ANYSIS™ System

For Anysis Instrument (Model: ANYSIS-300, ANYSIS-300S),
Anysis C/EPI Test Cartridges, Anysis C/ADP Test Cartridges,
Anysis Aspirin Test Cartridges, or Anysis P2Y12 Test Cartridges

User Manual

CE

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We reserve the right to make changes in the course of technical development without previous notice.

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CHAPTER OVERVIEW

1 Introduction

2 Safety and Handling

3 Delivery, Storage, and Disposal

4 Description of the Hardware

5 Description of the Software

6 Configuring the System

7 Preparing for the Analysis

8 Performing the Analysis

9 Finishing the Analysis

10 Cleaning the System

11 Performing Maintenance

12 Troubleshooting

13 Appendix

TABLE OF CONTENTS

1 Introduction 8

1.1 Document Orientation 8

1.2 Service 9

1.3 Warranty 9

1.4 Order Information 10

2 Safety and Handling 11

2.1 Intended Use 11

2.2 Operator Qualifications 11

2.3 General Safety Information 12

2.3.1 Safe handling of the instrument 12

2.3.2 Safe handling of blood samples, reagents, and test cartridges 13

2.4 Quality Control 14

2.5 Safety Messages 14

2.5.1 Signal words in safety messages 15

2.5.2 Structure of safety messages 15

2.6 Symbols 16

2.6.1 Symbols on the instrument box 16

2.6.2 Symbols on test instrument 17

2.6.3 Symbols on test cartridge box 19

2.6.4 Symbols on test cartridges 21

2.7 Statuary Requirements 22

2.8 Obligations of the System User 23

3 Delivery, Storage, and Disposal 24

3.1 Delivery 24

3.1.1 Unpacking and checking the delivery 24

3.1.2 Scope of delivery 24

3.2 Installation 25

3.3 Storage 26

3.4 Disposal 26

4 Description of the Hardware 28

4.1 Test Instrument 29

4.1.1 Cartridge tray 29

4.1.2 Touch screen 29

4.1.3 QR / Barcode scanner 30

4.1.4 Printer / printer paper slot 30

4.1.5 Ports, power switch, and fuses 30

4.2 Connection of External Devices 31

4.3 Accessories 31

4.3.1 USB flash drive 31

4.3.2 Printer paper 31

4.4 Test Cartridges 31

5 Description of the Software 32

5.1 Overview 32

5.2 Analysis Screen 33

5.3 Result Screen 34

5.4 Maintenance Screen 35

5.5 User Rights 36

6 Configuring the System 37

6.1 Setting the Date and Time 38

6.2 Managing User Accounts 38

6.3 Further Configurations 38

7 Preparing for the Analysis 39

7.1 Sample Collection 39

7.1.1 Sample collection precautions 39

7.2 Preparing the Test Cartridges 40

7.3 Starting the System 40

7.4 Logging In 41

7.5 Performing Quality Control 41

8 Performing the Analysis 43

8.1 Measuring Patient Samples 43

8.1.1 Manually entering the test information 43

8.1.2 Scanning the test information 44

8.1.3 Loading patient samples 44

8.1.4 Performing the test 45

8.1.5 Stopping a test 46

8.1.6 Removing used cartridges with samples 46

8.2 Managing Results 46

9 Finishing the Analysis 48

9.1 Logging Out 48

9.2 Shutting Down the System 48

10 Cleaning the System 49

10.1 Cleaning the System 49

11 Performing Maintenance 50

11.1 Periodic Maintenance 50

11.2 Printer 50

11.2.1 Reloading printer paper 50

11.2.2 Advancing printer paper 52

12 Troubleshooting 53

12.1 Installing Fuses 53

12.2 Other Hardware-Related Troubleshooting 53

12.3 Error Messages 53

12.3.1 Common error messages 53

12.3.2 Warning messages 65

12.3.3 Additional alerts 66

13 Appendix 68

13.1 Principle of the System 68

13.2 Technical Specifications 69

13.3 Manufacturer Catalog 70

13.3.1 Spare parts and accessories 70

INTRODUCTON

This manual describes the use of the RheoMeditech Anysis™ System in clinical laboratories.

