sample blood or saliva.

The target molecules end up locked between the active surface (binding magnet [1]) and attached nanoparticles.

A second magnetic field is then generated (washing magnet [2]) to pull unbound magnetic nanoparticles away from the active surface. A very fast and accurately controlled separation between bound and unbound magnetic nanoparticles is thereby achieved.

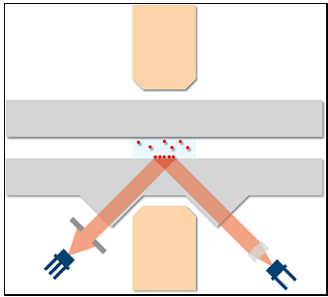


Figure 4.2 Magnotech process - final phase

In the final phase, the number of bound nanoparticles is measured using an optical technique based on frustrated total internal reflection.

4.2 Performance and limitations

4.2.1 Performance characteristics

Philips minicare analyzer
The analyzer can perform 10 typical tests on a partial battery charge.
The analyzer goes into sleep mode after 20 minutes of inactivity if it is not in the minicare docking station.
The analyzer takes 10 seconds to resume from sleep mode and be ready for testing.
The analyzer goes into deep sleep mode when it has been in sleep mode for 5 hours and is not in the minicare docking station.
The analyzer takes 40 seconds to resume from deep sleep mode and be ready for testing.
The analyzer is designed to perform correctly at an ambient temperature between 2° C and 27° C, at a relative humidity between 20% and 80%.
The analyzer measurement stability is ≤ 0.03% over a period of 8 minutes, starting after the sample has filled the chambers.
The analyzer is ready to perform a test 30 seconds after the previous test.

4.2.2 Limitations of use

Depending on the application (duration and strength of measurement) and the conditions (ambient temperature), the number of measurements in a row is limited.

In case a limitation is needed, the system will detect this and will give a warning.

Refer to the Instructions for Use of the specific application cartridges for further limitations.

[NOTE TO REVIEWERS — the information above taken from defect sheet responses after review 1. No further information at this time. More information about limitations of use to be provided during the verification phase and further reviews.]

4.3 Preparation prior to use

First, ensure that the minicare analyzer docking station is properly connected to the mains supply.

Prior to use, you must charge the minicare analyzer battery to ensure that the minicare analyzer can function correctly when it is not docked in the minicare docking station. A partial battery charge takes one hour; a full battery charge takes 12 hours. For instructions on docking the minicare analyzer to charge the battery, see section “Docking the minicare analyzer” on page 4-5.

The system is capable of performing at least one test after one hour of battery charging, but it is preferable to fully charge the battery before use.

4.4 Installing the data manager software

The system requires an available PC for data manager software installation.

Installation from CD

Insert the installation CD in the drive on the host PC. Follow the on-screen instructions as the CD guides you through the installation process.

Installation from file

Double-click the “setup.exe” installation file on the host PC. Follow the on-screen instructions as the program guides you through the installation process.

4.5 Docking and undocking the minicare analyzer

4.5.1 Docking the minicare analyzer

To establish data transfer between the minicare analyzer and data manager software, as well as to charge the analyzer battery, the minicare analyzer must be docked in the minicare docking station. Follow the procedure below to dock the minicare analyzer.

- To dock the minicare analyzer, put the analyzer in the minicare docking station so that the docking station connectors are engaged.



Figure 4.3 Docked minicare analyzer



See section “Equipment connections” on page 3-2 for details of the connectors.

The minicare analyzer screen displays the confirmation messages “Analyzer Docked” and “Connected”.

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Data automatically transfers between the minicare analyzer and the data manager software as indicated on the minicare analyzer screen. Do not disconnect the minicare analyzer from the minicare docking station during data transfer.

The docking station has the following status indicators.

Status light		Status
Docked/Undocked status		White <ul style="list-style-type: none">The minicare analyzer is correctly docked. Red <ul style="list-style-type: none">The minicare analyzer is not correctly docked.Please try docking the analyzer again.
Mains connection status		White <ul style="list-style-type: none">The docking station is connected to the main supply.The docking station automatically charges the minicare analyzer battery when the analyzer is docked.

Data automatically transfers between the minicare analyzer and the data manager software as indicated on the minicare analyzer screen. Do not disconnect the minicare analyzer from the minicare docking station during data transfer.

4.5.2 Undocking the minicare analyzer

- Lift the minicare analyzer out of the minicare docking station.

NOTE

- When the minicare analyzer is undocked, it:*
- does not receive data from the data manager software.*
 - does not transfer data to the data manager software.*
 - performs a self test.*

4.6 Configuring analyzer connectivity

Conditions:

- You must have information from your network administrator about whether the IP address used for the analyzer is a static address or assigned dynamically by a DHCP server.
- You must have Administrator rights for the minicare analyzer and data manager software.
- The minicare analyzer displays “Analyzer docked”.

You must configure analyzer connectivity before you can transfer data to and from the data manager software. You must perform configuration tasks on both the minicare analyzer and the data manager software.

4.6.1 Configuring the minicare analyzer with a static IP address

This is the procedure to follow on the minicare analyzer if you are assigning a static IP address.

- 1 On the minicare analyzer screen, press **Menu**.
- 2 If required, log on to the system.
- 3 Press **Network settings**.
- 4 Press **Change**.
- 5 To clear the warning screen, press **OK**.
- 6 To enter the static IP address details,
 - Select **Static**.
 - Press **Next**.
 - Enter the IP address, using the displayed numeric pad, and then press **Next**.
 - Enter the Subnet mask, using the displayed numeric pad, and then press **Next**.
 - Enter the default gateway, using the displayed numeric pad, and then press **Next**.

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10 **7** On the restart screen, press **Yes**.

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12 The minicare analyzer restarts.

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15 You can now proceed to the configuration procedure for the data manager
16 software, to complete the configuration.

17
18 **4.6.2 Configuring the minicare analyzer with a DHCP server**

19 This is the procedure to follow on the minicare analyzer if your network
20 uses a DHCP server.

21
22 **1** On the minicare analyzer screen, press **Menu**.

23
24 **2** If required, log on to the system.

25
26 **3** Press **Network settings**.

27
28 **4** Press **Change**.

29
30 **5** To clear the warning screen, press **OK**.

31
32 **6** Select **DHCP**.

33
34 **7** Press **Next**.

35
36 **8** On the restart screen, press **Yes**.

37 The minicare analyzer restarts.

38
39 **9** Press **Menu**.

40
41 **10** Press **Network settings**.

42
43 **11** Write down the IP address.

44
45 You can now proceed to the configuration procedure for the data manager
46 software, to complete the configuration.

4.6.3

Configuring the minicare analyzer on the data manager software

After you have changed the configuration settings on the minicare analyzer, you must ensure that the data manager software has the correct IP address for the minicare analyzer.

- 1 Start the data manager software, and log on as an administrator.
- 2 From the **System** menu, select **Host configuration**.
- 3 Enter the minicare analyzer IP address in the **Analyzer address** text box.
- 4 Press **OK**.

The minicare analyzer is now configured to exchange data with the data manager software.

4.7

Configuring LIS connectivity

NOTE

LIS connectivity is a complex task. Contact your local sales organization if you require further information.

The data manager software contains an LIS Configuration screen that can be used to specify a limited number of options. You can access the LIS Configuration screen from the data manager software, by selecting **LIS configuration** from the **System** menu.

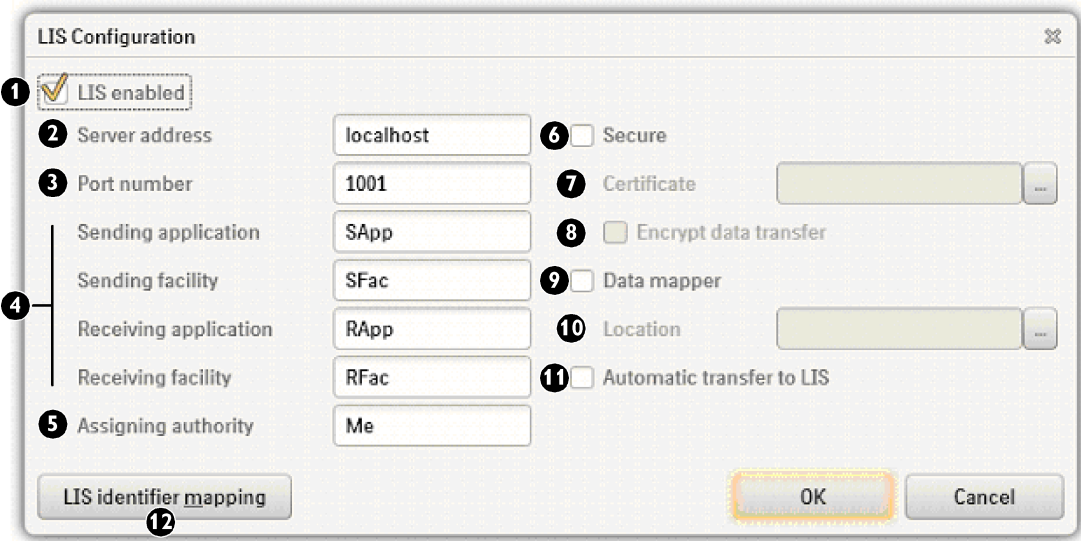


Figure 4.4 LIS Configuration screen

- [1] **LIS enabled**
Select this check box to enable communication between the data manager software and the LIS.
- [2] **Server address**
The host name, IPv4 or IPv6 address of the LIS server.
- [3] **Port number**
The TCP port to which the LIS server should connect.
- [4] **IHE/HL7 MSH parameters**
These values correspond to parameters of the same name (message header) in the IHE/HL7 MSH segment.
 - **Sending application**
 - **Sending facility**

- **Receiving application**
- **Receiving facility**

[5] **Assigning authority**

Used in the Patient ID field of the IHE/HL7 PID (patient identification) segment.

[6] **Secure**

Select this check box to enable node authentication, which means that the data manager software and the LIS verify that they are communicating to the correct machine.

When this box is not selected, no node authentication takes place and data is transferred unencrypted, making it possible to intercept all sent data.

[7] **Certificate**

Node authentication uses certificates to verify the identity of computers. These certificates need to be installed on the PC, but the data manager software needs to be told which certificate to send to the LIS when asked for it.

[8] **Encrypt data transfer**

Besides node authentication, data transfer can be made more secure by encrypting, which happens when this box is checked. When it is not checked, communication will happen unencrypted.

[9] **Data mapper**

The data manager software uses the Symphonia library in its implementation and as such leaves the possibility to map messages to and from the LIS to any desired format, using a message mapping configuration.

[10] **Location**

The path to the Symphonia message mapping configuration. The configuration file must be created with Orion Health's Map Designer tool.

[11] **Automatic transfer to LIS**

When this check box is selected, any incoming analysis result that is received from an analyzer, is automatically transferred to the LIS on the condition that the result is complete, in other words, that there is no missing data that must be filled in by an operator of the data manager software

[12] **LIS identifier mapping**
This button opens a dialog box that enables editing of the cartridge and target IDs of any installed cartridge file. These parameters manipulate the Universal Service Identifier field in the IHE/HL7 OBR (Observation Order) segment and the Observation Identifier in the IHE/HL7 OBX (Observation Result) segment for cartridge and target results.

4.8 Configuring analyzer settings

- Conditions:**
- The minicare analyzer must be connected to the data manager software.
 - You must have administrator privileges for the data manager software.

The minicare analyzer configuration settings show the analyzer currently connected, control the language used, how the user and patient identification process is handled, and treatment of results. The screen also shows hardware and software information about the analyzer. For further details, see section “Configuring the minicare analyzer” on page 12-4

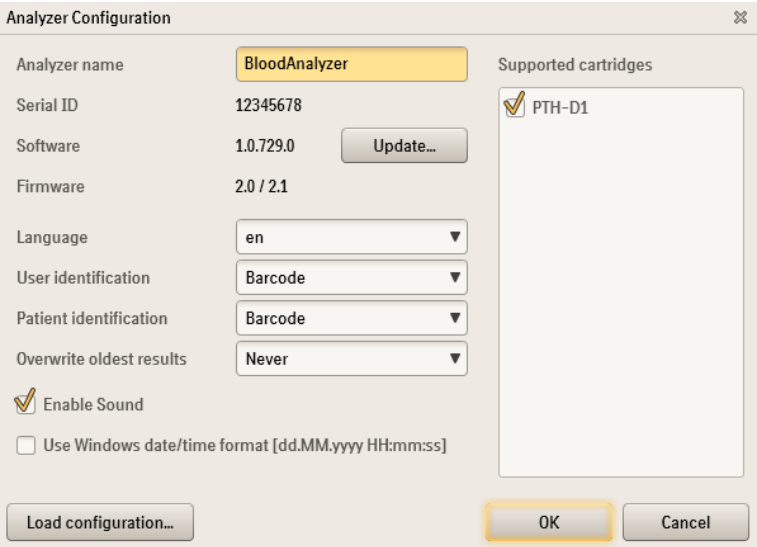


Figure 4.5 Analyzer Configuration screen

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5 Operation - minicare analyzer

5.1 minicare analyzer overview

5.1.1 Main screen

The main screen of the minicare analyzer displays the following items.

