PFA-100® System

Instruction Manual

– Instructions for Use –

Manual Version: 1.3
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CE

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Updating

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1.1	3.0 and higher	2009/11	Update
1.2	3.0 and higher	2009/12	Update
1.3	3.0 and higher	2010/01	Update

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Table of Contents

1 About this document 1-1

1.1 Orientation tips 1-1

1.2 Meaning of symbols in the document 1-2

1.2.1 Symbols used in the warning and safety instructions 1-2

1.2.2 Abbreviations 1-2

2 Safe handling 2-1

2.1 Intended use 2-1

2.2 Statutory requirements 2-2

2.2.1 CE mark 2-2

2.2.2 Instrument safety 2-2

2.2.3 Electromagnetic compatibility (EMC), radio interference suppression and immunity to interference 2-3

2.3 Operator qualification 2-3

2.4 Hazard and safety instructions 2-3

2.4.1 Meaning of the warning and information symbols on the instrument 2-4

2.4.2 Safe handling of the instrument 2-4

2.4.2.1 Electrical safety 2-5

2.4.2.2 Operational safety 2-6

2.4.2.3 Flammable and explosive materials 2-6

2.4.3 Safe handling of samples, reagents and consumables 2-6

2.4.3.1 Disposal 2-7

2.4.4 Correct functionality of the instrument 2-7

2.5 Operator’s obligations 2-7

3 Delivery and installation 3-1

3.1 Delivery 3-1

3.1.1 Transporting the instrument 3-1

3.1.2 Scope of delivery 3-1

3.1.2.1 Accepting delivery 3-1
3.1.2.2 Unpacking 3-2
3.1.2.3 Inventory instrument accessories 3-4

3.2 Installation 3-7
3.2.1 Operating conditions 3-7
3.2.1.1 Ambient conditions for storage 3-7
3.2.1.2 Ambient conditions for operation 3-7
3.2.2 Requirements of worktop 3-8
3.2.3 Connecting the instrument 3-9
3.2.3.1 Installing fuses 3-10
3.2.3.2 Connecting the instrument to the power source 3-12
3.2.3.3 Loading printer paper 3-12
3.2.3.4 Threading printer paper 3-14
3.2.3.5 Loading trigger solution 3-15
3.2.3.6 Checking for correct installation 3-17

3.3 Preparing the instrument for longer periods of non-operation 3-17

4 Quick reference guide 4-1

5 Service and warranty 5-1

5.1 Siemens Service 5-1

5.2 Warranty 5-1

5.3 Ordering information 5-2

5.4 Disposal of the instrument 5-3

6 Description of the instrument 6-1

6.1 Instrument 6-1
6.1.1 Carousel 6-2
6.1.2 Trigger solution compartment 6-3
6.1.3 LCD display 6-3
6.1.4 Keyboard 6-4
6.1.5 Printer 6-4

6.2 Consumables 6-5
6.2.1 Consumables' labels 6-5
6.2.2 Consumables/parts list 6-6
6.2.3 Test cartridges 6-6

6.3 Technical specifications 6-6

6.4 Data connections 6-8

6.5 Laboratory information system (LIS) 6-9

6.6 Principle of operation 6-10

7 Setup and changing configuration 7-1

7.1 Priming the instrument 7-1

7.2 Setup of the software 7-2
7.2.1 Selecting language 7-3
7.2.2 Setting the time format 7-4
7.2.3 Setting the date format 7-5
7.2.4 Patient identification request 7-7
7.2.5 Instrument initialization 7-8

7.3 Configuration 7-8
7.3.1 Low/high flag ranges 7-8
7.3.2 Audible keys 7-10
7.3.3 Laboratory information system (LIS) 7-11

8 Performing tests 8-1

8.1 Sample loading 8-2

8.2 Test request with patient ID number option disabled 8-3
8.2.1 Single test 8-3
8.2.2 Duplicate test or two test types, same patient ID 8-4
8.2.3 Two different test types, different patient ID 8-4

8.3 Test request with patient ID number option enabled 8-5
8.3.1 Single test 8-5
8.3.2 Duplicate test or two test types, same patient ID 8-6
8.3.3 Two test types, different patient ID 8-7

8.4 Canceling tests 8-8

8.5 Printing results 8-9

8.5.1 Automatic printing after test 8-9

8.5.2 Printing the results of the last run 8-9

8.5.3 Printing stored test results 8-9

8.5.4 Printing usage history 8-10

9 QC procedures 9-1

9.1 Self test and daily alignment check for trigger solution dispensing 9-1

9.2 Run control 9-4

9.3 Printing control results 9-6

10 Cleaning and disinfection 10-1

10.1 Cleaning the instrument 10-1

10.2 Disinfecting the instrument 10-1

11 Maintenance 11-1

11.1 Replacing trigger solution 11-1

11.2 Priming the system 11-2

11.3 O-Ring maintenance 11-3

11.3.1 Maintaining and inspecting the O-Ring 11-3

11.3.2 Removing the O-Ring 11-4

11.3.3 Installing the O-Ring 11-5

11.3.4 Cleaning O-Ring using cleaning pads 11-6

11.4 Replacing printer paper 11-8

11.5 Replacing printer ribbon 11-10

11.6 Replacing fuses 11-10

12 Diagnostics and troubleshooting 12-1

12.1 Power on diagnostics **12-1**

12.2 Self test **12-1**

12.3 Printing error log **12-2**

12.4 Displaying test results **12-3**

12.5 Common status messages **12-4**

12.5.1 Maximum Test Time Exceeded 12-6

12.5.2 Test Terminated Due To Air Leak 12-7

12.5.3 Test Terminated Due To Flow Obstruction 12-8

12.5.4 Test Terminated Due To Insufficient Sample 12-9

12.5.5 Test Terminated Due To Maximum Syringe Travel 12-10

12.6 Other status messages **12-11**

Index **IX-1**

Table of Contents

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

1

1 About this document

This chapter contains information about:

– Orientation tips (Chapter 1.1)
– Meaning of the symbols and abbreviations used (Chapter 1.2)

1.1 Orientation tips

The following conventions are used to make the manual easier to handle.

Page numbering

The page number consists of:

1st number (in green box):	**Chapter**
2nd number (to the right of the box):	**Page of chapter**

Example:

1	3	= page 3 of chapter 1

Bold point

A **bold point** • indicates an **instruction**.

Example:

To save the result on hard disk:

- click on **Save**.

Header and keyword

All functions or instructions are listed as a header or key word in the left hand column of the page.

Bold type

Names and commands and important phrases are printed in **bold type**.

Examples:

– Command **Print**
– Input box **Date of birth**
– Click on **Input**
– Menu **Routine**

1.2 Meaning of symbols in the document

NOTE



The meaning of warning and information symbols used on the instrument can be found in Chapter 2.4.1.

1.2.1 Symbols used in the warning and safety instructions

NOTE



Notes are indicated in the function column (left-hand column) by an **arrow** and the word **Note**. The note is highlighted in gray.

Warnings

Three different hazard levels are indicated in the function column (left hand column) by a **black warning triangle** and the relevant word. The warning is highlighted in gray.

CAUTION



Hazard level:

Potential hazard which can result in **minor injury/property damage**.

WARNING



Hazard level:

Potential hazard which can **possibly** result in **serious injury/death** if precautions are not taken.

DANGER



Hazard level:

Actual hazard which will **certainly** result in **serious injury/death** if precautions are not taken.

1.2.2 Abbreviations

The following abbreviations are used in the manual:

Abbreviations	Meaning
ADP	Adenosine-5'-diphosphate
CE	Communauté Européen
COL	Collagen
CT	Closure Time
EMC	Electromagnetic compatibility
EPI	Epinephrine

Table 1-1 Abbreviations

Abbreviations	Meaning
GS	Geprüfte Sicherheit (safety-tested)
ID	Identification
P2Y	INNOVANCE® PFA P2Y
PFA	PFA-100® System

Table 1-1 Abbreviations (Continued)

NOTE



For information on software upgrades see the installation guide.

1 About this document

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

2

2 Safe handling

This chapter contains information about:

- The intended use (Chapter 2.1)
- The statutory requirements (Chapter 2.2)
- The necessary operator qualification (Chapter 2.3)
- Hazard and safety instructions (Chapter 2.4)
- The operator's obligations (Chapter 2.5)

2.1 Intended use

The instrument's intended use is 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 instrument's functions are:

- **Moving** the carousel (containing cartridges with samples) into the instrument
- **Reading** the test code
- **Dispensing** the trigger solution into each test cartridge
- **Incubating** the samples
- **Aspirating** the sample through the aperture of the 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 three seconds below 10% of the initial flow rate at the beginning of the test
- **Calculating** and **analyzing** the readings
- **Printing** the readings

One or two test cartridges containing samples can be placed in the instrument after:

- Loading the required test cartridges
- Entering the test

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

For in-vitro diagnostics only!

NOTE



In the event that the PFA-100 System is not used according to its intended use, Siemens Healthcare Diagnostics disclaims all liability for any damage which might occur (see also disclaimer on back of title page).

WARNING



All the prescribed safety precautions for the instrument may be ineffective if the instrument is used in any other way than prescribed by the manufacturer.

2.2 Statutory requirements

2.2.1 CE mark

The instrument conforms to the relevant European directives.

The instrument described in this manual bears a CE mark which certifies that it meets the fundamental requirements of the following European directives:

If the instrument has an IVD symbol on the nameplate, it complies with the following directive:

– 98/79/EC In-Vitro Diagnostics Directive

If the instrument has no IVD symbol on the nameplate, it complies with the following directives:

– 73/23/EEC Low-Voltage Directive

– 89/336/EEC EMC Directive

2.2.2 Instrument safety

The PFA-100 System has been designed and tested to comply with safety standards EN 61010 and IEC 61010 under the conditions listed in Chapter 6.3.

2.2.3 Electromagnetic compatibility (EMC), radio interference suppression and immunity to interference

NOTE



The basis for the test is EN 61326 or IEC 61326. The instrument has been developed and tested according to EN 61326-1 class A. In case of radio interference in a home environment measures may be necessary to reduce the interference. If other peripherals such as an external barcode scanner are to be connected, screened cables and plugs are absolutely essential.

NOTE



It is recommended against operating strong electromagnetic transmitters (e.g. mobile phones, walkie-talkies, door openers) in the vicinity of the instrument.

2.3 Operator qualification

CAUTION



The PFA-100 System should only be operated by a skilled employee who has received instruction in operating the instrument. Instruction in operating the PFA-100 System is given at the time of installation of the instrument by Siemens. If you have any further training requirement, contact your local Siemens office.

2.4 Hazard and safety instructions

This instrument was in perfectly safe working order when it left the factory. In order to maintain this status and to ensure hazard-free operation, the user must follow the hazard and safety instructions contained in this instruction manual.

NOTE



The meanings of the warning and information symbols in the document can be found in Chapter 2.4.1.

2.4.1 Meaning of the warning and information symbols on the instrument

	General warning which draws the user's attention to particular potential hazards.
	This label certifies that the instrument has been tested according to canadian and US safety standards by the nationally recognized testing laboratory TÜV.
	Biohazard The marked area of the instrument can come into contact with potentially infectious material. The safety instructions for working with infectious material must be followed.

Table 2-1 Warning and information symbols

2.4.2 Safe handling of the instrument

According to EN 61010, use the instrument only in accordance with the conditions specified in Chapter 6.3.

Disposal of used PFA cartridges

WARNING



The used cartridges are a biohazard.

- Dispose of cartridges as indicated in the cartridge procedure manual.
- Follow your laboratory's safe biohazard waste disposal procedures regarding personnel protective equipment, contact with and disposal of these materials.

Trigger bottle door

CAUTION



Be sure the access door is fully closed before pushing the lever down to avoid damaging the trigger bottle spiking needle.

Electrical shock

DANGER



To prevent electrical shock, the instrument must be unplugged before replacing fuses.

2.4.2.1 Electrical safety

DANGER



- Check that the voltage is set correctly before connecting the instrument to the mains supply.
- Only use sockets with a ground contact (earth) for connecting to the mains supply to minimize the danger of an electric shock.
- Only extension cables with a protective conductor and a ground contact should be used.
- Never disconnect the ground contacts on purpose. There is a danger of electric shock when the protective conductor is interrupted inside or outside the instrument or the ground contact is disconnected from the line.
- Never remove protective guards or fused components as you could expose live parts in this way. Electrical connections (plugs, sockets, etc.) may be live, i.e. carry an electric charge. Even when the instrument is switched off components (e.g. condensers) can be live as they may still be electrically charged. All live parts are a potential electric shock source.
- Switch the instrument off and disconnect it from all voltage sources if you have to open it before any calibration, maintenance, repair or replacement work. If any calibration, maintenance or repair work has to be carried out on the open instrument while connected to a mains power source, this may only be done by a specialist who is familiar with the dangers associated with such action.
- Only use replacement fuses of the specified type and current rating.
- Only use fuses in perfect technical order.
- Never short-circuit the fuse holder.
- Surfaces (floor, bench top) must not be wet when you are working at the instrument.
- Do not use the instrument on a wet base.
- Never place containers of liquid on the instrument. If liquid is spilled in the instrument, this can result in contact with live parts and cause an electric shock.
- If liquid is spilled in the area of the mains input of the instrument, pull out the plug.

2.4.2.2 Operational safety

WARNING



- Keep clear of moving parts when the instrument is in operation.
- Never open or remove the cover during operation of the instrument. Opening of the cover may only be carried out by Siemens Service.
- If you feel that safe operation is no longer possible, shut the instrument down and secure it against accidental operation.

It may be assumed that safe operation is no longer possible:

– If there is visible damage to the instrument

– If the instrument is no longer working after a fault

– After an extended period of storage

– After being transported in harsh conditions

2.4.2.3 Flammable and explosive materials

DANGER



- Never operate the instrument in an environment containing explosive mixtures of oxygen, hydrogen or other flammable gases. The instrument’s switch contacts generate sparks which can result in ignition of the mixture.

2.4.3 Safe handling of samples, reagents and consumables

WARNING



The samples and reagents as well as all parts which come into contact with them are potentially infectious. Reagents can irritate skin and mucous membranes.

- Avoid contact of the skin and mucosae with samples, reagents and contaminated parts.
- Wear appropriate gloves and safety glasses. Pay attention to the manufacturer's information regarding the gloves' compatibility with the materials and liquids used.
- See the instructions for using the reagents.

2.4.3.1 Disposal

WARNING



The cartridges and the consumables are potentially infectious material.

- Dispose of the cartridges as described in the appropriate instructions for use.
- Dispose of consumables and the cartridges according to national regulations.

2.4.4 Correct functionality of the instrument

CAUTION



Erroneous measurements can result in a misdiagnosis which is dangerous for the patient.

To guarantee trouble-free operation of the instrument:

- Check the function of the instrument.
- Check the functionality of the instrument daily with the **Self Test** function of the software.

2.5 Operator's obligations

NOTE



The operator of the PFA-100 System takes on the obligations arising from the national right to operate IVD instruments.

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

3

3 Delivery and installation

This chapter contains information about everything you need to bear in mind regarding delivery (Chapter 3.1) and installation (Chapter 3.2) of the PFA-100 System.

In addition, this chapter contains information about taking the instrument out of operation (Chapter 3.3) for storage or disposal.

3.1 Delivery

This chapter contains information about transport and delivery as well as the steps to be performed immediately after delivery of the PFA-100 System.

3.1.1 Transporting the instrument

NOTE

The PFA-100 System has to be handled with care during transport.

3.1.2 Scope of delivery

The PFA-100 System is delivered with the following components:

– PFA-100 Instrument

– Accessory kit with:

2x PFA O-Rings B4170-78
2x PFA Cassette B4170-70
35x PFA Vacuum Cups B4170-75
1x PFA O-Ring Service Tool B4170-77
1x PFA-100 Printer Paper B4170-71
1x Fuse 3106-2422
2x Fuse 3106-2437
35x PFA Cleaning Pads B4170-73
2x PFA Priming Cartridge B4170-74
1x Paper Roll Axle 5400-2397
1x PFA-100 Printer Ribbon B4170-72

3.1.2.1 Accepting delivery

Immediately after delivery, check the PFA-100 System as follows:

- Check the transport box for signs of external damage before opening.
- Check the delivery for completeness (see Chapter 3.1.2.3) and intact condition immediately after opening.

- Inform your Siemens Healthcare Diagnostics Service immediately if anything is missing or damaged.

3.1.2.2 Unpacking

To unpack the PFA-100 System after delivery, proceed as follows:

- Remove the accessories box.



- Remove the foam packing.



- Remove the instrument from the box.



- Remove the plastic wrapping.



3.1.2.3 Inventory instrument accessories

The accessories box (see Figure 3-1) contains the items shown in Figure 3-2 to Figure 3-12.

