PFA-100 System

Instruction Manual – US only
2024-12

siemens-healthineers.com

SIEMENS Healthineers

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1 Introduction

This chapter gives introductory information.

1.1 About this manual

This manual describes the use of the PFA-100® System in clinical laboratories.

This manual is only valid in conjunction with other user manuals available electronically on the system or in print.

1.2 Orientation tips

	Indicates a hint Is used to provide information on how to avoid operating errors or information emphasizing important details
	Indicates the solution of a problem Is used to provide troubleshooting information or answers to frequently asked questions
●	Indicates a list item
✓	Indicates a prerequisite Is used for a condition that has to be fulfilled before starting a particular procedure
◆	Indicates a 1-step procedure or procedural steps to solve a problem
1 2 3	Indicate steps within procedures
➔	Indicates a link to related information as well as previous or next steps
→	Indicates the result of a procedural step or a procedure
Italic	Is used for references
Bold	Is used for table or figure titles and to identify window titles, menu items, function names, buttons, and keys, for example, the button **Enter**
Menu > Menu item	Is used for the navigation to a certain submenu entry
Orange	Is used to emphasize particularly important sections of the text

1.3 Identification

The model numbers of the PFA-100 System and the accessories used with the system are:

Product	SMN	Order number
PFA-100 System	10444868	B4170-00
Dade PFA Priming Cartridges	10445702	B4170-74

Product	SMN	Order number
Dade PFA Vacuum Cups	10445703	B4170-75
PFA Cassettes	10459383	B4170-70
PFA Cleaning Pads	10459386	B4170-73
PFA O-Ring Service Tool	10459387	B4170-77
PFA O-Rings	10459388	B4170-78
PFA-100 Printer Paper	10459384	B4170-71
PFA-100 Barcode Scanner	11539138	B4170-6
PFA-100 Printer Ribbon	10459385	B4170-72

See product catalog for latest information.

1.4 Service

Siemens Healthineers and its representatives are available to repair the system during customary local office hours. If service is required at any other time, contact Siemens Healthineers service or a local Siemens Healthineers representative. In the following, “Siemens Healthineers service” refers to both Siemens Healthineers service or any local representative authorized by Siemens Healthineers. Information about how to reach Siemens Healthineers service is provided when the system is installed, or visit siemens-healthineers.com to find contact information.

Siemens Healthineers will provide information about the availability and cost of updates.

The scope of agreed service is included in the service contract.

1.5 Warranty

Siemens Healthineers and its representatives guarantee that the system shows no defects during operation if installed and operated according to this manual. For more information on warranty, contact Siemens Healthineers service. The warranty is not valid for damage that occurs as a consequence of non-observance of this manual. Only perform maintenance as described in this manual. Incorrect interventions on the system void the warranty and can result in service charges.

Repairs and servicing must only be carried out by persons authorized by Siemens Healthineers.

Only use the system as intended. If the system is not used as intended, Siemens Healthineers disclaims all liability for damage to the system.

1.5.1 Limited warranty on wear and tear parts

The warranty is limited for the following wear and tear parts:

- Priming cartridges
- Vacuum cups
- Cassettes

- O-rings
- Cleaning pads
- Printer ribbon
- Printer paper

The warranty term for these wear and tear parts is included in the service contract.

1.6 Ordering information

Only use original Siemens Healthineers consumables, accessories, and spare parts. Order these only from Siemens Healthineers. For ordering information, see the Siemens Healthineers product catalog or contact Siemens Healthineers service.

1.7 Trademarks

Dade and PFA-100 are trademarks of Siemens Healthineers.

All other trademarks are the property of their respective owners.

1.8 Manual version history

Manual

Version	Date	Changes
1.0	2016-11	First version
1.0.1	2017-12	Update
01	2024-12	Update

2 Safe handling

This chapter describes the intended use of the system and gives general safety instructions.

2.1 Intended use

The PFA-100 Platelet Function Analyzer and Dade PFA-100 Reagents are in vitro diagnostic devices intended to aid in the detection of platelet dysfunction in citrated human whole blood.

The PFA-100 System is an instrument and test cartridge system in which the process of platelet adhesion and aggregation following a vascular injury is simulated in vitro. Platelet dysfunction detected by the PFA-100 System may be acquired, inherited, or induced by platelet inhibiting agents.

The PFA-100 System is for in-vitro diagnostics only.

2.1.1 System functions

The system functions are:

- **Moving** the carousel (containing PFA test cartridges with samples) into the instrument
- **Reading** the test code
- **Dispensing** the trigger solution into each PFA test cartridge
- **Incubating** the samples
- **Aspirating** the sample through the aperture of the PFA test cartridge
- **Measuring** the blood flow rate through aperture at a constant vacuum
- **Determining** the closure time by detecting a flow rate, which is for 3 seconds below 10 % of the initial flow rate at the beginning of the test
- **Calculating** and **analyzing** the readings
- **Printing** the readings

1 or 2 PFA test cartridges containing samples can be placed in the instrument after:

- Loading the required PFA test cartridges
- Entering the test

Then the samples are processed fully automatically as far as the analysis stage.

2.2 Intended user

The system is intended for laboratory professional use only.

2.3 Use environment

The system is to be used in professional healthcare facility environment only.

2.4 General safety information

The system has been inspected for technical safety before distribution. To maintain this status and to ensure hazard-free operation:

- Always follow the instructions in this manual.
- If an addendum is published, read the addendum. The information in the addenda reflects the current status and supersedes other information in the corresponding manual, if applicable.
- Keep this manual for future reference unless a new version of this manual is published.
- Only use the system as intended. If the system is not used as intended, Siemens Healthineers disclaims all liability for any personal injury and property damage.
- Only perform maintenance as described in this manual. If maintenance is not performed as described or if maintenance other than described in this manual is performed, Siemens Healthineers disclaims all liability for any personal injury and property damage.
- Always follow good laboratory practice.
- Make sure that the environmental and electrical conditions are met, see (➔ Page 96 *Environmental*) and (➔ Page 96 *Electrical*).

2.4.1 Operator qualification

Risk of death and serious injury due to lack of knowledge. To avoid this hazard:

- The system must be operated only by persons whose skills, knowledge, and practical experience qualify them to do so, and who have read and understood this manual.
- Instruction in operating the PFA-100 System is given when the analyzer is installed by Siemens Healthineers.
- For information on available training options and suggested duration and frequency of such training, contact Siemens Healthineers service.

2.4.2 Electrical safety

Risk of electric shock when coming into contact with live parts. Even when the system is switched off, some components, for example, capacitors, can be live as they can still be electrically charged. Death or serious injury can result. To avoid this hazard:

- Check the operating voltage prior to connecting the system to the power supply.
- Connect the system only to a socket with a ground contact (earth).
- Only use double insulated extension cables with a protective conductor and ground contact.
- Never disconnect the ground contacts from the line.

- Never interrupt the protective conductor inside or outside the system.
- Never remove protective guards or fused components.
- Ensure that all surfaces, including the floor, are dry when using and maintaining the system.
- Make sure that the power switch is easily accessible.
- If the analyzer needs to be opened for calibration, maintenance, repair, or replacement, switch off the analyzer and disconnect it from all voltage sources as described in the relevant procedure.
- If any calibration, maintenance or repair work has to be carried out on the **open** analyzer while **connected** to a main power source, this may **only** be done by a **specialist** who is familiar with the dangers associated with such action.
- Use only replacement fuses of the stated type and the stated nominal current.
- Never use fuses which have been repaired.
- Do not short-circuit the fuse holder.

Risk of short-circuit by spilled liquids that can come into contact with live parts. Damage to the system can result. To avoid this hazard:

- Never pour liquids or place containers with liquid on top of the system.
- Disconnect the mains plug immediately if liquid is spilled into the system.

Risk of malfunctions in nearby electrical devices due to radio interference. The system complies with the emission and immunity requirements described in IEC 61326-2-6. The analyzer has been designed and tested according to CISPR 11 group 1, class A. In a domestic environment, it can cause radio interference. To avoid this hazard:

- Assess the electromagnetic environment prior to operating the system.
- Use the cables supplied.
- Use shielded cables, plugs and grounded ports if external devices are connected, for example, a network.

Risk of malfunctions of the system such as incorrect results due to radio interference from other electrical devices. To avoid this hazard:

- Do not operate strong electromagnetic transmitters, for example, mobile phones, walkie-talkies, door openers, or elevators, in the vicinity of the system.
- In places where the quality of the power supply line is poor or impacted by other electrical devices, consider the use of an external uninterruptible power supply (UPS).

2.4.3 Mechanical safety

Risk of serious injury due to moving parts. To avoid this hazard:

- Do not touch the carousel while the measurement is in progress.
- Never bypass or remove safety devices, for example, cover switches.
- Never open or remove the covers of the system during operation. The cover may only be opened by Siemens Healthineers service.

- Keep clear of moving parts when the system is in operation or maintenance is performed. Long hair, necklaces, bracelets, and similar objects can get caught in moving parts.

Risk of injury by the spiking needle of the trigger solution bottle. To avoid this hazard:

- Lift up the lever of the spiking needle completely before opening the access door.
- Take care not to touch the spiking needle when changing the trigger solution bottle.

Risk of damage to the spiking needle of the trigger solution bottle. To avoid this hazard:

- Make sure that the access door for the trigger bottle is fully closed before pushing the lever down.

2.4.4 Operational safety

Risk of burns due to combustion of flammable liquids. Death or serious injury can result. To avoid this hazard:

- Keep flammable liquids away from heat or open flame.
- Place the system in a well-ventilated area.

If a flammable liquid has been spilled, immediately take the following measures to prevent combustion:

- Eliminate all sources of ignition.
- Remove flammable liquid with a non-combustible absorbent material.
- Vent the room.

Risk of explosion due to ignition caused by sparks generated by the switch contacts of the system. Death or serious injury can result. To avoid this hazard:

- Never operate the system in an environment containing explosive mixtures of oxygen, hydrogen, or other flammable gases.

Risk of property damage due to inaccurate handling of the system. Rough handling or dropping can disturb or damage internal components. Improper interventions on the system void the warranty and can result in service work having to be charged for. To avoid this hazard:

- Always handle the system with care.
- Switch off the system and secure it against accidental operation if there is visible damage to the system or if safe operation is no longer possible. This may be assumed:
  - If the analyzer is no longer working after a technical malfunction
  - After an extended period of storage
  - After being transported in harsh conditions
- Only carry out maintenance or replace parts as described in this manual.
- Only use Siemens Healthineers spare parts.
- Do not use solvents or abrasive cloths to clean the system.

2.4.5 Safe handling of samples, test cartridges, trigger solution, accessories, and consumables

Risk of infection due to infectious material. Samples, test cartridges, trigger solution, accessories, consumables, and parts of the system which have come into contact with this material are potentially infectious. Death or serious injury can result. To avoid this hazard:

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask, according to national and local standards and regulations.
- Handle potentially infectious material in accordance with good laboratory practice, for example, as described in CLSI documents available at www.clsi.org.
- Only open covers as described in this manual.
- Avoid contact of the skin and mucosa with potentially infectious material.
- See the instructions for use of the PFA test cartridges as well as the application sheets.
- Check with local waste disposal authorities for specific requirements regarding potentially infectious material.
- Discard potentially infectious material according to national and local standards and regulations.

Risk of incorrect results. Incorrect results can lead to misdiagnosis and incorrect treatment. To avoid this hazard:

- Only use approved Siemens Healthineers consumables.
- Monitor the stability of the PFA test cartridges and trigger solution, see the instructions for use.

Risk of irritation of the skin and mucous membranes due to liquids for cleaning and purging. Minor or moderate injury can result. To avoid this hazard:

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask, according to national and local standards and regulations.
- Pay attention to the information from the manufacturer regarding the compatibility of the gloves with the materials and liquids used.
- Follow all product instructions from the manufacturer.

Risk of property damage due to incorrect handling of samples, PFA test cartridges, and consumables. To avoid this hazard:

- Only use approved Siemens Healthineers consumables.
- See the instructions for use of the PFA test cartridges and consumables.

Risk of pollution due to incorrect waste disposal. Damage to the environment can result. To avoid this hazard:

- Discard waste material according to national and local standards and regulations.

2.4.6 Correct functionality of the analyzer

Risk of false results or delayed results due to incorrect functioning of the analyzer. False results can lead to misdiagnosis and incorrect treatment. To avoid this hazard:

- Check that the analyzer is functioning correctly.
- Check the functionality of the analyzer daily with the software's function **Self Test**.

2.5 Safety messages

All safety messages must be observed to avoid hazardous situations which can result in death, injury, or damage to the equipment.

The following explains the signal words and their meanings.

Signal word	Meaning
WARNING	Indicates a hazardous situation which, if not avoided, could result in death or serious injury
CAUTION	Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury
NOTICE	Indicates a hazardous situation which, if not avoided, could result in potential damage to property

The following explains the structure of safety messages.

⚠ WARNING

This section states nature and source of the hazard.

This section states potential consequences of not avoiding the hazard. This section can be combined with the previous section.

◆ This section lists preventive actions to avoid the hazard.

2.6 Symbols

This chapter describes all symbols except symbols in the software.

Symbol	Meaning
LOT	Batch code
CASSETTE	Cassettes
REF	Catalog number
	Caution: Consult instructions for use for important cautionary information
PAD	Cleaning pads

Symbol	Meaning
CE	CE mark
	Consult instructions for use
CONTENTS	Contents
	Date of manufacture
	Do not re-use
EAC	EAC mark
FUSE	Fuses
	Handle with care
IVD	In vitro diagnostic medical device
	Keep dry
	Manufacturer
O RING SERVICE TOOL	O-ring service tool
O RING	O-rings
	Power off
	Power on
PRIME CARTRIDGE	Priming cartridges
PRINTER PAPER	Printer paper
SN	Serial number
	Temperature limit

Symbol	Meaning
	This way up Store in upright position
PFA TRIGGER	Trigger solution
UDI	Unique device identification barcode
	Use-by date
VAC CUP	Vacuum cups
	Warning; Biological hazard The labeled area can come into contact with infectious material. The safety instructions for infectious material must be observed, see (→ Page 12 *Safe handling of samples, test cartridges, trigger solution, accessories, and consumables*).
	Warning: Consult instructions for use for important cautionary information

Symbols

2.7 Statutory requirements

The system meets the requirements of the following European directives:

- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)
- Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators

The system has been developed, tested, and manufactured in accordance with IEC 61010-1 and IEC 61010-2-101, ISO 14971, IEC 61326-1 and IEC 61326-2-6, IEC 62304, and IEC 62366.

The product has been tested in accordance with IEC 61326-2-6 in conjunction with IEC 61326-1 for professional healthcare facility environment. The product corresponds to CISPR 11 group 1, class A regarding emissions related to radio-frequency disturbances.

The product is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

The system owner takes on the obligations arising from the national legislation about the operation of in vitro diagnostic medical devices.

3 Life cycle

This chapter describes the stages the system goes through, from delivery to disposal, and the requirements involved for the user with each stage.

3.1 Delivery

3.1.1 Unpacking and checking the delivery

To unpack and check the delivery, proceed as follows:

1 Before opening, check the transport box for signs of external damage.

2 If the transport box shows any visible signs of damage, immediately file a complaint with the carrier.

3 Open the transport box.

4 Remove the accessory kit.



5 Remove the foam packing.



6 Remove the analyzer from the transport box. There are indentations on the analyzer that can be used as handles.



7 Remove the plastic wrapping from the analyzer.



8 Open the accessory kit.

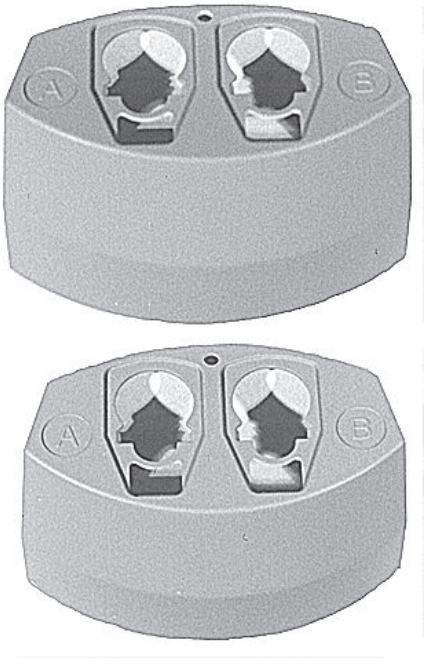
The accessory kit contains the items shown in the figures below.



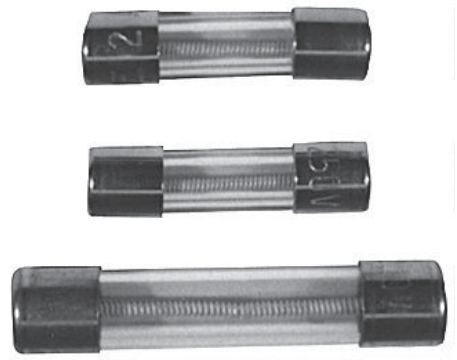
Accessory kit



PFA O-Rings



PFA Cassettes



Fuses



Paper Roll Axle



Dade PFA Vacuum Cup



PFA Cleaning Pads



PFA-100 Printer Ribbon



Dade PFA Priming Cartridges



PFA-100 Printer Paper



PFA O-Ring Service Tool

9 Check the content for completeness, see (➔ Page 21 *Scope of delivery*), and intact condition.

10 If anything is missing or damaged, inform Siemens Healthineers service immediately.

3.1.2 Scope of delivery

The delivery includes:

- 1 analyzer
- 1 accessory kit
- 1 instruction manual

The accessory kit contains:

Quantity	Item	Order number
2	PFA O-Rings	B4170-78
2	PFA Cassettes	B4170-70
35	Dade PFA Vacuum Cups	B4170-75
1	PFA O-Ring Service Tool	B4170-77
1	PFA-100 Printer Paper	B4170-71
1	Fuse 120 VAC	3106-2422
2	Fuses 220 VAC	3106-2437
35	PFA Cleaning Pads	B4170-73
2	Dade PFA Priming Cartridges	B4170-74
1	Paper Roll Axle	5400-2397
1	PFA-100 Printer Ribbon	B4170-72

Contents of the accessory kit

The Dade PFA Trigger Solution (order number:B4170-50), Test Cartridges (order number Collagen/ADP: B4170-21A, order number Collagen/EPI: B4170-20A) and the power cord (order number: 10452340) are required for operation, but **not** included in the delivery and must be ordered separately.

3.2 Installation

This chapter contains information about the operating conditions and worktop requirements for the installation of the system as well as the steps to be performed during installation.

3.2.1 Operating conditions

Ambient conditions for storage

The recommended storage temperature for the analyzer is between -29 °C and 50 °C. The Non-operating storage and transportation humidity is between 0 and 95 % RH.

Ambient conditions for operation

WARNING

False results or delay of results due to incorrect functioning of the analyzer.

Death or serious injury to the patient can result.

◆ Only operate the analyzer under specified conditions.

The system may be operated under the following ambient conditions:

- Only use indoors
- Altitude up to 2000 m
- Temperature range: 18–29 °C
- Maximum relative humidity in the permissible temperature range: 20–90 % RH (non-condensing)
- Voltage fluctuations in the mains supply not greater than ± 10 % of the rated voltage
- Transient overvoltages as they usually occur in the mains supply
- Low as possible an influence on the analyzer by steam, solvents and acid fumes
- Protect against direct exposure to sunlight.

The degree of protection for the system housing corresponds to IP20 according to IEC 60529.

3.2.2 Requirements of worktop

The small size of the system requires an area on the laboratory bench top which is approximately 30 cm wide and 50 cm deep, with about 50 cm clearance above the bench.