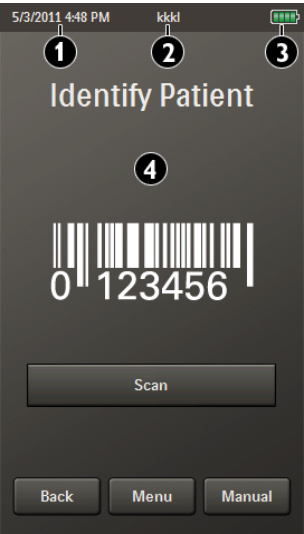


Figure 5.1 Main screen of the minicare analyzer

Legend			
1	Date and time	3	Battery charge level
2	Current user	4	Main display area

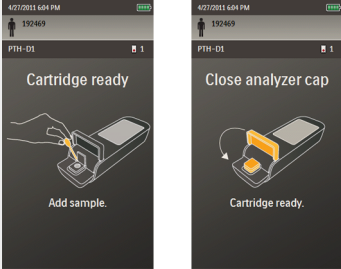
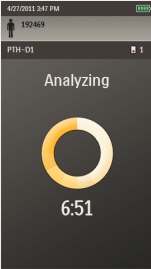
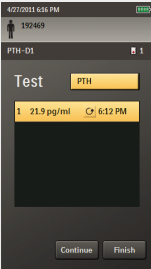
5.1.2 Blood analysis workflow

Depending on your needs and available resources, you can perform tests using the minicare analyzer in several different ways. The information below describes the most common workflow.

Workflow step	Analyzer user interface
<p>1 Identify the patient by scanning a barcode.</p> <p>See section “Identifying the patient by barcode scanning” on page 5-10 for details.</p> <p>You can also choose a patient from a list of analysis orders that have been transferred from the data manager software. See section “Identifying the patient from a list” on page 5-11 for details</p>	<div><div><p>4/27/2011 9:54 AM</p><p>Identify Patient</p><p>0 123456</p><p>Scan</p><p>Back Menu Manual</p></div><div><p>4/27/2011 4:54 PM</p><p>Scan Barcode</p><p>0 123456</p><p>Position the patient barcode in front of the barcode scanner.</p></div></div>
<p>2 Insert the cartridge.</p>	<div><p>4/27/2011 3:43 PM</p><p>152469</p><p>Ready for use</p><p>Insert cartridge.</p><p>Back</p></div>
<p>3 The analyzer validates the cartridge.</p>	<div><p>4/27/2011 3:43 PM</p><p>152469</p><p>Validating cartridge</p><p>Please wait...</p></div>

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Workflow step	Analyzer user interface
4 Add the sample and close the analyzer cap.	
5 Wait for analysis.	
6 View the result.	

5.2 Starting up and shutting down

5.2.1 Starting the minicare analyzer



WARNING

Safety awareness: do not start up the product unless you and all other users present have read, fully understood and know all the safety information and emergency procedures given in the SAFETY section of this Instructions for Use. Operation of the

product without having read, understood and knowing ALL the safety information and procedures in the SAFETY section could lead to fatal or other serious personal injury. It could also lead to clinical misdiagnosis.

- 1 Press the **Power** button located on the side of the minicare analyzer shown in the figure below.



Figure 5.2 Power button

- 2 The minicare analyzer starts and performs a self-test to ensure correct operation.

Details of the self-test are displayed on the minicare analyzer screen. During the test, the system performs a sound check. You should hear an audible tone.

NOTE

Watch the minicare analyzer screen carefully during startup to ensure that all elements on the screen display properly.

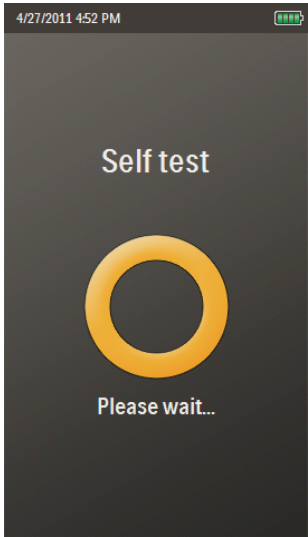


Figure 5.3 minicare analyzer self-test screen

- 3 Wait for the minicare analyzer to finish the self-test before continuing to operate it.

The analyzer screen indicates when the self-test is finished.

NOTE

- The minicare analyzer performs a self-test each time that you:*
- *Start up the analyzer after it has been shut down (turned off).*
 - *Undock the analyzer.*
 - *Restart the analyzer after it has entered “sleep” or “deep sleep” mode to conserve battery power during periods of inactivity.*

5.2.2 Shutting down the minicare analyzer

The minicare analyzer can be shut down (powered off) or put into standby mode using the **Power** button.

NOTE

The minicare analyzer cannot be shut down during certain workflow steps. [Project team to provide details after Review 2 - not available at time of writing]

- 1 To shut down the minicare analyzer, press the **Power** button for a long duration (several seconds).
- 2 To put the minicare analyzer into standby mode, press the **Power** button for a short duration.

5.3 Identifying the user

5.3.1 Logging on

If your minicare analyzer is configured to require user logon, the **Log on** screen appears after starting the system.

- 1 There are two different ways you log on and begin using the analyzer:
 - To identify yourself by scanning your personal identification barcode, press **Scan**.
 - To identify yourself by entering your user PIN, press **Manual**.

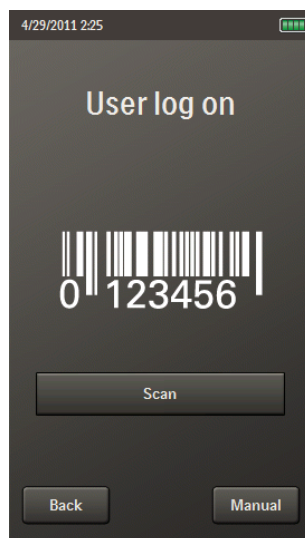


Figure 5.4 User log on screen

If you select **Scan**, the minicare analyzer displays “Scan Barcode.”

If you select **Manual**, the analyzer displays “User log on” with a numeric keypad.

- 2 Log in with your personal identification barcode or your user PIN, depending on your selection in step 1.
 - Scan your personal identification barcode with the barcode reader located on the front of the minicare analyzer, **OR**
 - Enter your user PIN using the numeric keypad on the minicare analyzer screen and press **OK**.

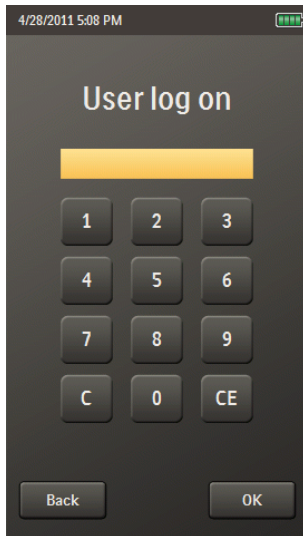


Figure 5.5 Log on with your user PIN

The system displays your user information on the screen after you have successfully logged on.

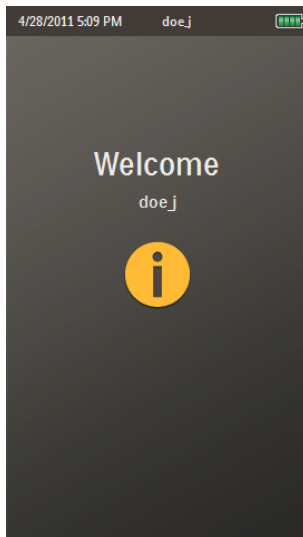


Figure 5.6 User identification on analyzer

5.3.2 Logging out

When you are logged on and finish using the minicare analyzer, follow the instructions below to logout:

1 From the minicare analyzer home screen, press **Menu**.

2 Press **Logout**

The analyzer screen displays “Are you sure you want to Logout?”

3 Press **Yes**.

The “User log on” screen appears.

5.4 Starting analysis

Conditions

- The minicare analyzer is docked. The analyzer screen displays “Analyzer docked”.

The minicare analyzer may remain in docked position on the docking station during an analysis, but it must be disconnected from the data manager software to perform a test. Follow the steps below to terminate the connection between the minicare analyzer and data manager software for a docked analysis.

1 Press **Start** to terminate the connection between the docked minicare analyzer and the data manager software.

2 Press **Yes** to disconnect from the data manager software.

The “Identify patient” screen is displayed. See section “Identifying the patient” on page 5-10.

5.5 Identifying the patient

You can identify the patient before testing by either barcode scanning or by locating patient data in a list that has been loaded by the data manager software. If necessary, you can also perform an anonymous test and enter patient data later using the data manager software or using the HIS/LIS.

NOTE

*You can cancel a test at any time by pressing **Abort** on the minicare analyzer screen. By confirming cancellation, the minicare analyzer settings will be reset to **Identifying the patient**. If **Abort** is not on the minicare analyzer screen, you can cancel the test by removing the cartridge.*

5.5.1 Identifying the patient by barcode scanning

Conditions

- The analyzer screen displays “Identify Patient” and the patient has a patient identification barcode available for scanning.

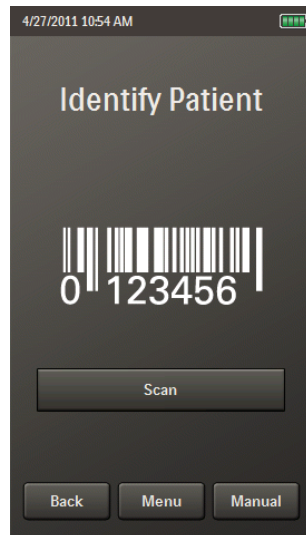


Figure 5.7 Identify Patient screen

- 1 Press **Scan**.

The minicare analyzer displays “Scan Barcode”.

- 2 Scan the patient barcode using the scanner on the front of the minicare analyzer.

The minicare analyzer displays the patient ID at the top of the “Ready for use” screen.

5.5.2

Identifying the patient from a list

Conditions

- The minicare analyzer screen displays the “Identify Patient” and relevant patient data has been transferred to the minicare analyzer from the data manager software. See section “Transferring an analysis order to the minicare analyzer” on page 6-15.

- 1 Press **Manual** on the “Identify Patient” screen.

The “Select Patient” screen appears.

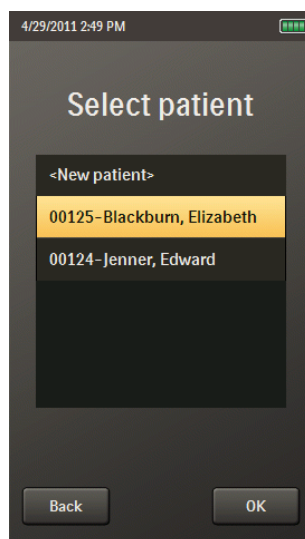


Figure 5.8 Select Patient screen

- 8
9
10 2 Touch the correct patient name on the list.

11
12 The selected patient name is highlighted.

- 13
14 3 Press **OK**.

15
16 The minicare analyzer displays the patient ID and name at the top of the
17 “Ready for use” screen.

18
19 If you selected the incorrect patient, press **Abort** and confirm your decision
20 by pressing **Yes** on the “Abort Analysis” screen to return to the “Identify
21 Patient” screen.
22

23
24 5.5.3 Performing an anonymous test

25 **Conditions**

- 26
27 • The minicare analyzer screen displays “Identify Patient”.
28 • No patient barcode is available for scanning, and the patient data has not
29 been transferred to the minicare analyzer from the data manager software.
30

- 31 1 Press **Manual**.

32 The “Select Patient” screen appears.

- 33 2 Touch **<New patient>**.

- 34 3 Press **OK**.

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36 The minicare analyzer displays “Anonymous” as the patient name on the
37 “Ready for use” screen. The Patient ID field is left blank.
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5.6 Inserting a cartridge

Conditions

- The minicare analyzer displays the message “Ready for Use” and “Insert Cartridge.”

NOTE

Read the assay Instructions for Use supplied with the cartridge for adding a blood sample to the cartridge. Each assay type has specific procedures that you must follow when collecting and handling blood samples.

- 1 Open the cartridge chamber cap on the minicare analyzer.



Figure 5.9 Opening the minicare analyzer cap

- 2 Insert the cartridge in the cartridge chamber as shown in the figure below.

NOTE

Always be sure to insert the correct cartridge for the intended test.



Figure 5.10 Inserting a cartridge

The minicare analyzer automatically validates the cartridge, using the information stored in the RFID tag.

If the cartridge is validated, the minicare analyzer displays “Cartridge ready” and “Add blood sample”.

5.7 Adding a blood sample and performing a test

Conditions

- The cartridge has been inserted in and validated by the minicare analyzer. The minicare analyzer displays “Cartridge ready” and “Add blood sample.”

NOTE

Read the assay Instructions for Use supplied with the cartridge for adding a blood sample to the cartridge. Each assay type has specific procedures that you must follow when collecting and handling blood samples.