Note: Depending on the operating system, the selected languages, and regional settings, the screenshots in this manual may differ from the display on your screen.

This chapter gives information regarding document orientation, service, and warranty.

1.1 Document Orientation

Bullets

Bullets indicate a list.

Example:
The ANYSIS™ System is capable of running:

- The ANYSIS™ C/EPI Test
- The ANYSIS™ C/ADP Test
- The ANYSIS™ Aspirin Test
- The ANYSIS™ P2Y12 Test

Numbers

Numbers indicate a procedure.

Example:

1. Turn on the instrument.
2. Insert the cartridge.
3. Run the assay.

Arrow

Arrows indicate one or more results of an action.

Example:

- Turn on the instrument → The Self-Test (ST) automatically begins.

Bold type

Terms used in the software are printed in **bold type**.

Example:

- Press **Start**.

Bold type is also used to apply emphasis.

Example:

Note: Do not shift the test cartridge once the test trial has been initiated.

Gray note

Gray notes indicate important background information.

Example:

> **Note: Do not** shift the test cartridge once the test trial has been initiated.

1.2 Service

RheoMeditech and its representatives are available to repair the system after installation during customary local office hours. Should you require service at any other time, contact the RheoMeditech Tech Service. You will receive information about how to reach the RheoMeditech Tech Service when the system is installed.

To reduce complications involved with the hardware, RheoMeditech does not allow the operator to neither troubleshoot hardware-related problems nor perform instrument calibrations. To calibrate the Anysis™ Instrument (including, but not limited to concerns regarding the touch screen, vacuum system, motor system, thermoregulation, etc.), contact RheoMeditech Tech Service.

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

1.3 Warranty

RheoMeditech and its representatives guarantee that the system does not show any defects after the installation and during operation if operated as explained in this user manual. For further information regarding the warranty offered, contact the RheoMeditech Tech Service.

The warranty is not valid for damages that incur because of non-observance of this user manual.

Repairs and maintenance must only be carried out by persons authorized by RheoMeditech.

Improper interventions on the analyzer can void the warranty, and the operator becomes responsible for the service fees regarding the damage that result from the intervention.

Limited Warranty on Wear and Tear Parts

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

- Printer paper
- Fuses
- WQC solution

1.4 Order Information

Only original RheoMeditech components and spare parts must be used. Order these from your RheoMeditech representative.

For ordering information, see the RheoMeditech product catalog.

SAFETY AND HANDLING

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

2.1 Intended Use

The Anysis™ test is based on platelet aggregation-induced occlusion mechanism. Activated platelets tend to bind to fibrinogen-coated microparticles, which are densely packed in a microtube and subsequently recruit additional activated platelets. Accumulated platelet aggregation in the microbeads section leads to occlusion of blood flow. Then, Anysis™ determines the final migration distance (MD) of blood flow in a microtube.

The instrument measures and reports the final MD in a millimeter unit, which does not require any calculations or conversions. The platelet adhesion and aggregation to thousands of microbeads packed in a microtube result in rapid and reproducible results if the platelets are activated.

If the system is used in any other way than intended:

- All safety precautions may be ineffective.
- RheoMeditech disclaims all liability for all personal injury or damage to the system which might occur.

System Functions

The system functions are:

- Incubating the samples
- Scanning the QR / barcode of test cartridges, samples, etc.
- Maintaining the designated pressure within the test cartridge
- Aspirating the sample into the migration tube of the test cartridge
- Automatically pushing out the test cartridge from the cartridge tray
- Displaying test results
- Printing test results

2.2 Operator Qualifications

The system must be operated only by persons whose skills, knowledge, and practical experience qualify them to do so, and who have been trained in his or her operation.