The worktop for the analyzer must meet the following requirements:

- Stable, horizontal and dry.
- To ensure adequate ventilation, a free space of at least 5 cm must be left around the analyzer on all sides.
- Load capacity of at least 50 kg.
- Access to a single power outlet is required within 150 cm of the analyzer location.

To ensure the analyzer is stable, all of the feet must be in full contact with the worktop. The analyzer should not be positioned close to the edge of the worktop.

3.2.3 Connecting the analyzer

NOTICE

Failure of the analyzer due to bad power supply.

Damage to the system can result.

- ◆ Observe the conditions for operation relating to the power supply strictly.
- ◆ Use an uninterruptible power supply (UPS) in regions where the specified conditions cannot be provided.

The use of an uninterruptible power supply (UPS) is recommended. Contact Siemens Healthineers service for details of requirements.

The system must be connected with tested cables in which an IEC 320, C13 plug is used on the analyzer side and a nationally typical plug with PE contact on the other side.

The system is supplied without any power supply cables. Power supply cables that correspond to the requirements of the particular country must be used, for example, VDE, CSA-C22.2, No. 21, or CSA-C22.2, No. 49, see (➔ Page 97 *Approved peripheral devices*).

The system can be operated on a supply voltage (AC voltage with 50 Hz or 60 Hz) of 100–130 V or 200–250 V.

NOTICE

Setting the voltage incorrectly can result in damage to the analyzer.

Damage to the system can result.

- Do not connect the analyzer to the power supply until the correct operating voltage has been set.

- Connect the analyzer to the power supply using one distribution box.

Installing fuses

WARNING

Electric shock by contact with live parts

Death or serious injury can result.

- Unplug the supply cable from the power supply socket before replacing the fuses.

WARNING

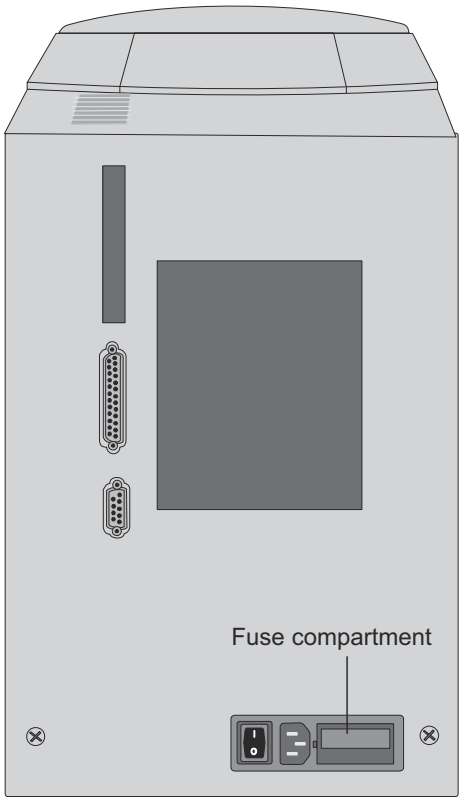
Infection by contaminated parts of the analyzer.

Death or serious injury can result.

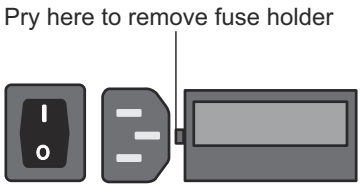
- Clean and disinfect the analyzer.

To install fuses on the analyzer, proceed as follows:

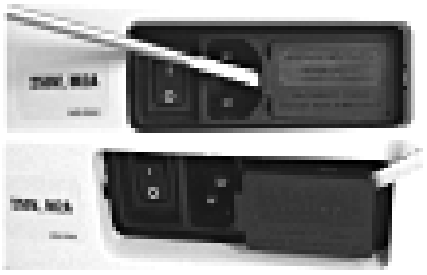
1 Pry open the fuse compartment with a small screw driver and remove the fuse holder from the analyzer, see figures below.



Location of fuse compartment with fuse holder



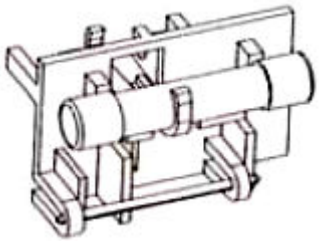
Removing fuse holder



Removing fuses

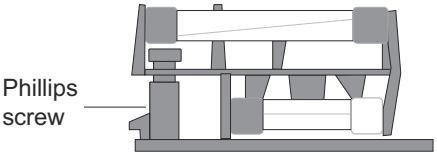
2 Install the correct fuse in the holder:

- For 120 VAC operation, install the larger single fuse (3106-2422) into the fuse holder, see figure below.

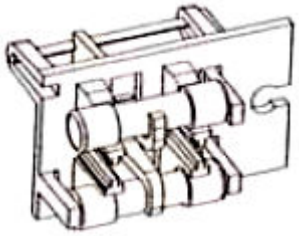


Fuse holder 120VAC

- For 220 VAC operation, remove the small Phillips screw and invert the fuse clip. Install the 2 small fuses (3106-2437) into the fuse holder, see figures below.



Remove Phillips screw



Fuse holder 220 VAC

→ Installing fuses on the analyzer is completed.

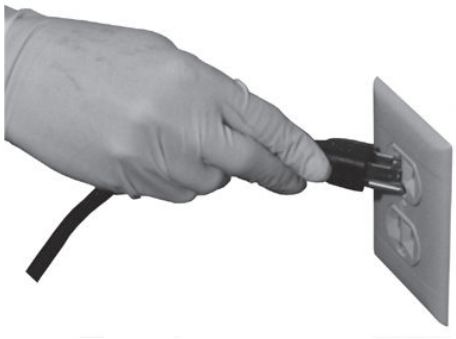
Connecting the analyzer to a power source

To connect the analyzer to a power source, proceed as follows:

1 Insert power cord.



2 Plug into AC outlet.



→ Connecting the analyzer to a power source is completed.

Loading printer paper

✓ Roll of printer paper is available

To insert a paper roll into the printer, proceed as follows:

1 Make sure that the analyzer is switched off.

2 Open access door.



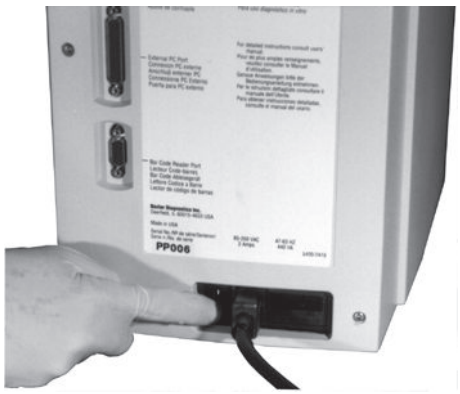
3 Insert paper roll axle.



4 Thread printer paper.



5 Switch power on.



→ Loading printer paper is completed.

The printer paper automatically feeds through the printhead.

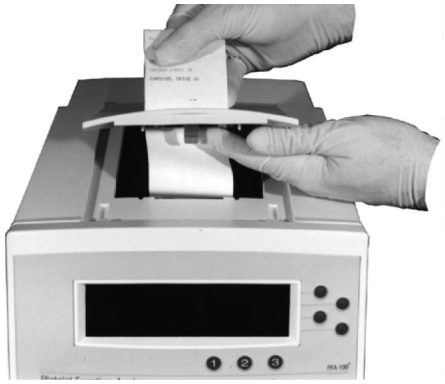
Threading printer paper

To thread the printer paper into the printer, proceed as follows:

1 Gently pull printer paper through printer.



2 Thread paper through slot in printer door.



3 Close printer door and tear off the excess paper.



→ Threading the printer paper is completed.

Loading trigger solution

✓ Trigger solution is available

To insert the trigger solution bottle into the analyzer, proceed as follows:

CAUTION

When the access door is open, the spiking needle of the trigger solution bottle can cause injuries.

Injury can result.

- Lift up the spiking needle lever completely before opening the access door.
- Take care not to touch the spiking needle.

1 Pull lever up to open the access door.



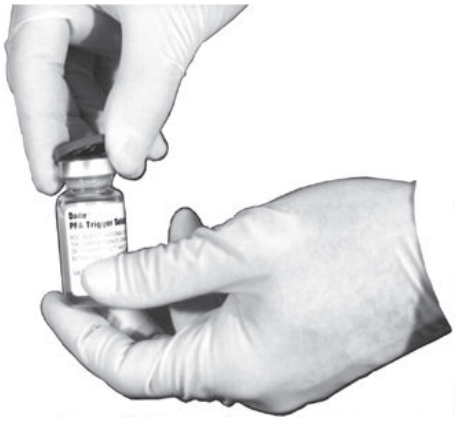
CAUTION

Delay of results caused by air in the trigger solution path as a result of a missing or insufficiently filled trigger solution bottle.

Minor or moderate injury to the patient can result.

- Take care to insert a trigger solution bottle.
- Make sure that the trigger solution bottle is sufficiently filled.

2 Remove flip-top from trigger solution bottle.



NOTICE

Risk of damage to the spiking needle if the spiking needle lever is pushed down before the access door is fully closed.

Damage to the system can result.

- Make sure the access door is fully closed before pushing the lever down.

3 Load trigger solution and close access door.



4 Push lever down.



5 Load cassette and the blue priming cartridge into the carousel.



→ Loading trigger solution is completed.

The system is now ready for priming.

Checking for correct installation

To check for correct installation, proceed as follows:

- Use the function **Self Test** from the **Maintenance** menu.

  → The analyzer has been installed correctly if the **Self Test** is passed without generating an error message.

For a quick reference on how to perform a **Self Test** see (➔ Page 100 *Quick reference guide*), for details see (➔ Page 53 *Self test and daily alignment check for trigger solution dispensing*) and/or (➔ Page 86 *Self test*), respectively.

3.3 Preparing the analyzer for longer periods of non-operation

To prepare the analyzer for longer periods of non-operation, proceed as follows:

WARNING

Infection by contaminated parts of the analyzer.

Death or serious injury can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the manufacturers information regarding the gloves compatibility with the materials and liquids used.

1. Before removing the PFA test cartridges, make sure that testing is completed and the carousel has moved to load position.
2. Remove the cassette carefully from the carousel.
3. Holding the cassette in one hand, remove the PFA test cartridges by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.
4. Dispose of the PFA test cartridges in a suitable biological hazard waste container.
5. Remove the O-Ring, see (➔ Page 77 *Removing the O-Ring*).
6. Only, if the analyzer is to be transported to another location for storage, select **Menu** > **Maintenance** > **0**.

   → The vacuum flask moves to rest position.
7. To switch off and store the analyzer, set the power switch on the back of the analyzer to **off**.
8. Pull out the mains plug from the AC outlet.
9. Unplug the power cord at the back of the analyzer.
10. Clean and disinfect the analyzer, see (➔ Page 71 *Cleaning the analyzer*) and (➔ Page 71 *Disinfecting the analyzer*).

11 Store the analyzer according to the non-operating storage conditions, see (➔ Page 22 *Ambient conditions for storage*) and (➔ Page 96 *Technical specifications*).

12 Transport the analyzer carefully to an appropriate storage place.

→ Preparing the analyzer for longer periods of non-operation is completed.

Before putting the analyzer into operation again, make sure that a new trigger solution bottle is inserted into the analyzer. For details on how to insert a trigger solution bottle, see (➔ Page 30 *Loading trigger solution*).

3.4 Disposal

WARNING

Infection by contaminated parts

Death or serious injury to the user can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the information from the manufacturer regarding the compatibility of the gloves with the materials and liquids used.
- Handle the potentially contaminated parts in accordance with good laboratory practices and the applicable safety standards and regulations.
- Always decontaminate the parts before transport or disposal.
- To get assistance, contact Siemens Healthineers service.

CAUTION

Irritation of the skin and mucous membranes by hazardous chemical material

Minor or moderate injury to the user can result.

- Make sure to handle this material according to the applicable safety standards and regulations.
- Always decontaminate the parts before transport or disposal.
- To get assistance, contact Siemens Healthineers service.

NOTICE

Pollution due to improper waste disposal

Damage to the environment can result.

- Contact Siemens Healthineers service with regard to disposal of the system.
- Do not treat electrical and electronic equipment as unsorted municipal waste.
- Check with the local waste disposal contractor for specific requirements regarding disposal.
- Collect waste electrical and electronic equipment separately, and return them to Siemens Healthineers in areas where the above mentioned directive is enforced.

To dispose of the system, proceed as follows:

1 Put the system out of operation, see (➔ Page 32 *Preparing the analyzer for longer periods of non-operation*).

2 Contact Siemens Healthineers service with regard to disposal of the system.

Siemens Healthineers is committed to taking back and recycling electrical and electronic equipment with best practice in order to support our customers and protect the environment.

Depending on the applications, parts of the system may be contaminated with biohazardous or hazardous chemical material.

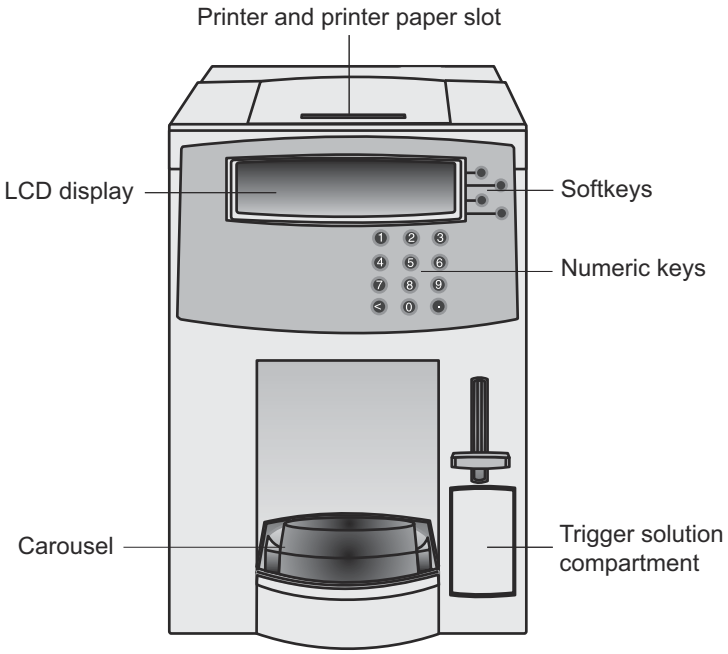
3 Dispose of the system according to national and local standards and regulations.

4 Description of the hardware

This chapter describes the operation and the functions of the hardware.

4.1 Analyzer

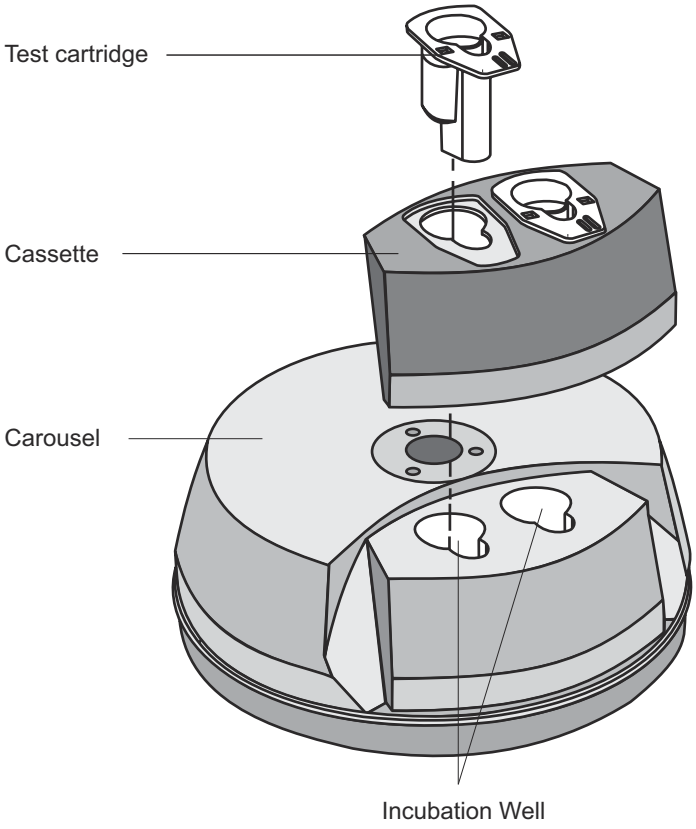
The PFA-100 System is a bench top analyzer. The analyzer consists of the function units described in following chapters.



Components of the PFA-100 System

4.1.1 Carousel with cartridge cassette

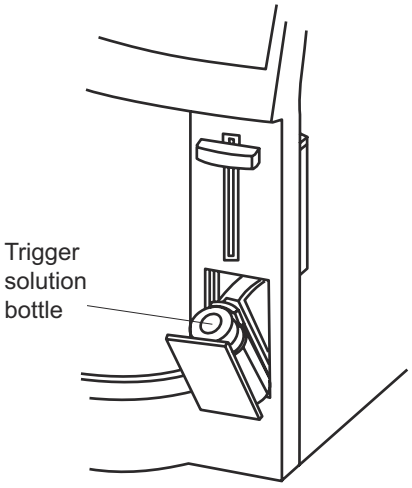
The carousel is located on the lower front of the analyzer and holds the cassette containing up to 2 PFA test cartridges for sample testing. The sample to be processed is placed in the PFA test cartridge. After pressing the softkey located next to the word **Run**, the carousel rotates clockwise to the inside of the analyzer to identify the number and type of PFA test cartridges loaded, dispense the trigger solution into each PFA test cartridge, incubate the samples, and then interface with each PFA test cartridge to perform the test. When testing is complete, the carousel returns to the outside position to allow removal of the used PFA test cartridges.



Carousel

4.1.2 Trigger solution compartment

The trigger solution compartment is located on the right front of the analyzer. The compartment is opened by lifting the knob all the way up. The replaceable bottle of trigger solution is located inside this compartment. When the bottle is empty, the system displays a message to replace the trigger solution.



Trigger solution compartment

4.1.3 LCD display

The LCD display is located on the upper front of the analyzer and displays the software commands for running samples, running control, maintenance, setup, and printing data.

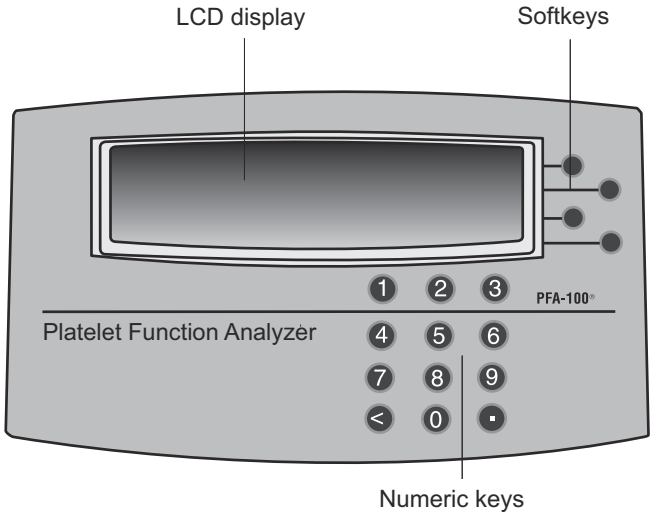
Display saver

The system automatically turns off the LCD backlight after 5 min of inactivity following the conclusion of a test or if no key has been pressed for the same length of time.

Pressing any key turns the light on again.

Contrast adjustment

The contrast adjustment button is located on the back side of the analyzer, between the **Software Upgrade Slot** and the **External PC Port**. By rotating this button, the analyzer display can be set to the required contrast.