The minicare analyzer can be either docked or undocked for this procedure.

- 1 Add the blood sample to the cartridge as specified in the assay instructions.

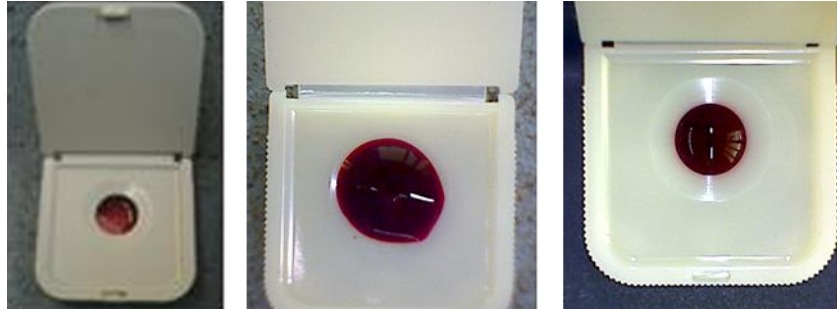


Figure 5.11 Cartridge underfilled (left), overfilled (middle), and correctly filled (right)

The blood sample must be added to the cartridge and read by the minicare analyzer within the time limit for the assay, otherwise the system times out and the cartridge is no longer valid.

- 2 Close the cartridge chamber cap as soon as the blood sample is added.

The analyzer will show instructions for closing the analyzer cap and cartridge lid

If the minicare analyzer cannot read the blood sample after a short period, the system times out and the cartridge is no longer valid.

The cartridge registers the blood sample. There is a short waiting period during analysis.

- 3 When the cartridge registers the blood sample, the minicare analyzer automatically begins blood analysis.

The minicare analyzer displays “Analyzing” and the remaining time needed for analysis.

- 4 The minicare analyzer completes the test and displays the analysis results.

- 5 Press **Continue** if you want to perform additional tests for the same analysis, or press **Finish** if you do not want to perform additional tests.

5.8 Removing a cartridge

Conditions

- The minicare analyzer displays “Remove cartridge” .
- 1 Open the cartridge chamber cap on the minicare analyzer.
 - 2 Pull the cartridge out of the minicare analyzer.
 - 3 Dispose of the cartridge immediately as described in the assay Instructions for Use supplied with the cartridge.
 - 4 Close the minicare analyzer cap.

CAUTION

Close the cap after each use to prevent dust and other foreign particles and substances from entering the cartridge chamber on the minicare analyzer.

5.9 Performing multiple tests

Conditions

- The **Continue** button has been pressed after a previous test.
 - Certain assays require multiple tests before completing the entire analysis.
- 1 Follow the procedures described in the previous sections for inserting a cartridge (section “Inserting a cartridge” on page 5-13), performing analysis (section “Adding a blood sample and performing a test” on page 5-14), and removing a cartridge (section “Removing a cartridge” on page 5-16).
 - 2 Press **Continue** to perform additional tests.
 - 3 Press **Finish** to complete all tests in the analysis.

5.10 Finishing a test or analysis

Conditions

- You have finished a test or multiple tests in an analysis.
- The minicare analyzer displays test results.

1 Press **Finish**.

The minicare analyzer displays a confirmation message.

2 Press **Accept** to accept the results and finish the analysis. The minicare analyzer automatically transfers the results to the data manager software.

Press **Reject** to reject the entire analysis.

Press **Cancel** to return to the previous screen and continue with the current analysis (run additional tests).

The minicare analyzer displays “Remove cartridge.”

3 Remove the cartridge. See section “Removing a cartridge” on page 5-16.

If the minicare analyzer is currently docked and connected, it automatically transfers the results to the data manager software. If the minicare analyzer is not currently docked and connected, the results will transfer automatically the next time it is docked and connected.

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Finishing a test or analysis

6 Operation - minicare data manager

The data manager software connects to your minicare analyzer through the minicare docking station. It enables you to load patient data, transfer the patient data to the minicare analyzer, transfer test results from the minicare analyzer to the software, and then transfer analysis results to the hospital LIS. The data manager software also provides areas for you to configure your minicare analyzer and manage user accounts.

Security

The data manager software provides the facility for user names and passwords to protect patient data from unauthorized access. The system also automatically logs the user off after a period of inactivity.

For further details contact your Hospital Administrator.

6.1 Starting and stopping the data manager software

6.1.1 Starting the data manager software

- 1 Click the Windows **Start** menu.
- 2 Select **Programs**.
- 3 Select **Philips Magnotech Host Software**.
- 4 Click **Philips Magnotech Host Software**.

The Philips Magnotech Host Software logon screen appears.

6.1.2 Logging on

It is recommended that each user of the system is identifiable via a unique user name, and that each user name is protected with a password known only to the user. User names and passwords are usually created by your Point of Care Coordinator or Hospital Administrator whenever a new user name is required.



Figure 6.1 The Data Manager Software Logon panel

- 1 Type your user name in the **User Name** field.
- 2 Type your password in the **Password** field.
- 3 Click **OK**.

The system opens to the **Analysis orders** tab.

6.1.3 Logging off

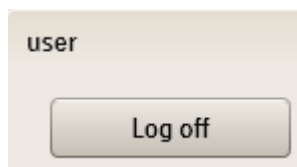


Figure 6.2 Log off button

- Click **Log off**.

Your work is saved and the Logon screen is displayed for the next user.

NOTE

An automatic logoff feature terminates the current user session after 15 minutes of inactivity.

6.1.4 Exiting the data manager software

Follow the steps below to close the data manager software application completely.

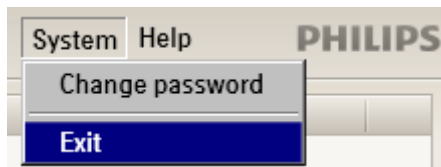


Figure 6.3 Exiting the data manager software

- 1 Click **System**
- 2 Click **Exit**.

The entire data manager software application closes.

6.2 System overview

The data manager software provides an environment for creating analysis orders, transferring analyses, and managing patient analyses. There are two main areas for managing patient data. In addition, there is an area to manage Quality Control (QC) test results from the analyzer.

For details on configuring data manager software settings, see section “Configuring the data manager software” on page 12-2.

Analysis orders

The **Analysis orders** tab displays the list of active patient orders for analysis.

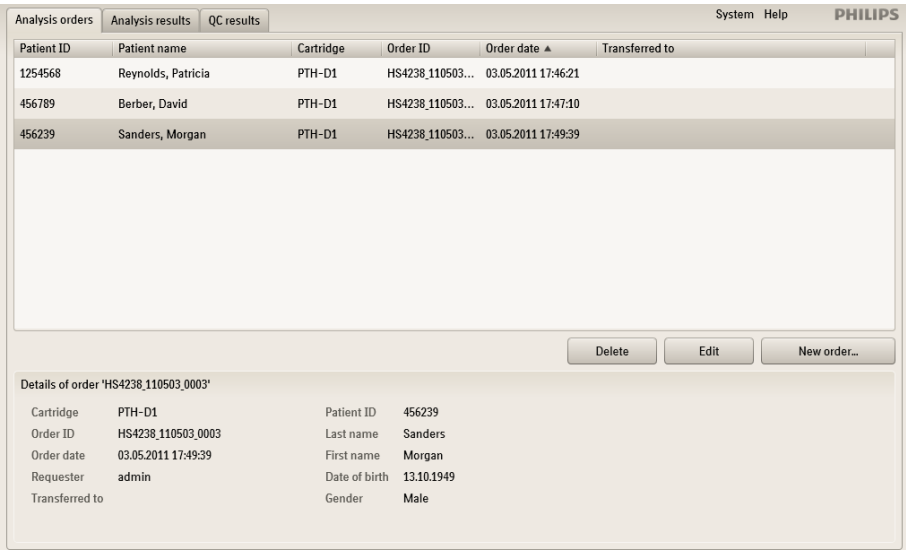


Figure 6.4 Analysis orders tab

Use this area to:

- Enter and edit patient data.
- Create new orders for analysis.
- Transfer orders to the minicare analyzer.

Analysis results

The **Analysis results** tab displays the results of patient analyses.

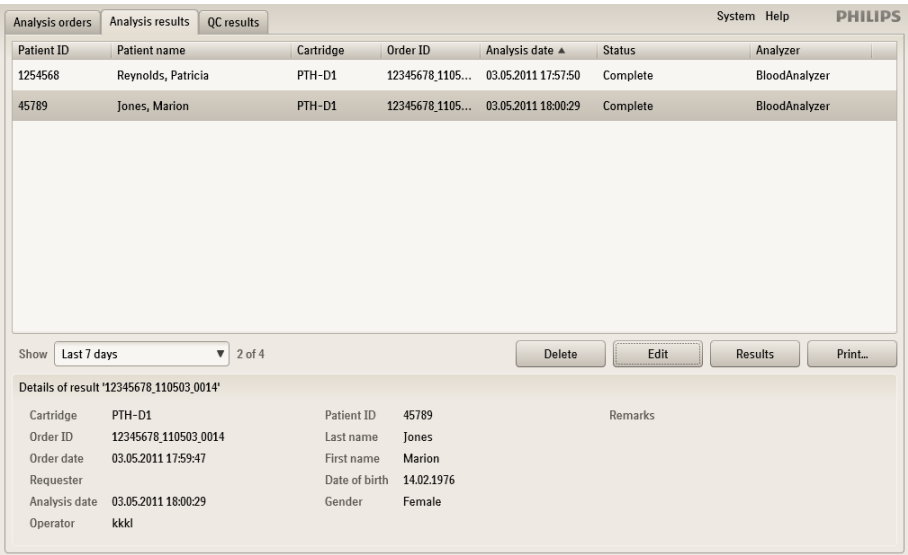


Figure 6.5 Analysis results tab

Use this area to:

- View analysis results.
- Transfer analyses to the LIS.
- Edit, delete, and print analysis results.

QC results tab

The **QC results** tab displays the results of Quality Control (QC) tests.

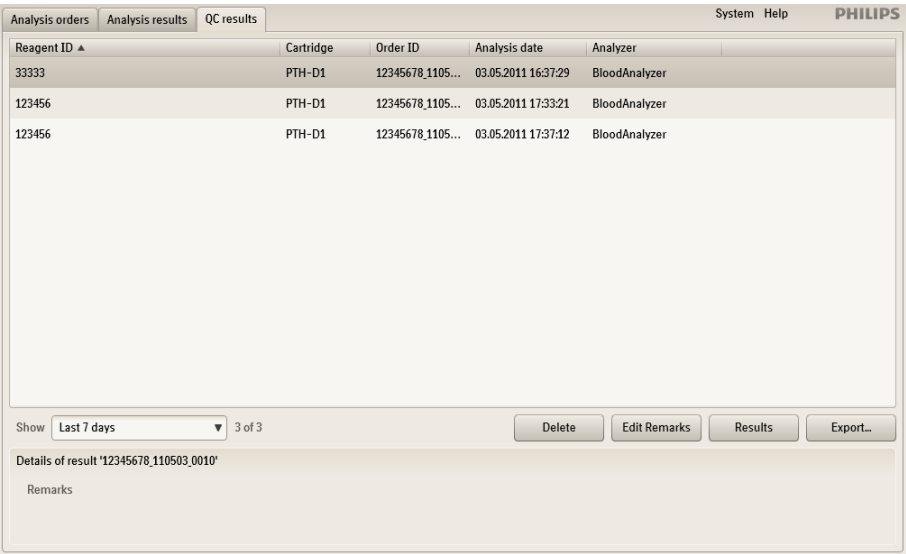


Figure 6.6 QC results tab

Use this area to:

- View QC test results.
- Edit, delete and export QC test results.

6.2.1 Common elements

The following controls are available in all activities.

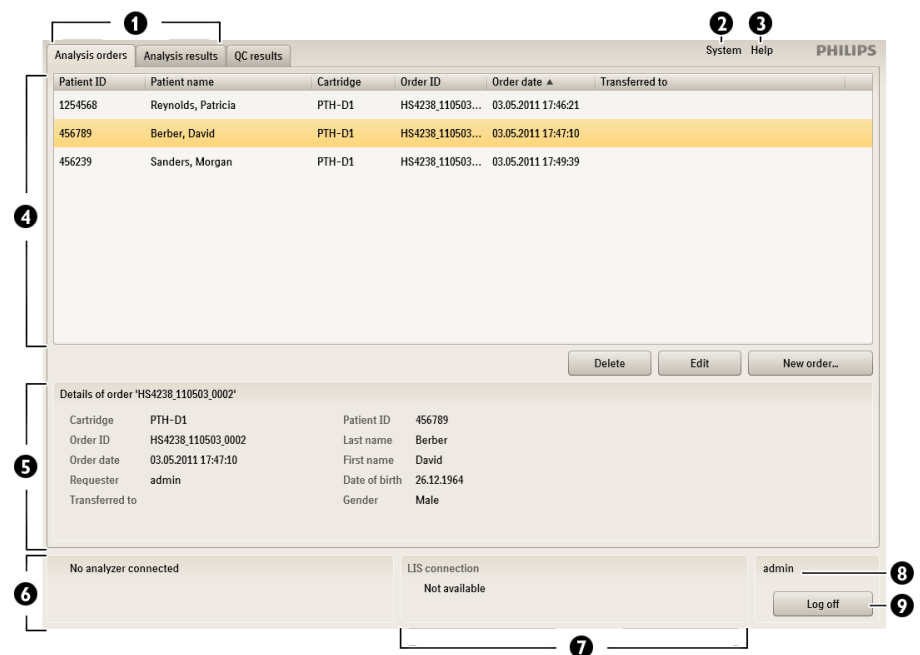


Figure 6.7 Data manager software common elements

Legend			
1	Navigation tabs	2	System menu
3	Help menu	4	Patient List
5	Details area	6	Analyzer information
7	Analyzer connection	8	User Identification
9	Log off button		

Navigation tabs

The navigation tabs allow you to switch between the two main screens. The navigation tabs are described in more detail later in this Instructions for Use. See section “Analysis orders” on page 6-11 and section “Analysis results” on page 6-16 and .