2.3 General Safety Information

This analyzer has been inspected before shipment for technical safety. 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.

2.3.1 Safe handling of the instrument

Operational Safety

To ensure safe handling of the instrument, the following instructions on operational safety must be observed:

- Make sure the conditions described in *Environmental* on Chapter 13.2 are met.
- Only use RheoMeditech instrument components.
- Never operate the instrument in an environment containing explosive mixtures of oxygen, hydrogen, or other flammable gases.
- If there is visible damage to the analyzer, it must be switched off and secured against accidental operation.

Electrical Safety

To ensure safe handling of the instrument and to avoid serious risks such as electric shock or damage by short-circuit, the following instructions on electrical safety must be observed:

- Make sure the conditions described in *Electrical* on Chapter 13.2 are met.
- To minimize the danger of an electric shock, only use sockets with a ground contact (earth) for connecting to the mains supply.
- Never disconnect the ground contacts. There is a danger of electric shock when the protective conductor is interrupted inside or outside the analyzer or the ground contact is disconnected from the line.
- Never remove protective guards or fused components because live parts could be exposed. Electrical connections (plugs, sockets, etc.) may be live, that means carry an electric charge. Even when the analyzer is switched off, some components, for example, capacitors, can be live as they may still be electrically charged. All live parts are a potential electric shock source.
- To prevent electric shock, switch off and unplug the analyzer before replacing fuses.
- Never short-circuit the fuse holder.
- All surfaces (for example, floor, worktop) must be dry when you are working at the analyzer.

- To prevent electric shock, never place containers with liquid on top of the analyzer as spilled liquid can come into contact with live parts. If liquid is spilled in the analyzer, disconnect the mains plug.
- Assess the electromagnetic environment prior to operating the analyzer. It corresponds to CISPR 11 class A. In the event of radio interference in domestic settings, measures may be necessary to reduce the interference. The data cable supplied must be used to ensure that the relevant provisions are complied with. If other external devices such as a printer or a network are connected, shielded cables and plugs are essential.
- Do not operate strong electromagnetic transmitters (for example, mobile phones, walkie-talkies, door openers) in the vicinity of the analyzer. Electrical fields may disrupt normal operation of the analyzer.

Mechanical Safety

To ensure safe handling of the instrument, the following instructions on mechanical safety must be observed:

- Keep clear of moving parts when the instrument is in operation.
- To prevent the instrument from tilting or canting due to maladjustment, the worktop must be stable and horizontal. All of the instrument's feet must be in full contact with the worktop.
- To avoid damaging the piercing needle, insert the test cartridge all the way into the cartridge tray.

Precision and Accuracy of Test Results

To ensure the accuracy and precision of test results, RheoMeditech recommends the operator to perform a Self-Diagnosis daily.

2.3.2 Safe Handling of Blood Samples, Reagents, and Test Cartridges

To ensure safe handling of the blood samples, reagents, and test cartridges, the following safety instructions must be observed:

- Do not reuse the test cartridges.
- Refer to instructions for use for a detailed procedure regarding collection and storage procedures for blood samples.

Potentially Infectious Material

Blood samples and reagents, as well as all parts that come into contact with them are potentially infectious. Some reagents can irritate skin and mucous membranes.

- Avoid contact of the skin and mucosa with samples, reagents, and with parts of the instrument which have come into contact with this material.
- Wear appropriate gloves and safety glasses.

Disposal

The test cartridges and blood samples are potentially infectious material.

- Dispose of the test cartridges as described in the appropriate instructions for use.
- Dispose of the blood samples according to laboratory standards and national regulations.

2.4 Quality Control

Self-Diagnosis

The Anysis™ Instrument has a self-diagnostic built-in to verify proper performance. At the instrument startup, Self-Diagnosis will automatically be performed to ensure that the instrument mechanisms are in working order. Self-Diagnosis can be run whenever the operator feels the need to assess instrument performance; See Chapter 7.5.