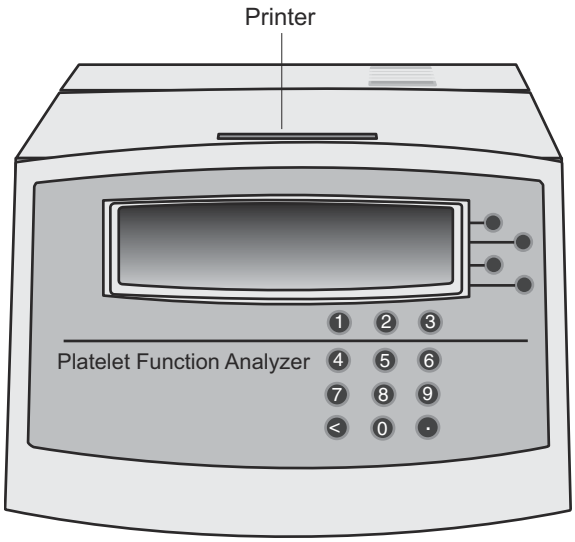
LCD display and keyboard

4.1.4 Keyboard

The keyboard is composed of 2 types of keys, see (➔ Page 37 *LCD display and keyboard*). The numeric keys and the softkeys. The setup allows the user to select an audible tone to sound when pressing the keys.

4.1.5 Printer

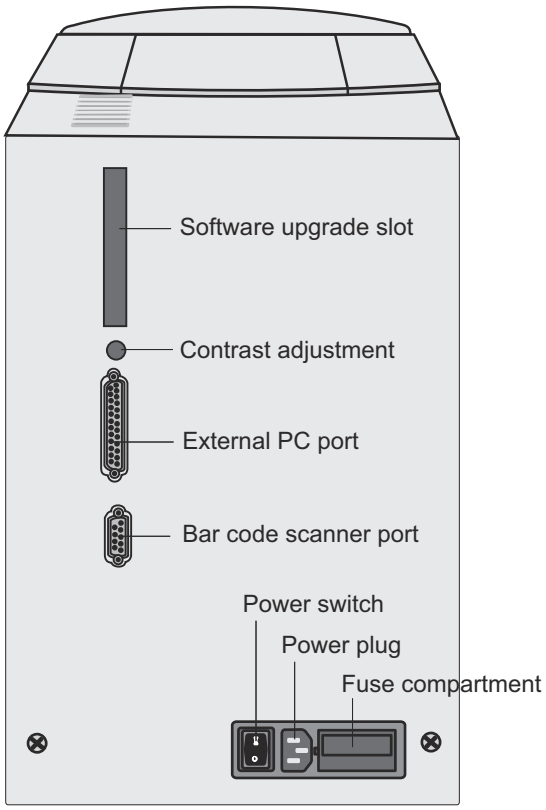
The printer is located on top of the analyzer. A small cartridge ribbon allows printing of the data on any standard 58 mm wide plain paper.



Printer and printer paper slot

4.2 Data connections

Ports for data connections are located on the back of analyzer.



Back of the analyzer

4.2.1 Barcode scanner port

The barcode scanner port can be used to connect the analyzer to a barcode scanner. The barcode scanner reads the bar code label placed on the sample tube, the number is transmitted to the analyzer and is used as the patient ID number at the start of a run.

4.2.2 External PC port

The external PC port can be used to download the electronic data to an external computer via a suitable interface software. For the respective technical specifications, see (➔ Page 96 *Technical specifications*).

4.2.3 Software upgrade slot

The software upgrade slot is used to update the software of the analyzer by inserting a PCMCIA card into the slot. When the analyzer is powered on, the software is loaded automatically. When the update is completed, the user is instructed to remove the PCMCIA card. To perform a software upgrade, contact Siemens Healthineers service.

4.3 Laboratory information system (LIS)

This option allows the user to transmit the printed results to a host computer via the external PC port.

To select this option via the LCD display, see (➔ Page 51 *Selecting the laboratory information system (LIS)*).

The system transmits each result with a checksum. The format for the checksum line is: cs: nnnnn<LF><CR>. It is the responsibility of the user to ensure that the data received by the host computer is accurate. To do so, the communication software used by the laboratory should have the capability to calculate the checksum value by adding up the transmitted characters one byte at a time, starting with the first character of the header until the last character before the checksum line. The checksum is a twobyte module 65536 value. Each line has a <LF><CR> at the end.

Cable connectors

PFA-100 System	DB-25 male connector
Computer	DB-9 female connector

Cable connectors

Pin assignment DB-9 to DB-25

DB-9	DB-25
Pin 5	Pin 7
Pin 3	Pin 3
Pin 2	Pin 2

Pin assignment DB-9 to DB-25

Communication parameters	
Baud rate	9600
Parity	None
Data bits	8
Stop bits	1

Communication parameters

4.4 Consumables

This chapter contains information about the consumables used for the PFA-100 System.

4.4.1 PFA test cartridges

Detailed descriptions of the PFA test cartridges, their handling, and their applications are provided in the instructions for use of each PFA test cartridge type. For more information, see the according instructions for use.

5 Configuring the system

This chapter describes how to configure the system.

5.1 Priming the analyzer

To prime the analyzer, proceed as follows:

NOTICE

Pollution of the incubation block with trigger solution due to a defective priming cartridge.

Damage to the environment can result.

- Check that the aluminum foil at the bottom of the priming cartridge is intact.
- Check the priming cartridge for scratches, marks, or debris and replace or clean it, if required.
- Change the priming cartridges periodically, depending on their condition.

1 Ensure trigger solution and a priming cartridge (blue cartridge with no foil on top) is installed in the analyzer.

Save the blue priming cartridge for future use.

CAUTION

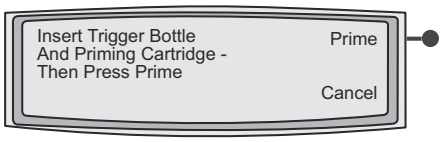
Touching the analyzer carousel while it is turning may result in pinching of fingers.

Minor or moderate injury can result.

- Always wait until the measurement has finished before inserting or removing cartridges.

2 Select **Menu** > **Maintenance** > **Trigger Prime**.

3 Press the softkey **Prime** to start priming the trigger system.



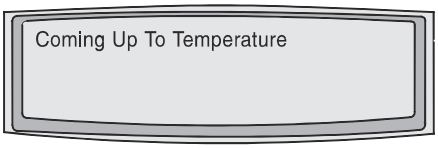
→ The carousel rotates and the dialog displays **Trigger Priming**, **Please Wait**. When trigger priming is complete, the cassette rotates to the load position.

4 Remove the priming cartridge and discard the trigger solution accumulated during the priming cycle.

5 Rinse the priming cartridge with purified water.

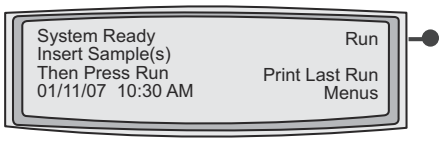
6 Press the softkey **Continue**.





When the analyzer is first powered on, at least 15 min are required to reach the operating temperature of 37 °C. When the system heater block has reached operating temperature, the dialog **System Ready** is displayed.

7 Press the softkey **Run**.



→ Priming the analyzer is completed.

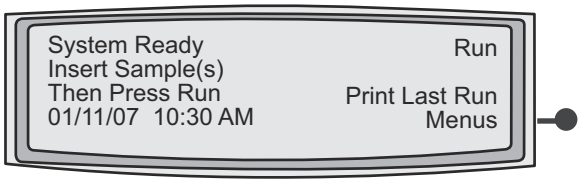
5.2 Selecting the language

This option allows the operator to select 1 of the following languages:

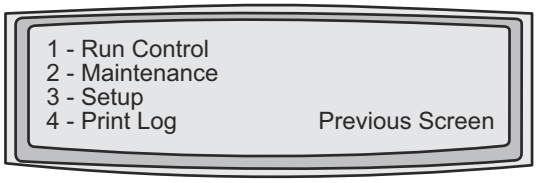
- German
- Spanish
- Italian
- English
- French

To select the language, proceed as follows:

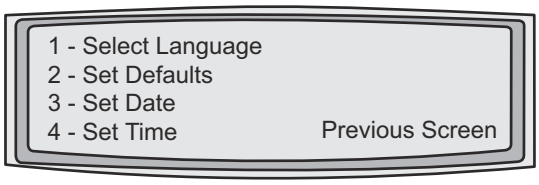
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



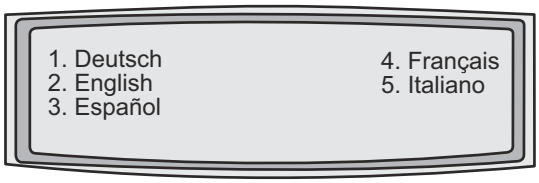
2 Press the numeric key **3** to select the option **Setup**.



3 Press the numeric key **1** to select the option **Select Language**.



4 Press the numeric key corresponding to the required language.



→ The system displays and prints in the selected language.

5 To return to the dialog **System Ready**, press the softkey located next to **Previous Screen** twice.

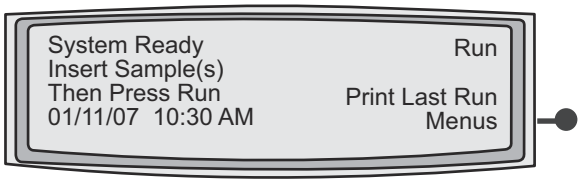
→ Selecting the language is completed.

5.3 Setting the time format

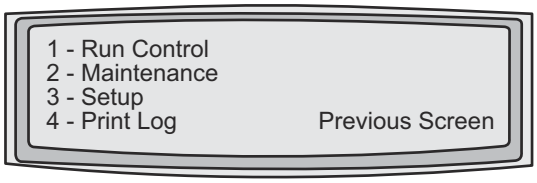
5.3.1 12-hour format

To select the time in a 12-hour format, proceed as follows:

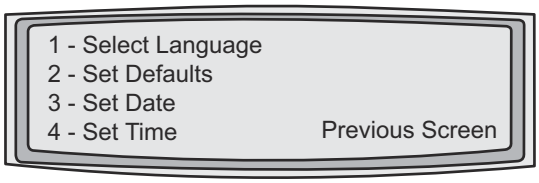
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



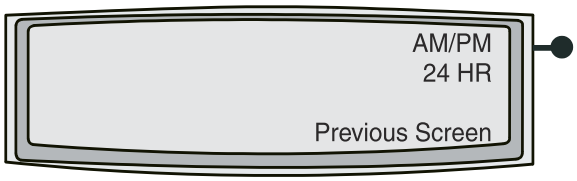
2 Press the numeric key **3** to select the option **Setup**.



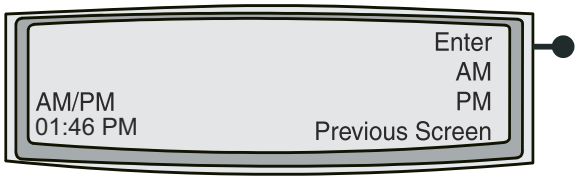
3 Press the numeric key **4** to select the option **Set Time**.



4 Press the softkey **AM/PM** for 12-hour format.



5 Press the softkey **AM** or **PM**.



6 To change the time or to delete an error in entry, press the key **<** to erase the existing time, then use the numeric keys to enter the new time (enter 0 first if a single digit hour is being entered, for example, 01:00).

→ The newly formatted time is displayed on the left.

7 To save the selection, press the softkey located next to **Enter**.

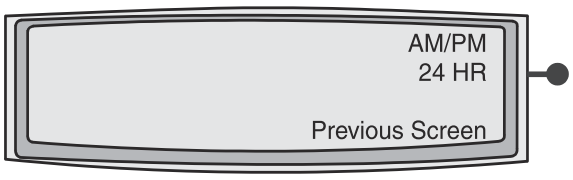
→ Selecting the time in a 12-hour format is completed.

To return to the dialog **System Ready**, press the softkey located next to **Previous Screen** twice.

5.3.2 24-hour format

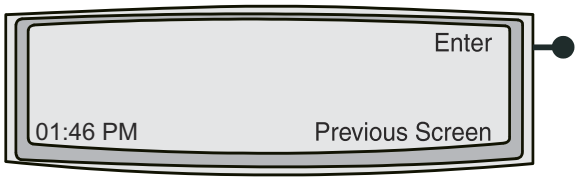
To set the 24-hour format, proceed as described for the setting of the 12-hour format:

1 Press the softkey **24 HR** for 24-hour format.



2 To change the time or to delete an error in entry, press the key **<** to erase the existing time, then use the numeric keys to enter the new time (enter 0 first if a single digit hour is being entered, for example, 01:00).

→ The new formatted time is displayed on the left.



3 To save the selection, press the softkey located next to **Enter**.

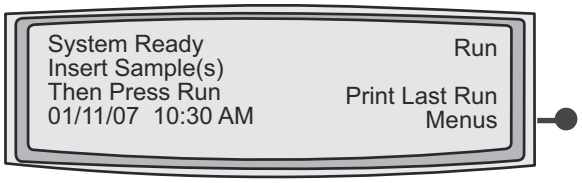
→ Selecting the time in a 24-hour format is completed.

To return to the dialog **System Ready**, press the softkey located next to **Previous Screen** twice.

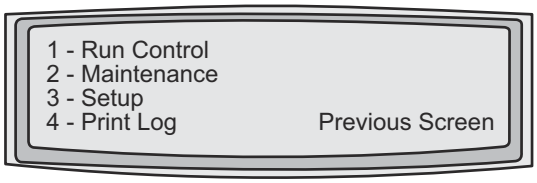
5.4 Setting the date format

To set the date format, proceed as follows:

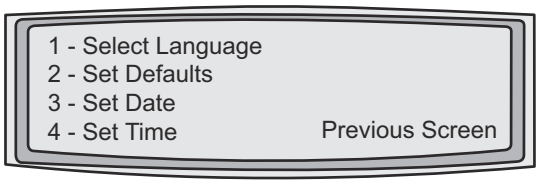
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



2 Press the numeric key **3** to select the option **Setup**.



3 Press the numeric key **3** to select the option **Set Date**.



→ The dialog displays the currently selected format above the date.

4 To change the format, press the softkey located next to the required option.

→ The new format is displayed above the date.

5 To change the date, use the key **<** to erase the existing date, then use the numeric keys to enter the new date (enter 0 first if a single digit month or day is entered, for example, 01/01/01) (displayed from left to right).



6 To save the selection, press the softkey located next to **Enter**.

→ Setting the date format is completed.

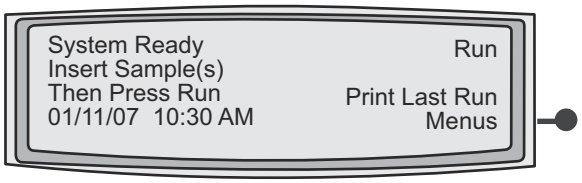
To return to the dialog **System Ready**, press the softkey located next to **Previous Screen** twice.

5.5 Setting the patient identification request

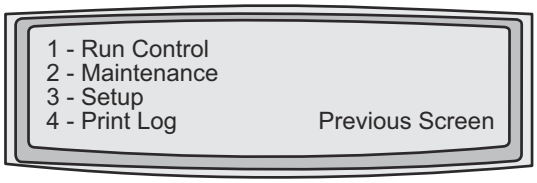
This option sets up the system to request the entry of a specific patient identification number (maximum 12 characters) when running a test.

To set the patient identification request, proceed as follows:

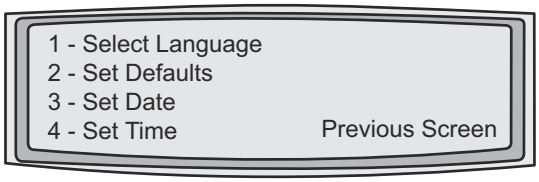
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



2 Press the numeric key **3** to select the option **Setup**.

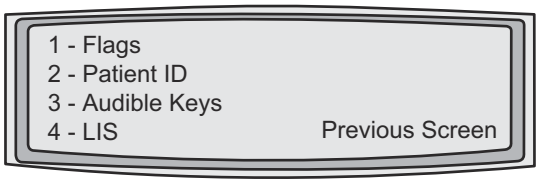


3 Press the numeric key **2** to select the option **Set Defaults**.

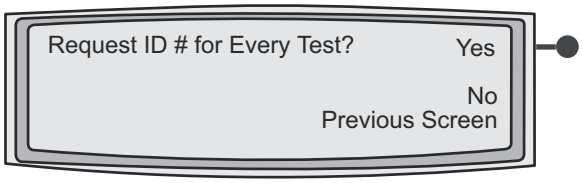


→ The dialog displays the currently selected format above the date.

4 Press the numeric key **2** to select the option **Patient ID**.



5 Press the softkey **Yes**to enable this option (system requests an **ID No. for Every Test**) or press the softkey **No** to disable this option (system does not request an **ID No. for Every Test**, but automatically assigns a unique number).



→ Setting the patient identification request is completed.

Upon initial start-up only, the system starts the initialization automatically. Otherwise, no further action is performed by the analyzer.

To return to the dialog **System Ready**, press the softkey located next to **Previous Screen** 3 times.

5.6 Initializing the system

During initialization, the system proceeds with power on diagnostics tests automatically. The results of each test are printed after each test is completed.

5.6.1 Power on diagnostics

When turning the power on, the system checks if a software update card is present. If so, the software on the software update card is loaded. Any previously stored test history data, error history data, or analyzer parameters remain unchanged.

The analyzer initializes the registers and ports, then proceeds with power on diagnostic tests. The result of each test is printed after the test is completed. If the analyzer detects a problem, an error message is displayed and printed, and in some cases the analyzer is disabled to prevent erroneous results. To take the appropriate action if a problem occurs, see (→ Page 88 *Common status messages*).

The diagnostics tests are performed in the following sequence:

Memory test The memory test consists of 2 parts: a checksum verification of the software which verifies the software integrity, followed by a test of the RAM (memory where data is stored). After successful completion, the message **Memory Ok** is displayed and printed.

Vacuum chuck The analyzer checks that the vacuum chuck which forms a vacuum tight seal with the PFA test cartridge is functional and fully raised or at the home position. After successful completion, the message **Vacuum Chuck Ok** is displayed and printed. This test only checks the mechanical functions of the vacuum chuck. Perform a **Self Test** from the dialog **Maintenance** to test the integrity of the vacuum system.

Carousel drive The analyzer checks that the carousel drive is functional by rotating the carousel clockwise. After successful completion, the message **Carousel Drive Ok** is displayed and printed.

Trigger system The analyzer initializes the trigger system to check that no air is present within the lines. After successful completion, the message **Trigger System Ok** is displayed and printed.

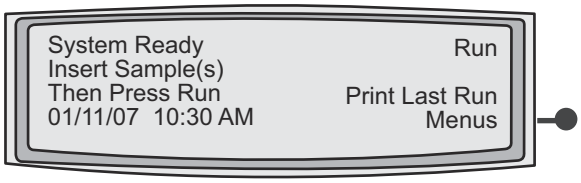
Incubation system The analyzer checks the heater block temperature. If the temperature is below 37.9 °C and increasing, the message **Incubation System Ok** is displayed and printed, followed by the display **Coming Up To Temperature**. When the analyzer reaches the operational temperature, the **System Ready** prompt is displayed.

5.7 Selecting low/high flag ranges

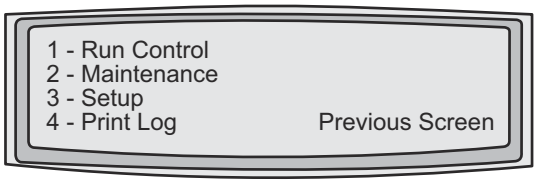
This option, if enabled, flags patient results that fall above (**High Flag**) and below (**Low Flag**) the established reference range for the laboratory. The high and low values (flags) are set by the operator. The high and low values must be between 0–300 seconds. Any test result that falls above or below the set values are flagged on the printout with an asterisk (*).