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10 **System menu**

11 You can use the system menu to change your password or exit the system.
12
13 For additional system menu options for Hospital Administrators, see section
14 “Additional host software options for Administrators” on page 12-1.
15

16
17 **Changing your password**

18 Your first password will be configured by your Hospital Administrator. It is
19 advised that you change your password initially and at regular intervals as
20 recommended by your institution’s security guidelines.
21

- 22
- 23 1 Click **System**.
 - 24 2 Select and click **Change password**.
 - 25 The Change Password dialog appears.
 - 26
 - 27 3 Type your old password in the **Old password** field.
 - 28
 - 29 4 Enter your new password in the **New password** field.
 - 30
 - 31 5 Reenter your new password in the **Reenter password** field.
 - 32
 - 33 6 Click **OK** to confirm your password change. If you do not want to change
 - 34 your password, click **Cancel** and your changes will not be saved.
35

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37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55	NOTE <i>If you forget your user name or password, contact your Hospital Administrator. If the Hospital Administrator cannot reset the user name or password, contact Service.</i>
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Help menu

The help menu provides options for online assistance as well as system information.

Help

Clicking **Help** opens this Instructions for Use, where you can search for guidance on functions and features.

Online help

Clicking **Online Help** opens the Philips web site, where you can search for information within the larger context of Philips.

About Magnotech Host software

Clicking **About Magnotech Host software** displays a window containing the following system information:

- Version number
- Build ID
- Philips Electronics name and address
- Copyright information and date

Click **Close** to exit the window and return to the main screen.

Patient List

Depending on the selected tab, the Patient List displays either current orders or analysis results. The Patient Lists are described in more detail later in this Instructions for Use. See section “Patient List” on page 6-11 and section “Patient List” on page 6-16.

Details area

The Details area displays more information on the patient order selected from the Patient List. The Details areas are described in more detail later in this Instructions for Use. See

section “Details area” on page 6-13 and section “Details area” on page 6-18.

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10 **Analyzer area**

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12 The Analyzer area provides information about the minicare analyzer
13 connected to the data manager software. It also displays a status bar during
14 data transfer between the minicare analyzer and data manager software.

15
16 The message “No analyzer connected” is displayed when there is no
17 minicare analyzer connected to the data manager software via the minicare
18 docking station. When an analyzer is not connected, all options to transfer
19 orders to an analyzer are disabled until the connection is established.

20
21 **LIS connection**

22
23 The LIS connection area displays whether the data manager software is
24 connected to the LIS.

25
26 The message “Not available” is displayed when there is no active LIS
27 connection. When the LIS is not connected, all options to transfer results to
28 the LIS are disabled until the connection is established.
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User information

The User area displays the user name currently logged on. The User area also contains the **Log off** button.

6.3 Analysis orders

The **Analysis orders** screen provides an overview of patient orders awaiting or undergoing analysis.

You use the **Analysis orders** screen to create a new order, transfer an order to the minicare analyzer, view and edit order details, and delete orders.

6.3.1 Patient List

The Patient List shows patient orders waiting for analysis.

Patient ID	Patient name	Cartridge	Order ID	Order date	Transferred to
0112587986	Smith, Jane	PTH-D1	HS0278_101210...	10.12.2010 16:41:00	
0785626842	Brown, Adam	PTH-D1	HS0278_101210...	10.12.2010 16:51:48	
1896547854	Schaffer, Maria	PTH-D1	HS0278_101210...	10.12.2010 16:52:39	
1274582547	Walker, Nils	PTH-D1	HS0278_101210...	10.12.2010 16:55:19	
4587452145	Beyer, Ron	PTH-D1	HS0278_101210...	10.12.2010 16:56:55	

Buttons: Delete, Edit, New order...

Figure 6.8 Patient List entry attributes on the Analysis orders tab

- [1] **Patient ID**
The unique number assigned to the patient upon admission.
- [2] **Patient name**
The patient’s name, in (lastname, firstname) format.
- [3] **Cartridge**
The type of cartridge assigned to the particular test the patient requires.

- [4] **Order ID**
The unique ID generated by the data manager software when the order was created.
- [5] **Order date**
The date the order was created.
- [6] **Transferred to**
The minicare analyzer the order was transferred to. If the order has not been transferred to an analyzer, the field remains blank.

Patient List basic actions

To	Do this
Sort the Patient List on an attribute in ascending order	Click a Patient entry attribute
Sort the Patient List on an attribute in descending order	Click a Patient entry attribute
Change the width of an attribute column	Move the pointer over the split bar. When the pointer becomes a doubleheaded arrow, drag the pointer to move the split bar.
Reorder Patient List attributes	Drag the attribute to a new position.
Delete patient entry	Select the patient entry and click Delete . You must confirm your action before it is completed. All series and associated objects contained in the patient entry are deleted.

[12nc xxxx xxx xxxx] [Draft version 0.2 This label will be removed]

Philips Electronics Nederland B.V.

6.3.2

Details area

Analysis orders Details area

The Details area displays additional information on a specific order selected from the Patient List.



Figure 6.9 Analysis orders Details area

1

Cartridge

The type of cartridge assigned to the particular test the patient requires.

2

Order ID

The unique ID generated by the data manager software when the order was created.

3

Order date

The date the order was created.

4

Requester

The user who created the order.

5

Transferred to

The name of the minicare analyzer to which the order was transferred.

6

Patient ID

The unique number assigned to the patient upon admission.

7

Last name

The patient's last name.

8

First name

The patient's first name.

[9] **Date of birth**
The patient's birth date.

[10] **Gender**
The patient's sex (male or female).

6.3.3 Creating a new analysis order

- 1 Click the **Analysis orders** tab.
- 2 Click the **New order** button.
The New Order dialog box appears.
- 3 Enter the patient information for each field in the New Order dialog box. Fields marked with an asterisk (*) are mandatory.

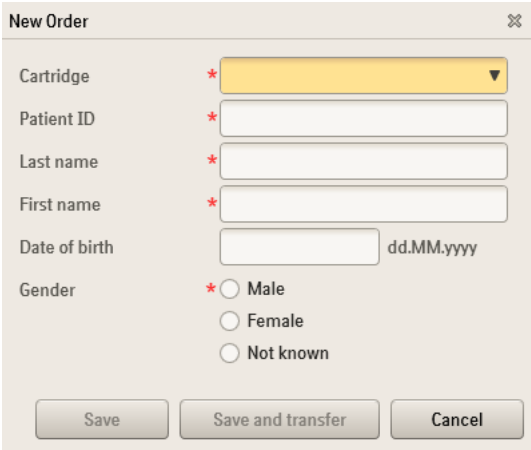


Figure 6.10 New Order dialog box

- 4 When all fields are complete, do one of the following:
 - Click **Save** to save the new order in the data manager software without transferring it to the minicare analyzer immediately.
 - Click **Save and transfer** to transfer the order to the minicare analyzer immediately. This option is only available when an analyzer is connected.
 - Click **Cancel** to cancel the order. The information is deleted.

The new order appears in the Analysis orders Patient List.

6.3.4 Transferring an analysis order to the minicare analyzer

Conditions

- An analyzer is connected.
- The analysis order saved in the Analysis orders Patient List has not already been transferred.

If the order has not yet been created, see section “Creating a new analysis order” on page 6-14.

- Click the **Transfer** button next to the patient order in the Analysis orders Patient List.

The order transfers to the minicare analyzer and the status changes to the minicare analyzer name. You can now select the patient for analysis from the Patient List on the minicare analyzer.

6.3.5 Deleting an analysis order

Conditions

- An analysis order is saved in the Analysis orders Patient List.

- 1 Click the **Delete** button.
- 2 A confirmation dialog appears. Click **OK** to complete the deletion or **Cancel** to keep the order in the Analysis orders Patient List.

If the analysis order has already been transferred to the minicare analyzer, a dialog appears advising that deleting the order from the data manager software will not delete the order from the minicare analyzer, even if the minicare analyzer is connected.

6.4 Analysis results

The **Analysis results** screen provides an overview of patient analyses that have been transferred from the minicare analyzer.

You use the **Analysis results** screen to view analysis results, transfer analysis results to the LIS, as well as edit, print, and delete results.

6.4.1 Patient List

The Patient List shows results of patient analysis before being transferred to the LIS.

1 Patient ID	2 Patient name	3 Cartridge	4 Order ID	5 Analysis date	6 Status	7 Analyzer
0247895556	Doe, Jane	PTH-D1	HS0278_101109...	09.11.2010 14:10:27	Complete	BloodAnalyzer
0785626842	Brown, Adam	PTH-D1	HS0278_101210...	10.12.2010 17:57:55	Complete	BloodAnalyzer
1896547854	Schaffer, Maria	PTH-D1	HS0278_101210...	10.12.2010 18:04:31	Incomplete	BloodAnalyzer

Figure 6.11 Patient List entry attributes on the Analysis results tab

- [1] **Patient ID**
The unique number assigned to the patient upon admission.
- [2] **Patient name**
The patient’s name, in (lastname, firstname) format.
- [3] **Cartridge**
The type of cartridge assigned to the particular test the patient requires.
- [4] **Order ID**
The unique ID generated by the data manager software when the order was created.

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- [5] **Analysis date**
The date the analysis was completed on the minicare analyzer.
- [6] **Status**
Information whether the analysis is complete, incomplete, or rejected.
- [7] **Analyzer**
The name of the minicare analyzer on which the test was performed and registered.

Patient List basic actions

To	Do this
Sort the Patient List on an attribute in ascending order	Click a Patient entry attribute
Sort the Patient List on an attribute in descending order	Click a Patient entry attribute
Change the width of an attribute column	Move the pointer over the split bar. When the pointer becomes a doubleheaded arrow, drag the pointer to move the split bar.
Reorder Patient List attributes	Drag the attribute to a new position.
Delete patient entry	Select the patient entry and click Delete . You must confirm your action before it is completed. All series and associated objects contained in the patient entry are deleted.
Filter the results list	Click the Show field and choose the filter method that you want to use.

6.4.2 Details area

Analysis results Details area

The Details area displays additional information on a specific patient result selected from the Patient List.

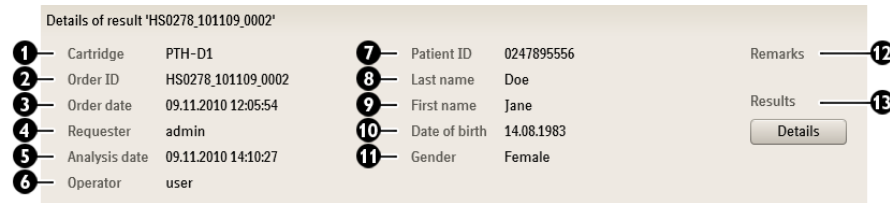


Figure 6.12 Analysis results Details area

[1]

Cartridge

The type of cartridge assigned to the particular test the patient requires.

[2]

Order ID

The unique ID generated by the data manager software when the order was created.

[3]

Order date

The date the order was created.

[4]

Requester

The user who created the order.

[5]

Analysis date

The date the analysis was completed on the minicare analyzer.

[6]

Operator

The name of the current operator.

[7]

Patient ID

The unique number assigned to the patient upon admission.

[8]

Last name

The patient's last name.

[9]

First name

The patient's first name.

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- [10] **Date of birth**
The patient's birth date.
- [11] **Gender**
The patient's sex (male/female).
- [12] **Remarks**
Shows any remarks entered for the patient using the **Edit** function.
- [13] **Results**
Click the **Details** button for analysis results, including the time of each test in the analysis as well as the result of each test.

6.4.3 Transferring analysis results from the minicare analyzer

- Dock the minicare analyzer on the minicare docking station.

Any completed test results that have not already transferred to the minicare analyzer transfer automatically. The transfer progress appears in the Analyzer area on the data manager software.

When the transfer is complete, all new results appear in the Analysis results Patient List. The patient data is automatically deleted from the minicare analyzer after it is transferred to the data manager software.