Wet Quality Control (WQC)

The Wet Quality Control (WQC) is also available for separate purchase for verifying continued performance. It consists of solutions, used in lieu of a patient sample, which are formulated to behave like a whole blood sample at clinically relevant levels. They are individually packaged in tubes (WQC 1, WQC 2) and can be used until the expiration date printed on each WQC box; Refer to Chapter 7.5 for further instructions.

RheoMeditech recommends that the laboratory maintains a hard copy of the Quality Control (QC) results. If enabled by the RheoMeditech service, you can also create PDF files of QC results.

Each laboratory is responsible for the proper storage and retention of printed and electronic QC records.

2.5 Safety Messages

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

2.5.1 Signal words in safety messages

Symbol	Meaning
⚠ DANGER	Indicates a hazardous situation which, if not avoided, **will** result in death or serious injury
⚠ WARNING	Indicates a hazardous situation which, if not avoided, **could**, result in death or serious injury
⚠ CAUTION	Indicates a hazardous situation which, if not avoided, may result in minor or moderate injury
NOTICE	Indicates a property damage message

2.5.2 Structure of safety messages

The following explains the structure of safety messages:

⚠ WARNING

In this section, the nature and source of the hazard are stated.
In this section potential consequences of not avoiding the hazard are stated.

- In this section, preventive actions to be taken are listed.
- Further preventive action
- …

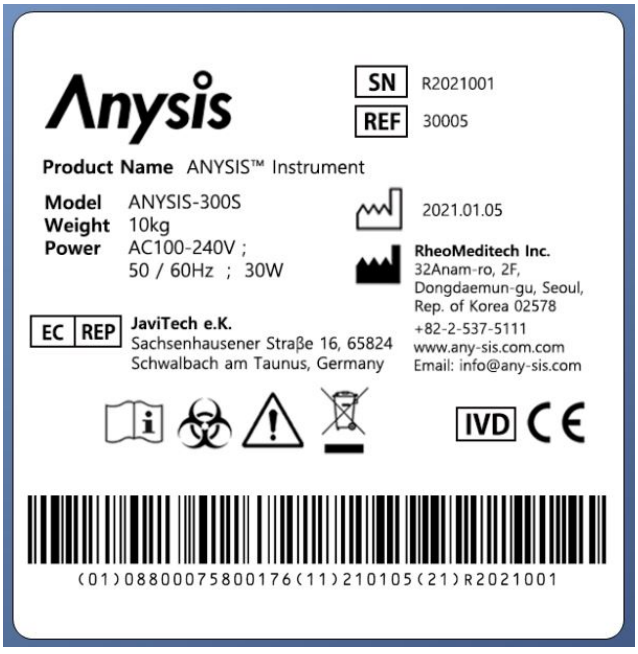
2.6 Symbols

2.6.1 Symbols on the instrument box

Symbol	Meaning
EC REP	European representative
	Consult instructions for use
	Biohazard
	Caution, consult accompanying documents
	Keep Dry
	Waste electrical and electronic equipment The labeled system must not be treated as unsorted municipal waste. Waste electrical and electronic equipment must be collected separately and returned to the manufacturer.