To select the flag ranges, proceed as follows:

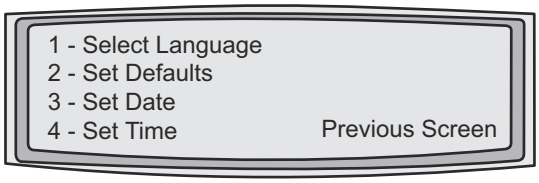
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



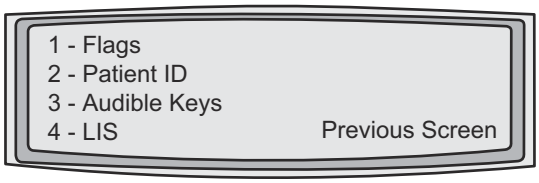
2 Press the numeric key **3** to select the option **Setup**.



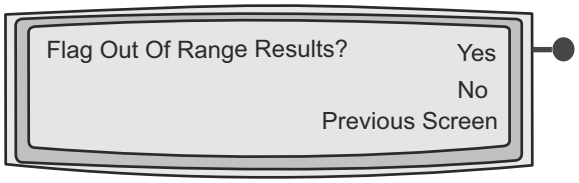
3 Press the numeric key **2** to select the option **Set Defaults**.



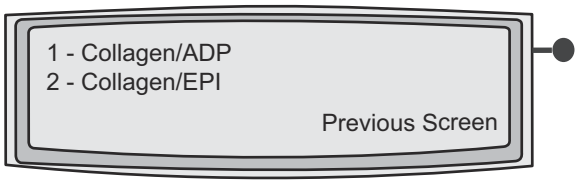
4 Press the numeric key **1** to select the **Flags** to set the above (**High Flag**) and below (**Low Flag**) values at which a test result are be flagged with an asterisk (*) on the result printout.



5 Press the softkey located next to **Yes** to enable or **No** to disable the option **Flag Out Of Range Results**.

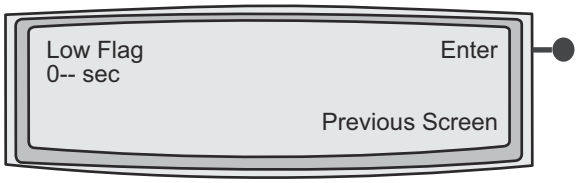


6 Use the numeric key to select the PFA test cartridge type to be set for flag ranges, for example, **Collagen/EPI** or **Collagen/ADP**.



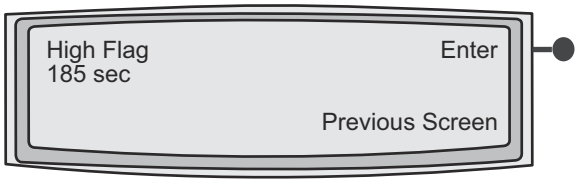
7 Use the numeric key to enter the low flag value (time below which the result will be flagged).

8 Then press the softkey located next to **Enter** to save the entry.



9 Use the numeric key to enter the high flag value (time above which the result will be flagged).

10 Then press the softkey located next to **Enter** to save the entry.



→ Selecting the flag ranges is completed.

The system defaults to **No** if no selection is made.

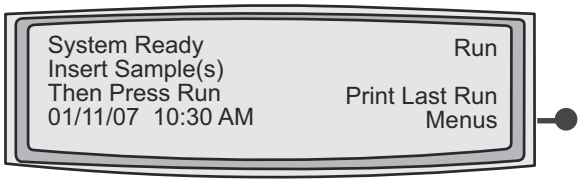
Press the softkey located next to **Previous Screen** 3 times to return to the dialog **System Ready**.

5.8 Using option Audible Keys

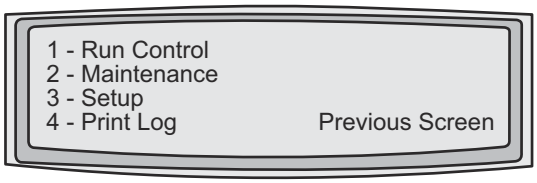
This option allows the operator to enable or disable an audible tone to sound when a softkey or a numeric key is pressed.

To enable or disable the audible tone, proceed as follows:

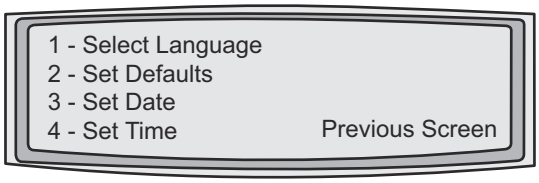
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



2 Press the numeric key **3** to select the option **Setup**.



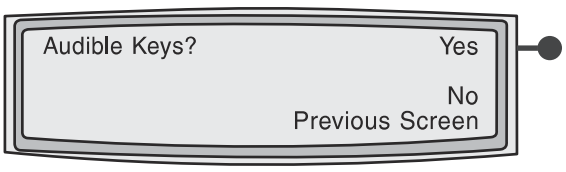
3 Press the numeric key **2** to select the option **Set Defaults**.



4 Press the numeric key **3** to select the option **Audible Keys**.



5 Press the softkey located next to **Yes** to enable the option or **No** to disable the option.



→ Enabling or disabling the audible tone is completed.

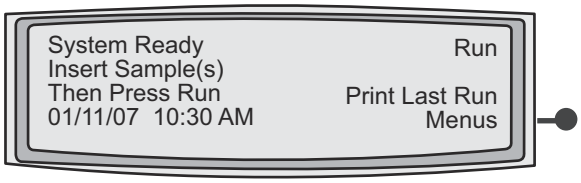
Press the softkey located next to **Previous Screen** 3 times to return to the dialog **System Ready**.

5.9 Selecting the laboratory information system (LIS)

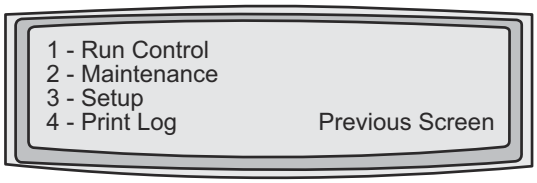
This option allows the user to transmit the printed results to a host computer via the external PC port.

To select the laboratory information system, proceed as follows:

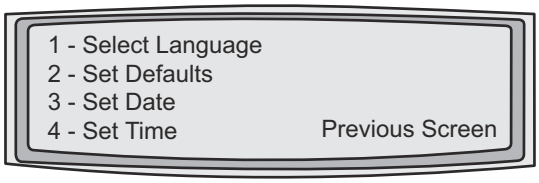
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



2 In the dialog **Menu**, press the numeric key **3** to select the option **Setup**.



3 Press the numeric key **2** to select the option **Set Defaults**.



4 Press the numeric key **4** to select the option **LIS**.



5 Press the softkey next to **Enable** to turn on the transmission of results or **Disable** to turn it off.



→ Selecting the laboratory information system is completed.

To return to the dialog **System Ready**, press the softkey located next to **Continue**, and then the softkey next to **Previous Screen** 3 times.

6 QC procedures

WARNING

False results due to insufficient maintenance of the analyzer.

False results can lead to misdiagnosis and incorrect treatment.

- Perform the **Self Test** and related maintenance procedures on a regular basis, as described below.

CAUTION

Delay of results due to insufficient maintenance of the analyzer.

Minor or moderate injury to the patient can result.

- Perform the **Self Test** and related maintenance procedures on a regular basis, as described below.

The manual O-Ring cleaning has to be carried out once a week.

The system has a self diagnostic built in to verify proper analyzer performance. Perform the **Self Test** from the **Maintenance** menu at least once at the start of each shift, this is part of the QC practice. If the system is first powered on, perform the **Self Test** after the initialization and power on diagnostic tests are completed. The result of the test is printed along with the date and time for incorporation into the QC records.

Blood drawn from healthy adult individuals may be used as normal controls for the system test. As part of the analyzer quality control, it is recommended to test 2 cartridges of each new lot with a control donor, or whenever the institution wishes to verify the performance of the system. For further instructions, see the PFA test cartridges instructions for use. A separate test mode called **Run Control** is used when running these samples. The only difference between the control mode and the sample mode is that the mode **Run Control** requires the entry of the lot number for the PFA test cartridge being used, and the results are stored in a separate database (the last 50 results are saved in memory). It is recommended that the laboratory maintains a hard copy of the stored control results.

6.1 Self test and daily alignment check for trigger solution dispensing

WARNING

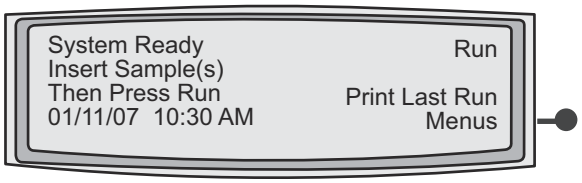
False results due to a vacuum leak not being noticed.

False results can lead to misdiagnosis and incorrect treatment.

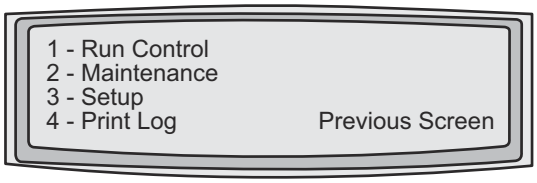
- When performing the **Self Test**, strictly follow the instructions given below.
- Always use a new vacuum test cup and a new cleaning pad.

To initiate a system self test, proceed as follows:

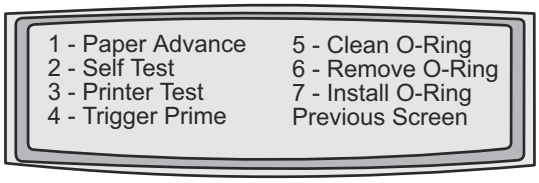
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



2 In the dialog **Menu**, press the numeric key **2** to select the option **Maintenance**.



3 Press the numeric key **2** to select the option **Self Test**.



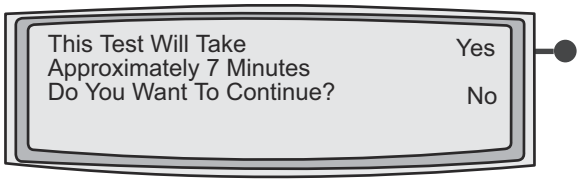
NOTICE

Vacuum test failure.

The vacuum test may fail if the following is not observed:

- Make sure that a vacuum cup is inserted into the priming cartridge.
- Check the priming cartridge (bottom foil intact, no scratches or debris) and replace it, if required.
- Check the vacuum cup for scratches or debris and replace it, if required.

4 Press the softkey located next to **Yes** to continue the self test.



5 Load 2 vacuum test cartridges (create the vacuum test cartridge by inserting a grayish blue vacuum test cup into the blue priming cartridge) in position A and B.

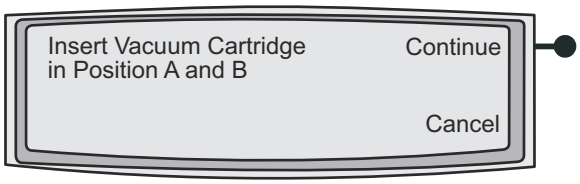
NOTICE

Contamination of the cleaning pad when touching it with bare fingers.

Contamination may be transferred from the cleaning pad to the O-Ring during cleaning.

- Only touch the cleaning pads with appropriate gloves.
- Pay attention to the manufacturers information regarding the gloves compatibility with isopropanol.

6 Press the softkey located next to **Continue**.



→ The system then rotates the carousel and instructs the user to load the cleaning pad (circular foam sponge) in the well.

7 Once the cleaning pad is in position in the carousel well, apply 4 to 5 drops of isopropanol to the center of the pad.

8 Press gently on the pad with gloved index finger 2 to 3 times to help distribute the isopropanol.

WARNING

Infection by contaminated cleaning pads.

Death or serious injury can result.

- After usage, cleaning pads must be treated as a potential source of infection.
- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the manufacturers information regarding the gloves compatibility with the materials and liquids used.

9 Press the softkey located next to **Continue**.

→ The system performs the O-Ring cleaning procedure and a vacuum test in addition to the power on diagnostics test. The memory test is performed only during power on and not performed during the self test.

The system prints the pass/fail results each time a test is completed.

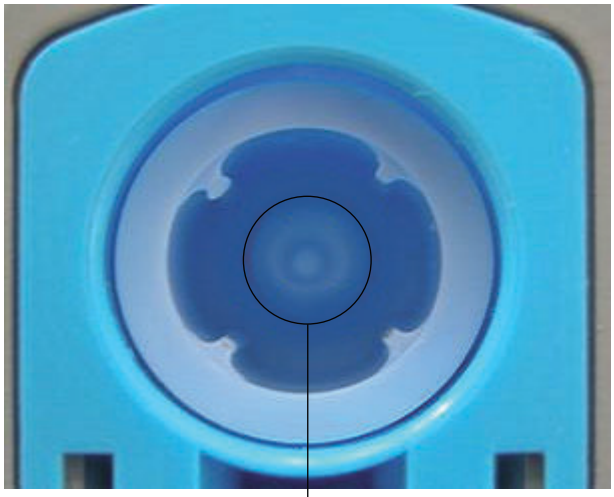
After the self tests are completed, the system prints the high/low flag ranges for each test type.

At the end of the self test, the system prompts the user to remove the cleaning pad.

10 Remove the pad and dispose of it in a suitable biological hazard waste container.

11 Press the softkey located next to **Continue**.

12 Remove the vacuum test cartridge from position B and inspect the trigger solution dispensing. Check that the trigger solution is dispensed on the raised platform of the vacuum cup, see circle in figure below.



Trigger solution dispensing

The size and exact centering of the drop is not critical. If there is a drop visible on the platform, the trigger solution dispensing is adequate. If there is no drop visible on the platform, call Siemens Healthineers service.

WARNING

Infection by contaminated vacuum test cups.

Death or serious injury can result.

- After usage, vacuum test cups must be treated as a potential source of infection.
- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the manufacturers information regarding the gloves compatibility with the materials and liquids used.

13 Remove the vacuum test cartridge from position A.

14 Remove the vacuum test cup from both priming cartridges with gloved index finger and discard them in a suitable biological hazard waste container.

15 Rinse both priming cartridges with purified water and save them for further use.

→ Self test and daily alignment check for trigger solution dispensing is completed.

Press the softkey located next to **Previous Screen** twice to return to the dialog **System Ready**.

6.2 Performing run control

To perform a run control, proceed as follows:

WARNING

Infection by contaminated samples and PFA test cartridges.

Death or serious injury can result.

- All blood samples and blood components must be treated as a potential source of infection.
- All used PFA test cartridges must be treated as a potential source of infection.
- These items must be handled in accordance with good laboratory practices using appropriate precautions.
- Personal protective equipment must be worn when **inserting** or **removing** PFA test cartridges from the analyzer.

1 Collect and handle the samples to be used as controls as described in the instructions for use.

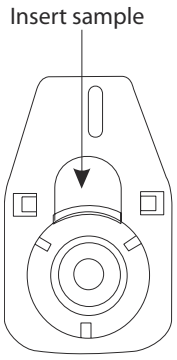
2 Peel off and discard the top foil seal of the PFA test cartridge.

Make sure the PFA test cartridges have reached room temperature before utilization (usually, this takes approximately 15 min).

3 Snap the PFA test cartridge into position A (left position) of the cassette. When running 2 tests, place a second PFA test cartridge into position B (right position).

4 Resuspend the whole blood sample by gently inverting the collection tube 3 to 4 times by hand.

5 Holding the cassette with PFA test cartridges on a flat surface, pipette 800 µL of sample into the smaller opening (sample reservoir opening) of the PFA test cartridge.



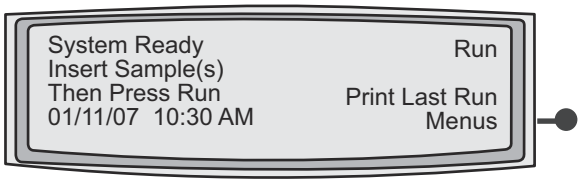
Insert sample into PFA test cartridge

To minimize the risk of trapping an air bubble, place the tip of the pipette against one of the inside corners of the opening while slowly pipetting in the sample.

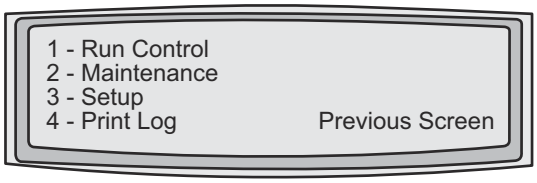
6 Place the cassette with the PFA test cartridges into the incubation wells of the analyzer so that the cassette is flush to the carousel surface.

Do not apply pressure to the sample reservoir opening.

7 In the dialog **System Ready**, press the softkey located next to **Menus**.



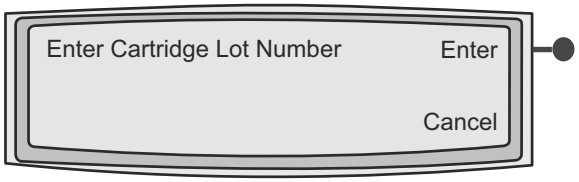
8 In the dialog **Menu**, press the numeric key **1** to select the option **Run Control**.



9 Use the numeric keypad to enter the numeric portion of the lot number of the PFA test cartridge being used (located on the PFA test cartridge pouch and on the PFA test cartridge itself).

10 To modify the lot number, use the key **<** to erase it, then enter the correct number.

11 Press the softkey located next to **Enter**.

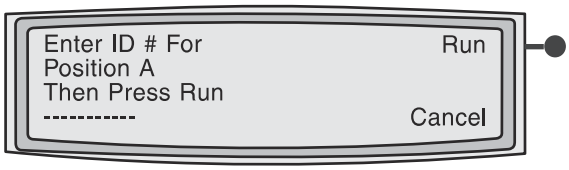


12 Use the numeric keypad to enter the control ID (maximum 12 characters).

13 To modify the control ID, use the **<** key to erase it, then enter the correct number.

To minimize the risk of trapping an air bubble, place the tip of the pipette against one of the inside corners of the opening while slowly pipetting in the sample.

14 Press the softkey located next to **Run**.



→ When testing is complete, the analyzer prints and displays the results along with the test type, the control ID number and lot number entered, a CV% and a MEAN value if 2 tests were run.

15 Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the PFA test cartridge by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

16 Dispose of the PFA test cartridge in a suitable biological hazard waste container.

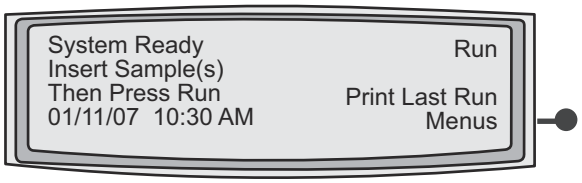
→ Performing a run control is completed.

Events or conditions (status messages) detected during the test run are indicated below the printed test result. See (➔ Page 88 *Common status messages*) and (➔ Page 93 *Other status messages*), for full explanation of status messages.

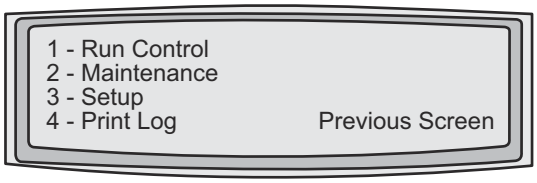
6.3 Printing control results

To print the results of the control runs, proceed as follows:

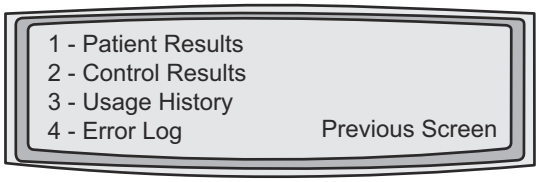
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



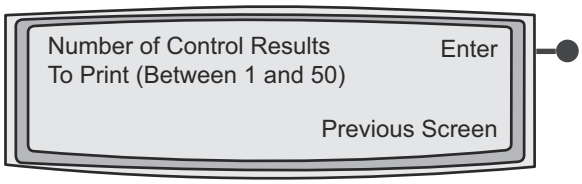
2 In the dialog **Menu**, press the numeric key **4** to select the option **Print Log**.