- Open the accessories box and verify if all items are present and in good working order.



Figure 3-1 Accessories box

NOTE

The trigger solution is required for PFA-100 System operation, but is **not** included in the accessory box. The Dade® PFA Trigger Solution must be ordered separately using part number B4170-50.

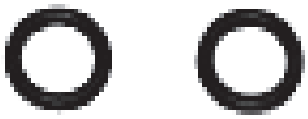


Figure 3-2 PFA O-Rings (B4170-78) (Qty. 2)

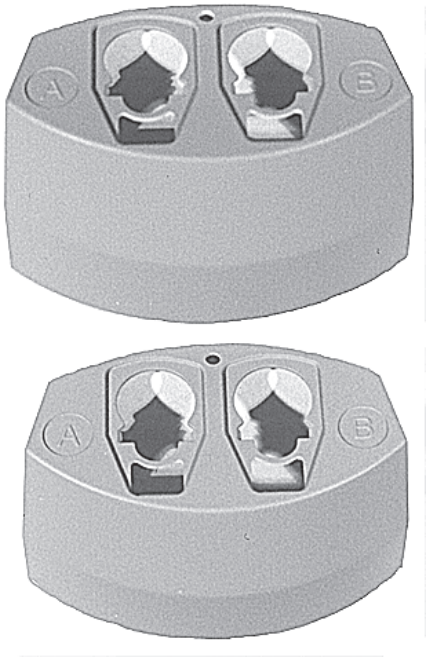


Figure 3-3 PFA Cassettes (B4170-70) (Qty. 2)

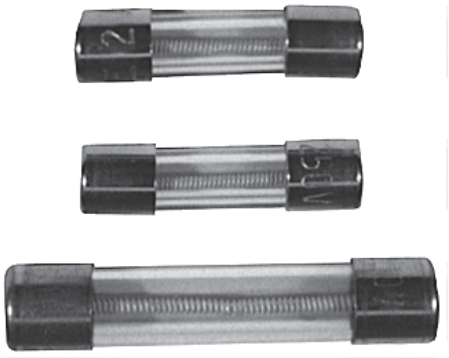


Figure 3-4 Fuses (3106-2422, Qty. 1) (3106-2437, Qty. 2)



Figure 3-5 Paper Roll Axle (5400-2397) (Qty. 1)



Figure 3-6 PFA Vacuum Cup (B4170-75) (Qty.35)



Figure 3-7 Power Cord, language kit specific (country-specific) (Qty. 1)



Figure 3-8 PFA Cleaning Pads (B4170-73) (Qty. 35)



Figure 3-9 PFA-100 Printer Ribbon (B4170-72) (Qty. 1)



Figure 3-10 PFA Priming Cartridges (B4170-74) (Qty. 2)



Figure 3-11 PFA-100 Printer Paper (B4170-71) (Qty. 1)



Figure 3-12 PFA O-Ring Service Tool (B4170-77) (Qty. 1)

3.2 Installation

This chapter contains information about the operating conditions and worktop requirements for the installation of the PFA-100 System as well as the steps to be performed during installation.

3.2.1 Operating conditions

3.2.1.1 Ambient conditions for storage

NOTE

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

3.2.1.2 Ambient conditions for operation

The PFA-100 System may be operated under the following ambient conditions:

– Only use indoors

- Altitude up to 2000 m
- Temperature range: 18 °C to 29 °C
- Maximum relative humidity in the permissible temperature range: 20 % to 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 instrument by steam, solvents and acid fumes
- Protect against direct exposure to sunlight.

NOTE

The degree of protection for the PFA-100 System housing corresponds to IP20 according to IEC 60529.

3.2.2 Requirements of worktop

The small size of the PFA-100 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 instrument 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 instrument on all sides.
- Load capacity of at least 50 kg

CAUTION

All the feet of the instrument must be in full contact with the worktop.

NOTE

Access to a single power outlet is required within 150 cm of the instrument location.

3.2.3 Connecting the instrument

NOTE



The use of an **uninterruptible power supply** (UPS) is recommended. Contact your local Siemens Service Center for details of requirements.

NOTE



The PFA-100 System must be connected with tested cables in which an IEC 320, C13 plug is used on the instrument side and a nationally typical plug with PE contact on the other side.

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

CAUTION



Do not connect the PFA-100 System to the power supply before the correct operating voltage has been set.

- Connect the PFA-100 System to the power supply using **one** distribution box.

3.2.3.1 Installing fuses

WARNING



The instrument may be opened by authorized personnel only.

- Before opening the instrument and installing fuses, pull out the mains plug to prevent electrical shock.

When opening the instrument after routine use, there is a risk of infection.

- To avoid infection, clean and disinfect the instrument (according to Chapter 10).

To install fuses on the instrument, proceed as follows:

- Pry open the fuse compartment with a small screw driver and remove the fuse holder from the instrument.

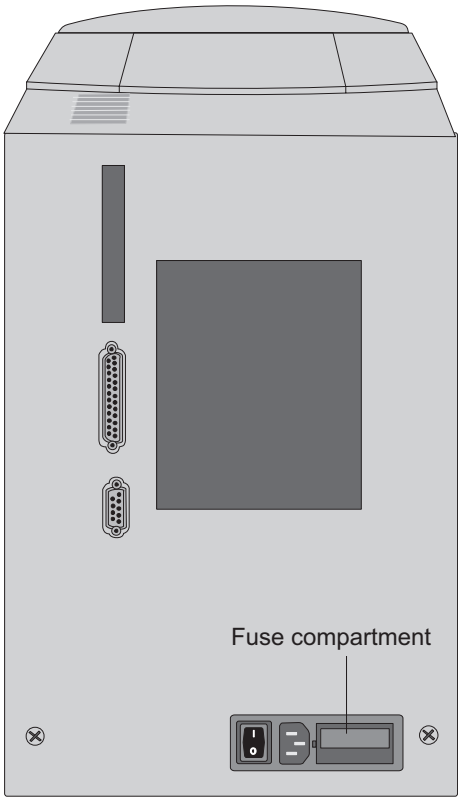


Figure 3-13 Location of fuse compartment with fuse holder

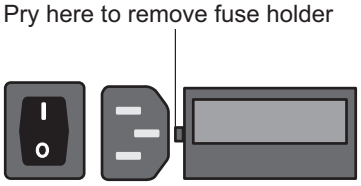


Figure 3-14 Removing fuse holder

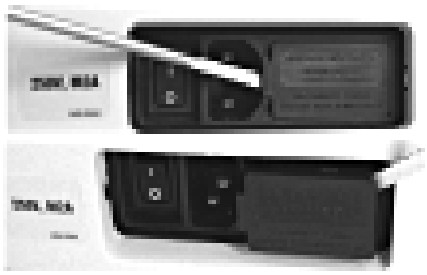


Figure 3-15 Removing fuses

- Install the correct fuse in the holder.

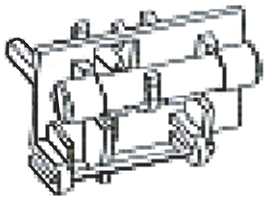


Figure 3-16 Fuse holder 120 VAC

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

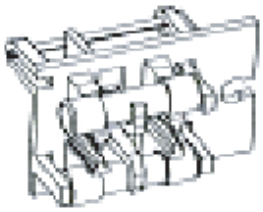


Figure 3-17 Fuse holder 220 VAC

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

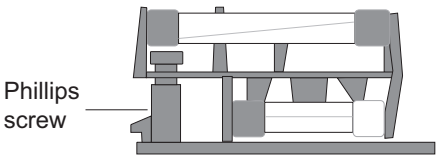


Figure 3-18 Remove Phillips screw

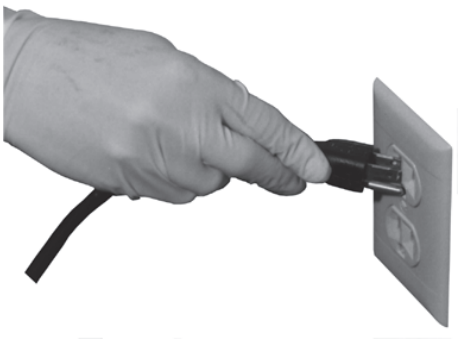
3.2.3.2 Connecting the instrument to the power source

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

- Insert power cord.



- Plug into AC outlet.



3.2.3.3 Loading printer paper

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

- Make sure that the instrument is switched off.

- Open access door.



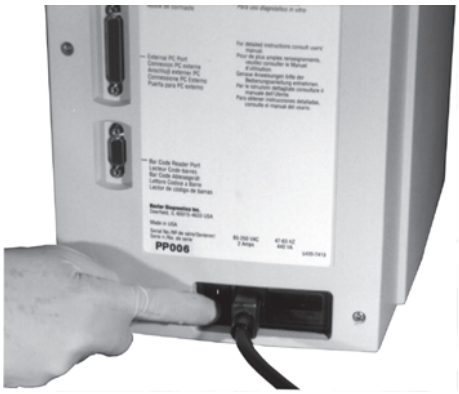
- Insert paper roll axle.



- Thread printer paper.



- Switch power on.



→ The printer paper will automatically feed through the printhead.

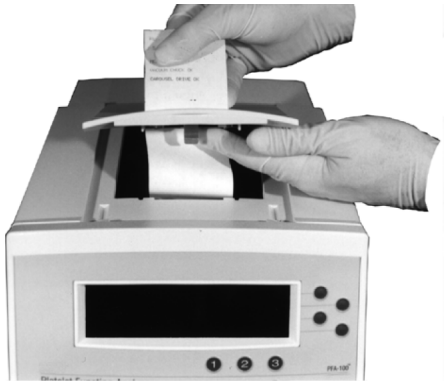
3.2.3.4 Threading printer paper

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

- Gently pull printer paper through printer.



- Thread paper through slot in printer door.



- Close printer door and tear off the excess paper.



3.2.3.5 Loading trigger solution

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

- Pull lever up to open the access door.



- Remove flip-top from trigger solution bottle.



- Load trigger solution and close access door.



CAUTION

Be sure the access door is fully closed before pushing the lever down to avoid damaging the trigger bottle spiking needle.

- Push lever down.



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



The system is now ready for priming.

3.2.3.6 Checking for correct installation

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

- Check for correct installation using the **Self Test** function from the **Maintenance** menu.

For a quick reference on how to perform a **Self Test** see Chapter 4, for details refer to Chapter 9.1 and/or Chapter 12.2, respectively.

3.3 Preparing the instrument for longer periods of non-operation

If the instrument will not be used for a longer period of time, proceed as follows:

- Put on appropriate gloves and safety glasses.

WARNING



Pay attention to the manufacturer's information regarding the gloves' compatibility with the materials and liquids used.

Removing the test cartridge(s)

- Make sure that testing is completed and the carousel has moved to load position.
- Remove the cassette carefully from the carousel.
- Holding the cassette in one hand, remove the test cartridge(s) by gently pulling the bottom of the cartridge toward you until it unsnaps.
- Dispose of the test cartridge(s) in a suitable biohazard waste container.

Removing the O-Ring

- Remove the O-Ring as is described in Chapter 11.3.2.

NOTE



If the instrument is to be transported to another location for storage:

- Select **Menu > Maintenance > 0**.

→ The vacuum flask will move to rest position.

Switching off and storing the instrument

- Set the power switch on the back of the instrument to **off**.
- Pull out the mains plug from the AC outlet.
- Unplug the power cord at the back of the instrument.
- Clean and disinfect the instrument according to Chapter 10.
- Store the instrument according to the non-operating storage conditions given in Chapter 3.2.1.1 and Chapter 6.3.

- Transport the instrument carefully to an appropriate storage place.

NOTE



Before putting the instrument into operation again make sure that a new trigger solution bottle is inserted into the instrument. For details on how to insert a trigger solution bottle refer to Chapter 3.2.3.5.

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

4

4 Quick reference guide

The quick reference guide contains the steps of a routine run on the PFA-100 System from switching on the instrument, preparation of the samples and the instrument up to printing out the results of the samples and switching the instrument off again.

NOTE

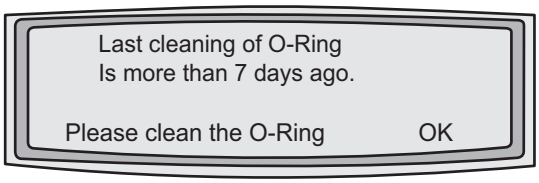
This quick reference guide is aimed at experienced users. For detailed instructions for use, refer to the following chapters of this instruction manual.

Switching on instrument

- Switch on the instrument at the power switch on the back of the instrument (if already switched on, start with the next step).

→ The instrument initializes and heats the incubation block.

→ If the last cleaning of the O-Ring has been carried out more than seven days ago, the following text is displayed:



For cleaning the O-Ring refer to Chapter 11.3.4.

Carrying out Self Test

- Select **Menu > Maintenance > Self Test**.
- Follow the instructions on the display (place a vacuum cup in blue priming cartridge in position **A** and **B**, moisten the cleaning pad with isopropanol before loading).
- When **Self Test** is completed, check the print out. For the self test refer to Chapter 9.1.

Cleaning O-Ring manually

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

- Select **Menu > Maintenance > Remove O-Ring**.
- Follow the instructions on the display (place the O-Ring service tool in the instrument).
- Put on appropriate gloves and safety glasses.

WARNING

Pay attention to the manufacturer's information regarding the gloves' compatibility with the materials and liquids used.

- Remove the O-Ring manually and clean it with distilled or deionized water and a dust-free tissue.
- Replace the O-Ring in the instrument: Select **Menu > Maintenance > Install O-Ring**.
- Repeat the **Self Test**.

For the self test refer to Chapter 9.1.

Priming trigger solution

- Select **Menu > Maintenance > Trigger Prime**.
- Place a priming cartridge in the instrument and follow the instructions on the display.

For the daily alignment check for trigger solution dispensing refer to Chapter 9.1.

Loading sample

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

WARNING



Wear appropriate gloves and safety glasses. Pay attention to the manufacturer's information regarding the gloves' compatibility with the materials and liquids used.

- Remove and discard the top foil seal from the test cartridge(s).
- Place the test cartridge(s) in the cassette and push until the test cartridge(s) securely snap(s) in place.
- Mix the blood sample by inverting the collection tube gently by hand 3-4 times.
- Pipette 800 µL of blood into the smaller opening (sample reservoir opening) of the test cartridge by dispensing slowly along one of the inside corners.
- Start the test: **Run**.
- Type in the sample ID.

When testing is completed, results are printed out automatically.

Disposal of used test cartridge(s)

- Dispose of the test cartridge in a suitable biohazard waste container.

Switching off instrument

Before switching off the instrument, it is recommended to remove the test cartridge(s) from the carousel:

- Put on appropriate gloves and safety glasses.
- Make sure that testing is completed and the carousel has moved to load position.

- Remove the cassette carefully from the carousel.
- Holding the cassette in one hand, remove the test cartridge(s) by gently pulling the bottom of the cartridge toward you until it unsnaps.
- Dispose of the test cartridge(s) in a suitable biohazard waste container.

After having removed the test cartridge(s):

- Set the power switch on the back of the instrument to **off**.

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

5

5 Service and warranty

This chapter contains information about:

- The Siemens Healthcare Diagnostics Service (Chapter 5.1)
- Warranty services (Chapter 5.2)
- Ordering of spare parts (Chapter 5.3)
- Disposal of the instrument (Chapter 5.4)

5.1 Siemens Service

Siemens and its local offices abroad undertake to provide a repair service for installed instruments during normal working hours from Monday to Friday with the exception of public holidays. Contact your local Siemens office for service calls outside these times. Siemens and its local offices will keep you advised of the availability and cost of software updates. In accordance with our service agreement, qualified personnel will be on call.

NOTE



When the instrument is installed you will receive information (phone number, etc.) how to reach the Siemens Service hotline.

5.2 Warranty

Siemens or its agent or authorized dealer guarantees that, if used in accordance with the instruction manual, the instruments will have no material or processing faults after installation. The warranty does not apply to damage arising from:

- Accidents, negligence or non-observance of the instruction manual
- The use of non-approved reagents or consumables
- Operating the instrument in an environment which conflicts with the specifications of the instruction manual

Repairs and service work may only be carried out by persons authorized by Siemens.

Restricted warranty on wearing parts

NOTE

There is a warranty with a restricted duration for the following wearing parts:

– PFA Priming Cartridges

– PFA Vacuum Cups

– PFA Cassettes

– PFA O-Rings and PFA Cleaning Pads

– PFA-100 Printer Ribbon and PFA-100 Printer Paper

The warranty term for these wearing parts is laid down by the local Siemens office in your country as part of a service or maintenance contract.