6.4.4 Editing analysis results

- 1 Click on a patient row in the Analysis results Patient List.
The selected result is highlighted.
- 2 Click the **Edit** button
The Edit Result dialog appears.

Edit Result

Operator

user

Patient ID

0247895556

Last name

Doe

First name

Jane

Date of birth

14.08.1983

dd.MM.yyyy

Gender

Male

Female

Not known

Remarks

Save

Save and transfer

Cancel

Figure 6.13 Edit Result dialog

- 3 Edit any of the patient information or add comments in the Remarks area.
- 4 Click **Save** to save your changes.
If you click **Cancel**, your changes will not be saved.

6.4.5

Condition: a printer is configured for your workstation.

- 1 Click on a patient row in the Analysis results Patient List.

The selected result is highlighted.

- 2** Click the **Print** button

The Windows Print dialog appears.

- 3** Select the printer from the list and click **Print**.

Transferring analysis results to the LIS

6.4.6

You can transfer results to a LIS using the Transfer button.

Condition: LIS connectivity must be enabled.

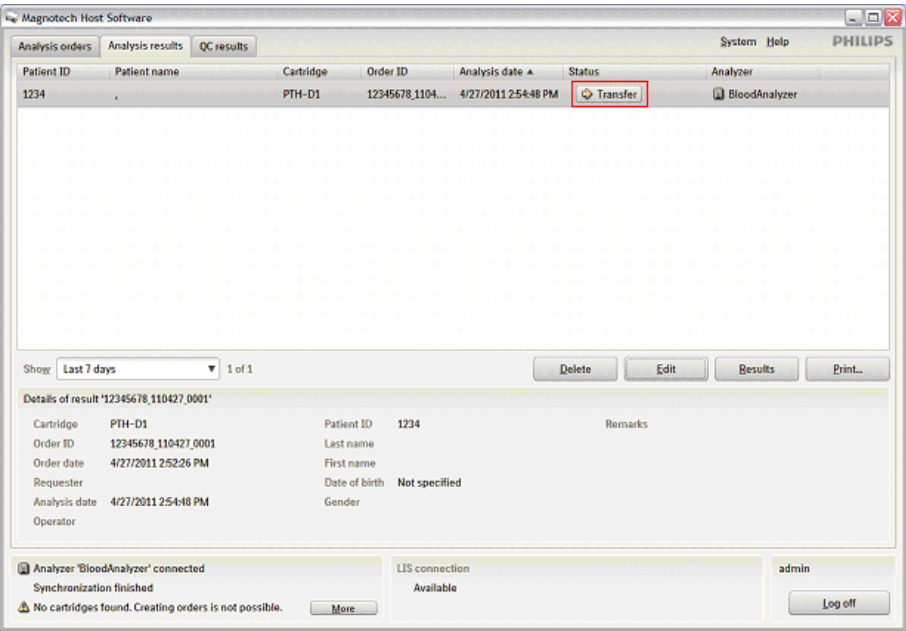


Figure 6.14 Transfer button on the Analysis results tab

- On the Analysis results tab, press the Transfer button next to the result that you want to transfer.

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6.5 QC results

The **QC results** screen provides an overview of QC tests that have been transferred from the minicare analyzer.

You use the **QC results** screen to view QC test analysis results, export analysis results, as well as edit remarks and delete results.

6.5.1 QC results list

The QC results list shows results of QC tests before being exported or deleted.

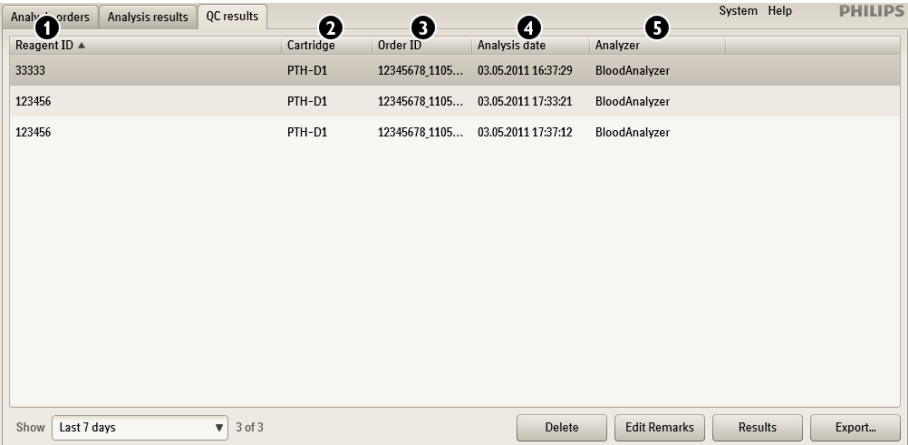


Figure 6.15 QC results entry attributes on the QC results tab

- [1] **Reagent ID**
The number assigned to the reagent.
- [2] **Cartridge**
The type of cartridge assigned to the particular test.
- [3] **Order ID**
The unique ID generated by the data manager software when the order was created.
- [4] **Analysis date**
The date the QC test analysis was completed on the minicare analyzer.

[5] **Analyzer**
The name of the minicare analyzer on which the test was performed and registered.

QC results list basic actions

To	Do this
Sort the QC results list on an attribute in ascending order	Click QC entry attribute
Sort the QC results list on an attribute in descending order	Click a QC entry attribute
Change the width of an attribute column	Move the pointer over the split bar. When the pointer becomes a doubleheaded arrow, drag the pointer to move the split bar.
Reorder QC results list attributes	Drag the attribute to a new position.
Delete QC test entry	Select the QC result entry and click Delete . You must confirm your action before it is completed. All series and associated objects contained in the entry are deleted.
Filter the results list	Click the Show field and choose the filter method that you want to use.

6.5.2 Additional QC results options

Details area
The Details area shows any remarks that have been written when you highlight a specific QC result selected from the list.

Transferring results from the minicare analyzer
Dock the minicare analyzer on the minicare docking station as you would when transferring analysis results. See section “Transferring analysis results from the minicare analyzer” on page 6-19.

Any completed QC test results that have not already transferred to the minicare analyzer transfer automatically. The transfer progress appears in the Analyzer area on the data manager software.

When the transfer is complete, all new results appear in the QC test results list.

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Editing QC results remarks

Click the **Edit Remarks** button below the results list. Click **Save** to save your changes and return to the patient list.

Exporting QC results

Click the **Export** button. You can then select where you would like to save your results in Microsoft Excel format.

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QC results

7 System messages and troubleshooting

7.1 System and error messages

7.1.1 Philips minicare analyzer

Message number	Category	Description	Action
1000	Analyzer Failure	Measuring unit power off failed.	Please try again. If the problem persists contact your local representative.
1001	Analyzer Failure	Measuring unit power on failed with code '{0}'.	Please try again. If the problem persists contact your local representative.
1100	Analyzer Failure	Failure during cartridge detection.	Please try again. If the problem persists contact your local representative.
1101	Cartridge Failure	Cartridge expired on '{0}'.	Please use another cartridge
1102	Workflow Failure	Cartridge has been used before.	Please use another cartridge.
1103	Workflow Failure	Cartridge '{0}' is not supported by analyzer.	Install the cartridge using host software or use a supported cartridge type.
1104	Workflow Failure	The selected patient requires cartridge '{0}'. Inserted cartridge is '{1}'.	Use cartridge '{0}'.
1105	Workflow Failure	Cartridge was removed during analysis. The analysis has been aborted.	Please try again.
1106	Cartridge Failure	Cartridge is invalid.	Use another cartridge.
1107	Analyzer Failure	Access to protocol for cartridge '{0}' failed.	Please try again. If the problem persists contact your local representative.
1108	Cartridge Failure	Cartridge is invalid.	Use another cartridge.
1109	Analyzer Failure	Cartridge configuration is invalid.	Please contact your local representative.
1110	Power Failure	Battery level too low for cartridge measurement. The analyzer has stopped operation.	Please charge the analyzer and then retry the cartridge measurement.
1200	Analyzer Failure	RFID hardware failed.	Please try again. If the problem persists contact your local representative.
1201	Cartridge Failure	Invalid RFID format.	Use another cartridge.
1202	Cartridge Failure	RFID version '{0}' is not supported.	Use another cartridge.
1203	Cartridge Failure	Cartridge RFID could not be read.	Remove cartridge and try again.

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7.1 System and error messages
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Message number	Category	Description	Action
1300	Analyzer Failure	Temperature hardware failed.	Please try again. If the problem persists contact your local representative.
1302	Analyzer Failure	Sample detection hardware failed.	Please try again. If the problem persists contact your local representative.
1303	Workflow Failure	Sample timeout.	Please apply sample within '{0}' seconds and apply sufficient volume of sample.
1304	Workflow Failure	A sample was added before target temperature was reached.	Please add sample after analyzer reaches target temperature.
1305	Cartridge Failure	Target temperature '{0}' out of analyzer range.	Cartridge '{1}' cannot be measured on this analyzer. Contact your local representative.
1350	Analyzer Failure	Frame capturing hardware failed.	Please try again. If the problem persists contact your local representative.
1400	Update Failure	Update of firmware failed. The analyzer has stopped operation.	Please reset the analyzer to retry the firmware update.
1401	Update Failure	Update of firmware failed. The previous version is running and the upgrade is aborted.	Please retry the firmware update using the host software.
1402	Update Failure	Battery level too low for firmware upgrade. The analyzer has stopped operation.	Please charge the analyzer and then retry the firmware update.
1410	Analyzer Failure	Self test failed with code '{0}'. The analyzer will not allow to perform an analysis.	Try to reset the analyzer. If the problem persists contact your local representative.
1500	Analyzer Failure	Result calculation failed.	Contact your local representative.
1600	Analyzer Failure	Image of the cartridge is invalid.	Please try another cartridge.
1601	Cartridge Failure	Sample did not reach the measurement chamber within the maximum '{0}' seconds.	Please try another cartridge. Make sure sufficient blood is applied.
1602	Analyzer Failure	Measurement hardware failed.	Please try again. If the problem persists contact your local representative.
1603	Analyzer Failure	Temperature was too low during measurement.	Please try another cartridge.
1604	Analyzer Failure	Temperature was too high during measurement.	Please try another cartridge.
1605	Analyzer Failure	Data processing has failed.	Please try another cartridge.
1606	Analyzer Failure	Measurement failed.	Please try again. If the problem persists contact your local representative.
1700	Workflow Failure	Storage of new measurement results is full.	Synchronize the analyzer with the Host software to free storage.

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Message number	Category	Description	Action
1800	Analyzer Failure	Cap hardware failed.	Please try again. If the problem persists contact your local representative.
1801	Workflow Failure	Cap not closed on time.	Please try again. Make sure to close the cap when prompted.
1900	Analyzer Failure	Power button hardware failed.	Please try again. If the problem persists contact your local representative.
2000	Barcode Failure	Unable to scan barcode.	Please try again. If the problem persists contact your local representative.
2100	Analyzer Failure	Battery hardware failed.	Please try again. If the problem persists contact your local representative.
2200	Hardware failure	Unable to detect docking station.	Try to reset the analyzer. If the problem persists contact your local representative.
9000	Critical Error	Critical error '{0}' occurred. The analyzer has stopped.	Try to reset the analyzer. If the problem persists contact your local representative.
9001	Critical Error	Data access failed. The analyzer has stopped.	Try to reset the analyzer. If the problem persists contact your local representative.

7.1.2 Data manager software

Error messages

Number	Category	Description	Action
TBD	Analyzer Cartridge Not Compatible	Cartridge file '{0}' is not compatible with the current analyzer.	Contact the POC administrator to check the software version of the analyzer and to provide compatible cartridge file.
TBD	Analyzer Communication Incompatibility	Analyzer and Magnotech Host Software incompatibility detected.	Contact the POC Administrator to check the versions of the analyzer and Magnotech Host Software.
TBD	Analyzer Connection Exception	Connection with analyzer lost during communication.	Try docking the analyzer to reestablish the connection.
TBD	Analyzer Firmware File Not Found	The analyzer firmware update pack '{0}' could not be found.	Contact the POC administrator to make sure the firmware update pack exists and sufficient permissions to access the file are available.