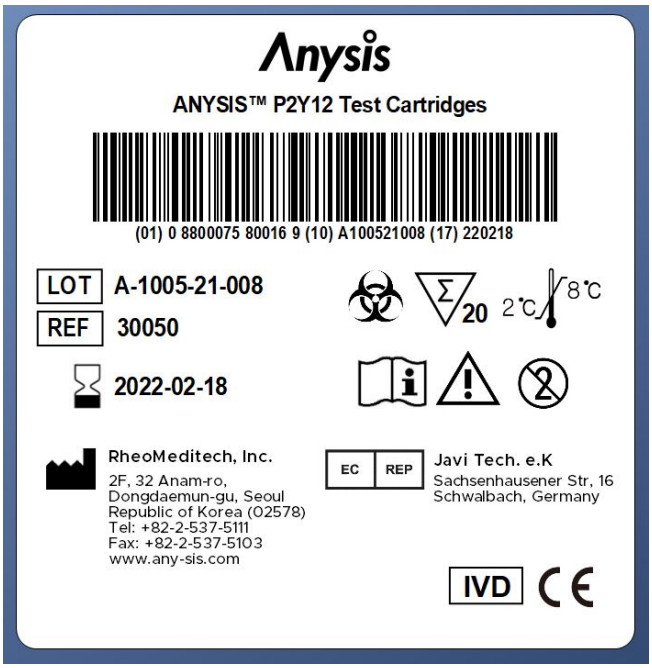
SN	Serial number
REF	Catalog number
	Manufactured date
	Manufacturer
IVD	*In-vitro* diagnostic device
CE	CE certification

2.6.2 Symbols on the instrument



Symbol	Meaning
	European representative
	Consult instructions for use
	Biohazard
	Caution, consult accompanying documents
	Waste electrical and electronic equipment The labeled system must not be treated as unsorted municipal waste. Waste electrical and electronic equipment must be collected separately and returned to the manufacturer.
	Serial number
	Catalog number
	Manufactured date
	Manufacturer
	*In-vitro* diagnostic device
	CE certification

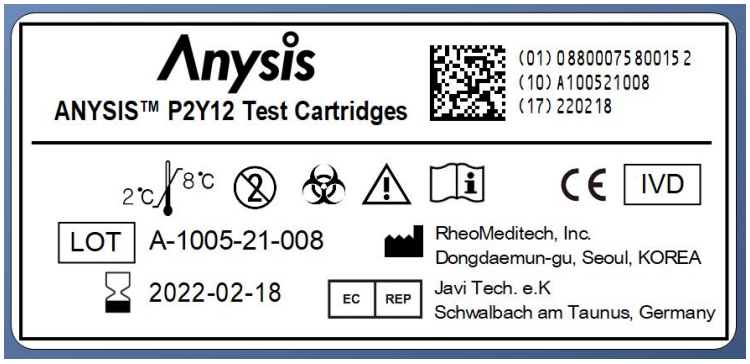
2.6.3 Symbols on test cartridge box

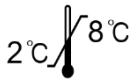


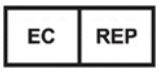
Symbol	Meaning
LOT	Lot number
REF	Catalog number
	Expiration Date
	Biohazard
Σ 20	Sufficient for <n> appliances
2℃ 8℃	Storage temperature range; 2 degrees Celsius – 8 degrees Celsius

	Consult instructions for use
	Caution, consult accompanying documents
	Do not reuse
	Manufacturer
	European representative
	*In-vitro* diagnostic device
	CE certification

2.6.4 Symbols on test cartridges



Symbol	Meaning
	Storage temperature range; 2 degrees Celsius – 8 degrees Celsius

	Do not reuse
	Biohazard
	Caution, consult accompanying documents
	Consult instructions for use
	CE certification
	*In-vitro* diagnostic device
	Lot number
	Expiration Date
	Manufacturer information
	European representative

2.7 Statuary Requirements

CE Conformity

The instrument bears a CE mark, which certifies that the instrument meets the essential requirements of the following European directives:

- *In-Vitro* Diagnostic Medical Devices Directive 98/79/EC
- European Directive on Waste Electrical and Electronic Equipment 2012/19/EU
- Commission Delegated Directive 2015/863/EU
- European Directive on Restriction of Hazardous Substances 2011/65/EU

International Standards

The instrument has been developed, tested, and manufactured in accordance with IEC61010-1, IEC 61010-2-101, IEC55011:2009+A1, IEC61326-1, IEC61326-2-6, IEC61000-3-2, IEC61000-3-3, IEC61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8, IEC 61000-411.