5.3 Ordering information

NOTE

Only original Siemens spare parts may be used.

- Order these from your Siemens representative.

You will find ordering information in the Siemens product catalogue.

The following parts are delivered with the instrument and can be re-ordered:

– PFA Priming Cartridges (B4170-74, Qty. 10)

– PFA Cassettes (B4170-70, Qty. 5)

– PFA Vacuum Cups (B4170-75, Qty. 35)

– PFA O-Rings (B4170-78, Qty. 2)

– PFA Cleaning Pads (B4170-73, Qty. 35)

– PFA O-Ring Service Tool (B4170-77)

– PFA-100 Printer Ribbon (B4170-72)

– PFA-100 Printer Paper (B4170-71, Qty. 10)

– Paper Roll Axel (5400-2397)

– Power Cord (country-specific)

– Fuses (3106-2422, Qty. 1) (3106-2437, Qty. 1)

NOTE

The trigger solution is required for PFA-100 System operation, but is **not** included in the accessory box. The Dade PFA Trigger Solution must be ordered separately using part number B4170-50.

5.4 Disposal of the instrument

If the instrument will not be put into service again, proceed as follows:

- Put the instrument out of operation as described in (Chapter 3.3).
- Contact your local Siemens Service with regard to disposal of the instrument.

NOTE



The disposal of Waste Electrical and Electronic Equipment is regulated by the European Directive on WEEE; 2002/96/EC and corresponding national transpositions.

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

CAUTION



Damage to the environment may result by improper waste disposal.

Do not treat electrical and electronic equipment as unsorted municipal waste.

Collect waste electrical and electronic equipment separately and return it to Siemens.

WARNING



Serious disease or death by infection may result due to contaminated material.

Depending on the applications, parts of the PFA-100 may have been in contact with biohazardous or hazardous chemical material.

– Make sure to treat this material according to the applicable safety standards and regulations.
– Always decontaminate the parts before transport or disposal.
– Contact your local Siemens Service if you need support.

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

6 Description of the instrument

This chapter contains information about:

– Components of the instrument (Chapter 6.1.1 to Chapter 6.1.5)
– Consumables (Chapter 6.2)
– Technical specifications (Chapter 6.3)
– Data connections (Chapter 6.4)
– Laboratory information system (LIS) (Chapter 6.5)
– Principle of operation (Chapter 6.6)

6.1 Instrument

The PFA-100 System is a bench top instrument. The instrument consists of the following function units:

– Carousel and the cassette (Chapter 6.1.1)
– Compartment for the trigger solution (Chapter 6.1.2)
– LCD display (Chapter 6.1.3)
– Keypad (Chapter 6.1.4)
– Integrated printer (Chapter 6.1.5)

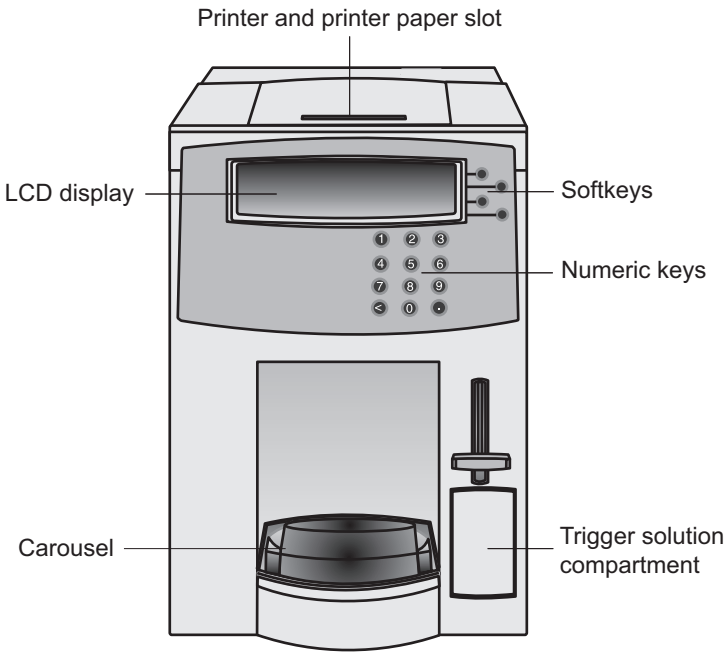


Figure 6-1 Components of the PFA-100 System

6.1.1 Carousel

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

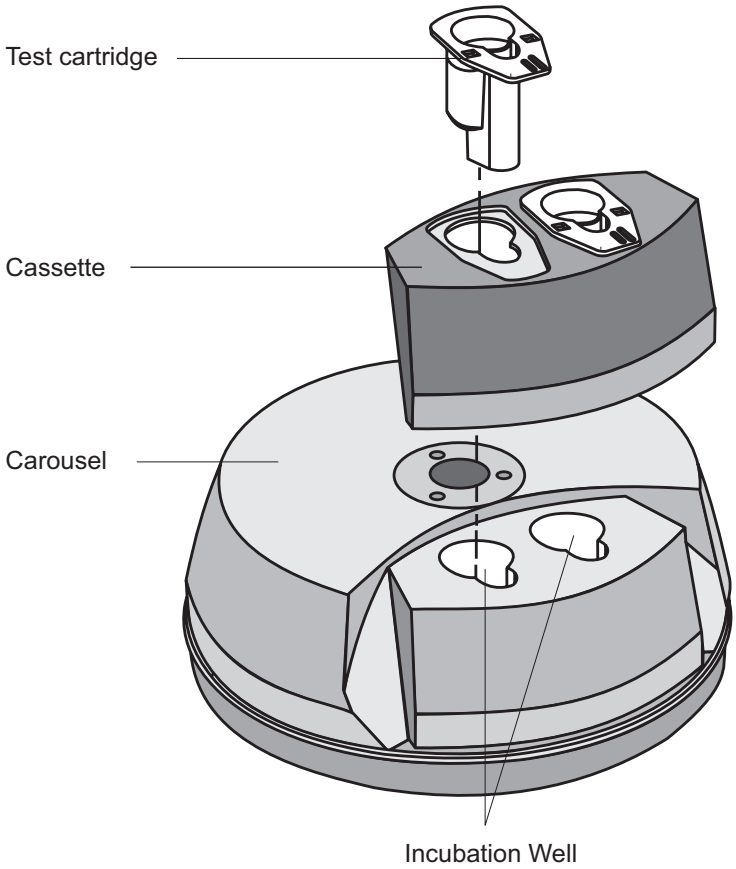


Figure 6-2 Carousel

6.1.2 Trigger solution compartment

The trigger solution compartment is located on the right front of the instrument. 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 will display a message to replace the trigger solution.

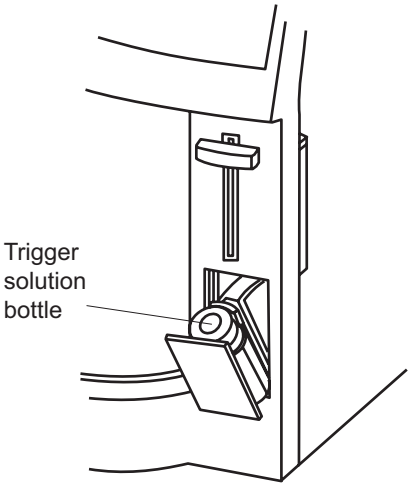


Figure 6-3 Trigger solution compartment

6.1.3 LCD display

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

Display saver

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

- Press any key to turn the light on again.

Contrast adjustment

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

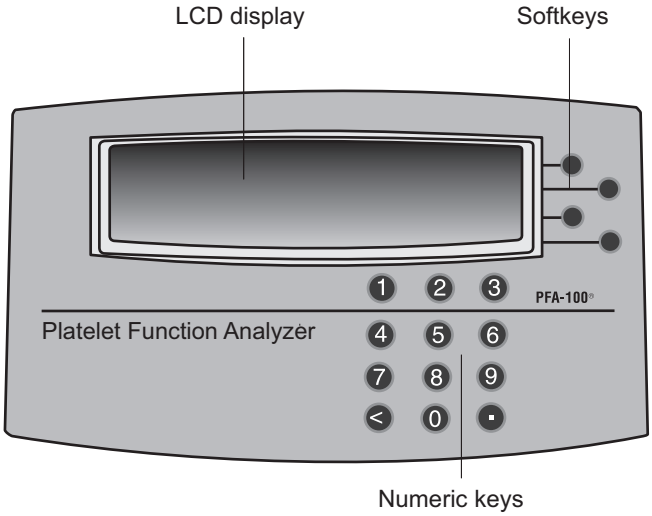


Figure 6-4 LCD display and keyboard

6.1.4 Keyboard

The keyboard is composed of two types of keys (See Figure 6-4.): The numeric keys and the softkeys. The setup allows the user to select an audible tone to sound when pressing the keys.

6.1.5 Printer

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

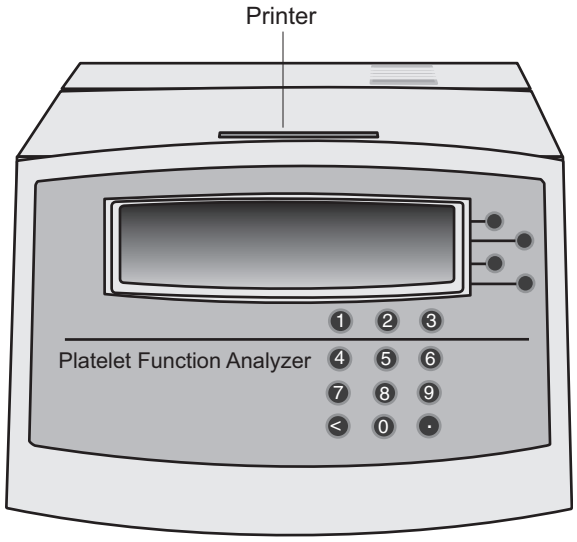


Figure 6-5 Printer and printer paper slot

6.2 Consumables

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

– Labels used on consumables (Chapter 6.2.1)
– Consumables and their specifications (Chapter 6.2.2)
– Test cartridges (Chapter 6.2.3)

6.2.1 Consumables' labels

The following table explains the meaning of the labels used on Siemens Healthcare Diagnostics consumables:

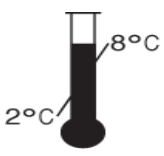
Symbol	Explanation
	Manufactured by
	In-vitro diagnostics
	Lot designation
	CE symbol
	Catalogue number
	Follow instruction manual
	Must not be re-used
	Use by
	Storage temperature

Table 6-1 Consumables' labels

6.2.2 Consumables/parts list

Refer to product catalog for latest information.

Description	Specifications	CAT.
PFA-100 Barcode Scanner		B4170-6
PFA-100 Printer Paper	Standard 58 mm wide x 70 mm max. diameter adding machine/cash register paper - pkg. of 10	B4170-71
PFA-100 Printer Ribbon	EPSON part No. ERC-22	B4170-72
PFA Cassettes	Pkg. of 5	B4170-70
PFA Cleaning Pads	Pkg. of 35	B4170-73
PFA Priming Cartridges	Pkg. of 10	B4170-74
PFA Vacuum Cups	Pkg. of 35	B4170-75
Dade PFA Trigger Solution	Pkg. of 3 x 10 mL Bottles	B4170-50
Test Cartridges	Dade PFA Collagen/EPI Test Cartridge	B4170-20
	Dade PFA Collagen/ADP Test Cartridge	B4170-21
	INNOVANCE PFA P2Y	B4170-22
PFA O-Ring Service Tool	Tool and 2 O-Rings	B4170-77
PFA O-Rings	Pkg. of 2 O-Rings	B4170-78

Table 6-2 Consumables parts list

6.2.3 Test cartridges

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

6.3 Technical specifications

Physical

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

Electrical

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

CAUTION

Main supply voltage must not exceed recommended ranges.

Environmental

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

NOTE

This instrument is for indoor use only.

General

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

NOTE

During sound pressure level measurement the machine is operated as in normal use with all accessories connected. The sound pressure level was measured from a distance of 1 meter from the surface of the machinery and a height of 1.6 meters from the floor or access platform. The measurement was made using an A-weighted sound pressure level meter. The ambient noise was measured as 42 dBA.

Printer

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

Software

External computer	RS232
Interface connector	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	PC card

6.4 Data connections

Barcode scanner port

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

External PC port

The external PC port can be used to download the electronic data to an external computer via a suitable interface software.

Refer to Chapter 6.3 for the respective technical specifications.

Software upgrade slot

The software upgrade slot is used to update the software of the instrument by inserting a PC card into the slot. When the instrument is powered on, the software is loaded automatically. When the update is completed, the user is instructed to remove the PC card. To perform a software upgrade, see installation guide.

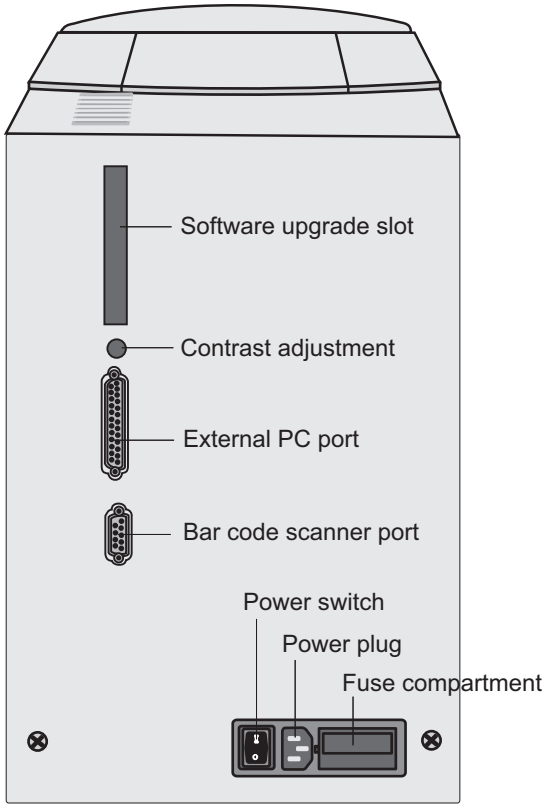


Figure 6-6 Rear view of the instrument

6.5 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, refer to Chapter 7.3.3.

The PFA-100 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 two-byte 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

Table 6-3 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

Table 6-4 Pin assignment DB-9 to DB-25

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

Table 6-5 Communication parameters

6.6 Principle of operation

Principle of platelet function analysis

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.

System functional operation

The PFA-100 System 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-100 System test cartridge consists of a number of integrated parts including a capillary, a sample reservoir and a biochemically active membrane with a central aperture. 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.

[1] Kratzer, MAA: Born, GVR: Simulation of Primary Hemostasis in Vitro. Haemostasis (1985) 5, 357-362.

At the beginning of a PFA-100 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[1], 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 PFA-100 System, the process of platelet aggregation builds a platelet thrombus at the aperture thereby gradually diminishing and finally arresting the blood flow[1]. The PFA-100 System 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 cartridge types refer to the corresponding instructions for use.

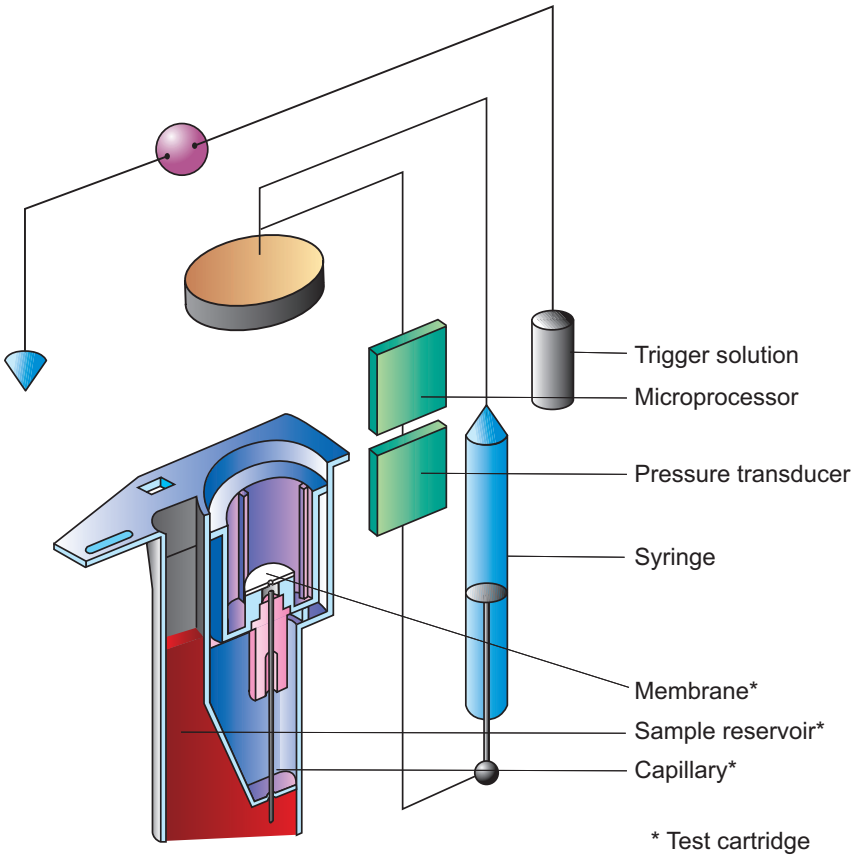


Figure 6-7 Test cartridge, exploded view

[1] Born, GVR: Aggregation of blood platelets by adenosine diphosphate and its reversal. Nature 194:927, 1962.