7.1 System and error messages

Number	Category	Description	Action
TBD	Analyzer General	An unexpected problem with the analyzer has occurred. The analyzer cannot perform the requested action.	Try to reset the analyzer and/or the Magnotech Host Software. If the problem persists contact the POC administrator.
TBD	Analyzer Language File Not Found	The analyzer language pack '{0}' could not be found.	Contact the POC Administrator to make sure that the selected analyzer language pack is installed in the Magnotech Host Software.
TBD	Analyzer Language In Use	Unable to install this language on the analyzer. This language is currently active.	To update the active language, change the active language to another language and back again.
TBD	Analyzer Language Invalid File	Invalid analyzer language pack '{0}'.	Contact the POC Administrator to reinstall the analyzer language pack.
TBD	Analyzer Order Adding Failed	Failed to transfer order '{0}' to the analyzer.	Try to restart the analyzer and retransmit the order. If the problem persists contact the POC administrator.
TBD	Analyzer Order Cartridge Not Supported	Order '{0}' cannot be transferred to the analyzer due to missing cartridge '{1}' on the analyzer.	Contact the POC Administrator to add cartridge '{1}' to the analyzer. This can be done in the Analyzer Configuration screen.
TBD	Analyzer Results Receiving Failed	Failed to transfer result '{0}' from the analyzer.	Try to restart the analyzer. Docking the analyzer automatically retries the result transmission. If the problem persists contact the POC administrator.
TBD	Analyzer Settings Cannot Be Saved	Load settings failed because of the following reason : {0}	Save settings failed because of the following reason : {0}
TBD	Analyzer Time Date Synchronization Failed	Failed to synchronize date and time with the analyzer.	Try to restart the analyzer. Docking the analyzer automatically synchronizes the date and time. If the problem persists contact the POC administrator.
TBD	Analyzer Time Zone Synchronization Failed	Failed to synchronize time zone with the analyzer.	Try to restart the analyzer. Docking the analyzer automatically synchronizes the time zone if needed. If the problem persists contact the POC administrator.
TBD	Analyzer Users Synchronization Failed	Failed to synchronize users list with the analyzer.	Try to restart the analyzer. Docking the analyzer automatically synchronizes the users list. If the problem persists contact the POC administrator.
TBD	Cartridge Already Exists	–	No action is necessary.

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Number	Category	Description	Action
TBD	Cartridge Already In Use	Cannot remove Cartridge '{0}'. Orders have been sent to an analyzer.	First process the orders on the analyzer to generate results or delete the orders from the analyzer, before removing the cartridge.
TBD	Cartridge Invalid	The selected cartridge file '{0}' is not valid.	Contact the POC Administrator to obtain a valid cartridge file.
TBD	Cartridge Not Found	The analyzer cartridge '{0}' could not be found.	Contact the POC administrator to make sure that the cartridge file still exists and sufficient permissions to access the file are available.
TBD	Cartridge Not Installed In HS	Cartridge "{0}-{1}" is not installed on HS.	
TBD	Cartridge Xml Problem	Cartridge '{0}' could not be transferred to the analyzer, due to internal XML problem.	Contact the POC administrator to inspect the log files.
TBD	Configuration Setting Key Does Not Exist	Failed to read/write setting '{0}' from/to the configuration.	Please contact the POC administrator. The log file contains further details. An uninstall and install of the Magnotech Host Software will repair the configuration file.
TBD	Configuration Setting Save Failed	Saving configuration setting '{0}' failed.	Contact the POC administrator.
TBD	Database Cartridges Problem	Failed to store or retrieve cartridge information.	Contact the POC administrator and inspect the logs for further details.
TBD	Database Orders Problem	Failed to store or retrieve order information.	Contact the POC administrator and inspect the logs for further details.
TBD	Database Results Problem	Failed to store or retrieve result information.	Contact the POC administrator and inspect the logs for further details.
TBD	Database Settings Problem	Failed to store or retrieve setting information.	Contact the POC administrator and inspect the logs for further details.
TBD	Database Users Problem	Failed to store or retrieve user information.	Contact the POC administrator and inspect the logs for further details.
TBD	General Unhandled Analyzer	Unexpected problem in background communication with analyzer.	Try restarting the computer. If the problem persists contact the POC Administrator. The log file contains further details.
TBD	General Unhandled Application	An unexpected problem occurred. The Magnotech Host Software will now close.	Try restarting the computer. Please contact the POC administrator to inspect the log files for further analysis.

Number	Category	Description	Action
TBD	General Unhandled Lis	Unexpected problem in background communication with the LIS.	Try restarting the computer. If the problem persists contact the POC Administrator. The log file contains further details.
TBD	Help File Not Found	The help file cannot be opened.	Contact the POC administrator to reinstall the Magnotech Host Software installation. This will repair the help file.
TBD	Lis Ack Does Not Match	An unexpected message from the LIS was received. Message for order {0} received while waiting for a message for order {1}	Contact the POC administrator to inform something is wrong with the LIS communication.
TBD	Lis Ack Time Out	An acknowledge from the LIS was not received for analysis result '{0}'.	Try to resend the result. If the problem persists, contact the POC administrator to check LIS availability.
TBD	Lis Certificate Invalid	Invalid certificate '{0}' for secure LIS communication.	Contact the POC administrator to make sure the certificate is a valid X509 certificate.
TBD	LisConnectionAuthentication	A 'secure' connection with the LIS could not be established. The Magnotech Host Software will keep trying to connect.	Contact the POC administrator to check the certificate in the LIS settings.
TBD	Lis Connection	Connection with the LIS could not be established. The Magnotech Host Software will keep trying to connect until the set amount of retries is reached.	Contact the POC administrator to check the LIS settings.
TBD	Lis Could Not Parse Lis Message	An invalid message received from the LIS. The message is not a valid HL7 message.	Contact the POC administrator to inform something is wrong with the LIS communication. The log file contain more details.
TBD	Lis HL7 Conversion	Result '{0}' could not be transferred to the LIS. An internal HL7 message parsing error occurred.	Contact the POC administrator to inspect the details in the log file.
TBD	Lis HL7 Mapping Error	Failed to tranfer result '{0}' to the LIS. The data mapper could not map the result message.	Contact the POC administrator to inspect the logs for futher details.
TBD	Lis Invalid HL7 Message Error	Invalid HL7 message: {0}	Contact the POC administrator.
TBD	Lis Mapper Configuration File Not Found	The data mapper configuration file '{0}' could not be found.	Contact the POC administrator to make sure the data mapper configuration file exists and sufficient permissions to access the file are available.

Number	Category	Description	Action
TBD	Lis Mapper Configuration Invalid	Invalid data mapper configuration file '{0}'.	Contact the POC administrator to make sure a valid OrionHealth Symphonia HL7 mapper configuration file is selected.
TBD	Lis No Symphonia License	No valid Symphonia runtime license is available	Contact the POC administrator to install a valid Symphonia runtime license.
TBD	Lis No Symphonia Mapper License	No valid Symphonia Mapper runtime license is available	Contact the POC administrator to install a valid Symphonia Mapper runtime license.
TBD	Login Incorrect	User name or password invalid.	Please enter a valid combination of user name and password.
TBD	Login User Blocked	User '{0}' is blocked.	Please contact an administrator to unblock your account.
TBD	Order Xml Problem	Order '{0}' could not be transferred to the analyzer, due to internal XML problem.	Contact the POC administrator to inspect the log files.
TBD	Result Xml Problem	Result '{0}' could not be transferred from the analyzer, due to internal XML problem.	Contact the POC administrator to inspect the log files.
TBD	Service Data Too Large	The service data could not be retrieved, because it is too large.	Retrieve the service data via the file system of the analyzer (only possible when access is granted).
TBD	Start Up Configuration Not Found	The Magnotech Host Software configuration is missing or broken. The application will now close.	Contact the POC administrator to reinstall the software. The configuration will be repaired.
TBD	Start Up Configuration Setting Wrong Version	The Magnotech Host Software configuration has an incompatible version. The application will now close. Current version = {0} Expected version = {1}	Contact the POC administrator to reinstall the software. The configuration will be repaired.
TBD	Start Up Error App Already Running	The user interface is already running.	Please use the user interface that is already running.
TBD	Start Up Error Back End Connect	Connection to the Magnotech Host Software Service could not be made. The user interface will now close.	Try restarting the computer. If the problem persists, please contact the POC administrator.
TBD	Start Up Error No Database Access	The Magnotech Host Software Service could not initialize the database. The service will now close.	Contact the POC administrator to make sure that the Windows service 'SQL Server (HIP)' is running or try restarting the computer. The log file may contain more detailed information.
TBD	Start Up Error No Database Space	Insufficient database space. The Magnotech Host Software will now close.	Contact the POC administrator to free database space.

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7.1 System and error messages

Number	Category	Description	Action
TBD	Start Up Error No Disk Space	Insufficient disk space on drive '{0}'. The minimum disk space level is '{1}' bytes. The Magnotech Host Software will now close.	Contact the POC administrator to free disk space.
TBD	Start Up Error No Host Languages		Contact the POC administrator to reinstall the Magnotech Host Software installation.
TBD	Start Up Error Security Keys Missing	Could not retrieve security keys required to communicate with the analyzer. The software will now close.	Contact the POC administrator.
TBD	Start Up Error Wrong Database Scheme	Incompatible database version detected. Current version = {0} Expected version = {1} The Magnotech Host Software will now close.	Contact the POC administrator.
TBD	Unhandled Exception	The Magnotech Host Software user interface caught an unexpected exception and will now shutdown.	Contact the POC administrator to check the logs for details. Restart the computer and restart Magnotech Host Software.
TBD	User Xml Problem	User '{0}' could not be transferred to or from the analyzer, due to internal XML problem.	Contact the POC administrator to inspect the log files.
TBD	Write To Selected Directory Not Successful	Failed to write to selected directory '{0}'. The directory does not exist or writing is not permitted.	Please select an existing directory with write access.
TBD	Xml Parse Exception	Failed to load the views of the user interface.	Contact the POC administrator. A customized 'Decimal symbol' and 'Digit grouping symbol' for US English in the Regional Settings of the Control Panel is not supported. Use a dot for the 'Decimal symbol' and a comma for 'Digit grouping symbol'. The user interface should now start.

Warning messages

Number	Category	Description	Action
TBD	Analyzer Expected Reboot	The analyzer performed a reboot to effectuate analyzer setting changes. Changes that require a reboot are installation of analyzer languages, firmware updates and time zone synchronization.	It may take a few minutes for the analyzer to become available again. The analyzer will reconnect automatically.
TBD	Analyzer Firmware Invalid	The firmware update pack '{0}' is invalid and cannot be used.	Contact the POC administrator to obtain a valid firmware update pack.

Number	Category	Description	Action
TBD	Analyzer Firmware Upgrade Not Compatible	The firmware update pack '{0}' is not compatible with the connected analyzer.	Contact the POC administrator to check the compatibility of the firmware update pack.
TBD	Analyzer Firmware Upgrade Not Possible	It is not safe to perform an analyzer firmware update at this moment.	Retry the firmware update when the battery is not empty and the analyzer is not executing a measurement, booting or performing a self test.
TBD	Analyzer Language Invalid Language	The selected language '{0}' is not a valid language code supported by the analyzer.	Contact the POC administrator.
TBD	Analyzer Language Not Compatible	Language Pack '{0}' is not compatible with current analyzer.	Contact the POC administrator to provide compatible language packs for the analyzer.
TBD	Analyzer No Service Data	No service data is available on the analyzer.	This is normal behavior when no measurements are performed.
TBD	Analyzer Order Already Exists	Order '{0}' already exists on analyzer '{1}'.	The order was already transferred to this analyzer.
TBD	Analyzer Result Already Exists	Result for order '{0}' already available.	A result cannot be overwritten.
TBD	Analyzer Start	Failed to communicate with the analyzer on address '{0}'.	Contact the POC Administrator to configure the IP address in the Host Configuration menu.
TBD	Language Changed Restart Needed	Restart the User Interface to make the language change visible.	Please restart the user interface.
TBD	Number Of Users With Access Code Zero	The last user with an access code has been removed. If User Logon is enabled for your analyzers, it will not be possible anymore to logon the analyzer.	Add access codes to the users who need to operate the analyzer or disable 'User logon' for the analyzer.
TBD	StartUp Warning No Cartridges	No cartridges found. Creating orders is not possible.	Contact the POC administrator to install one or more cartridges in the Magnotech Host Software.
TBD	Start Up Warning No Database Space	Database space is low.	Contact the POC administrator to free database space.
TBD	Start Up Warning No Disk Space	Low disk space on drive '{0}'. Warning disk space level is '{1}' bytes. The Magnotech Host Software will continue.	Contact the POC administrator to free disk space.
TBD	Warning Max Idle Time Incorrect Value	The configuration contains an incorrect value for the automatic logoff function. Key='{0}'	Contact the POC administrator. Use value 0 to disable automatic logout or specify the number of seconds.

7.2 Contacting Service

When assistance is needed with your minicare analyzer, contact your local Philips Electronics representative.

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8 Maintenance

8.1 Cleaning and disinfection

Use only the Philips-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods. Philips makes no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. Consult your hospital’s Infection Control Officer or Epidemiologist.

For comprehensive details on cleaning agents and their efficacy refer to “Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health Care and Public-Safety Workers” issued by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia, February 1989. See also any local policies that apply within your hospital, and country.

General points

Keep your minicare analyzer, docking station, associated cables, and any accessories free of dust and dirt. After cleaning and disinfection, check the equipment carefully. Do not use if you see signs of deterioration or damage. If you need to return any equipment to Philips, decontaminate it first. Observe the following general precautions:

- Always dilute according to the manufacturer’s instructions or use lowest possible concentration.
- Do not allow liquid to enter the minicare analyzer or docking station case.
- Do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Never use abrasive material (such as steel wool or silver polish).
- Never use bleach.

WARNINGS



Sterilization

Sterilization is not recommended for this analyzer, docking station, related products, accessories, or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies.