3 In the dialog **Print Log**, press the numeric key **2** to select the option **Control Results**.



4 Use the numeric keypad to enter the number of control results to be printed, then press the softkey located next to **Enter**.



→ The system prints the number of results entered, starting with the most recent control performed.

7 Performing the analysis

This chapter describes how to perform the analysis.

7.1 Loading samples

General information on handling and collection of blood samples as well as detailed information on performance and applications of each PFA test cartridge type is described in the specific instructions for use of the PFA test cartridge types.

To insert PFA test cartridges into the analyzer, proceed as follows:

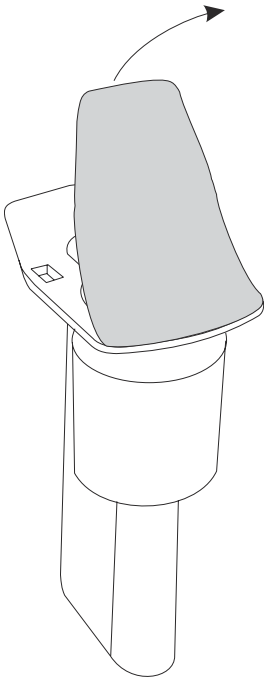
CAUTION

Touching the analyzer carousel while it is turning may result in pinching of fingers.

Minor or moderate injury can result.

- Always wait until the measurement has finished before inserting or removing cartridges.

1 Peel off and discard the top foil seal of the PFA test cartridge.



PFA test cartridge

2 Snap the PFA test cartridge into position A (left position) of the cassette.

WARNING

False results due to mix-up of patient samples.

Death or serious injury to the patient can result.

- Make sure to assign the PFA test cartridge position to the correct patient.

WARNING

Infection by contaminated samples and PFA test cartridges.

Death or serious injury can result.

- All blood samples and blood components must be treated as potential sources of infection.
- All used PFA test cartridges must be treated as potential sources of infection.
- These items must be handled in accordance with good laboratory practices using appropriate precautions.
- Personal protective equipment must be worn when inserting or removing PFA test cartridges from the analyzer.

3 When running duplicates or 2 tests, place a second PFA test cartridge into position B (right position).

→ The analyzer automatically determines the PFA test cartridge type before testing the sample.

CAUTION

No result or delay of results due to missing blood sample or incorrect preparation of blood samples.

Minor or moderate injury to the patient can result.

- Make sure the blood sample is properly pipetted into the PFA test cartridge.

NOTICE

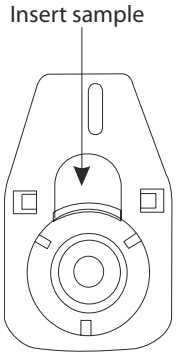
PFA test cartridge is processed without a blood sample.

PFA test cartridge will be unusable afterwards.

- Make sure the blood sample is pipetted into the PFA test cartridge.

4 Resuspend the whole blood sample by gently inverting the collection tube 3 to 4 times by hand.

5 Holding the cassette with 1 or more PFA test cartridges on a flat surface, pipette 800 µL of sample into the smaller opening (sample reservoir opening) of the PFA test cartridge.



Insert sample into PFA test cartridge

To minimize the risk of trapping an air bubble, place the tip of the pipette against one of the inside corners of the opening while slowly pipetting in the sample.

6 Place the cassette with the PFA test cartridges into the incubation wells of the analyzer so that the cassette is flush to the carousel surface.

Do not apply pressure to the sample reservoir opening.

→ Loading the samples is completed. The test can now be started.

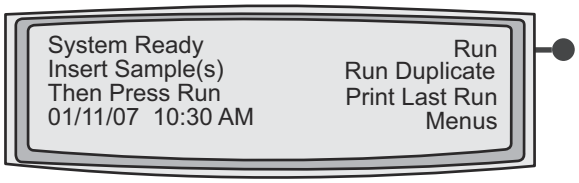
7.2 Requesting a test with option patient ID number disabled

If the option **Patient ID number** was disabled in the setup menu, the system does not prompt for the patient ID number, see (→ Page 46 *Setting the patient identification request*).

7.2.1 Performing a single test

To start a single test, proceed as follows:

1 Press the softkey located next to **Run** in the dialog **System Ready**.



→ The analyzer starts the test. When testing is complete, the system prints and displays the results along with an ID number assigned by the analyzer and the test type.

2 Remove the cassette carefully from the carousel.

3 Holding the cassette in one hand, remove the PFA test cartridge by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

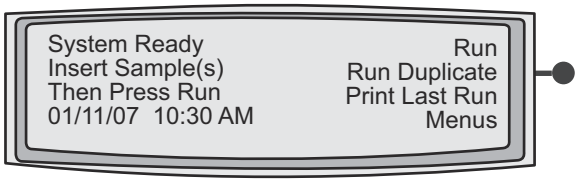
4 Dispose of the PFA test cartridge in a suitable biological hazard waste container.

→ Performing a single test is completed.

7.2.2 Performing duplicate test or 2 test types with the same patient ID

To perform a duplicate test or 2 different test types with the same patient ID, proceed as follows:

1 Press the softkey located next to **Run Duplicate** on the dialog **System Ready**.



→ The analyzer starts testing and displays the processing stage of the sample (incubation or performing testing sample A or sample B). When testing is complete, the analyzer prints and displays the results along with an ID number assigned by the analyzer and the test type.

The MEAN and CV% are calculated as follows (for duplicate tests, only):

MEAN = (CT(A)-CT(B)) / 2

CV% = (CT(A)-CT(B)) / (CT(A)+CT(B)) * 100

2 Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the PFA test cartridge by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

3 Dispose of the PFA test cartridge in a suitable biological hazard waste container.

→ Performing a duplicate test or 2 different test types with the same patient ID is completed.

7.2.3 Performing 2 different test types with different patient IDs

WARNING

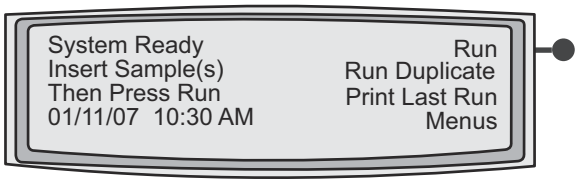
False results due to mix-up of patient samples.

Death or serious injury to the patient can result.

- Make sure to assign the PFA test cartridge position to the correct patient.

To perform 2 different test types with different blood samples, proceed as follows:

1 Press the softkey located next to **Run** in the dialog **System Ready**.



→ The analyzer starts testing and displays the processing stage of the sample (incubation or performing testing sample A or sample B). When testing is complete, the analyzer prints and displays the results along with an ID number assigned by the analyzer and the test type.

2 Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the PFA test cartridge by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

3 Dispose of the PFA test cartridge in a suitable biological hazard waste container.

→ Performing 2 different test types with different patient IDs is completed.

7.3 Requesting test with option patient ID number enabled

If the patient ID was enabled in the setup menu, the system prompts for entry of the patient ID number after **Run** was pressed in the dialog **System Ready**. See (➔ Page 46 *Setting the patient identification request*).

WARNING

False results due to mix-up of patient samples. This can lead to incorrect diagnosis and the wrong medication being prescribed.

Death or serious injury to the patient can result.

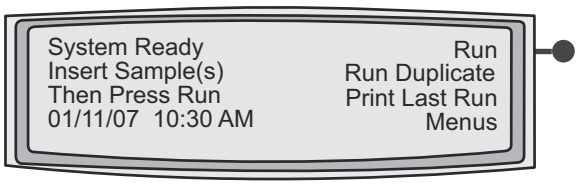
◆ Make sure to assign the PFA test cartridge position to the correct patient.

If a patient ID number is not entered before completion of the incubation cycle (about 3 min), the analyzer automatically assigns the next available consecutive number. This number is printed with the result.

7.3.1 Performing a single test

To perform a single test, proceed as follows:

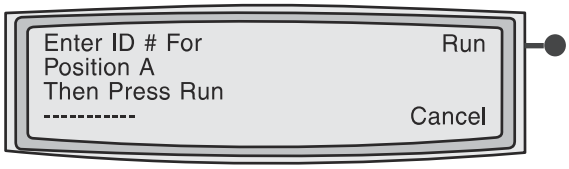
1 Press the softkey located next to **Run** on the dialog **System Ready**.



2 Use the numeric keypad or the optional barcode scanner to enter the patient ID (maximum 12 characters).

3 Holding the cassette in one hand, remove the PFA test cartridge by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

4 Press the softkey located next to **Run**.



→ The analyzer starts testing. When testing is complete, the analyzer prints and displays the results along with the patient ID number entered and the test type.

5 Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the PFA test cartridge by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

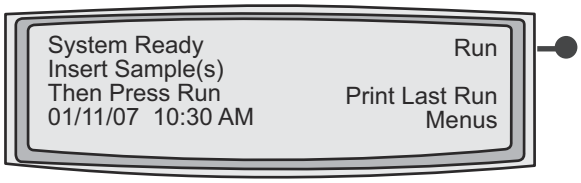
6 Dispose of the PFA test cartridge in a suitable biological hazard waste container.

→ Performing a single test is completed.

7.3.2 Performing duplicate test or 2 test types with the same patient ID

To perform a duplicate test or 2 test types for the same patient ID, proceed as follows:

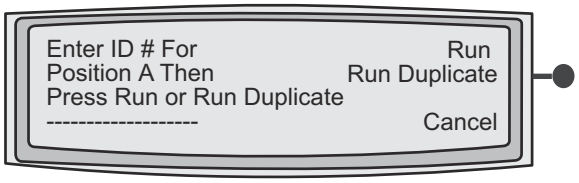
1 Press the softkey located next to **Run** on the dialog **System Ready**.



2 Use the numeric keypad or the optional barcode scanner to enter the patient ID (maximum 12 characters).

3 Dispose of the PFA test cartridge in a suitable biological hazard waste container.

4 Press the softkey located next to **Run Duplicate**.



→ The analyzer starts testing and displays the processing stage of the sample (incubation or performing testing sample A or sample B).

Duplicate: When testing is complete, the analyzer prints and displays the results, the CV% and a MEAN value along with the patient ID number entered and the test type.

2 Test Types: When testing is complete, the analyzer prints and displays the results along with the patient ID number entered and the test types.

5 Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the PFA test cartridge by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

6 Dispose of the PFA test cartridges in a suitable biological hazard waste container.

→ Performing duplicate test or 2 test types with the same patient ID is completed.

7.3.3 Performing 2 test types with different patient IDs

WARNING

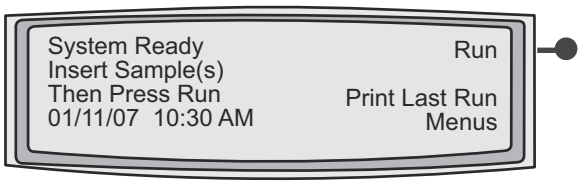
False results due to mix-up of patient samples.

Death or serious injury to the patient can result.

- Make sure to assign the PFA test cartridge position to the correct patient.

To perform 2 test types for different patient IDs, proceed as follows:

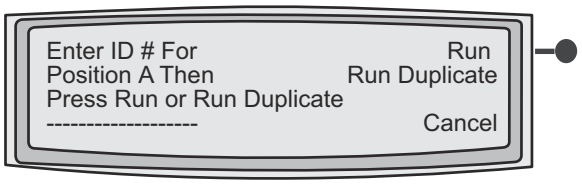
1 Press the softkey located next to **Run** on the dialog **System Ready**.



2 Use the numeric keypad or the optional barcode scanner to enter the patient ID (maximum 12 characters) for the sample loaded in position A (left position).

3 Dispose of the PFA test cartridge in a suitable biological hazard waste container.

4 Press the softkey located next to **Run**.

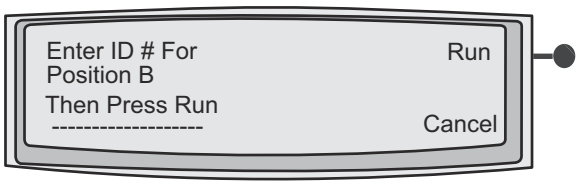


→ The system then prompts for the patient ID number related to the PFA test cartridge loaded in position B (right position).

5 Use the numeric keypad or the optional barcode scanner to enter the patient ID for the sample loaded in position B (right position).

6 Dispose of the PFA test cartridges in a suitable biological hazard waste container.

7 Press the softkey located next to **Run**.



→ The analyzer starts testing and displays the processing stage of the sample (incubation or performing testing for sample A or sample B). When testing is complete, the analyzer prints and displays the results along with the respective patient ID numbers entered and test type.

8 Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the PFA test cartridge by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

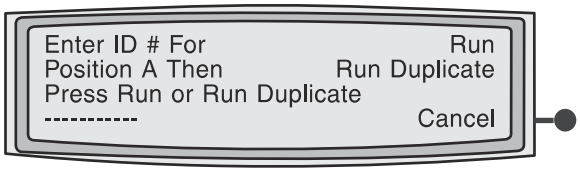
9 Dispose of the PFA test cartridge in a suitable biological hazard waste container.

→ Performing 2 test types with different patient IDs is completed.

7.4 Canceling tests

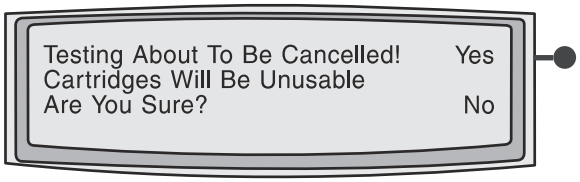
To cancel a test, proceed as follows:

1 Press the softkey located next to **Cancel**.



If the test cycle is already started, that is trigger solution dispensed into the PFA test cartridge, the system prompts for confirmation.

2 Press the softkey located next to **Yes** to cancel the test.



→ The carousel rotates to the load position and the system displays **System Ready**.

3 Remove and dispose of the PFA test cartridges in a suitable biological hazard waste container.

→ Canceling a test is completed.

7.5 Printing results

WARNING

False results due to problems with the type code sensor or the readability of the type codes on the PFA test cartridges. This can cause a mix-up of test types in the instrument software.

False results can lead to misdiagnosis and incorrect treatment. Death or serious injury to the patient can result.

- Do not use the results obtained whenever the status message **TYPE CODE CALIBRATION REQUIRED** or **INVALID CARTRIDGE TYPE DETECTED** is displayed.
- Remeasure the samples concerned when the issue is solved.
- Compare the type code on the printout with the type code on the cartridge.

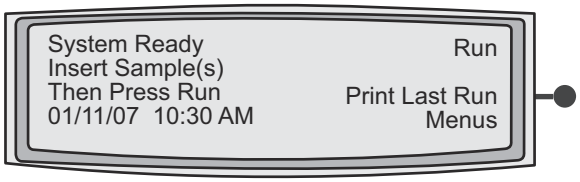
7.5.1 Automatic printing after test

The system is set to automatically print the results after testing is complete.

7.5.2 Printing the results of the last run

To print the results of the last run, proceed as follows:

- In the dialog **System Ready**, press the softkey located next to **Print Last Run**.

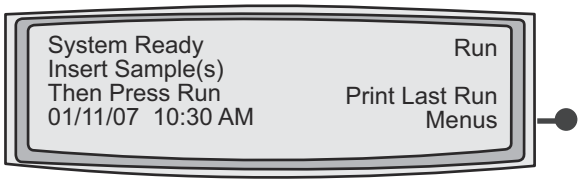


→ Printing the results of the last run is completed.

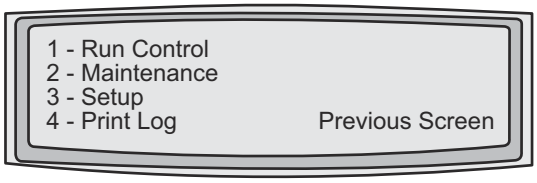
7.5.3 Printing stored test results

To print the stored test results, proceed as follows:

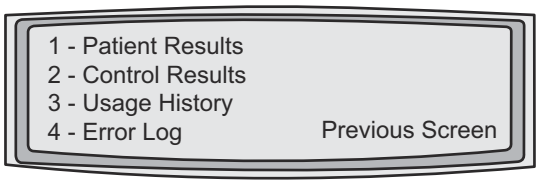
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



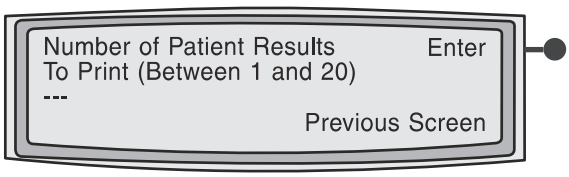
2 Press the numeric key **4** to select the option **Print Log**.



3 Press the numeric key **1** to select the option **Patient Results**.



4 Using the numeric keys, enter the number of patient results to be printed (maximum 20), then press the softkey located next to **Enter**.



→ The system begins printing the results of previous tests starting with the most recent one. Printing stored results is completed.

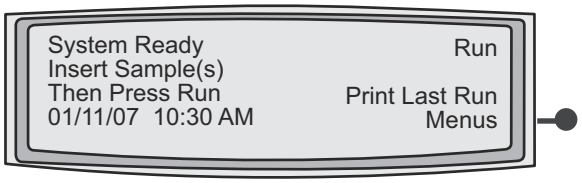
Events or conditions (status messages) detected during the test run are indicated below the printed test result. For full explanation of status messages, see (→ Page 86 *Troubleshooting*).

7.5.4 Printing usage history

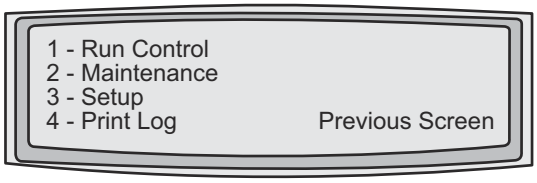
When printing a usage history, the system prints the serial number and the software version of the analyzer, the date and time, and the number of tests performed by the analyzer over the last 30 days, and since the installation.

To print a usage history, proceed as follows:

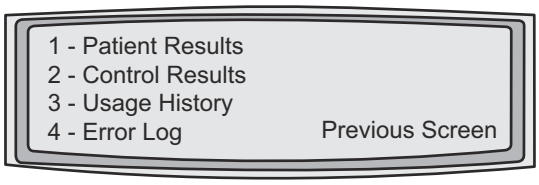
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



2 Press the numeric key **4** to select the option **Print Log**.



3 Press the numeric key **3** to select the option **Usage History**.



→ The system prints the usage history. Printing the usage history is completed.

To return to the dialog **System Ready**, press the softkey located next to **Previous Screen** twice.

8 Performing maintenance and cleaning

WARNING

False results or delay of results due to insufficient maintenance of the analyzer.

False results can lead to misdiagnosis and incorrect treatment. Death or serious injury to the patient can result.

- Perform all maintenance procedures on a regular basis, as described below.
- Check the functionality of the analyzer daily with the function **Self Test**.

NOTICE

Damage to the analyzer by sterilization.

Analyzer may break down.

- Never use methods of cleaning and disinfection other than those described in this manual.

This chapter describes how to perform maintenance and how to clean the system.