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

7

7 Setup and changing configuration

This chapter contains information about:

– The priming of the instrument (Chapter 7.1)
– The setup of the software (Chapter 7.2)
– The configuration of the instrument (Chapter 7.3)

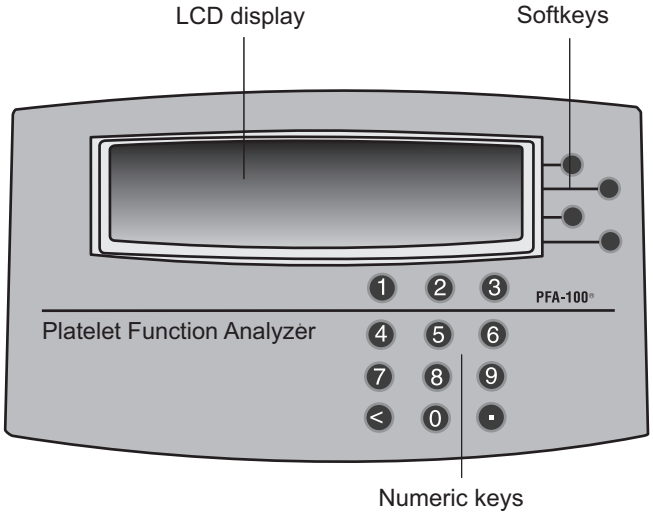


Figure 7-1 LCD display and keypads

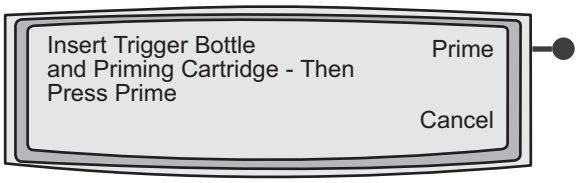
7.1 Priming the instrument

To prime the instrument, proceed as follows:

NOTE

Save the blue priming cartridge for future use.

- Ensure trigger solution and a priming cartridge (blue cartridge with no foil on top) is installed in the instrument.
- Select **Menu > Maintenance > Trigger Prime**.
- Then press the **Prime** softkey to start priming the trigger system.



→ The carousel will rotate and the screen will display **Trigger Priming, Please Wait**.

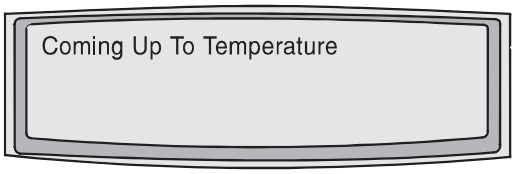
→ When trigger priming is complete, the cassette will rotate to the load position.

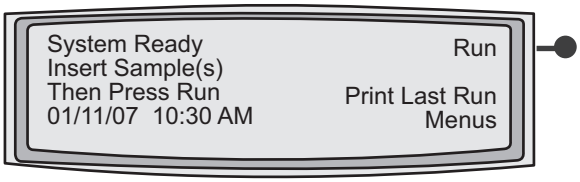
- Remove the priming cartridge and discard the trigger solution accumulated during the priming cycle.
- Rinse the priming cartridge with distilled or deionized water.
- Press the **Continue** softkey.



NOTE

When the instrument is first powered on, at least 15 minutes are required to reach the operating temperature of 37 °C. When the system heater block has reached operating temperature, the **System Ready** screen will be displayed.





7.2 Setup of the software

During setup, the following settings can be made:

– Selecting the language (Chapter 7.2.1)
– Setting the time format (Chapter 7.2.2)
– Setting the date format (Chapter 7.2.3)
– Setting the patient identification request (Chapter 7.2.4)

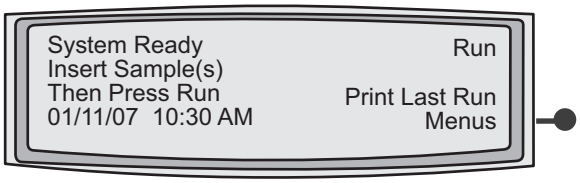
7.2.1 Selecting language

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

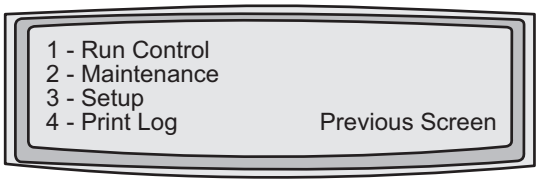
– German
– Spanish
– Italian
– English
– French

To select the language, proceed as follows:

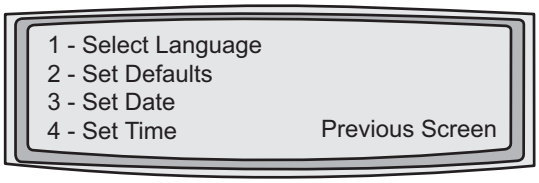
- From the **System Ready** display, press the softkey located next to **Menus**.



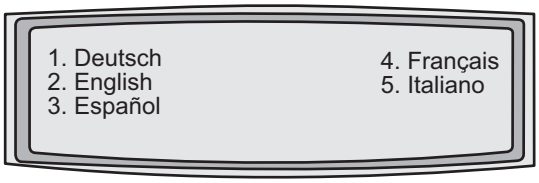
- Press the numeric key **3** to select the **Setup** option.



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



- Press the numeric key corresponding to the desired language.



→ The system will display and print in the selected language.

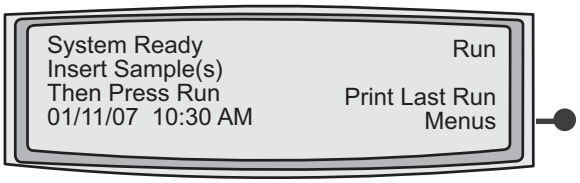
- To return to the **System Ready** display, press the softkey located next to **Previous Screen** twice.

7.2.2 Setting the time format

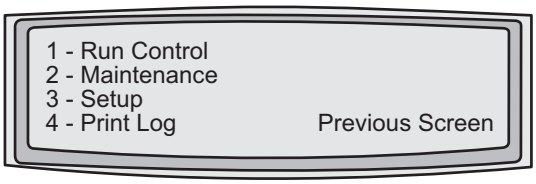
12-hour format

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

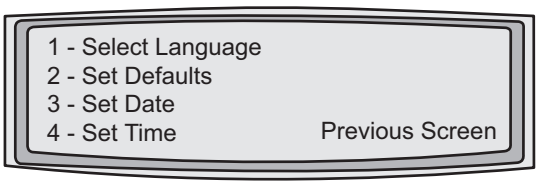
- From the **System Ready** display, press the softkey located next to **Menus**.



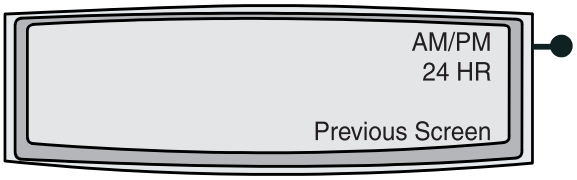
- Press the numeric key **3** to select the **Setup** option.



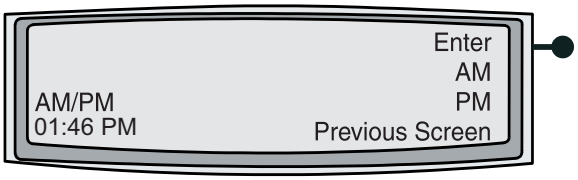
- Press the numeric key **4** to select the **Set Time** option.



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



- Press **AM** or **PM** softkey.



- 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, e.g., 01:00).

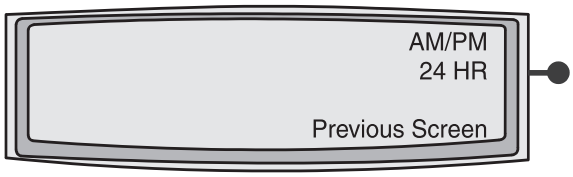
→ The newly formatted time will be displayed on the left.

- To save the selection, press the softkey located next to **Enter**.
- To return to the **System Ready** display, press the softkey located next to **Previous Screen** twice.

24-hour format

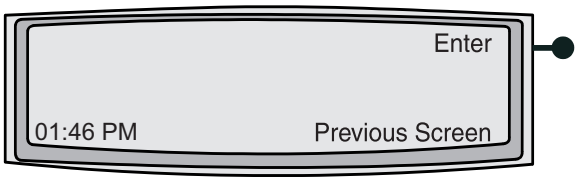
To set the 24-hour format, proceed as is described for the setting of the 12-hour format:

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



- 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, e.g., 01:00).

→ The new formatted time will be displayed on the left.

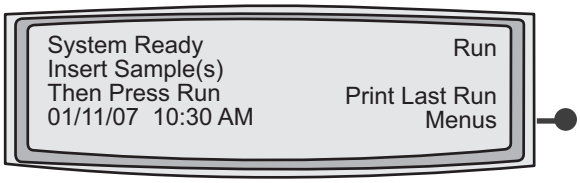


- To save the selection, press the softkey located next to **Enter**.
- To return to the **System Ready** display, press the softkey located next to **Previous Screen** twice.

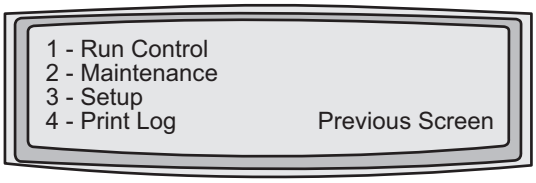
7.2.3 Setting the date format

To set the date format, proceed as follows:

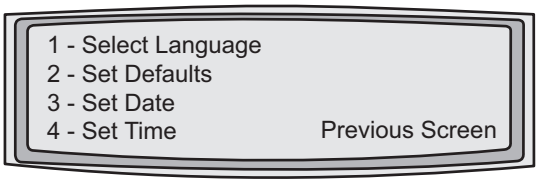
- From the **System Ready** display, press the softkey located next to **Menus**.



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



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

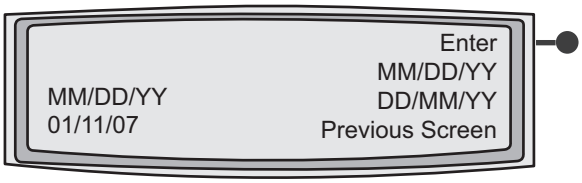


The screen will display (above the date) the currently selected format.

- To change the format, press the softkey located next to the desired option.

→ The new format will be displayed above the date.

- 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 singledigit month or day is entered, e.g., 01/01/01) (displayed from left to right).



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

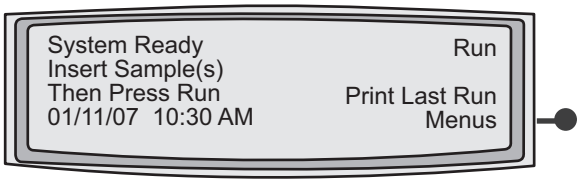
- To return to the **System Ready** display, press the softkey located next to **Previous Screen** twice.

7.2.4 Patient identification request

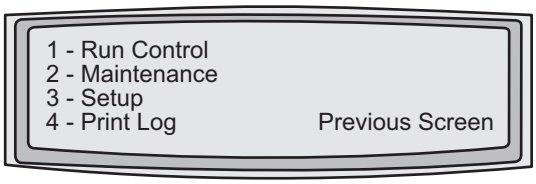
This option sets up the system to request the entry of a specific patient identification number (maximum 12 characters) when running a test.

To set the patient identification request, proceed as follows:

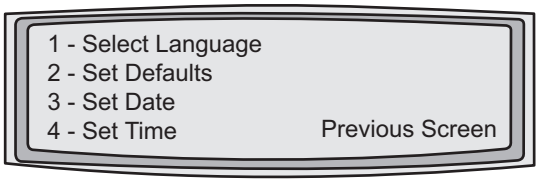
- From the **System Ready** display, press the softkey located next to **Menus**.



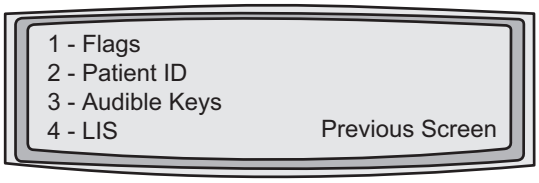
- Press the numeric key **3** to select the **Setup** option.



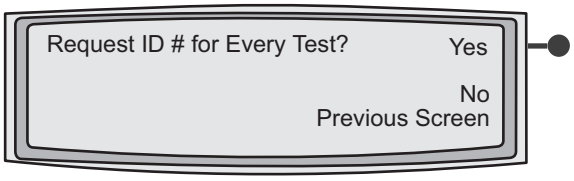
- Press the numeric key **2** to select the **Set Defaults** option.



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



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



→ The system will automatically begin initialization.

7.2.5 Instrument initialization

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

7.3 Configuration

This chapter contains information about:

– Configuring low/high flag ranges for results (Chapter 7.3.1)

– Activating/deactivating audible tones for softkeys (Chapter 7.3.2)

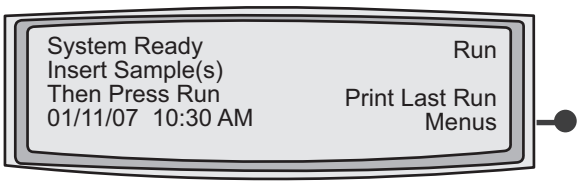
– Transmitting results to a host computer (Chapter 7.3.3)

7.3.1 Low/high flag ranges

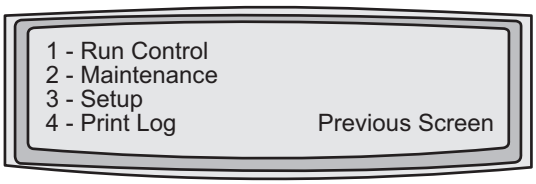
This option, if enabled, will flag patient results that fall above (**High Flag**) and below (**Low Flag**) the laboratory's established reference range. The high and low values (flags) are set by the operator. The high and low values must be between 0-300. Any test result that falls above or below the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

To select the flag ranges, proceed as follows:

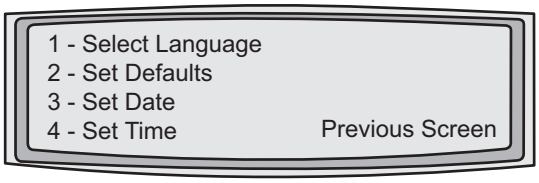
- From the **System Ready** display, press the softkey located next to **Menus**.



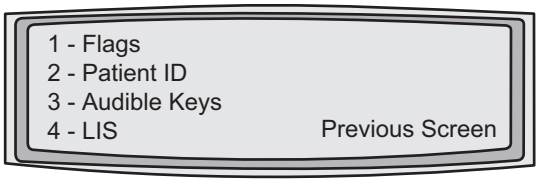
- Press the numeric key **3** to select the **Setup** option.



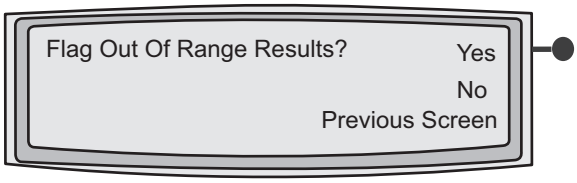
- Press the numeric key **2** to select the **Set Defaults** option.



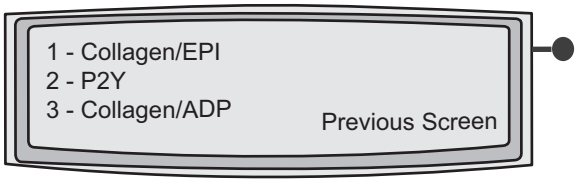
- Press the numeric key **1** to select the **Flags** to set the above (**High Flag**) and below (**Low Flag**) values at which a test result will be flagged with an asterisk (*****) on the result printout.