- *If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or Philips service engineer. Do not operate the equipment before it has been tested and approved for further use.*
- *Always isolate the product from the mains electrical supply before cleaning, disinfecting, or sterilizing to prevent electric shocks.*
- *Strictly follow cleaning and disinfection guidelines to ensure that patient is not exposed to infections.*
- *Cleaning and disinfection techniques for the product must comply with all applicable local laws and regulations.*

CAUTION

Never allow water or other liquids to enter the product, since these may cause electrical short-circuits or metal corrosion.

8.1.1 Cleaning the minicare analyzer

Clean with a lint-free cloth, moistened with warm water (40°C/104°F maximum) and soap, a diluted non-caustic detergent, tenside, ammonia- or alcohol-based cleaning agent. Do not use strong solvents such as acetone or trichloroethylene.

Take extra care when cleaning the minicare analyzer screen because it is more sensitive to rough cleaning methods than the housing.

Do not permit any liquid to enter the analyzer housing case and avoid pouring it on the minicare analyzer while cleaning. Do not allow water or cleaning solution to enter the measurement connectors. Wipe around, not over, connector sockets.

CAUTION

Recommended cleaning agents

- ### 8.1.2

Those parts of the minicare analyzer that are suitable for such treatment, including accessories and connecting cables, can be disinfected by wiping with a cloth dampened with a suitable agent. Never use corrosive or solvent disinfectants or sterilizing agents. If you are not sure about the properties of a disinfectant or sterilizing agent, do not use it.

Disinfect the product as determined by your hospital's policy, to avoid long term damage to the product.

Clean equipment before disinfecting. Recommended types of disinfecting agents are:

- 8-3**



WARNING

Do not use flammable or potentially explosive disinfecting sprays. Such sprays create vapors, which can ignite, causing fatal or other serious personal injury.

CAUTIONS

- *Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.*
- *Disinfecting a medical equipment room by means of sprays is not recommended since the vapor can penetrate the equipment causing electrical short-circuits or corrosion.*

8.1.3

Cleaning the battery in the battery compartment

Wipe with a lint-free cloth, moistened with warm water (40°C/104°F maximum) and soap. Do not use strong solvents.

Do not soak the battery.

8.2

Planned maintenance and user routine checks

This product requires proper operation, planned maintenance, and checks the user must perform routinely, which are essential to keep the product operating safely, effectively and reliably.

8.2.1

Planned maintenance program

Planned maintenance may only be carried out by qualified and authorized personnel, and is comprehensively described in the service documentation.

Philips provides a full planned maintenance and repair service on both a call basis and a contract basis. Full details are available from your Philips Service Organization.

A summary of the preventive maintenance program appears in the table below.

Where the user carries out planned maintenance, he or she should always take all practical steps to make sure that the Planned Maintenance Program is fully up to date before using the product with a patient.

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Preventive maintenance is to be performed on a regular basis.

Check	Actions	Frequency
[NOTE TO REVIEWERS: Project team to provide details after Review 2]		

8.2.2

User routine checks program

The user of the product must institute a User Routine Checks Program as detailed in the table below. The user of the product shall make sure that all checks and actions have been satisfactorily completed before using the product for its intended purpose

Check	Actions	Frequency
[NOTE TO REVIEWERS: Project team to provide details after Review 2]		

NOTE

Perform visual and/or audible checks during routine use.

8.3

Quality control

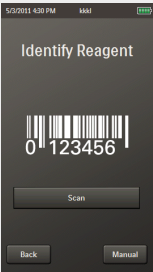

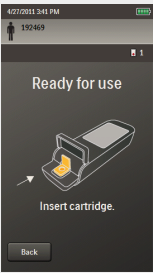
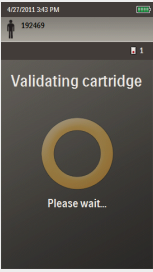
You can perform a Quality control (QC) test to ensure that the minicare analyzer results are as accurate as possible. The test procedure is described below.

QC test results are transferred to the data manager when the minicare analyzer is docked. For details of viewing and exporting stored QC test results, see section “QC results” on page 6-23.

8.3.1

QC test workflow

The information below describes the QC test workflow.

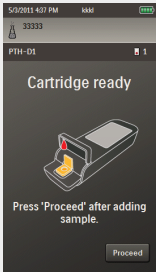
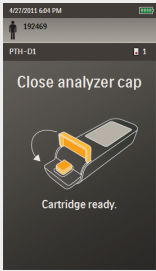
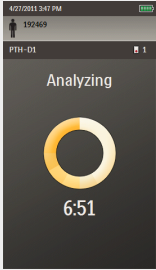
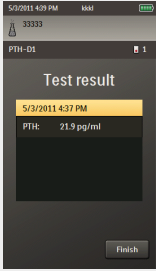
Workflow step	Analyzer user interface
1 Identify the reagent by either scanning or entering the reagent identification manually.	
2 Scan the barcode on the reagent sample label (or enter identification number manually).	
3 Insert the cartridge.	
4 The analyzer validates the cartridge.	

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Philips minicare analyzer Release 1.0
[120cxxxx xxxxxxx] [Data version 0.2 This label will be removed]

Workflow step	Analyzer user interface
5 Insert test reagent sample.	
6 Close the analyzer cap.	
7 Wait for analysis.	
8 View result.	

8.3.2 Performing a QC test

The QC test is performed in a similar manner to the blood analysis test.

- 1 Log on to the analyzer by scanning your user ID barcode or entering your PIN.

See section “Logging on” on page 5-6.

- 2 Press **Menu** from the “Identify Patient” screen.

- 3 Press **Perform QC Test**.

- 4 Select the method for identifying the test reagent.

- Press **Scan** if you want to scan the test reagent barcode.
- Press **Manual** if you want to enter the test reagent identification number manually.

- 5 Identify the test reagent.

- Scan the test reagent identification barcode on the test reagent packaging or label.
- Enter the test reagent identification number using the numeric keypad.

The analyzer will confirm the test reagent identification number.

- 6 When the “Ready for use” screen appears, insert a new cartridge.

See section “Inserting a cartridge” on page 5-13.

The “Cartridge ready” screen appears.

- 7 Add the test reagent sample to the cartridge, close the cartridge cap, and press **Proceed** to start the analysis.

The analyzer begins the analysis. The screen displays “Analyzing” and estimated analysis time remaining.

- 8 The analyzer displays test results. Press **Finish**.

- 9 The analyzer asks if you want to finish the current measurement. Select one of the following options:
 - Press **Cancel** to go back to the “Test result” screen.
 - Press **Reject** to delete the QC test you just performed. Your results are not saved.
 - Press **Accept** to save the QC test results. When the analyzer is docked the results will transfer to the **QC results** area of data manager software.
- 10 Remove the cartridge and close the analyzer cap.

8.4 **Antivirus protection**

We recommend that the data manager software system is equipped with antivirus software, which is designed to detect viruses on your system, and to deny access to infected files before they can do any damage.

Antivirus definitions should be updated on a regular basis. The majority of antivirus software automatically checks for updated virus definition files at system startup and implements them, if available.

NOTE *For optimal protection, it is advisable to restart the system as soon as new virus definitions are loaded onto the system.*

Malware

Although the system incorporates protection mechanisms to protect it against the intrusion of malware, a remote possibility remains that a system could become infected. If you notice that unfamiliar system behavior or performance occurs repeatedly, including after the system has been switched off and on again, you are advised to call Service to have the system checked and, if needed, cleaned of malware.

8.5 After-sales support

For the following services, please contact your local Philips Electronics representative.

- List of uses and applications
- Possibility of extension
- Service and assistance
- Warranty
- Replacement battery

NOTE

The minicare analyzer and docking station have no replaceable parts apart from the minicare analyzer battery.

9 Product disposal

Philips Electronics is concerned to help protect the natural environment and to help ensure continued safe and effective use of the this product through proper support, maintenance and training. Therefore Philips products are designed and manufactured to comply with relevant guidelines for environmental protection. As long as the product is properly operated and maintained it presents no environmental risks. However, the product may contain material[s] which could be harmful to the environment if disposed of incorrectly. Use of such material[s] is essential to performing the functions of the product, and for meeting statutory and other requirements.

This section of this Instructions for Use is directed mainly at the user of the equipment or system, the body with legal authority over the equipment. Operators are not usually involved in disposal, except in the case of certain batteries (see section section “Fitting, removing and disposing of batteries” on page 9-2).

9.1 Passing this product on to another user

If this product passes to another user, it must be in its complete state, including all product support documentation.

Make the new user aware of the support services that Philips Medical Systems provides for installing, commissioning and maintaining the product.

Before passing on the product or taking it out of service, all patient data must be backed up elsewhere if necessary, and then be deleted on the product.

It must be remembered by all existing users that passing on medical electrical products to new users may create serious technical, medical and legal (for example, privacy) risks. Such risks can arise even if the product is given away. Existing users are strongly advised to seek advice from their local Philips Medical Systems representative before committing themselves to passing on any product. Alternatively, contact the manufacturer.

Once the product has been passed on to a new user, a previous user may still receive important safety-related information, such as bulletins and field change orders. In many jurisdictions there is a clear duty on the previous user to communicate such safety-related information to new users. Previous users who are not able or prepared to do this should inform Philips Medical Systems about the new user, so that Philips Medical Systems can provide the new user with safety-related information.

9.2 Final disposal of this product



WARNING

Final disposal is when the user disposes of the equipment or system in such a way that it can no longer be used for its intended purposes.

The minicare analyzer and minicare docking station comply with the EU directive 2002/96/EC, Waste electrical and electronic equipment.



Do not dispose any parts of this product with industrial or domestic waste. The product contains hazardous substances, such as lithium, which require special disposal. Incorrect disposal of any hazardous materials may lead to serious environmental pollution.

Philips supports users in:

- Recovering reusable parts
- Recycling of useful materials by competent disposal companies
- Safe and effective disposal of the product.

For advice and information, contact your Philips Service Organization.

9.3 Fitting, removing and disposing of batteries

For continued optimal operation, the batteries must be replaced when their capacity is reduced. To replace the batteries, refer to the instructions in section “Replacing the minicare analyzer battery” on page 9-3.

Battery type: Philips XXX (BATTERY TYPE/NAME NEEDED)

NOTE

REACH requires Philips Medical Systems to provide chemical content information for substances of very high concern (SVHC) if they are present above 0.1% of the product weight. Components within electric and electronic equipment may contain phthalates above the threshold (for example, bis(2-ethyl(hexyl)phthalate), CAS nr.: 117-81-7). The SVHC list is updated on a regular basis. Therefore, refer to the following Philips REACH web site for the most up-to-date list of products containing SVHC above the threshold:

- <http://www.philips.com/about/sustainability/reach.page>

CAUTION

Always remove the batteries if the product will not be used for some time.

9.3.1

Replacing the minicare analyzer battery

Conditions

- A small flathead screwdriver is required to perform this procedure.
- 1 On the back of the minicare analyzer, locate the small screw holding the battery cover in place. Using the screwdriver, remove the screw completely and set it aside.
 - 2 Slide the cover upward to remove it from the minicare analyzer as shown below.

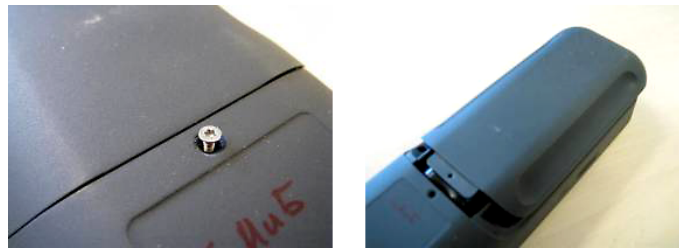


Figure 9.1 Removing the battery cover

- 3 Gently pull the battery from the battery compartment. Wires still connect the battery and the minicare analyzer.

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- 4 Using the screwdriver, gently press the wire connector as shown below to release it from the minicare analyzer.



Figure 9.2 Disconnecting the battery wires from the minicare analyzer

- 5 Remove the new battery from any packaging and insert the plastic wire connector into the minicare analyzer. You should hear or feel it snap into place.
- 6 Fit the new battery into the battery compartment. Ensure that the wires are not crimped and will not interfere with reattaching the battery cover.
- 7 Slide the battery cover back in place on the minicare analyzer.
- 8 Screw the small screw back in to secure the battery cover.

10 Technical data

10.1 Specifications

Property	Value
Dimensions	25 x 8 x 5 cm (approx)
Weight	750 g including battery pack (approx)
Power supply adapter	Input: 100–240 V AC, 47–63 Hz, 700 mA Output: 24 V DC, 1250 mA
Tests per battery cycle	15 tests on a fully charged battery (approx)

10.2 System requirements

The minicare analyzer has no special requirements.

The computer system requirements for the Data Manager software are shown in the following table.