8.1 Cleaning the analyzer

The exterior of the analyzer can be cleaned by wiping with a damp cloth containing a commercial disinfectant solution, for example Mikrozid. To remove blood stains use a damp cloth containing water. Do not immerse or pour liquid onto analyzer. It is recommended to maintain the type code black pad clean. This pad resides on the surface of the carousel underneath the cassette.

For cleaning the O-Ring, see (➔ Page 76 *O-Ring maintenance*).

8.2 Disinfecting the analyzer

The recommended disinfection interval for the analyzer and used parts (for example cassette) is daily after work.

The analyzer has to be disinfected by qualified laboratory personnel only.

To disinfect the analyzer, proceed as follows:

WARNING

Infection by contaminated parts of the analyzer.

Death or serious injury can result.

- Make sure to disinfect the analyzer in an area designated as a biological hazard area.
- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the manufacturers information regarding the gloves compatibility with the materials and liquids used.

1 As debris buildup typically occurs on the areas around the PFA test cartridges, remove the PFA test cartridges before starting disinfection:

2 Make sure that testing is completed and the carousel has moved to load position.

3 Remove the cassette carefully from the carousel.

4 Holding the cassette in one hand, remove the PFA test cartridges by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

5 Dispose of the PFA test cartridges in a suitable biological hazard waste container.

6 After having removed the PFA test cartridges:

Set the power switch on the back of the analyzer to **off**.

7 Pull out the mains plug from the AC outlet.

8 Unplug the power cord at the back of the analyzer.

9 Apply disinfectant solution on areas where there is visible contamination with blood, blood products or other body fluids.

Use a commercial disinfectant solution, for example Mikrozid.

Wherever possible, use a wipe method instead of a spray method to apply the disinfectant solution.

If a spray method is used, ensure that droplets of solution, rather than a mist, are expelled from the container.

10 If heavy buildup is visible, soften the debris by applying disinfectant solution on the area, letting it sit, then wiping up with a paper towel or other absorbent material.

11 Apply disinfectant solution on the area again and allow it to sit for 20 min.

12 Apply disinfectant solution to all external surfaces and allow it to sit for 20 min, then rinse with purified water.

13 Dispose of used paper towels or other wiping material in a suitable biological hazard waste container.

→ Disinfecting the analyzer is completed.

8.3 Replacing trigger solution

WARNING

False results due to expired or unusable trigger solution.

False results can lead to misdiagnosis and incorrect treatment.

- Do not use trigger solution whose use-by date has expired.
- Do not use trigger solution if turbid or if particulate matter is present.

To insert the trigger solution bottle into the analyzer, proceed as follows:

CAUTION

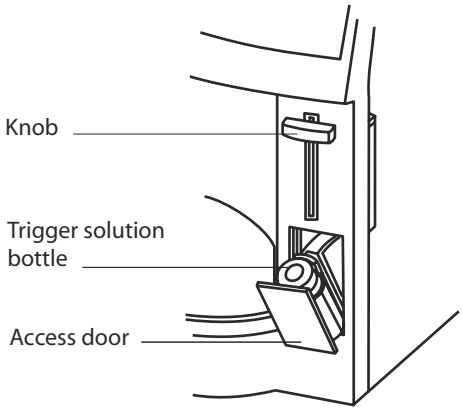
When the access door is open, the spiking needle of the trigger solution bottle can cause injuries.

Injury can result.

- Lift up the spiking needle lever completely before opening the access door.
- Take care not to touch the spiking needle.

1 Pull up the knob to remove the probe from the trigger solution bottle and unlatch the access door.

→ The door automatically opens when the knob is pulled all the way up.



Replacing trigger solution

CAUTION

Delay of results caused by air in the trigger solution path as a result of a missing or insufficiently filled trigger solution bottle.

Minor or moderate injury to the patient can result.

- Take care to insert a trigger solution bottle.
- Make sure that the trigger solution bottle is sufficiently filled.

2 Remove the empty bottle.

It is normal that residual solution remains in the bottle.

3 Remove the flip-top cap and insert the new bottle in place.

NOTICE

Risk of damage to the spiking needle if the spiking needle lever is pushed down before the access door is fully closed.

Damage to the system can result.

- Make sure the access door is fully closed before pushing the lever down.

4 Push the access door closed.

5 Push the knob all the way down to insert the probe into the trigger solution bottle.

→ Replacing trigger solution is completed.

It is required to prime the system after replacing the trigger solution.

8.4 Priming the system

CAUTION

Delay of results due to air in the trigger solution path.

Minor or moderate injury to the patient can result.

- Prime the system after any extended period (> 2 days) of non-use.
- After priming the system, perform a self test and a daily alignment check for trigger solution dispensing.

NOTICE

Contamination of the incubation block with trigger solution due to a defective priming cartridge.

Contamination may be transferred.

- Check that the aluminum foil at the bottom of the priming cartridge is intact.
- Check the priming cartridge for scratches, marks, or dirt and replace or clean it if required.
- Change the priming cartridges periodically, depending on their condition.

The priming procedure clears the system of any accumulated bubbles caused by the release of gases from the trigger solution.

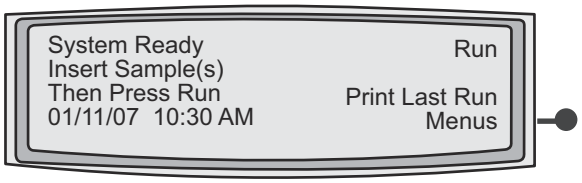
To prime the system, proceed as follows:

1 Locate the priming cartridge provided for priming the system (this cartridge is blue and does not have a top foil seal or a cup).

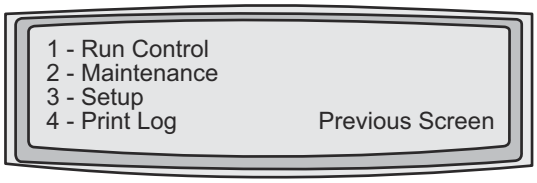
2 Snap the priming cartridge into the cassette.

Use only 1 priming cartridge in either position A or B.

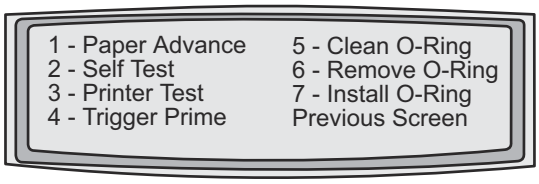
3 In the dialog **System Ready**, press the softkey located next to **Menus**.



4 Press the numeric key **2** to select the option **Maintenance**.



5 Press the numeric key **4** to select the option **Trigger Prime**.



6 Press the softkey located next to **Prime** to start priming the trigger system.

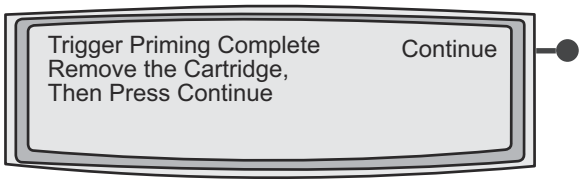
→ The cassette rotates and the dialog displays **Trigger Priming**, **Please Wait**. When priming is complete, the cassette rotates to the load position.

7 Remove the priming cartridge and discard the trigger solution accumulated in the priming cartridge during the priming cycle.

8 Rinse the priming cartridge with purified water.

It is recommended to replace the priming cartridges periodically, depending on their condition. The priming cartridge must show no scratches or marks and must be clear of debris. The bottom aluminum foil must be intact.

9 Save the priming cartridge for future use or discard if damaged.



10 Press the softkey located next to **Continue**.

→ Priming the system is completed.

To return to the dialog **System Ready**, press the softkey located next to **Previous Screen** twice.

8.5 O-Ring maintenance

This chapter contains information about the manual cleaning and replacement of the O-Ring.

NOTICE

Soiled and sticky O-Rings.

Fail of O-Ring removal tool can result.

- To prevent soiled and sticky O-Ring thoroughly clean the O-Ring as described in the following chapters.

The manual O-Ring cleaning procedure has to be carried out once a week and should be performed whenever the status message **VACUUM TEST FAIL** is obtained, after a self test is performed in the **Maintenance** menu, or whenever the status message **TEST TERMINATED DUE TO AIR LEAK** is printed after a test.

The O-Ring should be replaced once a year.

8.5.1 Maintaining and inspecting the O-Ring

WARNING

Infection by contaminated parts of the analyzer.

Death or serious injury can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the manufacturers information regarding the gloves compatibility with the materials and liquids used.

To inspect and maintain the O-Ring, proceed as follows:

1 Remove the O-Ring by performing the option **Remove O-Ring** in the **Maintenance** menu.

2 Rinse the O-Ring under purified water. Place O-Ring between forefinger and thumb and remove any debris by using a rubbing motion while rinsing under purified water.

WARNING

False results due to missing O-Ring.

False results can lead to misdiagnosis and incorrect treatment.

- Perform the following work steps thoroughly.

3 Visually inspect the O-Ring for debris or unusual wear and tear such as cracks.

4 If the O-Ring requires replacement, follow the option **Install O-Ring** in the **Maintenance** menu to install a new O-Ring. Discard the old O-Ring in a suitable biological hazard container.

5 Shake excess purified water off, dry the O-Ring with a lintfree cloth, and install the O-Ring by performing the option **Install O-Ring** in the **Maintenance** menu.

6 Perform the **Self Test** in the **Maintenance** menu to verify that the system has no vacuum leak.

→ Maintaining and inspecting the O-Ring is completed.

The self test must be performed in the **Maintenance** menu. Vacuum leak problems or the error **Maximum Syringe Travel Reached** may indicate that an O-Ring has been installed but incorrectly positioned, see (→ Page 88 *Common status messages*). If such messages are displayed, remove and reinstall the O-Ring.

If problems persist, contact Siemens Healthineers service.

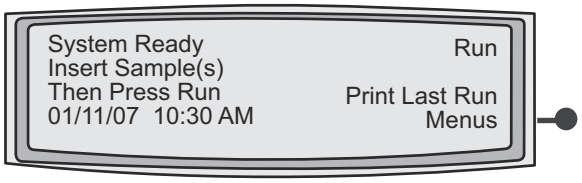
The **Run** and **Run Control** functions are disabled after completion of the options **Remove O-Ring** and **Install O-Ring**.

8.5.2 Removing the O-Ring

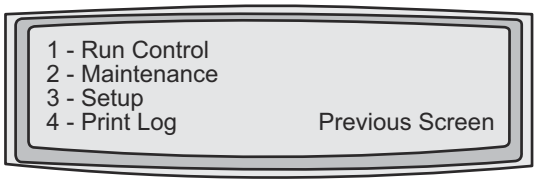
✓ O-Ring service tool is available

To remove the O-Ring, proceed as follows:

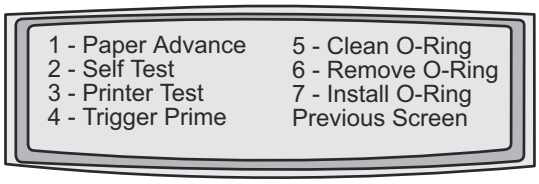
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



2 Press the numeric key **2** to select the option **Maintenance**.



3 Press the numeric key **6** to select the option **Remove O-Ring**.



→ The system displays the message **Load O-Ring Service Tool, Then Press Continue**.

4 Place the O-Ring service tool into the incubation wells of the analyzer so that the cassette is flush with the carousel surface.

5 Press the softkey located next to **Continue**.

→ The system rotates the carousel to the O-Ring removal position and bring the O-Ring in contact with position A of the O-Ring service tool. After approximately 30 seconds, the carousel rotates back allowing the removal of the O-Ring service tool.

6 Remove the O-Ring service tool and press the softkey located next to **Continue**.

If the O-Ring service tool fails to remove the O-Ring, the last 4 instructions should be repeated once more. If the service tool still fails to remove the O-Ring, contact Siemens Healthineers service.

The inability to remove the O-Ring can be the result of debris and sticky blood residues. Take care to thoroughly clean the O-Ring on a regular basis, see (➔ Page 76 *Maintaining and inspecting the O-Ring*) and (➔ Page 80 *Cleaning O-Ring using cleaning pads*).

7 Invert the O-Ring service tool and tap against the palm of the gloved hand to remove the O-Ring.

→ Removing the O-Ring is completed.

Follow the manual O-Ring cleaning or replacement procedure.

8.5.3 Installing the O-Ring

✓ O-Ring is available

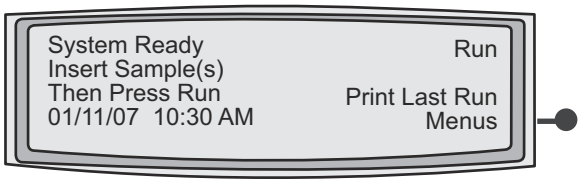
✓ O-Ring service tool is available

To install an O-Ring, proceed as follows:

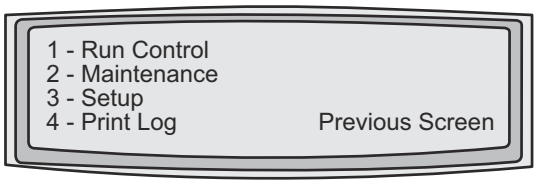
To minimize debris accumulating on the O-Ring service tool, store the tool in the packaging provided.

Make sure the O-Ring placement surface in position B of the O-Ring service tool is free of debris before loading the O-Ring. If required, clean the O-Ring placement surface with isopropanol.

1 In the dialog **System Ready**, press the softkey located next to **Menus**.



2 Press the numeric key **2** to select the option **Maintenance**.



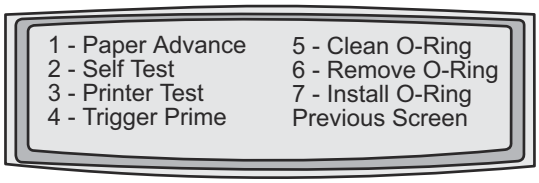
WARNING

False results due to a vacuum leak not being noticed.

False results can lead to misdiagnosis and incorrect treatment.

- Always use an intact, thoroughly cleaned or new O-Ring.

3 Press the numeric key **7** to select the option **Install O-Ring**.



→ The system displays the message **Load O-Ring Service Tool, Then Press Continue**.

4 Load O-Ring in position **B** of the O-Ring service tool.

5 Place the O-Ring service tool into the incubation wells of the analyzer so that the cassette is flush to the carousel surface.

6 Press the softkey located next to **Continue**.

→ The system rotates the carousel to the O-Ring removal position and bring the O-Ring in contact with the O-Ring service tool. After approximately 30 seconds, the carousel rotates back allowing the removal of the O-Ring service tool.

WARNING

False results or delayed results due to vacuum leak.

False results can lead to misdiagnosis and incorrect treatment.

- Always perform a **Self Test** after installing the O-Ring.
- Always use a new vacuum test cup and a new O-Ring cleaning pad when performing the **Self Test**.

7 Remove the O-Ring service tool and press the softkey located next to **Continue**.

8 Perform the **Self Test** in the **Maintenance** menu to verify that the system has no vacuum leak.

When performing the self test to ensure proper installation of the O-Ring, it is not required to insert a cleaning pad.

9 When prompted, press **Continue** to proceed with the self test.

→ Installing the O-Ring is completed.

8.5.4 Cleaning O-Ring using cleaning pads

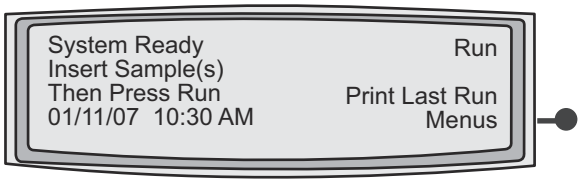
✓ PFA Cleaning pads are available

✓ Isopropanol is available

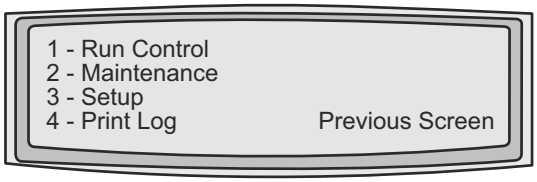
To clean the O-Ring using cleaning pads, proceed as follows:

1 Locate the cleaning pads (circular foam sponge) provided with the analyzer.

2 In the dialog **System Ready**, press the softkey located next to **Menus**.



3 Press the numeric key **2** to select the option **Maintenance**.



WARNING

False results or delayed results due to vacuum leak.

False results can lead to misdiagnosis and incorrect treatment.

- Always use a new O-Ring cleaning pad.

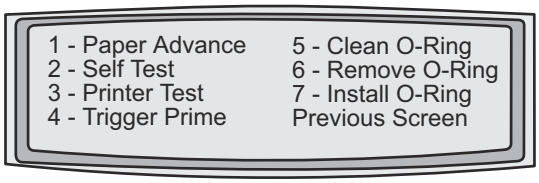
NOTICE

Contamination of the cleaning pad when touching it with bare fingers.

Contamination may be transferred from the cleaning pad to the O-Ring during cleaning.

- Only touch the cleaning pads with appropriate gloves.
- Pay attention to the manufacturers information regarding the gloves compatibility with isopropanol.

4 Press the numeric key **5** to select the option **Clean O-Ring**.



→ The system rotates the carousel and display the message **Load O-Ring Cleaning Pad, Then Press Continue**.

5 Place the cleaning pad in the well and apply 4 to 5 drops of isopropanol to the center of the pad.

6 Press gently on the pad with gloved index finger 2 to 3 times to help distribute isopropanol.

WARNING

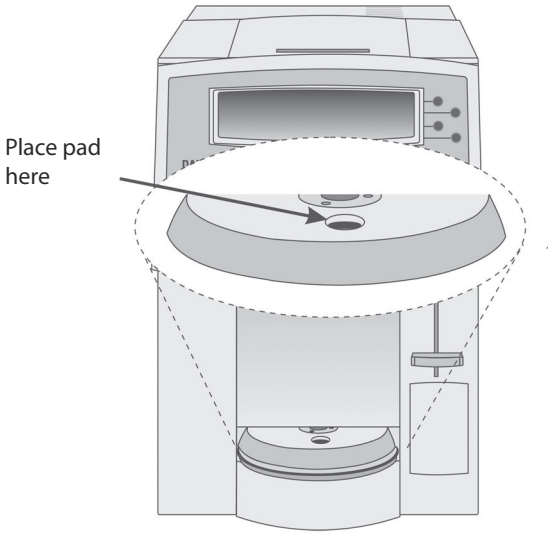
Infection by contaminated cleaning pads.

Death or serious injury can result.

- After usage, cleaning pads must be treated as a potential source of infection.
- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the manufacturers information regarding the gloves compatibility with the materials and liquids used.

7 Press the softkey located next to **Continue**.

→ The system turns the carousel to the test cartridge loading position and bring the O-Ring in contact with the cleaning pad. After approximately 30 seconds, the carousel rotates back allowing the removal of the pad.



Cleaning pad compartment

8 Dispose of the pad in a suitable biological hazard container.

9 Press the softkey located next to **Continue**.

→ Cleaning O-Ring using cleaning pads is completed.

The self test must be performed in the **Maintenance** menu.

In case the self test fails, a manual O-Ring cleaning has to be carried out. This manual O-Ring cleaning has to be performed with the O-Ring service tool.

To return to the dialog **System Ready**, press the softkey located next to **Previous Screen** twice.

8.6 Replacing printer paper

✓ Roll of printer paper is available.

NOTICE

Insufficient maintenance of the printer.

Loss of data will result. If archiving of the test results is required:

- Take care to install the printer paper properly.
- Replace the printer ribbon before it is worn out.
- Take care to install the printer ribbon properly.
- Keep the printing mechanism clean from dust and dirt.