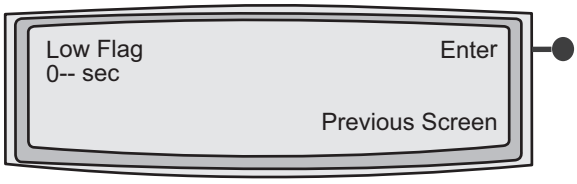
- Press the softkey located next to **Yes** to enable or **No** to disable the **Flag Out Of Range Results** option.



- Use the numeric key to select the test cartridge type to be set for flag ranges (e.g. **Collagen/EPI**, **P2Y** or **Collagen/ADP**).

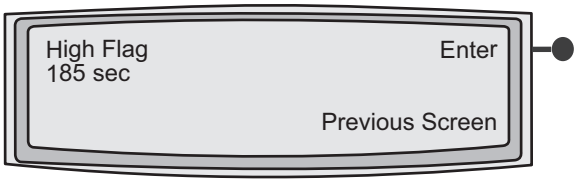


- Use the numeric key to enter the low flag value (time below which the result will be flagged).
- Then press the softkey located next to **Enter** to save the entry.



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

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



- Press the softkey located next to **Previous Screen** three times to return to the **System Ready** display.

NOTE

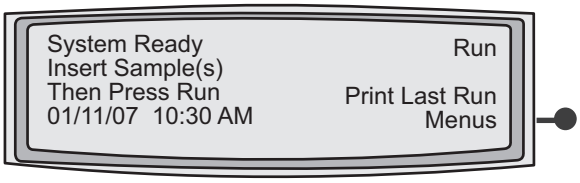
The system will default to **No** if no selection is made.

7.3.2 Audible keys

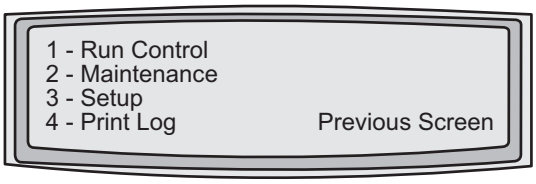
This option allows the operator to enable or disable an audible tone to sound when a softkey or a numeric key is pressed.

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

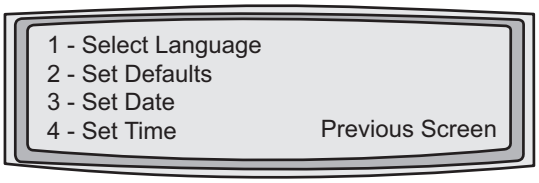
- From the **System Ready** display, press the softkey located next to **Menus**.



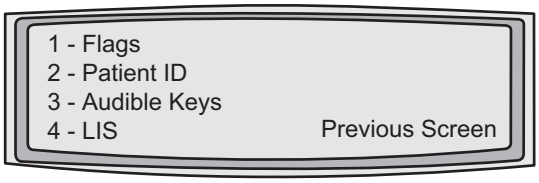
- Press the numeric key **3** to select the **Setup** option.



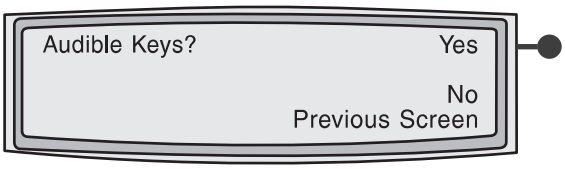
- Press the numeric key **2** to select the **Set Defaults** option.



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



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



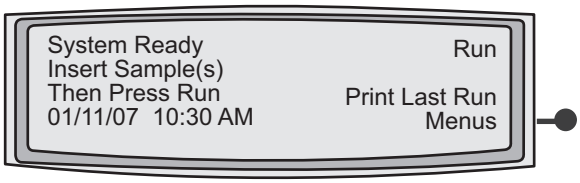
- Press the softkey located next to **Previous Screen** three times to return to the **System Ready** display.

7.3.3 Laboratory information system (LIS)

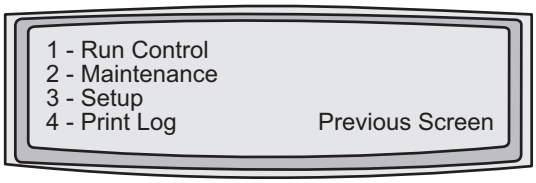
This option allows the user to transmit the printed results to a host computer via the external PC port.

To select the laboratory information system, proceed as follows:

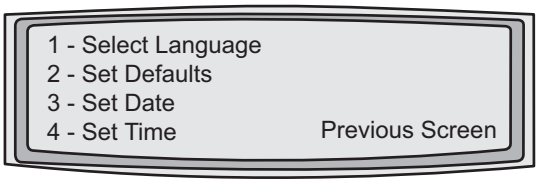
- From the **System Ready** display, press the softkey located next to **Menus**.



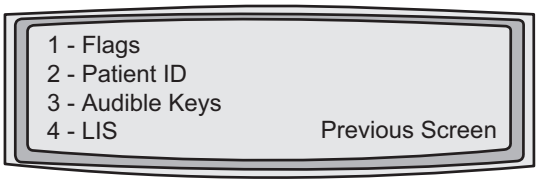
- From the Menu display, press the numeric key **3** to select the **Setup** option.



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



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



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



- Press the softkey located next to **Continue**, and then the softkey next to **Previous Screen** three times to return to the **System Ready** display.

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

8

8 Performing tests

This chapter contains information about:

- Sample loading (Chapter 8.1)
- Test requests (Chapter 8.2 and Chapter 8.3)
- Canceling test results (Chapter 8.4)
- Printing results (Chapter 8.5)

CAUTION



All blood samples and blood components should be treated as potentially infectious.

All samples should be handled in accordance with good laboratory practices using appropriate precautions.

Personal protective equipment should be worn when inserting or removing cartridges from the carousel.

8.1 Sample loading

NOTE

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

To insert test cartridges into the instrument, proceed as follows:

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

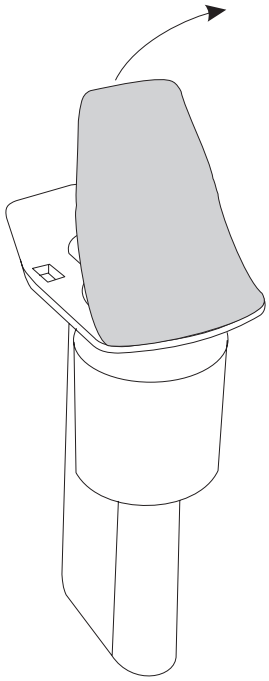


Figure 8-1 Test cartridge

- Snap the test cartridge into position **A** (left position) of the cassette.

When running duplicates or two tests:

- Place a second test cartridge into position **B** (right position).

→ The instrument will automatically determine the test cartridge type before testing the sample.

NOTE

When testing two different patient samples, note their respective cassette position (**A** or **B**).

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

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

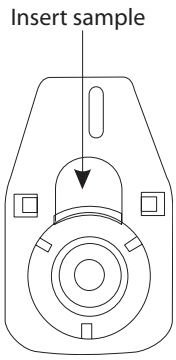


Figure 8-2 Insert sample into test cartridge

NOTE

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.

- Place the cassette with the test cartridge(s) into the incubation well(s) of the instrument so that the cassette is flush to the carousel surface. Do not apply pressure to the sample reservoir opening.

The test can now be started.

8.2 Test request with patient ID number option disabled

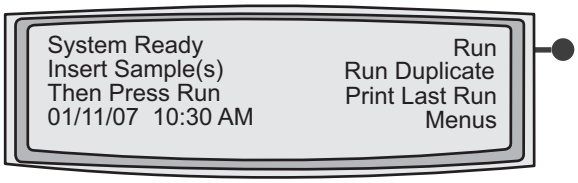
If the **Patient ID number** option was disabled in the setup menu (refer to Chapter 7.2.4), the system will not prompt for the patient ID number.

8.2.1 Single test

To start a single test, proceed as follows:

- Press the softkey located next to **Run** on the **System Ready** display.

→ The instrument will start the test.



When the testing is complete, the system will print and display the results along with an ID No. assigned by the instrument and the test type.

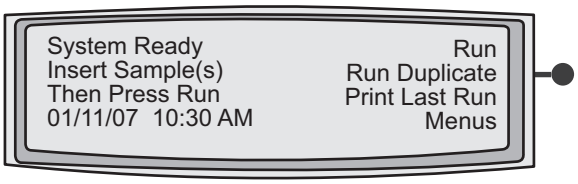
- Remove the cassette carefully from the carousel.
- Holding the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge toward you until it unsnaps.
- Dispose of the test cartridge in a suitable biohazard waste container.

8.2.2 Duplicate test or two test types, same patient ID

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

- Press the softkey located next to **Run Duplicate** on the **System Ready** display.

→ The instrument will start testing and display the processing stage of the sample (incubation or performing testing sample A or sample B).



When the testing is complete, the instrument will print and display the results along with an ID No. assigned by the instrument and the test type.

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

$$MEAN = \frac{CT(A) + CT(B))}{2}$$

$$CV\% = \frac{CT(A) - CT(B)}{CT(A) + CT(B)} \cdot 100$$

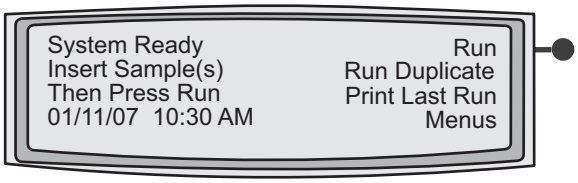
- Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge toward you until it unsnaps.
- Dispose of the test cartridge in a suitable biohazard waste container.

8.2.3 Two different test types, different patient ID

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

- Press the softkey located next to **Run** on the **System Ready** display.

→ The instrument will start testing and display the processing stage of the sample (incubation or performing testing sample A or sample B).



When the testing is complete, the instrument will print and display the results along with an ID No. assigned by the instrument and the test type.

- Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge toward you until it unsnaps.
- Dispose of the test cartridge in a suitable biohazard waste container.

8.3 Test request with patient ID number option enabled

If the Patient ID was enabled in the setup menu (refer to Chapter 7.2.4), the system will prompt for entry of the patient ID number after **Run** was pressed from the **System Ready** display.

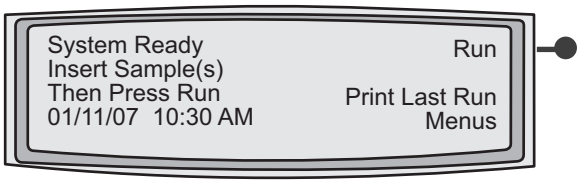
NOTE

If a patient ID No. is not entered before completion of the incubation cycle (about 3.0 minutes), the instrument will automatically assign the next available consecutive number. This number will be printed with the result.

8.3.1 Single test

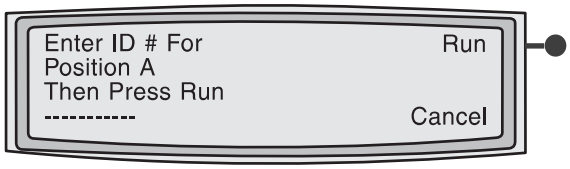
To perform a single test, proceed as follows:

- Press the softkey located next to **Run** on the **System Ready** display.



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

- To modify the patient ID, use the **<** key to erase it, then enter the correct ID.



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

→ The instrument will start testing.

When the testing is complete, the instrument will print and display the results along with the patient ID No. entered and the test type.

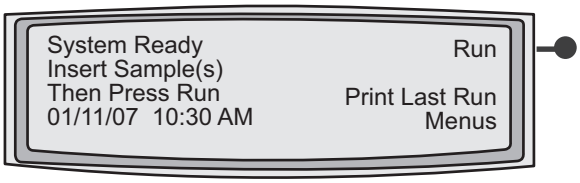
- Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge toward you until it unsnaps.

- Dispose of the test cartridge in a suitable biohazard waste container.

8.3.2 Duplicate test or two test types, same patient ID

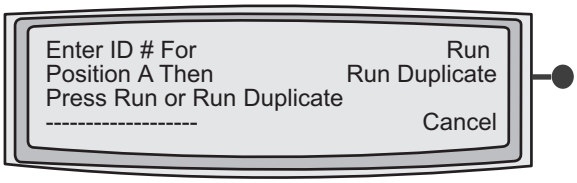
To perform a duplicate test or two test types for the same patient ID, proceed as follows:

- Press the softkey located next to **Run** on the **System Ready** display.



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

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



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

→ The instrument will start testing and display the processing stage of the sample (incubation or performing testing sample A or sample B).

Duplicate

When the testing is complete, the instrument will print and display the results, the CV% and a MEAN value along with the patient ID No. entered and the test type.

Two Test Types

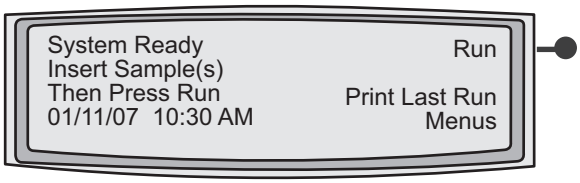
When the testing is complete, the instrument will print and display the results along with the patient ID No. entered and the test types.

- Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge toward you until it unsnaps.
- Dispose of the test cartridge in a suitable biohazard waste container.

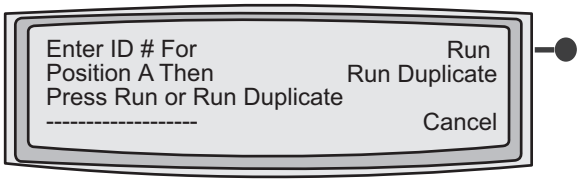
8.3.3 Two test types, different patient ID

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

- Press the softkey located next to **Run** on the **System Ready** display.



- 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).
- To modify the patient ID, use the **<** key to erase it, then enter the correct number.

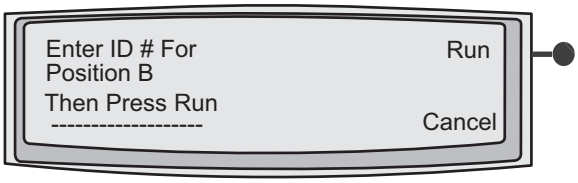


- Press the softkey located next to **Run**.

→ The system will then prompt for the patient ID number related to the cartridge loaded in position **B** (right position).

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

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



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

→ The instrument will start testing and display the processing stage of the sample (incubation or performing testing for sample A or sample B).

When the testing is complete, the instrument will print and display the results along with the respective patient ID numbers entered and test type.

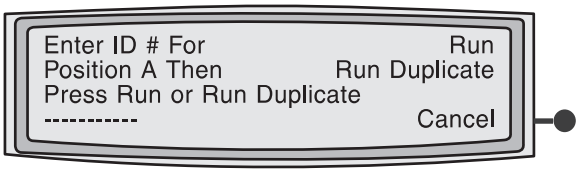
- Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge toward you until it unsnaps.

- Dispose of the test cartridge in a suitable biohazard waste container.

8.4 Canceling tests

To cancel a test, proceed as follows:

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

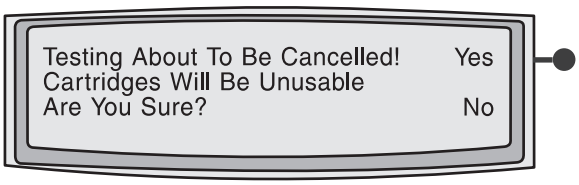


If the test cycle is already started (i.e. trigger solution dispensed into the test cartridge), the system will prompt for confirmation.

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

→ The carousel will rotate to the load position and the system will display **System Ready**.

- Remove and discard the test cartridges.



8.5 Printing results

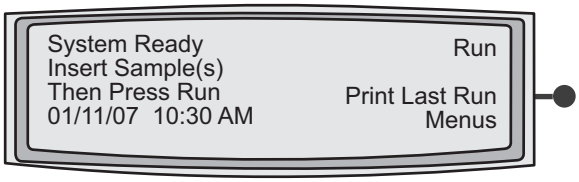
8.5.1 Automatic printing after test

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

8.5.2 Printing the results of the last run

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

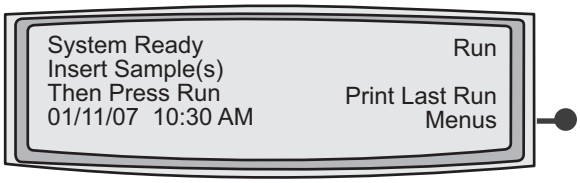
- From the **System Ready** display, press the softkey located next to **Print Last Run**.