Item	Requirement
Operating system	Windows Vista, Windows XP
RAM	2 GB
Disk space	15 GB

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System requirements

Technical data

11 Glossary

11.1 Definitions

Term	Explanation
analyzer	The minicare analyzer receives blood cartridges and performs tests on the blood sample. It is intended for use in medical care settings, for example, operating theaters.
application	
assay	
blood	
cartridge	
data manager	The minicare data manager software allows you to configure the minicare analyzer, and to exchange data from the minicare analyzer with an external information system, for example, LIS.
docking station	
Magnotech	
minicare	
operator	
self test	
system	
whole blood	
user	The intended users of the Philips minicare system are laboratory and non-laboratory medical professionals (for example, nurses).

11.2 Abbreviations

Abbreviation	Explanation
EMC	Electromagnetic compatibility
EMF	Electromagnetic fields
ESD	Electromagnetic discharge
HIS	Hospital information system

Abbreviation	Explanation
IfU	Instructions for Use
IP	Internet protocol
IVD	In vitro diagnostic
LIS	Laboratory information system
OS	Operating system
PC	Personal computer
PIN	Personal identification number
POC	Point of care
QRC	Quick reference card
RF	Radio frequency

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12 Appendices

12.1 Special functions

12.1.1 Additional host software options for Administrators

There are certain functions for the data manager software that can only be performed by a Point of Care Coordinator, including:

- minicare analyzer configuration, see section “Configuring the minicare analyzer” on page 12-4.
- Data manager software configuration, see section “Configuring the data manager software” on page 12-2.
- User accounts, see section “Managing user accounts” on page 12-6.

Configuring the data manager software

As a Hospital Administrator, you can configure the data manager software ID and language, which minicare analyzer is connected to the data manager software, and which cartridges are supported.

- 1 Click the **System** menu.
- 2 Roll the mouse pointer to **Host Configuration**, and click.

The Host Configuration dialog box appears.

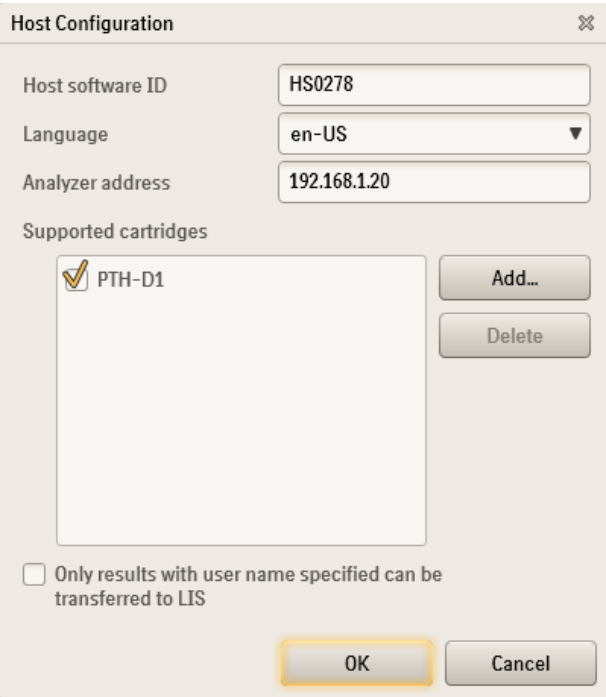


Figure 12.1 Host Configuration dialog box

3 Change your host configuration as desired.

To	Do this
Change the data manager software ID	Enter the new ID in the Host software ID field. The data manager software ID is used to ensure that generated orders have a unique ID. If you have multiple installations of the data manager software, you must give each data manager software installation a unique ID to avoid duplicate order IDs.
Change the data manager software language	Select the desired language from the Language drop-down menu.
Change the minicare analyzer currently connected	Enter the IP address for the new minicare analyzer. See section “Configuring analyzer connectivity” on page 4-7.
Add a new supported cartridge type	Click the Add button next to the Supported Cartridges field and select the new cartridge type (with extension ‘.crt’) from the appropriate local or network location. After importing a new cartridge type, you can enable and disable the supported cartridges by selecting and clearing the check boxes. Note that the selected cartridge must also be activated on the minicare analyzer being used. See section “Configuring the minicare analyzer” on page 12-4
Delete a currently supported cartridge type	Click the Delete button next to the Supported Cartridges field.
Ensure that only results with user name specified can be transferred to LIS	Click the check box so the checkmark appears. When the check box is cleared, all results (with or without username specified), can be transferred to the LIS.

4 Click **OK** to save your changes and close the dialog box.

If you click **Cancel**, the dialog box closes and your changes are not saved.

Configuring the minicare analyzer

Conditions

- An analyzer must be connected to view this menu.

As the Hospital Administrator, you can use the Analyzer Configuration menu to view and change minicare analyzer settings including the minicare analyzer name, software, language, user logon, print settings, and results overwriting.

- 1 Click the **System** menu.
- 2 Roll the mouse pointer to **Analyzer Configuration**, and click.

The Analyzer Configuration dialog box appears.

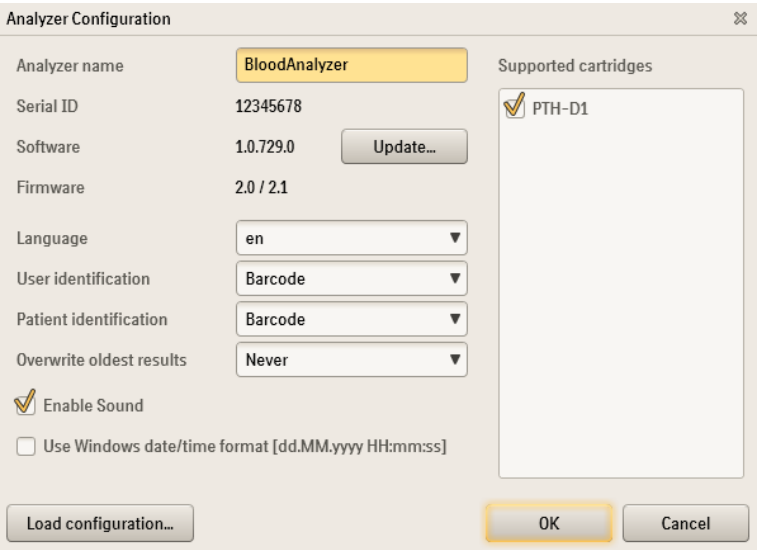


Figure 12.2 Analyzer Configuration dialog box

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3 Change the configuration for the connected minicare analyzer as desired.

To	Do this
Change the name of the minicare analyzer currently connected.	Enter the new minicare analyzer name in the Analyzer name field section “Analyzer menu and options” on page 12-9.
View the Serial ID of the minicare analyzer currently connected.	The Serial ID is displayed in the Serial ID field.
View the current minicare analyzer software.	The current software version number is displayed in the Software field.
Update the current minicare analyzer software.	Click the Update button and select the new software update from the appropriate local or network location. Note that this is not an automatic search function. Updates are communicated and provided through the Service organization.
View the current Firmware.	The current firmware number is displayed in the Firmware field
Change the minicare analyzer language.	Select the desired language from the Language drop-down menu
Change the identification options for the user logon screen or eliminate the requirement for a user to log on before performing a test.	Selecting Barcode requires users to scan an identification barcode before using the minicare analyzer. Selecting Manual requires users to enter a numeric PIN before using the minicare analyzer. Selecting None disables user identification. Users then do not have to enter any identification to use the minicare analyzer.
Change the identification options for the patient identification screen or eliminate the requirement for a patient identification before performing a test.	Selecting Barcode requires users to scan a patient identification barcode before performing a test. Selecting Manual requires users to enter a numeric PIN to identify the patient before performing a test. Selecting None disables user identification. Users then do not have to enter any patient identification before performing a test.

To	Do this
Overwrite the oldest results on the analyzer if memory is full.	<p>There is a limited amount of memory on the minicare analyzer for storing results.</p> <p>Select Automatic from the Overwrite oldest results drop-down menu if the oldest results on the minicare analyzer should automatically be overwritten by the newest results.</p> <p>Select Ask user from the Overwrite oldest results drop-down menu if results should only be overwritten after confirmation from the user.</p> <p>Select Never from the Overwrite oldest results drop-down menu if results should never be overwritten.</p> <p>Note that once results are transferred to the data manager software they are automatically marked for deletion on the minicare analyzer.</p>
Turn the analyzer sound on or off.	Check the box next to Enable Sound to turn on the sound. Uncheck the box to turn the sound off.
Use the Windows date/time format.	Check the box next to Use Windows date/time format to automatically synchronize the date and time with the host PC. The date/time format is synchronized between the data manager software and the minicare analyzer.
Specify the timeout period	Enter a value in Autologout timeout .
Select the supported cartridge type	You can enable and disable the supported cartridges for the minicare analyzer by selecting or clearing the check boxes next to the cartridge name in the Supported Cartridges area.

- 4 Click **OK** to save your changes and close the dialog box.
- If you click **Cancel**, the dialog box closes and your changes are not saved.

Managing user accounts

As the Hospital Administrator, you can allow additional users to access the data manager software. You can also disable user accounts.

- 1 Click the **System** menu.
- 2 Roll the mouse pointer to **User Accounts**, and click.

The User Accounts dialog box appears.

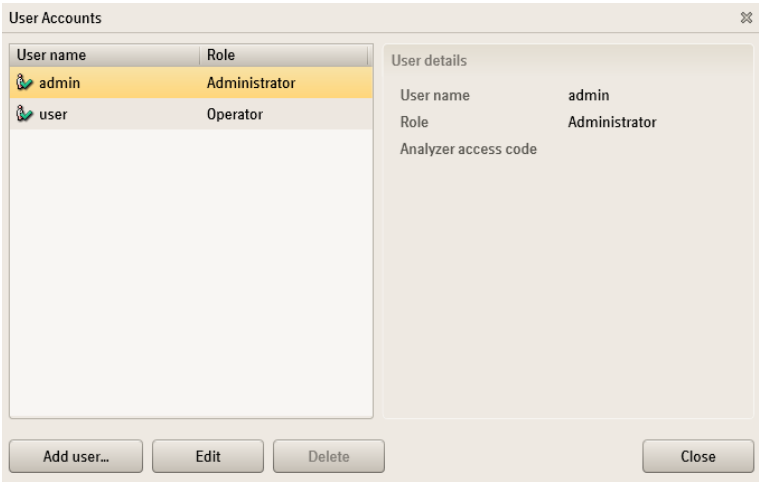


Figure 12.3 User Accounts dialog box

- 3 Configure the user accounts as desired.

To	Do this
View existing user name, role, and analyzer access code	<p>Click the User name from the list.</p> <p>The user information appears in the User details area to the right.</p>
Add a new user	<p>Click the Add user button and add the new user account details in the Add User Account dialog box.</p> <p>Select the new user name, role, analyzer access code, and password.</p> <p>Activate the user account by clicking the check box.</p> <p>Click Save to save changes and return to the User Accounts dialog box.</p>

To	Do this
Activate or deactivate a user account.	<p>Click the user name from the list and click the Edit button.</p> <p>Click the check box until the check mark appears to activate the user account.</p> <p>When the check box is cleared, the user account is inactive.</p> <p>Click Save to save changes and return to the User Accounts dialog box.</p>
Edit an existing user name, role assignment, analyzer access code, or password.	<p>Click the user name from the list and click the Edit button.</p> <p>Change the user information in the corresponding fields as desired.</p> <p>Click Save to save changes and return to the User Accounts dialog box.</p>
Delete an existing user	<p>Click the user name from the list and click the Delete button.</p> <p>A confirmation dialog box appears, click Yes to confirm deletion.</p> <p>If you click No, the user account will not be deleted.</p> <p>Click Save to save changes and return to the User Accounts dialog box.</p>

4 Click **Close** to save any changes and close the dialog box.

12.1.2 Analyzer menu and options

When you press **Menu** on the minicare analyzer main screen, you can view analyzer information, view results, change IP address, and logout.

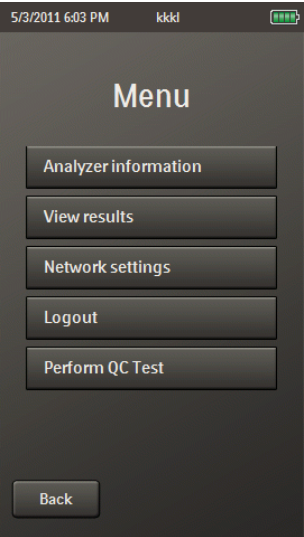


Figure 12.4 Analyzer menu

To	Do this
Find analyzer name, Serial ID, Software, Firmware, and OS	Press Analyzer information
View results	Press View results
Change the analyzer IP address	Press Network settings and change You can then enter the IP address. See section “Configuring analyzer settings” on page 4-12
Logout as the current user	Press Logout
Perform a Quality Control (QC) test	Press Perform QC Test . See section “Performing a QC test” on page 8-8.

12.2 Security and privacy requirements

Antivirus

The PC on which the data manager is installed should be protected from attack or damage by computer viruses or malware. See section “Antivirus protection” on page 8-9 for details.

[NOTE TO REVIEWERS: Details about the following items will be provided by the Project team after Review 2]

Network ports

Encryption

12.3 References

Magnotech

Information about the Magnotech process can be found at the following web site.

www.philips.com/magnotech

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