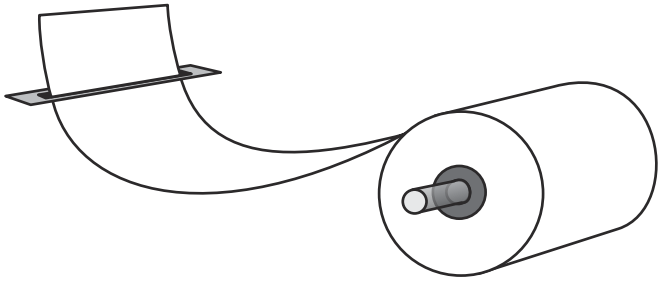
The readability of printouts depends on the proper installation of the printer paper, the printer ribbon, the age of the ribbon, and usage as well as the cleanliness of the print head.

If printouts are required, check these parameters before usage.

To replace the printer paper roll, proceed as follows:

1 Pull open the door located on the top of the analyzer to access the printer.

2 Remove the empty roll of printer paper.



Printer paper roll

3 Obtain a new roll of printer paper.

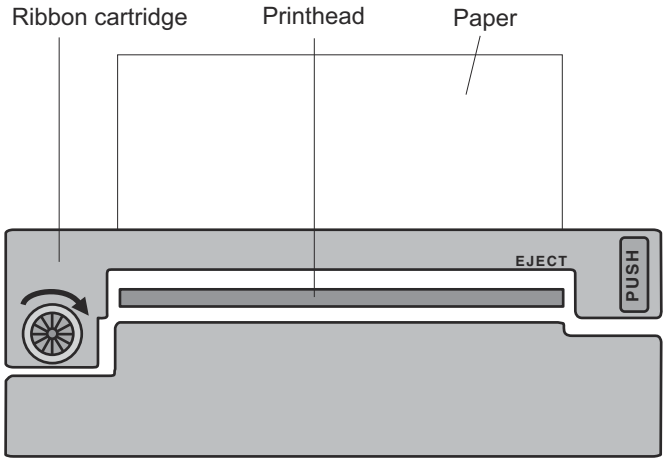
Any standard 58 mm wide paper used in calculators or cash registers can be used on the printer.

4 Place the spindle through the paper roll and snap it into the paper holder. The paper must unroll from the top.

5 Make sure the edge of the paper is cut straight, if required cut the paper.

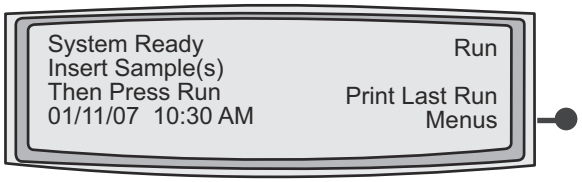
6 Engage the paper into the printhead, between the metallic support of the printhead and the printhead itself.

7 Push the paper inside the printhead.

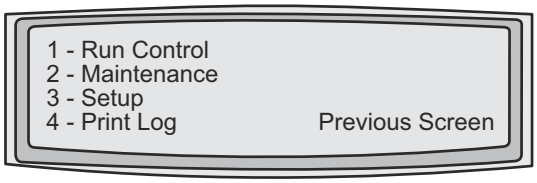


Printer ribbon

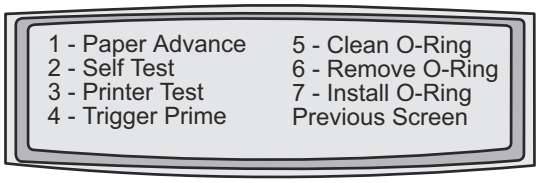
8 In the dialog **System Ready**, press the softkey located next to **Menus**.



9 In the dialog **Menu**, press the numeric key **2** to select the option **Maintenance**.



10 Press the numeric key **1** to select the option **Paper Advance**.



11 Press the softkey located next to **Load** to advance the paper into the printer.

12 Press the softkey located next to **Ready Screen** to return to the dialog **System Ready**.

13 Pass the paper through the door slot. If additional paper length is required, the paper can be manually pulled through the printer.

14 Close the top door.

→ Replacing the printer paper is completed.

8.7 Replacing printer ribbon

✓ Printer ribbon is available

NOTICE

Insufficient maintenance of the printer.

Loss of data will result. If archiving of the test results is required:

- Take care to install the printer paper properly.
- Replace the printer ribbon before it is worn out.
- Take care to install the printer ribbon properly.
- Keep the printing mechanism clean from dust and dirt.

The readability of printouts depends on the proper installation of the printer paper, the printer ribbon, the age of the ribbon, and usage as well as the cleanliness of the print head.

If printouts are required, check these parameters before usage.

To replace the printer ribbon, proceed as follows:

1. Pull open the door located on the top of the analyzer to access the printer.
2. Remove the paper from the printhead by pulling the paper back toward the paper roll.
3. Push down on the right side of the printer ribbon cartridge marked **PUSH** to eject the printer ribbon from the printer, see (➔ Page 83 *Printer ribbon*).
4. Obtain a new printer ribbon.
5. Place the left side of the printer ribbon into the wheel located on the left side of the printhead.
6. Push the right side of the printer ribbon in place.
7. If required, press the circle located on the left side of the printer ribbon and turn clockwise to adjust the printer ribbon inside the printhead.
8. Replace the printer paper, see (➔ Page 82 *Replacing printer paper*).

   → Replacing printer ribbon is completed.

8.8 Replacing fuses

✓ New fuses are available

✓ A small-blade screwdriver is available

WARNING

Electric shock by contact with live parts

Death or serious injury can result.

- Unplug the supply cable from the power supply socket before replacing the fuses.

WARNING

Infection by contaminated parts of the analyzer.

Death or serious injury can result.

- Clean and disinfect the analyzer.

To replace fuses on the analyzer, proceed as follows:

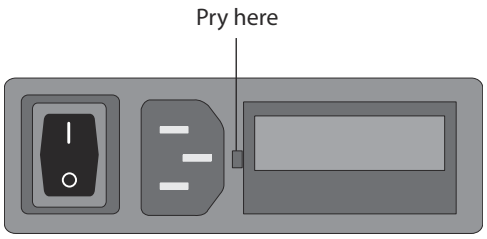
1 Set the power switch to **off**.

2 Unplug the power cord.

3 Using a small-blade screwdriver, open the fuse compartment and remove the fuse holder.

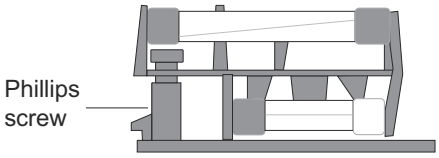
4 Place the fuse holder face down with the fuses facing up.

5 Remove the top fuse and replace with a new one.



Fuse compartment

6 To change the fuse configuration, loosen the Phillips screw with a few turns.



Phillips screw

7 Remove the fuse holder by sliding up and away from the Phillips screw.

8 Rotate the fuse holder so the required fusing arrangement is facing up.

9 Slide the fuse holder back onto the Phillips screw, then tighten the screw.

10 Put the fuse holder assembly back in the housing. Push in all the way.

11 Plug in the power cord and set power switch to **on** to resume testing.

→ Replacing fuses is completed.

9 Troubleshooting

9.1 Self test

When the analyzer performs the **Self Test**, the system performs a vacuum leak test and an O-Ring cleaning procedure in addition to the power on diagnostics tests with the exception of the memory test. During the **Self Test**, the analyzer prompts the user to load the vacuum test cartridge (priming cartridge containing a vacuum test cup), a priming cartridge and a cleaning pad on the carousel. The result of each test is printed after the test is completed. During a vacuum leak test, the vacuum pressure of the system is checked. After successful completion, the message **Vacuum Test Ok** is displayed and printed. If a problem is detected, an error message is displayed and printed and the system prevents the running of a test. To take the appropriate action if a problem occurs, see (➔ Page 88 *Common status messages*).

```
             PFA-100
             Self Test
REV. 2.2    S/N: 99031

01/10/16     02:32 PM

VACUUM CHUCK  OK
CAROUSEL DRIVE  OK
INCUBATION SYSTEM  OK
VACUUM TEST  OK
TRIGGER SYSTEM  OK


Test type  : Collagen/EPI
Low Flag   :         0
High Flag  :       300

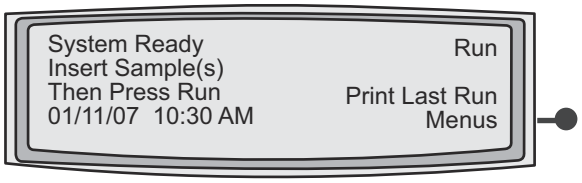

Test type  : Collagen/ADP
Low Flag   :         0
High Flag  :       300
```

Status messages list

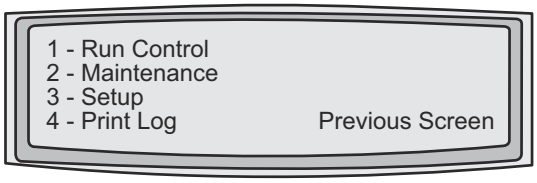
9.2 Printing error log

The software maintains a record of events or conditions detected by the system. This record is called the error log and may be useful in diagnosing problems. To print the error log, proceed as follows:

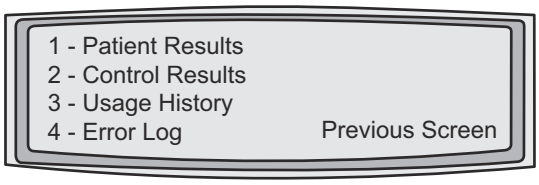
1 In the dialog **System Ready**, press the softkey located next to **Menus**.



2 Press the numeric key **4** to select the option **Print Log**.



3 Press the numeric key **4** to select the option **Error Log**.



→ The system prints the serial number and the software version of the analyzer, followed by the error messages (maximum of the last 25) with the date and time at which they occurred. Printing the error log is completed.

To return to the dialog **System Ready**, press the softkey located next to **Previous Screen** twice.

9.3 Displaying test results

When testing is complete, the analyzer displays the results with the respective patient ID numbers entered and test type. Events or conditions (status messages) detected during the test run are displayed below the test result.



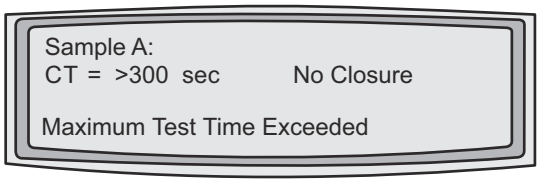
If the test was aborted, ***_INVALID TEST_*** is shown and the status message is displayed in the bottom line.

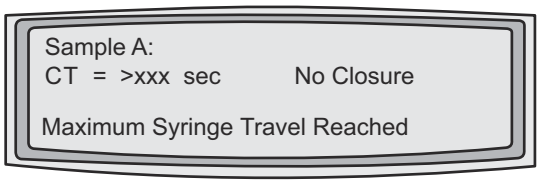


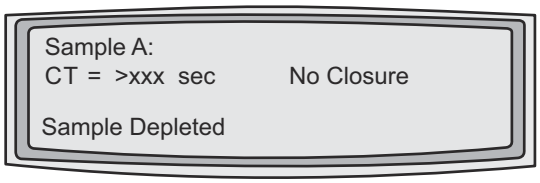
In case no closure is detected during a test until:

- the maximum test time has been reached,
- the pressure syringe has reached its maximum,
- the sample is depleted,

No Closure is displayed with the test result. The status message is displayed in the bottom line.







For more information on the status messages displayed above, see (➔ Page 88 *Common status messages*) and (➔ Page 93 *Other status messages*).

9.4 Common status messages

The following list of messages is uniquely associated with events or conditions detected during a test run. These messages report events that occur only when blood is flowing through the PFA test cartridge. The analyzer flags the event or condition with a **>** sign followed by the time of the event or condition and a description of the event.

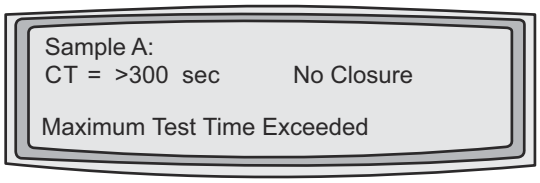
Test terminated due to flow obstruction, see (➔ Page 90 *Test terminated due to flow obstruction*).



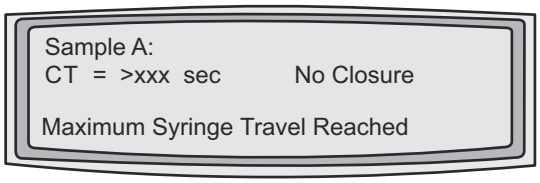
Test terminated due to air leak, see (➔ Page 90 *Test terminated due to air leak*).



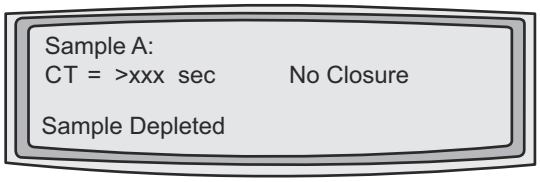
Maximum test time exceeded, see (➔ Page 89 *Maximum test time exceeded*).



Test terminated due to maximum syringe travel, see (➔ Page 92 *Test terminated due to maximum syringe travel*).



Test terminated due to insufficient sample, see (➔ Page 91 *Test terminated due to insufficient sample*).



9.4.1 Maximum test time exceeded

The following table contains information about the circumstances in which the message **MAXIMUM TEST TIME EXCEEDED** occurs and how to proceed afterwards.

Description	Causes	Solutions/Comments	Result Interpretation
The sample did not achieve closure of the aperture within the maximum time for a test (> 300 seconds, not including the incubation period).	• Sample with abnormal platelet function resulting in non-closure (NC) of the aperture • A possible vacuum leak in the analyzer causing a NC • Defective PFA test cartridge	• If a NC is obtained with a normal donor control or the result does not agree with the clinical history of the patient, a possible vacuum leak may be suspected. Perform a **Self Test** via the **Maintenance** menu without loading the cleaning pad. This tests if debris on the O-Ring is the cause of the vacuum leak. If self test passes, a defective PFA test cartridge may have caused the vacuum leak. If the vacuum leak test fails, perform the **Manual O-Ring Maintenance Procedure** via the **Maintenance** menu and rerun the self test. Cleaning or replacing the O-Ring may correct the vacuum leak. If the problem persists, contact Siemens Healthineers service. • Rerun the sample with new PFA test cartridge to verify the test result. If daily **Self Test** ok, then most likely this is an abnormal sample.	Report as **CT>300sec**, abnormal platelet function as confirmed by retest.

Maximum test time exceeded

9.4.2 Test terminated due to air leak

The following table contains information about the circumstances in which the message **TEST TERMINATED DUE TO AIR LEAK** occurs and how to proceed afterwards.

Description	Causes	Solutions/Comments	Result Interpretation
The analyzer has detected an initial air leak in the vacuum system. This condition is detected only at the beginning of a test.	• Possible vacuum leak in the analyzer or a malfunctioning trigger solenoid pump • No sample in PFA test cartridge • Air entrapped in PFA test cartridge when sample was loaded • Defective PFA test cartridge	• Verify that sample was added to PFA test cartridge. Rerun the test with appropriate sample volume (800 µL). Perform a **Self Test** via the **Maintenance** menu without the cleaning pad to test the vacuum system. If the vacuum test passes, a malfunctioning solenoid pump may be the cause for the air leak. Contact Siemens Healthineers service for solenoid pump troubleshooting procedure. If the vacuum test fails, perform **Manual O-Ring Maintenance Procedure** via the **Maintenance** menu. Clean or replace O-Ring as per maintenance instructions. Perform self test. If vacuum leak test passes, rerun sample. If problem persists, contact Siemens Healthineers service. • Prime system from **Maintenance** menu. • Rerun the test with a new PFA test cartridge and sample.	Non-reportable

Test terminated due to air leak

9.4.3 Test terminated due to flow obstruction

The following table contains information about the circumstances in which the message **TEST TERMINATED DUE TO FLOW OBSTRUCTION** occurs and how to proceed afterwards.

Description	Causes	Solutions/Comments	Result Interpretation
The analyzer has detected a sudden stoppage of blood flow during the test. A flow obstruction can occur at the start of a test or during a test run. For further information, see the instructions for use (section "Limitations of Procedure").	• **Initial Flow Obstruction** This type of flow obstruction occurs when the analyzer detects a failure to establish initial blood flow rate specifications subsequent to the first 30 seconds of testing. The analyzer aborts the run if these specifications are not met. The result is reported as **TEST TERMINATED DUE TO FLOW OBSTRUCTION**. This condition may be caused by micro thrombin in the sample or particulates introduced into the sample or PFA test cartridge from the environment. • **Flow Obstruction During a Test** A flow obstruction that occurs after initial blood flow rate conditions have been established is reported by the analyzer at the time the flow obstruction occurs; that is **> 80SEC. FLOW OBSTRUCTION**. This type of flow obstruction occurs when the capillary or the PFA test cartridge membrane aperture is suddenly plugged by micro aggregates that may form during the test or by particulates introduced into the sample or PFA test cartridge from the environment. • Defective PFA test cartridge	• Verify that the sample does not contain clots or aggregates. If no aggregates are visible, repeat once to rule out a defective PFA test cartridge. • A sample that results in repeated flow obstruction may have resulted from problems during blood collection. Recollect blood sample and repeat test. • If problems persist, contact Siemens Healthineers service.	Non-reportable

Test terminated due to flow obstruction

9.4.4 Test terminated due to insufficient sample

The following table contains information about the circumstances in which the message **TEST TERMINATED DUE TO INSUFFICIENT SAMPLE** occurs and how to proceed afterwards.

Description	Causes	Solutions/Comments	Result Interpretation
The analyzer has detected air being drawn subsequent to the first 30 seconds of testing. This condition is detected whenever the test runs out of sample and closure of the aperture has not occurred.	• Not enough sample was loaded in the PFA test cartridge. • Sufficient sample was loaded in the PFA test cartridge but closure of the aperture did not occur due to platelet dysfunction and/or low sample viscosity (low hematocrit, high sedimentation rate).	• Verify that 800 µL was added to the PFA test cartridge. Rerun sample using 900 µL. • Verify sample hematocrit is within normal range. For further information, see instructions for use (section "Limitations of Procedure"). An abnormal hematocrit may impair platelet function and result in prolongation of the closure time. Platelet dysfunction in combination with low hematocrit often induces this type of status message. Samples from patients treated with platelet antagonist drugs may exhibit characteristics that cause this type of status message. Adding additional specimen (up to 900 µL) could eliminate the insufficient sample message but a combination of low hematocrit and platelet dysfunction most likely results in a closure time > 300 seconds. • The PFA test cartridge cup serves as the receptacle where blood is collected after it passes through the membrane aperture. During a test, the analyzer vacuum chuck interfaces with the cup and comes in close proximity to blood. Air that is drawn into the cup whenever an insufficient sample occurs can cause blood to foam and contaminate either the vacuum chuck or O-Ring. It is recommended to perform manual cleaning of the O-Ring with the cleaning pad to avoid potential contamination.	An insufficient sample message that occurs at a time that is greater than the upper limit of the reference range may indicate abnormal platelet function due to the reasons stated above. In such cases this result may be reported as the time in which the test ended, **> xxx sec**, with a statement qualifying the properties of the sample (that is abnormal hematocrit and/or low platelet count) and suspicion of platelet dysfunction.

Test terminated due to insufficient sample

9.4.5 Test terminated due to maximum syringe travel

The following table contains information about the circumstances in which the message **TEST TERMINATED DUE TO MAXIMUM SYRINGE TRAVEL** occurs and how to proceed afterwards.