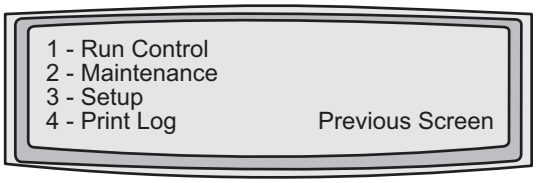
8.5.3 Printing stored test results

To print the stored test results, proceed as follows:

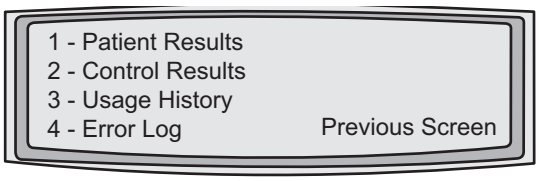
- From the **System Ready** display, press the softkey located next to **Menus**.



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

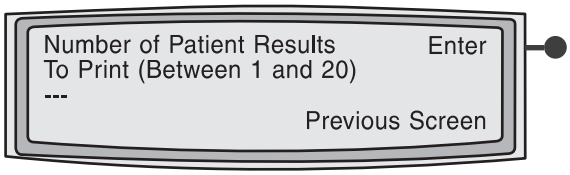


- Press the numeric key **1** to select the **Patient Results** option.



- 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 will begin printing the results of previous tests starting with the most recent one.



NOTE

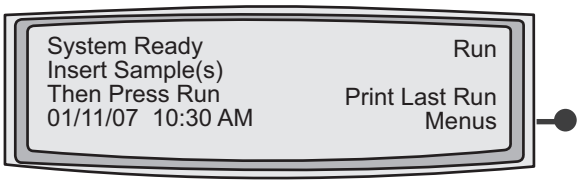
Events or conditions (status messages) detected during the test run are indicated below the printed test result. Refer to Chapter 12, for full explanation of status messages.

8.5.4 Printing usage history

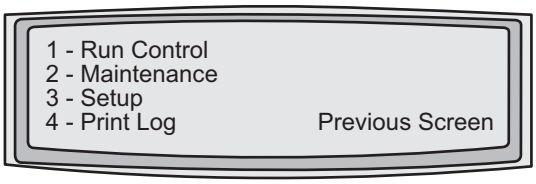
When printing a usage history, the system will print the serial number and the software version of the instrument, the date and time, and the number of tests performed by the instrument over the last 30 days, and since the installation.

To print a usage history, proceed as follows:

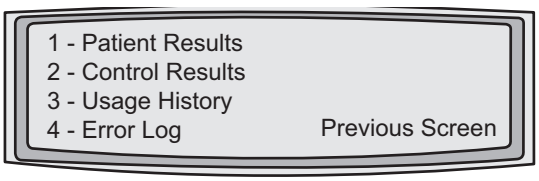
- From the **System Ready** display, press the softkey located next to **Menus**.



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



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



→ The system prints the usage history.

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

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

9 QC procedures

NOTE

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

The PFA-100 System has a self diagnostic built in to verify proper instrument 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 will be 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 PFA-100 System test. As part of the instrument quality control, it is recommended to test two cartridges of each new lot with a control donor, or whenever the institution wishes to verify the performance of the system. Refer to the instructions for use for further instructions. 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 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.

9.1 Self test and daily alignment check for trigger solution dispensing

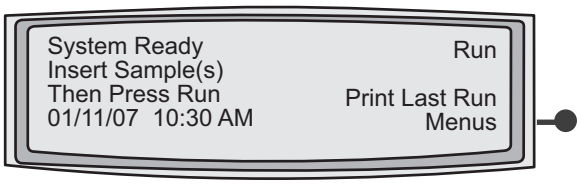
NOTE

Each time the self test is performed, a new vacuum test cup and O-ring cleaning pad must be used.

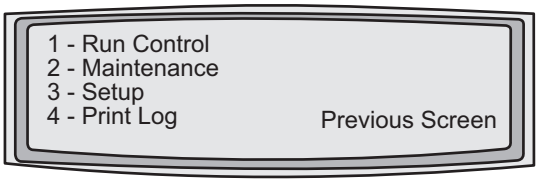
Follow the instructions displayed during the test.

To initiate a system self test, proceed as follows:

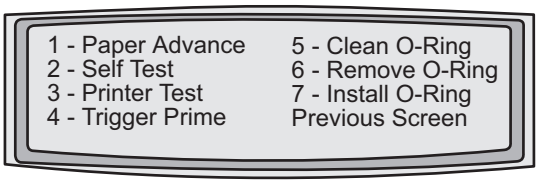
- From the **System Ready** display, press the softkey located next to **Menus**.



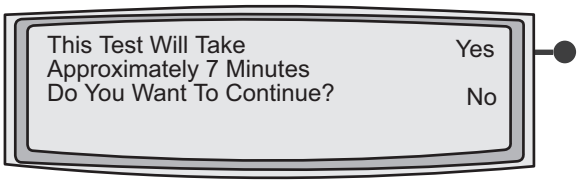
- From the **Menu** display, press the numeric key **2** to select the **Maintenance** option.



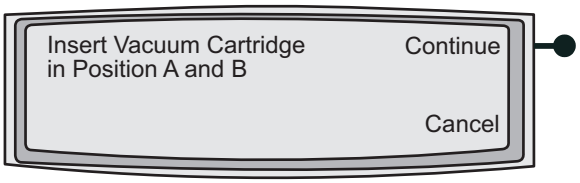
- Press the numeric key **2** to select the **Self Test** option.



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



- Load two 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**.
- Press the softkey located next to **Continue**.



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

- Once the cleaning pad is in position in the carousel well, apply 4-5 drops of isopropanol to the center of the pad.
- Press gently on the pad with gloved index finger 2-3 times to help distribute the isopropanol.
- Press the softkey located next to **Continue**.

→ The system will perform 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 will print the pass/fail results each time a test is completed.

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

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

- Remove the pad and dispose of it in a suitable biohazard waste container.
- Press the softkey located next to **Continue**.
- 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 (circled in the figure below).

NOTE

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 your Siemens Healthcare Diagnostics Service.



Figure 9-1 Trigger solution dispensing

- Remove the vacuum test cartridge from position **A**.
- Remove the vacuum test cup from both cartridges with gloved index finger and discard them in a suitable biohazard waste container.
- Rinse both priming cartridges with distilled or deionized water and save them for further use.
- Press the softkey located next to **Previous Screen** twice to return to the **System Ready** display.

9.2 Run control

To perform a run control, proceed as follows:

- Collect and handle the samples to be used as controls as described in the instructions for use.
- Peel off and discard the top foil seal of the test cartridge.

NOTE

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

- Snap the test cartridge into position **A** (left position) of the cassette. When running two tests, place a second test cartridge into position **B** (right position).
- Resuspend the whole blood sample by gently inverting the collection tube 3-4 times by hand.
- Holding the cassette with test cartridge(s) on a flat surface, pipette 800 µL of sample into the smaller opening (sample reservoir opening) of the test cartridge.

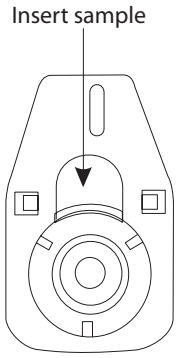


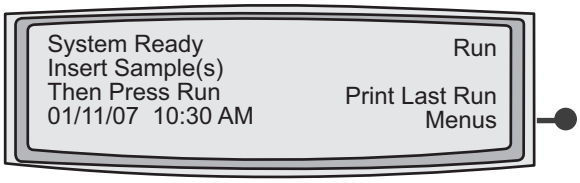
Figure 9-2 Insert sample into test cartridge

NOTE

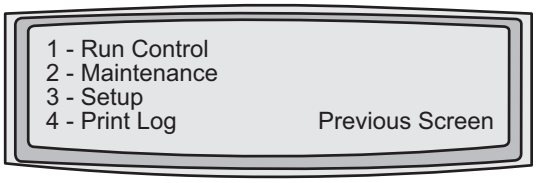
To minimize the risk of trapping an air bubble, place the tip of the pipette against one of the inside corners of the opening while slowly pipetting in the sample.

- Place the cassette with the test cartridge(s) into the incubation well(s) of the instrument so that the cassette is flush to the carousel surface. Do not apply pressure to the sample reservoir opening.

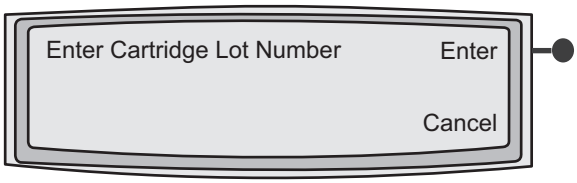
- From the **System Ready** display, press the softkey located next to **Menus**.



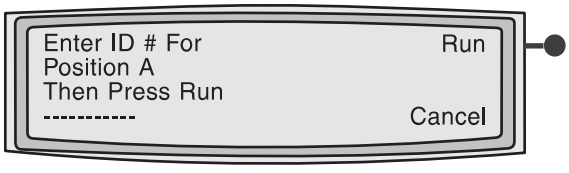
- From the **Menu** display, press the numeric key **1** to select the **Run Control** option.



- Use the numeric keypad to enter the numeric portion of the lot number of the test cartridge being used (located on the test cartridge pouch and on the test cartridge itself).
- To modify the lot number, use the **<** key to erase it, then enter the correct number.
- Press the softkey located next to **Enter**.



- Use the numeric keypad to enter the control ID (maximum 12 characters).
- To modify the control ID, use the **<** key to erase it, then enter the correct number.
- Press the softkey located next to **Run**.



NOTE

If two cartridges have been loaded, the system will assign the same Control ID number to both cartridges.

→ When the testing is complete, the instrument will print and display the results along with the test type, the control ID number and lot number entered, a CV% and a MEAN value if two tests were run.

- Remove the cassette carefully from the carousel: Holding the cassette in one hand, remove the test cartridge by gently pulling the bottom of the cartridge toward you until it unsnaps.
- Dispose of the test cartridge in a suitable biohazard waste container.

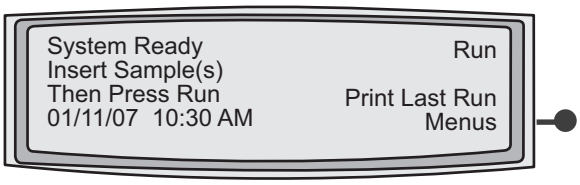
NOTE

Events or conditions (status messages) detected during the test run are indicated below the printed test result. Refer to Chapter 12.5 and Chapter 12.6, for full explanation of status messages.

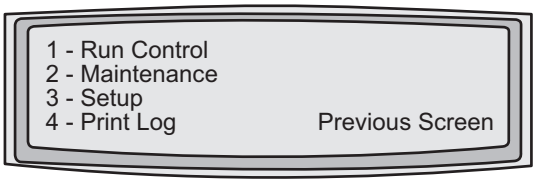
9.3 Printing control results

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

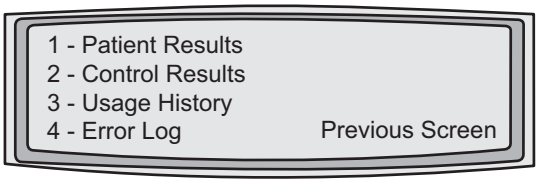
- From the **System Ready** display, press the softkey located next to **Menus**.



- From the **Menu** display, press the numeric key **4** to select the **Print Log** option.

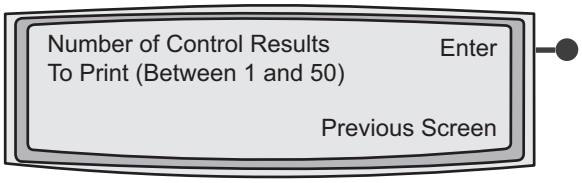


- From the **Print Log** display, press the numeric key **2** to select the **Control Results** option.



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

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



1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

10

10 Cleaning and disinfection

This chapter contains information about:

– Regular cleaning of the instrument (Chapter 10.1)
– Disinfecting the instrument (Chapter 10.2)

CAUTION



To avoid material damage, never sterilize the instrument.

10.1 Cleaning the instrument

The exterior of the PFA-100 System can be cleaned by wiping with a damp cloth containing a commercial disinfectant solution, e.g. Mikrozid®. To remove blood stains use a damp cloth containing water. Do not immerse or pour liquid onto instrument. 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 refer to Chapter 11.3.

10.2 Disinfecting the instrument

NOTE



The recommeded disinfection interval for the instrument and used parts (e.g. cassette) is daily after work.

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

To disinfect the instrument, proceed as follows:

WARNING



- Be sure the instrument is disinfected in an area designated as a biohazard area.
- Wear appropriate protective equipment such as disposable gloves, laboratory coat and safety glasses with side shields or splash-resistant glasses. Pay special attention to manufacturer's information regarding gloves compatibility with the materials and liquids used.

- As debris buildup typically occurs on the areas around the test cartridges, remove the test cartridges before starting disinfection:
- Make sure that testing is completed and the carousel has moved to load position.
- Remove the cassette carefully from the carousel.

- Holding the cassette in one hand, remove the test cartridge(s) by gently pulling the bottom of the cartridge toward you until it unsnaps.
- Dispose of the test cartridge(s) in a suitable biohazard waste container.

After having removed the test cartridge(s):

- Set the power switch on the back of the instrument to **off**.
- Pull out the mains plug from the AC outlet.
- Unplug the power cord at the back of the instrument.
- Apply disinfectant solution on areas where there is visible contamination with blood, blood products or other body fluids.

NOTE



Use a commercial disinfectant solution, e.g. 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.

- 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.
- Apply disinfectant solution on the area again and allow it to sit for 20 minutes.
- Apply disinfectant solution to all external surfaces and allow it to sit for 20 minutes, then rinse with distilled or deionized water.
- Dispose of used paper towels or other wiping material in a suitable biohazard waste container.

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

11 Maintenance

11.1 Replacing trigger solution

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

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

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

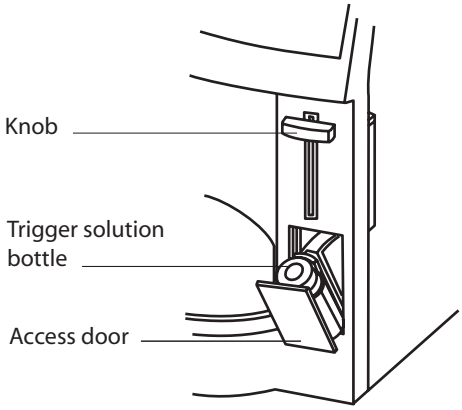


Figure 11-1 Replace trigger solution

- Remove the empty bottle.

NOTE

It is normal that residual solution remains in the bottle.

- Remove the flip-top cap and insert the new bottle in place.
- Push the access door closed.

CAUTION

Be sure the access door is fully closed before pushing the lever down to avoid damaging the trigger bottle spiking needle.

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

NOTE

It is necessary to prime the system after replacing the trigger solution. Do not use trigger solution if turbid or if particulate matter is present.

11.2 Priming the system

To prime the system, proceed as follows:

NOTE

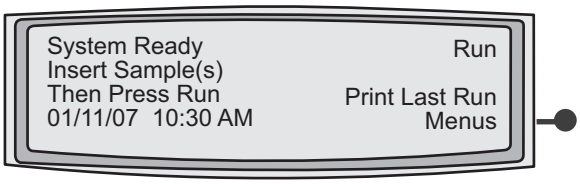
It is recommended to prime the system and run the **Self Test** after any extended period (> 2 days) of non-use. This procedure will clear the system of any accumulated bubbles caused by the outgassing of the trigger solution.

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

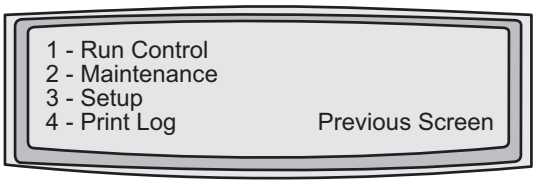
NOTE

Use only one cartridge in either position **A** or **B**.

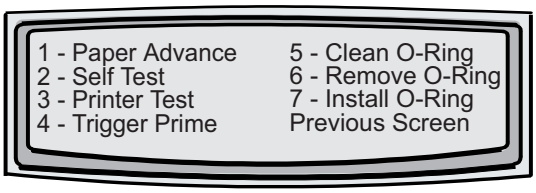
- From the **System Ready** display, press the softkey located next to **Menus**.



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



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



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

→ The cassette will rotate and the screen will display **Trigger Priming**, **Please Wait**.

→ When priming is complete, the cassette will rotate to the load position.

- Remove the cartridge, discard the trigger solution accumulated in the cartridge during the priming cycle.
- Rinse the priming cartridge with distilled or deionized water.
- Save for future use or discard if damaged.



- Press the softkey located next to **Continue**.
- To return to the **System Ready** display, press the softkey located next to **Previous Screen** twice.

11.3 O-Ring maintenance

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

NOTE

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 from 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.

11.3.1 Maintaining and inspecting the O-Ring

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

WARNING

Wear appropriate gloves and safety glasses. Pay attention to the manufacturer's information regarding the gloves' compatibility with the materials and liquids used.

- Remove the O-Ring by performing the **Remove O-Ring** option from the **Maintenance** menu.
- Rinse the O-Ring under distilled or deionized water. Place O-Ring between forefinger and thumb and remove any debris by using a rubbing motion while rinsing under distilled or deionized water.
- Visually inspect the O-Ring for debris or unusual wear and tear such as cracks.

- If the O-Ring requires replacement, follow the **Install O-Ring** option from the **Maintenance** menu to install a new O-Ring. Discard the old O-Ring in a suitable biohazard container.
- Shake excess distilled or deionized water off, dry the O-Ring with a lint-free cloth and install the O-Ring by performing the **Install O-Ring** option from the **Maintenance** menu.
- Perform the **Self Test** from the **Maintenance** menu to verify that the system has no vacuum leak.

NOTE

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

If problems persist, contact the Siemens Healthcare Diagnostics Service.

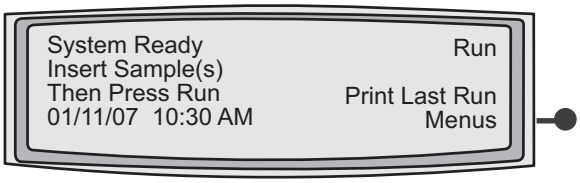
NOTE

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

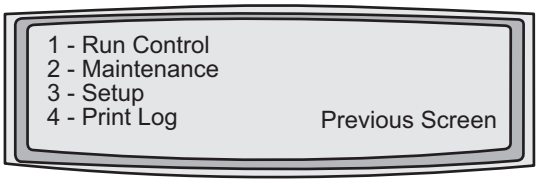
11.3.2 Removing the O-Ring

To remove the O-Ring, proceed as follows:

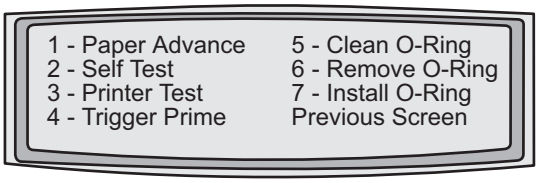
- From the **System Ready** display, press the softkey located next to **Menus**.



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



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



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

- Place the O-Ring service tool into the incubation wells of the instrument so that the cassette is flush with the carousel surface.
- Press the softkey located next to **Continue**.

→ The system will rotate 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 will rotate back allowing the removal of the O-Ring service tool.

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

- Invert the O-Ring service tool and tap against the palm of your gloved hand to remove the O-Ring. Follow the manual O-Ring cleaning or replacement procedure.

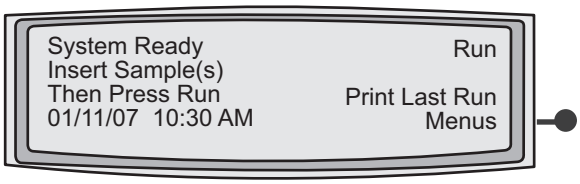
11.3.3 Installing the O-Ring

To install an O-Ring, proceed as follows:

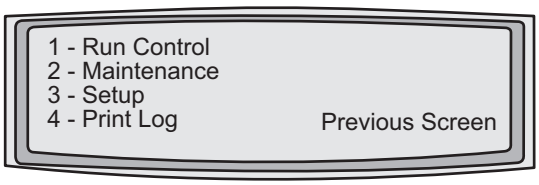
NOTE

- To minimize dirt or 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.

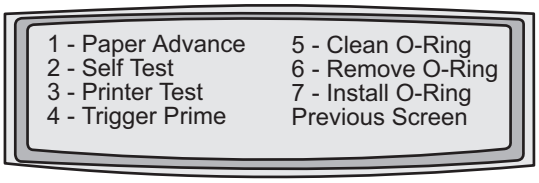
- From the **System Ready** display, press the softkey located next to **Menus**.



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



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



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

- Load O-Ring in position **B** of the O-Ring service tool.
- Place the O-Ring service tool into the incubation wells of the instrument so that the cassette is flush to the carousel surface.
- Press the softkey located next to **Continue**.

→ The system will rotate 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 will rotate back allowing the removal of the O-Ring service tool.

- Remove the O-Ring service tool and press the softkey located next to **Continue**.
- Perform the **Self Test** from the **Maintenance** menu to verify that the system has no vacuum leak.

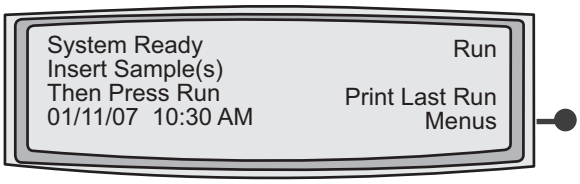
When performing the self test to ensure proper installation of the O-Ring, it is not necessary to insert a cleaning pad.

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

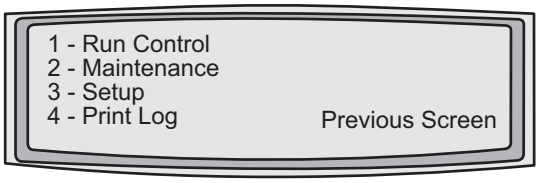
11.3.4 Cleaning O-Ring using cleaning pads

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

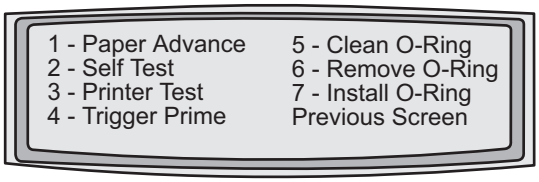
- Locate the cleaning pads (circular foam sponge) provided with the instrument.
- From the **System Ready** display, press the softkey located next to **Menus**.



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



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



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

- Place the cleaning pad in the well and apply 4-5 drops of isopropanol to the center of the pad.
- Press gently on the pad with gloved index finger 2-3 times to help distribute isopropanol.
- Press the softkey located next to **Continue**.

→ The system will turn the carousel to the test cartridge loading position and bring the O-Ring in contact with the cleaning pad.

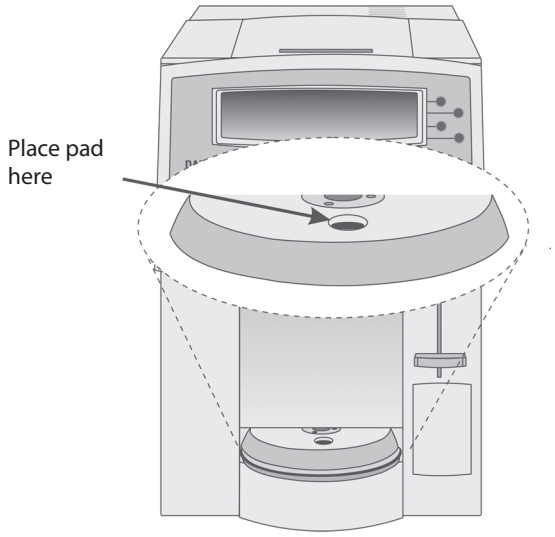


Figure 11-2 Cleaning pad compartment

→ After approximately 30 seconds, the carousel will rotate back allowing the removal of the pad.

- Dispose of the pad in a suitable biohazard container.

- Press the softkey located next to **Continue**.
- To return to the **System Ready** display, press the softkey located next to **Previous Screen** twice.

NOTE

The self test must be performed from 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.

11.4 Replacing printer paper

To replace the printer paper roll, proceed as follows:

- Pull open the door located on the top of the instrument to access the printer.
- Remove the empty roll of printer paper.

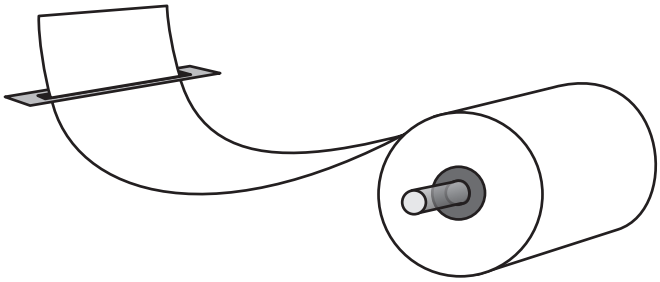


Figure 11-3 Printer paper roll

Any standard 58 mm wide paper used in calculators or cash registers (refer to the consumables list in Chapter 6.2) can be used on the printer.

- Obtain a new roll of printer paper.
- Place the spindle through the paper roll and snap it into the paper holder. The paper must unroll from the top.
- Make sure the edge of the paper is cut straight, if necessary cut the paper.
- Engage the paper into the printhead, between the metallic support of the printhead and the printhead itself.

- Push the paper inside the printhead.

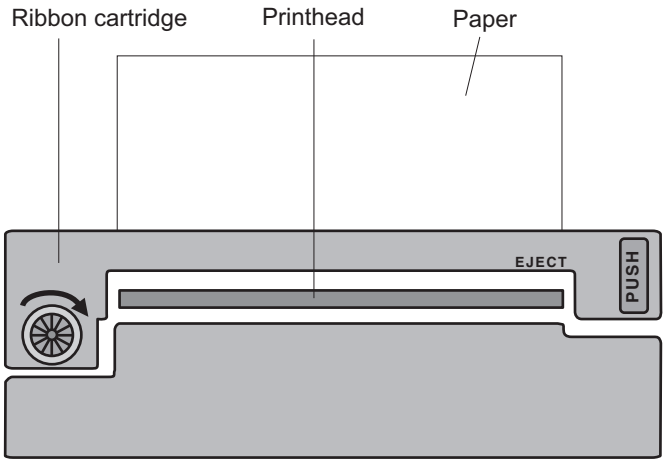
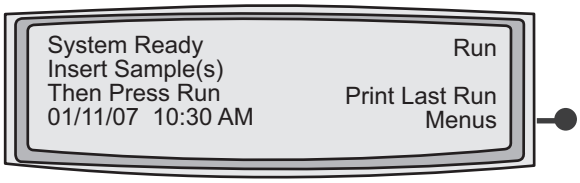
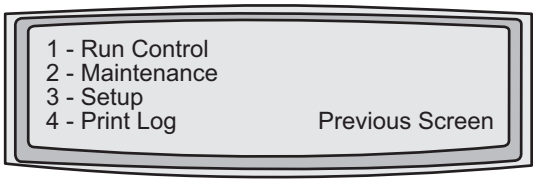


Figure 11-4 Printer ribbon

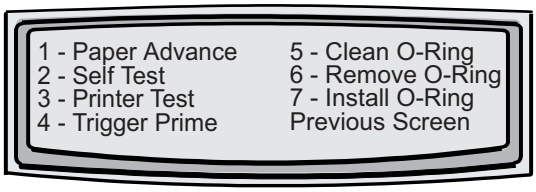
- From the **System Ready** display, press the softkey located next to **Menus**.



- From the **Menu** display, press the numeric key **2** to select the **Maintenance** option.



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



- Press the softkey located next to **Load** to advance the paper into the printer.
- Press the softkey located next to **Ready Screen** to return to the **System Ready** display.

- Pass the paper through the door slot. If additional paper length is needed, the paper can be manually pulled through the printer.
- Close the top door.

11.5 Replacing printer ribbon

To replace the printer ribbon, proceed as follows:

- Pull open the door located on the top of the instrument to access the printer.
- Remove the paper from the printhead by pulling the paper back toward the paper roll.
- Push down on the right side of the printer ribbon cartridge marked **PUSH** to eject the printer ribbon from the printer (refer to Figure 11-4).
- Obtain a new printer ribbon (refer to the consumables list in Chapter 6.2).
- Place the left side of the printer ribbon into the wheel located on the left side of the printhead.
- Push the right side of the printer ribbon in place.
- If necessary, press the circle located on the left side of the printer ribbon and turn clockwise to adjust the printer ribbon inside the printhead.
- Replace the printer paper (refer to Chapter 11.4).

11.6 Replacing fuses

To replace fuses on the instrument, proceed as follows:

CAUTION



To prevent electric shock, the instrument must be unplugged before replacing fuses.

- Set the power switch to **off**.
- Unplug the power cord.
- Using a small-blade screwdriver, open the fuse compartment and remove the fuse holder.
- Place the fuse holder face down with the fuses facing up.

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

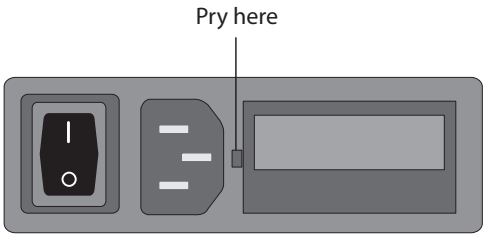


Figure 11-5 Fuse compartment

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

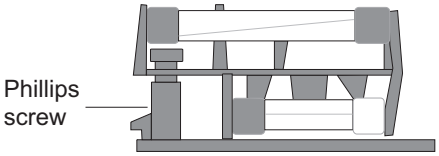


Figure 11-6 Phillips screw

- Remove the fuse holder by sliding up and away from the Phillips screw.
- Rotate the fuse holder so the desired fusing arrangement is facing up.
- Slide the fuse holder back onto the Phillips screw; then tighten the screw.
- Put the fuse holder assembly back in the housing. Push in all the way.
- Plug in the power cord and set power switch to **on** to resume testing.

1 About this document

2 Safe handling

3 Delivery and installation

4 Quick reference guide

5 Service and warranty

6 Description of the instrument

7 Setup and changing configuration

8 Performing tests

9 QC procedures

10 Cleaning and disinfection

11 Maintenance

12 Diagnostics and troubleshooting

Chapter Overview

12 Diagnostics and troubleshooting

12.1 Power on diagnostics

When turning the power on, the instrument 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 instrument parameters remain unchanged.

The instrument 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 instrument detects a problem, an error message is displayed and printed, and in some cases the instrument is disabled to prevent erroneous results. Refer to Chapter 12.5 to take the appropriate action if a problem occurs.

The diagnostics tests are performed in the following sequence:

Memory test

The memory test consists of two 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** will be displayed and printed.

Vacuum chuck

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

Carousel drive

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

Trigger system

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

Incubation system

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

12.2 Self test

When the instrument performs the **Self Test**, the system will perform 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 instrument 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** will be displayed and printed. If a problem is detected, an error message will be displayed and printed and the system will prevent the running of a test. Refer to Chapter 12.5 to take the appropriate action if a problem occurs.

```
                PFA-100
                Self Test
REV. 3.0      S/N: 99031

01/11/07      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     : P2Y
Low Flag      :          0
High Flag     :        300

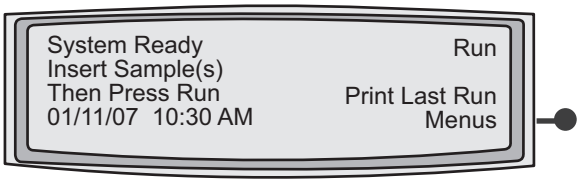
Test type     : Collagen/ADP
Low Flag      :          0
High Flag     :        300
```

Figure 12-1 Status messages list

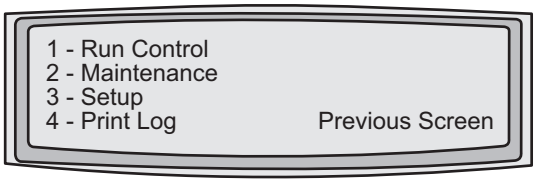
12.3 Printing error log

The PFA-100 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:

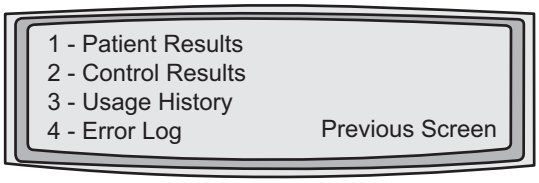
- From the **System Ready** display, press the softkey located next to **Menus**.



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



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



→ The system will print the serial number and the software version of the instrument, followed by the error messages (maximum of the last 25) with the date and time at which they occurred.

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

12.4 Displaying test results

When testing is complete, the instrument will display the result(s) 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.