Description	Causes	Solutions/Comments	Result Interpretation
The analyzer has stopped the current test because the syringe has reached the end of its travel prior to maximum test time.	• Syringe piston moved too far too quickly as a result of low sample viscosity. Sufficient sample in the PFA test cartridge but closure did not occur due to platelet dysfunction and/or low viscosity (low hematocrit, high sedimentation rate). • A defective PFA test cartridge causing a small vacuum leak • Debris is present on the vacuum seal between the analyzer and the PFA test cartridge, causing a small vacuum leak. • Analyzer malfunction causing a small vacuum leak	• Perform a **Self Test** via the **Maintenance** menu without the cleaning pad to rule out vacuum leaks. If no errors are reported by the self test, the analyzer is in control. • Verify sample hematocrit before performing a second test. If hematocrit is abnormal, the sample may have low viscosity, which may induce platelet dysfunction. For further information, see the instructions for use (section "Limitations of Procedure"). An abnormal hematocrit may impair platelet function and result in prolongation of the closure time. Platelet dysfunction in combination with low hematocrit often induces this type of status message. Samples from patients treated with platelet GPIIb/IIIa antagonist drugs may exhibit characteristics that may induce this type of status message. Adding additional specimen (up to 900 µL) could eliminate maximum syringe travel but most likely results in a closure time > 300 seconds. If the repeat result confirms the abnormality, platelet dysfunction may be suspected possibly due to abnormal hemodynamic properties of the sample and/or anti-platelet agents. • If problem persists, contact Siemens Healthineers service.	A maximum syringe travel message that occurs at a time that is greater than the upper limit of the reference range may indicate abnormal platelet function. The result may be reported as **> xxx sec** only if the time lies above the reference range. The report should include a statement qualifying the abnormal qualities of the sample and suspicion of platelet dysfunction.

Test terminated due to maximum syringe travel

9.5 Other status messages

The following list of messages is uniquely associated with the events or conditions detected during a test run.

Status messages	Causes	Solutions
CAROUSEL DRIVE FAILURE-PLEASE CHECK FOR OBSTRUCTIONS	Something is preventing the carousel from rotating.	Remove any PFA test cartridge, cassette or any other cause generating the obstruction. Press the softkey located next to **Retry**.
CAROUSEL DRIVE FAIL	Same as above, after 3 retries.	Turn the system off, turn it on again to reset the instrument. If the problem persists, contact Siemens Healthineers service.
INCUBATION SYSTEM FAIL	The heater block is not heating properly.	Contact Siemens Healthineers service.

Status messages	Causes	Solutions
MAIN MEMORY ERROR	An error occurred in the system operating program.	Perform a reset by turning the analyzer off and then back on. If the problem persists, contact Siemens Healthineers service.
MAXIMUM PID LENGTH EXCEEDED	The patient ID entered via the barcode scanner exceeds the maximum length of 12 characters.	Abbreviate patient ID to 12 or less characters and enter using the analyzer keypad.
TYPE CODE CALIBRATION REQUIRED	The analyzer has detected a problem with the type code sensor.	**Warning:** False results due to mix-up of test types in the instrument software Do not use the results for diagnosis while the problem persists. Contact Siemens Healthineers service.
AIL CALIBRATION REQUIRED	The analyzer has detected a problem with the Air-in-Line sensor.	Contact Siemens Healthineers service.
PREVIOUS TRIGGER PRIME CANCELLED-PRIME SYSTEM FROM MAINTENANCE MENU	The analyzer has detected that a trigger priming sequence has not been successfully completed.	For instructions, see (➔ Page 74 *Priming the system*).
PRINTER FAIL	The printer cannot be initialized by the analyzer.	Contact Siemens Healthineers service.
RAM MEMORY ERROR	The analyzer has detected a problem with the area of memory used for storage of data and system information.	Contact Siemens Healthineers service.
SYRINGE PUMP DRIVE FAIL	The analyzer has detected a problem with the movement of the syringe pump.	Perform a reset by turning the analyzer off and then back on. If the problem persists, contact Siemens Healthineers service.
TEST CANCELLED NO LOT OR ID NUMBER ENTERED, PRESS CONTINUE	A control ID number was not entered for the sample being run for QC. The PFA test cartridge lot number was not entered for the sample being run for QC.	Press the softkey located next to **Continue**. Rerun the sample, and enter the control ID number and the PFA test cartridge lot number required for control.
INVALID CARTRIDGE TYPE DETECTED	The PFA test cartridge loaded to perform a test is not a valid PFA test cartridge type (Collagen/ EPI or Collagen/ADP). The analyzer has detected an invalid PFA test cartridge due to a defective type code slot or sensor.	**Warning:** False results due to mix-up of test types in the instrument software Do not use the results for diagnosis while the problem persists. Rerun the sample using a new PFA test cartridge. If the problem persists, contact Siemens Healthineers service.

Status messages	Causes	Solutions
TRIGGER SYSTEM FAIL	Air was detected coming from the trigger solution bottle after 3 successive attempts to prime the analyzer.	Make sure the trigger solution bottle is full. Perform a reset by turning the analyzer off and then back on. If the problem persists, contact Siemens Healthineers service.
VACUUM CHUCK DRIVE FAIL	The analyzer has detected a problem in the movement of the vacuum chuck drive.	Perform a reset by turning the analyzer off and then back on. If the problem persists, contact Siemens Healthineers service.
VACUUM TEST FAIL	The analyzer has detected a leak in the vacuum system during a self test initiated from the Maintenance menu. The reasons can be: • Debris on the O-Ring seal • A possible vacuum leak in analyzer	Remove O-Ring via the **Maintenance** menu. Inspect O-Ring for debris or damage. Clean or replace O-Ring if required. Install O-Ring via the **Maintenance** menu. Repeat a **Self Test** via the **Maintenance** menu to verify that the analyzer has no vacuum leak. If the problem persists, contact Siemens Healthineers service.
VACUUM SYSTEM FAILED IN SELF TEST	The analyzer has detected that a self test has not been successfully completed due to a failure in the vacuum leak test.	See status message **Vacuum Test Fail**.
FSE TSK: XX ADDR: XX	The analyzer has detected a problem with the functioning of the software.	Perform a reset by turning the analyzer off and then back on. If the problem persists, contact Siemens Healthineers service.

Status messages

10 Technical specifications

This chapter describes the specifications of the system and the environmental conditions.

10.1 Physical

Dimensions (L x W x H)	38.4 cm x 22.9 cm x 36 cm (15.1 in x 9 in x 14.2 in)
Weight	10.9 kg (24 lbs)

10.2 Electrical

Operating voltage and frequency	100–240 VAC, 60 Hz 200–240 VAC, 50 Hz
Current (maximum)	1.5 A/100 VAC, 0.75 A/200 VAC
Power consumption (maximum)	110 W
Fuse	Slo-Blo, Littelfuse, 250 V, 1.5 A

10.3 Environmental

WARNING

False results or delay of results due to incorrect functioning of the analyzer.

Death or serious injury to the patient can result.

- Only operate the analyzer under specified conditions.

This analyzer is for indoor use only.

Operating temperature	18–29 °C
Non-operating storage and transportation temperature	-29–50 °C
Relative humidity	20–90%
Pollution degree	2
Altitude (maximum)	2000 m
Operating humidity	20–90% RH
Non-operating storage and transportation humidity	0–95% RH

10.4 General

Installation category	II
Incubation well temperature	37.9 °C ± 1 °C
Incubation well warm-up time (room to operating temperature)	Maximum 15 min
Incubation time	3.0 min
Cassette capacity	2 PFA test cartridges
Maximum sample volume	1000 µL
Vacuum set point	40 mBar
Sound pressure level[1)]	Printing: 77 dB(A) Priming/Test: 46 dB(A)

10.5 Printer

Type	24 character wide thermal line
Ribbon	Epson No. ERC-22 black or Epson No. ERC-09 purple
Paper	58 mm wide standard cash register or adding machine paper

10.6 Approved peripheral devices

See the approved peripheral devices in the list below.

Device	Manufacturer	Type
Supply cables	Any manufacturer	Type H 03 VV F, country-specific, for example, VDE, CSA C22.2 No. 21, CSA C22.2 No. 49 Length: 1.5 m Minimum cross-section: 3 × 0.75 mm^2 Analyzer: Plug according to IEC 60320-1 and IEC 60320-3 Standard sheet C13

Approved peripheral devices

1) During sound pressure level measurement, the system was operated as in normal use with all accessories connected. The sound pressure level was measured from a distance of 1 m from the surface of the system and a height of 1.6 m from the floor or access platform. The measurement was performed using an A-weighted sound pressure level meter. The ambient noise was measured as 42 dB(A).

10.7 Software

External computer Interface connector	RS232 25-pin D-connector
Barcode scanner	Optional
Patient ID	Maximum 12 characters
Stored control results	Last 50 results
Stored patient results	Last 20 results
Software update	PCMCIA card

11 Appendix

This chapter describes the principle of operation and the calculation of results.

11.1 Principle of operation

11.1.1 Principle of platelet function analysis

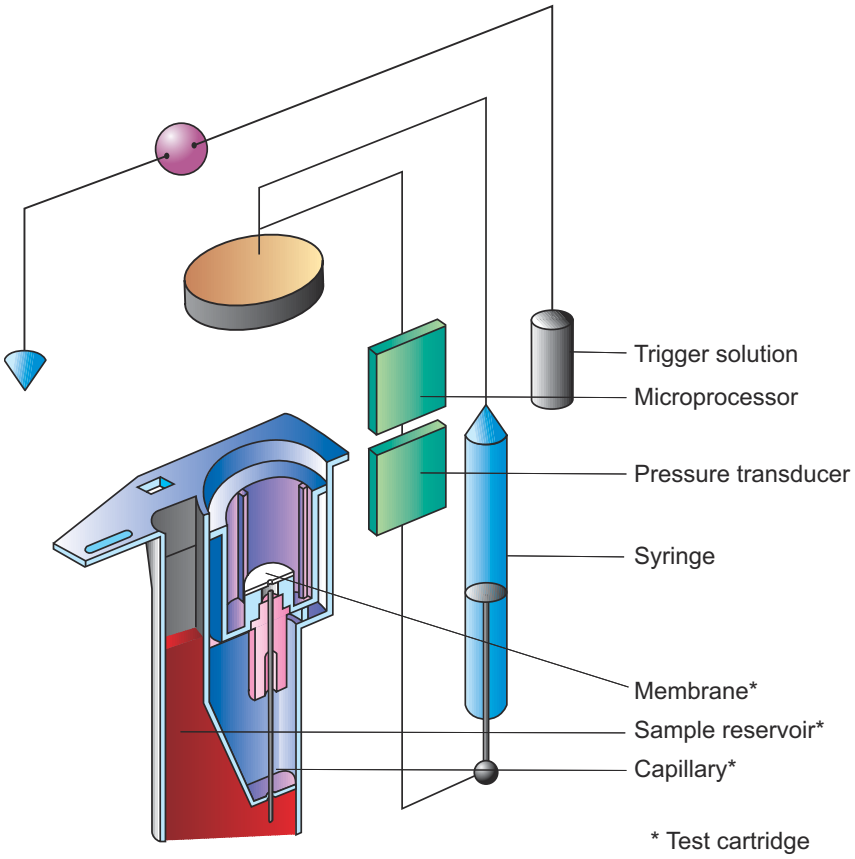
The PFA-100 System is an analyzer and test cartridge system in which the process of platelet adhesion and aggregation following a vascular injury is simulated in vitro. Platelet dysfunction detected by the analyzer may be acquired, inherited, or induced by platelet inhibiting agents.

11.1.2 System functional operation

The analyzer allows for rapid evaluation of platelet function on small samples of anti-coagulated whole blood based on work described by Kratzer and Born [1]. The single use PFA test cartridge consists of a number of integrated parts including a capillary, a sample reservoir, and a biochemically active membrane with a central aperture, see (➔ Page 100 *Schematic view of system components and test cartridge*). Anti-coagulated whole blood is aspirated from the sample reservoir through the capillary and the aperture, so that platelets are exposed to high shear flow conditions.

At the beginning of a test, trigger solution is dispensed to wet the membrane and to dissolve the active reagents. During the test, platelets adhere to the coated membrane. Then, similar to aggregometry [2], platelets become activated and release their granule contents. The release of granule contents is followed by adherence of platelets to each other to form aggregates. As a measure of platelet function in the analyzer, the process of platelet aggregation builds a platelet thrombus at the aperture thereby gradually diminishing and finally arresting the blood flow [2]. The analyzer determines the time from the start of the test until the platelet plug occludes the aperture, and reports that time interval as the Closure Time (CT). The CT is an indicator of platelet function in the analyzed whole blood sample.

For details on use, applications, and performance characteristics of the different PFA test cartridge types, see the corresponding instructions for use.



Schematic view of system components and test cartridge

11.2 Quick reference guide

The quick reference guide contains the steps of a routine run on the system from switching on the analyzer, preparation of the samples and the analyzer up to printing out the results of the samples, and switching the analyzer off again.

CAUTION

Touching the analyzer carousel while it is turning may result in pinching of fingers.

Minor or moderate injury can result.

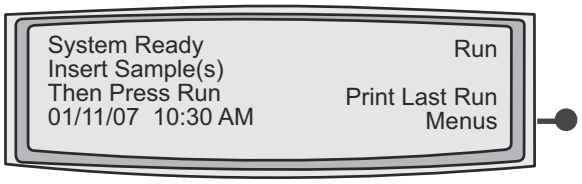
- Always wait until the measurement has finished before inserting or removing cartridges.

This quick reference guide is aimed at experienced users. For detailed instructions for use, see the previous chapters of this instruction manual.

11.2.1 Switching on the analyzer

- Switch on the analyzer at the power switch on the back of the analyzer.

→ The analyzer initializes and heats the incubation block.



If the instrument has not been in use for a longer period of time (> 7 days), clean the O-Ring, see (➔ Page 80 *Cleaning O-Ring using cleaning pads*) and (➔ Page 101 *Cleaning O-Ring manually*).

11.2.2 Carrying out Self Test

To carry out the **Self Test**, proceed as follows:

1 Select **Menu** > **Maintenance** > **Self Test**.

2 Follow the instructions on the screen (place a vacuum cup in blue priming cartridge in position A and B, moisten the cleaning pad with isopropanol before loading).

3 When **Self Test** is completed, check the print out. For the self test, see (➔ Page 53 *Self test and daily alignment check for trigger solution dispensing*).

→ Carrying out the **Self Test** is completed.

11.2.3 Cleaning O-Ring manually

If the vacuum test fails, the O-Ring has to be cleaned manually, proceed as follows:

1 Select **Menu** > **Maintenance** > **Remove O-Ring**.

WARNING

Infection by contaminated parts of the analyzer.

Death or serious injury can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the manufacturers information regarding the gloves compatibility with the materials and liquids used.

2 Follow the instructions on the screen (place the O-Ring service tool in the analyzer).

3 Remove the O-Ring manually and clean it with purified water and a dust-free tissue.

4 Replace the O-Ring in the analyzer. Select **Menu** > **Maintenance** > **Install O-Ring**.

→ Cleaning the O-Ring manually is completed.

5 Repeat the **Self Test**.

11.2.4 Priming trigger solution

If the vacuum test fails, the O-Ring has to be cleaned manually, proceed as follows:

1 Select **Menu** > **Maintenance** > **Trigger Prime**.

2 Place a priming cartridge in the analyzer and follow the instructions on the display.

→ Priming the trigger solution is completed.

For the daily alignment check for trigger solution dispensing, see (➔ Page 53 *Self test and daily alignment check for trigger solution dispensing*).

11.2.5 Loading sample

Use only fresh whole blood sample anti-coagulated with buffered sodium citrate.

To load sample, proceed as follows:

WARNING

Infection by contaminated samples.

Death or serious injury can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the manufacturers information regarding the gloves compatibility with the materials and liquids used.

1 Remove and discard the top foil seal from the PFA test cartridges.

2 Place the PFA test cartridges in the cassette and push until the PFA test cartridges securely snaps in place.

CAUTION

No result or delay of results due to missing blood sample or incorrect preparation of blood samples.

Minor or moderate injury to the patient can result.

- Make sure to have the blood sample properly pipetted into the PFA test cartridge.

NOTICE

PFA test cartridge is processed without a blood sample.

PFA test cartridge will be unusable afterwards.

- Make sure the blood sample is pipetted into the PFA test cartridge.

3 Mix the blood sample by inverting the collection tube gently by hand 3 to 4 times.

4 Pipette 800 µL of blood into the smaller opening (sample reservoir opening) of the PFA test cartridge by dispensing slowly along one of the inside corners.

5 Start the test: **Run**.

WARNING

False results due to problems with the type code sensor or the readability of the type codes on the PFA test cartridges. This can cause a mix-up of test types in the instrument software.

False results can lead to misdiagnosis and incorrect treatment. Death or serious injury to the patient can result.

- Do not use the results obtained whenever the status message **TYPE CODE CALIBRATION REQUIRED** or **INVALID CARTRIDGE TYPE DETECTED** is displayed.
- Remeasure the samples concerned when the issue is solved.
- Compare the type code on the printout with the type code on the cartridge.

6 Type in the sample ID.

→ Loading sample is completed.

When testing is completed, results are printed out automatically.

11.2.6 Disposal of used PFA test cartridges

To dispose used PFA test cartridges, proceed as follows:

- Dispose the PFA test cartridges in a suitable biological hazard waste container.

11.2.7 Switching off the analyzer

Before switching off the analyzer, it is recommended to remove the PFA test cartridges from the carousel.

WARNING

Infection by contaminated PFA test cartridges.

Death or serious injury can result.

- Wear appropriate personal protective equipment, that is, gloves, protective clothing, safety glasses, and mask.
- Pay attention to the manufacturers information regarding the gloves compatibility with the materials and liquids used.

To switch off the analyzer, proceed as follows:

1 Make sure that testing is completed and the carousel has moved to load position.

2 Remove the cassette carefully from the carousel.

3 Holding the cassette in one hand, remove the PFA test cartridges by gently pulling the bottom of the PFA test cartridge toward you until it unsnaps.

4 Dispose of the PFA test cartridges in a suitable biological hazard waste container.

5 After having removed the PFA test cartridges:

Set the power switch on the back of the analyzer to **off**.

→ Switching off the analyzer is completed.

11.3 EMC performance criteria

This chapter describes the performance criteria for electromagnetic compatibility (EMC) defined according to IEC 61326-1 and IEC 61326-2-6.

Function	Performance criteria		
	A	B	C
Measured vacuum	No errors	No errors	Errors allowed that lead to a measurement abort
Motor function	No step errors	No step errors	Step errors that lead to a measurement abort
Printout	No errors	No errors	Short-term interruption
Overtemperature fuse	No trip	No trip	No trip

12 Revision information

The revision information lists topics that have changed since the previously published version of this document.

Due to a layout and authoring tool change, content has been reworked. Manual corrections have been made, for example, typos, and minor improvements due to regulatory input as well as customer and internal feedback.

In addition to editorial changes, the following changes in content have been implemented:

Topic	Link
Identification	(➔ Page 5 *Identification*)
Intended user	(➔ Page 8 *Intended user*)
Use environment	(➔ Page 9 *Use environment*)
Approved peripheral devices	(➔ Page 97 *Approved peripheral devices*)
EMC performance criteria	(➔ Page 104 *EMC performance criteria*)

Introduced topics

13 References

This chapter lists the publications cited in this manual.

Reference	Publication
[1]	Kratzer, MAA: Born, GVR: Simulation of Primary Hemostasis in Vitro. Haemostasis (1985) 5, 357-362
[2]	Born, GVR: Aggregation of blood platelets by adenosine diphosphate and its reversal. Nature 194:927, 1962

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Gender inclusivity

At Siemens Healthineers, we want to address all genders equally in our Instructions for Use. It is not our intention to exclude anyone. We continue to update our documentation with this in mind.

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