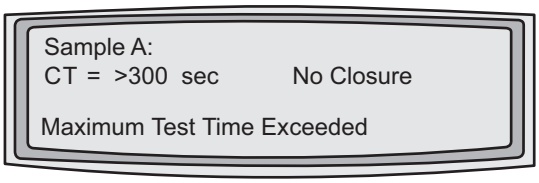
In case no closure is detected during a test until

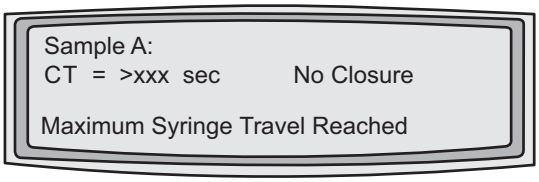
– the maximum test time has been reached

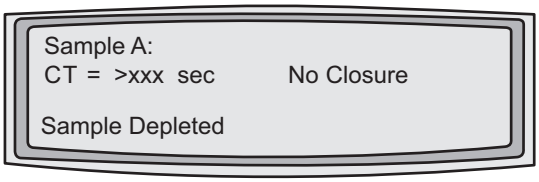
– the pressure syringe has reached its maximum

– the sample is depleted

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







NOTE

Refer to Chapter 12.5 and Chapter 12.6 for full explanation of the status messages shown above.

12.5 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 test cartridge. The instrument flags the event or condition with a **>** sign followed by the time of the event or condition and a description of the event.

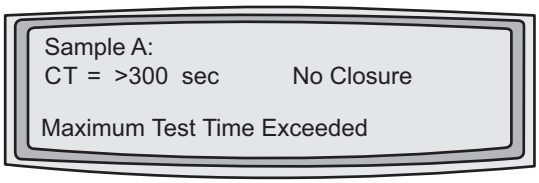
Test terminated due to flow obstruction (see Table 12-3)



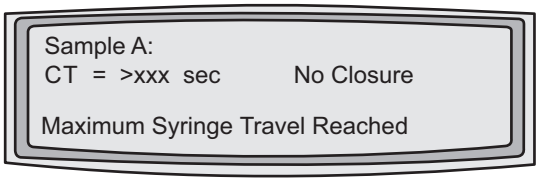
Test terminated due to air leak (see Table 12-2)



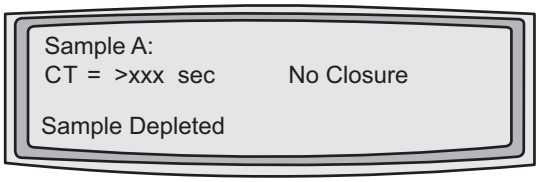
Maximum test time exceeded (see Table 12-1)



Test terminated due to maximum syringe travel (see Table 12-5)



Test terminated due to insufficient sample (see Table 12-4)



12.5.1 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 instrument causing a NC Defective test cartridge	If a NC is obtained with a normal donor control or the result does not agree with the patient's clinical history, a possible vacuum leak may be suspected. • Perform a **Self Test** via the **Maintenance** menu without loading the cleaning pad. This will test if dirt or debris on the O-Ring is the cause of the vacuum leak. If self test passes, a defective 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 the Siemens Healthcare Diagnostics Service. • Rerun the sample with new cartridge to verify the test result. If daily **Self Test** ok, then most likely this is an abnormal sample.	Report as **CT >300 sec**, abnormal platelet function as confirmed by retest.

Table 12-1 Maximum Test Time Exceeded

12.5.2 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 instrument 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 instrument or a malfunctioning trigger solenoid pump No sample in test cartridge Air entrapped in test cartridge when sample was loaded Defective test cartridge	• Verify that sample was added to 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 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 Service. • Prime system from **Maintenance** menu. • Rerun the test with a new cartridge and sample.	Non-reportable

Table 12-2 Test Terminated Due To Air Leak

12.5.3 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 instrument 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. Refer to the instructions for use (Limitations of Procedure section) for further information.	Initial Flow Obstruction This type of flow obstruction occurs when the instrument detects a failure to establish initial blood flow rate specifications subsequent to the first 30 seconds of testing. The instrument 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 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 instrument at the time the flow obstruction occurs; i.e. **> 80 SEC. FLOW OBSTRUCTION**. This type of flow obstruction occurs when the capillary or the test cartridge membrane aperture is suddenly plugged by micro aggregates that may form during the test or by particulates introduced into the sample or test cartridge from the environment. Defective test cartridge	• Verify that the sample does not contain clots or aggregates. If no aggregates are visible, repeat once to rule out a defective 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 Service.	Non-reportable

Table 12-3 Test Terminated Due To Flow Obstruction

12.5.4 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 instrument 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 test cartridge. Sufficient sample was loaded in the test cartridge but closure of the aperture did not occur due to platelet dysfunction and/or low sample viscosity (↓hematocrit, high sedimentation rate).	• Verify that 800 µL was added to the cartridge. Rerun sample using 900 µL. • Verify sample hematocrit is within normal range. Refer to the instructions for use (Limitations of Procedure section) for further information. An abnormal hematocrit may impair platelet function and result in prolongation of the closure time. Platelet dysfunction in combination with low hematocrit will often induce 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 will most likely result in a closure time > 300 sec. • The test cartridge cup serves as the receptacle where blood is collected after it passes through the membrane aperture. During a test, the instrument 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 (i.e. abnormal hematocrit and/or low platelet count) and suspicion of platelet dysfunction.

Table 12-4 Test Terminated Due To Insufficient Sample

12.5.5 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 instrument 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 cartridge but closure did not occur due to platelet dysfunction and/or low viscosity (↓hematocrit, high sedimentation rate). A defective test cartridge causing a small vacuum leak Dirt or debris is present on the vacuum seal between the instrument and the test cartridge, causing a small vacuum leak. Instrument 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 instrument 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. Refer to the instructions for use (Limitations of Procedure section) for further information. An abnormal hematocrit may impair platelet function and result in prolongation of the closure time. Platelet dysfunction in combination with low hematocrit will often induce 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 will most likely result in a closure time > 300 sec. 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 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.

Table 12-5 Test Terminated Due To Maximum Syringe Travel

12.6 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 test cartridge, cassette or any other cause generating the obstruction. • Press the softkey located next to **Retry**.
MAJOR SYSTEM ERROR	If the message occurs after a measurement: Step error on carousel drive might have caused a cartridge misidentification.	• Do not report the result, unless correct cartridge identification has been verified. • If the problem persists, contact Siemens Service.
	Something is preventing the carousel from rotating.	• Perform a reset by turning the instrument off and then on again. • If the problem persists after three retries, contact Siemens Service.
INCUBATION SYSTEM FAIL	The heater block is not heating properly.	• Contact Siemens Service.
MAIN MEMORY ERROR	An error occurred in the system operating program.	• Perform a reset by turning the instrument off and then back on. • If the problem persists, contact Siemens 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 instrument keypad.
TYPE CODE CALIBRATION REQUIRED	The instrument has detected a problem with the type code sensor.	• Contact Siemens Service.
AIL CALIBRATION REQUIRED	The instrument has detected a problem with the **A**ir-**i**n-**L**ine sensor.	• Contact Siemens Service.
PREVIOUS TRIGGER PRIME CANCELLED-PRIME SYSTEM FROM MAINTENANCE MENU	The instrument has detected that a trigger priming sequence has not been successfully completed.	• Refer to Chapter 11.2 for instructions.
PRINTER FAIL	The printer cannot be initialized by the instrument.	• Contact Siemens Service.

Table 12-6 Status messages

Status messages	Causes	Solutions
RAM MEMORY ERROR	The instrument has detected a problem with the area of memory used for storage of data and system information.	• Contact Siemens Service.
SYRINGE PUMP DRIVE FAIL	The instrument has detected a problem with the movement of the syringe pump.	• Perform a reset by turning the instrument off and then back on. • If the problem persists, contact Siemens 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 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 test cartridge lot number required for control.
INVALID CARTRIDGE TYPE DETECTED	The test cartridge loaded to perform a test is not a valid test cartridge type (e.g. Collagen/ EPI, Collagen/ADP or INNOVANCE PFA P2Y). The instrument has detected an invalid test cartridge due to a defective type code slot or sensor.	• Make sure a valid test cartridge type is being used • Rerun the sample using a new test cartridge. If the problem persists, contact Siemens Service.
TRIGGER SYSTEM FAIL	Air was detected coming from the trigger solution bottle after three successive attempts to prime the instrument.	• Make sure the trigger solution bottle is full. • Perform a reset by turning the instrument off and then back on. • If the problem persists, contact Siemens Service.

Table 12-6 Status messages (Continued)

Status messages	Causes	Solutions
VACUUM CHUCK DRIVE FAIL	The instrument has detected a problem in the movement of the vacuum chuck drive.	• Perform a reset by turning the instrument off and then back on. • If the problem persists, contact Siemens Service.
VACUUM TEST FAIL	The instrument has detected a leak in the vacuum system during a self test initiated from the **Maintenance** menu. The reasons can be: – Dirt or debris on the O-Ring seal – A possible vacuum leak in instrument	• Remove O-Ring via the **Maintenance** menu. Inspect O--Ring for dirt, 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 instrument has no vacuum leak. • If the problem persists, contact Siemens Service.
VACUUM SYSTEM FAILED IN SELF TEST	The instrument has detected that a self test has not been successfully completed due to a failure in the vacuum leak test.	• Refer to **Vacuum Test Fail** status message.
FSE TSK: XX ADDR: XX	The instrument has detected a problem with the functioning of the software.	• Perform a reset by turning the instrument off and then back on. • If the problem persists, contact Siemens Service.

Table 12-6 Status messages (Continued)

Index

A

abbreviation 1-2
- AIL (Air-in-Line) 12-11
- NC (non-closure) 12-6
- PID (patient identification) 7-7
- UPS (uninterruptible power supply) 3-9

access door 3-15

accessories 3-1, 3-4

AIL calibration 12-11

air leak 12-7

audible keys
- see keys

B

barcode scanner 2-3, 6-8

barcode scanner port 6-8

biohazard waste
- cartridge 2-4
- cleaning pad 11-7
- consumables 2-7
- O-Ring 11-4

C

carousel 6-2
- carousel drive 12-1, 12-11

carousel drive failure 12-11

cartridge
- cartridge capacity 6-7
- cartridge type 6-6
- insertion into the instrument 6-2, 8-2
- location of lot number 9-5
- priming cartridge 3-1, 3-6, 7-1
- quality control 9-1
- test cartridge 6-2, 8-2

cassette 3-5, 6-2

cleaning 10-1
- see also disinfection
- cleaning pad 3-6, 9-2
- manual O-Ring cleaning 9-1, 11-3, 11-6
- self test O-Ring cleaning procedure 9-2, 12-1

consumables 6-5
- labels 6-5
- ordering information 5-2
- parts list 6-6
- trigger solution 3-4
- warranty 5-2

control mode 9-1
- Run Control 9-1, 9-4

control results 6-8, 9-1
- see also test results
- printing 9-6

D

date format 7-5

decommissioning 3-17

decontamination
- see disinfection

disinfection 10-1
- isopropanol 4-1, 9-2, 11-5, 11-7

dispensing trigger solution 9-1

display
see LCD-display

disposal
cartridge 2-4, 2-7, 4-2
consumables 2-7
instrument and instrument components 5-3

download of data 6-8

duplicate test 8-4
see also tests

E

error log 12-2

error messages
see status messages

F

flow obstruction 12-8

FSE TSK XX ADDR XX 12-13
see also status messages

functions of the instrument 2-1
function units 6-1

fuse 3-5, 3-10, 6-7, 11-10
configuration 3-11, 11-11
fuse compartment 3-10, 11-11
fuse holder 3-11
installation 3-10
ordering information 5-2
replacement 11-10
safe handling 2-4, 2-5

G

general specifications 6-7

H

high flag 7-8

humidity 6-7
operating conditions 3-8
storage and transportation conditions 3-7
see also specifications

I

incubation
power on diagnostics 12-1
system failure 12-11

incubation time 6-7

incubation well 6-2
temperature 6-7
warm-up time 6-7

installation check 3-17

insufficient sample 12-9

intended use 2-1

interface
connector 6-8, 6-10
protocol 6-8

invalid cartridge type 12-12

K

keys 6-1
audible tones/sound 7-10
numeric keys 6-4

softkeys 6-1, 6-4

L

label
bar code 6-8
consumables 6-5
laboratory bench top
see worktop
language 7-3
LCD display 6-3
contrast adjustment 6-4
display saver 6-3
limit values
see reference range
logbook
see error log
test results 8-9
usage history 8-10
low flag 7-8

M

main memory error 12-11
main switch
see power switch
maximum current
see power
maximum PID length exceeded 12-11
maximum syringe travel 12-10
see also status messages
maximum test time exceeded 12-6
see also status messages
MEAN value 8-7
memory
main memory error 12-11
memory test 9-2, 12-1
RAM memory 12-12

N

non-operation 3-17
numeric keys
see keys

O

operating conditions 3-7
operating voltage 3-9, 6-7
order number
see consumables
ordering information 5-2
O-Ring 3-4, 4-1
cleaning pad 3-6, 11-6
cleaning pad compartment 11-7
installing 11-5
manual cleaning 9-1, 11-3, 11-6
replacement 11-4
self test cleaning procedure 9-2, 12-1
service tool 3-7, 11-5

P

parallel testing
see duplicate test
part number
see consumables

see trigger solution

patient identification number (PID) 7-7
failure of entry 8-5
setup patient identification request 7-7
test with PID 8-3
test without PID 8-5

patient results 6-8, 7-8
printing 8-9
see also test results

PID 12-11

pin assignment 6-10
see also interface

platelet dysfunction 2-1
excess of maximum time 12-6, 12-10
hematocrit 12-9, 12-10
insufficient sample 12-9
principle of analysis 6-10

power
maximum current 6-7
power consumption 6-7
power cord 3-6, 3-12
power supply 3-9
power switch 3-14, 4-1, 4-3, 6-9, 10-2
switch off 4-2
switch on 4-1

previous trigger prime cancelled 12-11

priming cartridge 3-6, 7-1
see also ordering information

printer 6-4
failure 12-11
paper 3-14, 6-8
paper roll 3-7, 3-12, 11-8
paper roll axle 3-5, 3-13
printhead 3-13, 11-8
ribbon 3-6, 6-8, 11-9, 11-10
type 6-8

protective equipment
gloves 2-6, 4-1, 4-2, 11-3

R

RAM memory error 12-12

range of application
see intended use

range of values
see reference range

reference range 7-8
see also status messages

repair service
see Siemens Service

results
see test results

S

safety standards 2-2
instructions 2-3

sample 4-2, 8-1
collection 8-2
duplicates 8-2, 8-4, 8-6
insertion into test cartridge 8-3
insufficient sample 12-9
low sample viscosity 12-9, 12-10
maximum sample volume 6-7
quality control sample 9-1

self diagnostics 12-1

self test 2-7, 4-1, 9-1, 11-2, 11-4, 12-1

Siemens Service 5-1

single test 8-3
see also tests

softkeys
see keys

software
setup 7-2
software update card 12-1
software upgrade slot 6-9
update 5-1, 6-8

sound pressure level 6-7

spare parts
see consumables

specifications
electrical 6-7
environmental 6-7
general 6-7
physical 6-6

status messages
air leak 12-7
flow obstruction 12-8
insufficient sample 12-9
maximum syringe travel 12-10
other status messages 12-11
reference range 12-9
test time exceeded 12-6

storage conditions 3-7, 3-17

switching off 4-2

switching on 3-14, 4-1

symbols 1-2, 2-4, 6-5

syringe 6-11
maximum syringe travel 12-10
syringe pump drive 12-12
syringe pump drive fail 12-12

system test
see self test

T

technical specifications
see specifications

temperature
incubation well 6-7
label 6-5
operation 3-8
storage and transportation 3-7
test cartridge 9-4

test cancelled 12-12

test results
control results 6-8
CV% 8-4, 8-7
displaying 12-3
mean value 8-4, 8-7
patient results 6-8
ranges 7-8
stored results 6-8

tests
duplicate test 8-4, 8-6
single test 8-3, 8-5

time format
12-hour format 7-4
24-hour format 7-5

transmission of data to host PC
see download of data

transportation conditions 3-7, 3-17

trigger solution 3-4, 5-2
ordering information 3-4
priming 4-2
replacement 11-1

residual solution 11-1
spiking needle 2-4
trigger bottle door 2-4
trigger solenoid pump 12-7
trigger solution bottle 2-4, 3-15
trigger solution compartment 6-3
trigger system 12-1, 12-11, 12-12
trigger system fail 12-12

trigger solution dispensing 9-1

troubleshooting 12-1
see also status messages

type code calibration 12-11

U

used test cartridges
see disposal

V

vacuum chuck 12-1
vacuum chuck drive fail 12-13

vacuum leak 12-6, 12-7
see also self test

vacuum leak test 12-1
see also vacuum test

vacuum set point 6-7

vacuum system failed 12-13

vacuum test 12-2
see also self test
vacuum test cup 3-5
vacuum test fail 12-13

voltage
fluctuations 3-8
operating voltage 6-7
overvoltages 3-8
supply voltage 3-9

W

warranty 5-1

waste disposal
see disposal

wearing parts
see consumables

worktop 3-8