Electromagnetic Compatibility (EMC), Radio Interference Suppression and Immunity to Interference

The instrument has been tested in accordance with IEC61326-1 and IEC61326-2-6. The instrument corresponds to CISPR 11 class A.

2.8 Obligations of the System User

The system owner takes on the obligations arising from the national right to operate *in-vitro* diagnostic medical devices.

DELIVERY, STORAGE, AND DISPOSAL

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

3.1 Delivery

3.1.1 Unpacking and checking the delivery

To unpack and check the delivery, proceed as follows:

1. Before opening, check the transport container for signs of external damage.
2. Open the transport container.
3. Remove the components checklist.
4. Remove the accessory kit.
5. Remove the inflatable / foam packaging.
6. Remove the instrument from the transport container.
7. Remove the plastic wrappings from the analyzer.
8. Open the accessory kit.
9. Check the content for completeness, see the components checklist or Chapter 3.1.2, and intact condition.
10. If there is anything missing or damaged, contact the RheoMeditech Tech Support immediately.

3.1.2 Scope of delivery

The delivery includes:

Instrument Box

- 1 RheoMeditech Anysis™ Test Instrument with 1 Roll of Printer Paper Installed
- 1 RheoMeditech Anysis™ Accessory Kit
- 1 Components Checklist

The accessory kit contains:

- 2 Fuses
- 1 Roll of Anysis™ Printer Paper
- 1 USB Flash Drive with User Manual (PDF)

Note: The following items are required for operation, but not included in the delivery, and must be ordered separately:

- Power Cord (country-specific)
- Anysis™ Test Cartridges

Instruction Manual (as an option)

- 1 Hard Copy of RheoMeditech Anysis™ System User Manual (language-specific)

3.2 Installation

To install the system, proceed as follows:

1. Make sure that the electrical and environment conditions are met, see *Electrical* and *Environmental* on Chapter 13.2.

⚠WARNING

Misdiagnosis by shortened closure times due to strong vibrations
Death or serious illness may result

- Do not position the system close to where strong vibrations are generated, for example, large centrifuges.

2. Make sure that the following requirements for the location of the system are fulfilled:
   - Access to a single power outlet within 150cm
   - No direct exposure to sunlight

Load Printer Paper

3. Load printer paper, see *Load Printer Paper* on Chapter 11.2.1.
4. Review the Anysis™ user manual, which is stored in the USB flash drive as a PDF file.

Connect External Devices

5. If you want to save PDF files with test results, plug the USB flash drive into a USB port and contact the RheoMeditech Tech Support with regard to enabling the creation of PDF files.

Connect Power Source

6. Plug the power cord into the back of the instrument.
7. Plug the power cord into the power outlet.
8. Launch the system, see Chapter 7.2. The system will automatically perform a self-diagnosis.

Launch System

9. Log in as administrator, see Chapter 7.3. The preset user account and the password are listed in the following table.

User ID	Password	User Group
User	0000	User

Configure System

10. Configure the system according to the needs of the laboratory, see Chapter 6.

Note: When configuring the system:
- Change the preset administrator password, see Chapter 6.2

Perform Wet Quality Control (WQC) (optional)

11. Perform WQC prior to testing and beginning a new test session, see Chapter 7.5.

3.3 Storage

To prepare the system for storage, proceed as follows:

1. Remove the blood sample, see Chapter 8.1.5.
2. Log off, see Chapter 9.1.
3. Shut down the system, see Chapter 9.2.
4. Pull out the power cord from the power outlet.
5. Unplug the power cord from the instrument port.
6. Disinfect the system, see Chapter 10.2.
7. Make sure that the storage location meets the non-operating storage conditions, see *Environmental* on page 13-4.
8. Carefully transport the system to the storage place.

3.4 Disposal

The disposal of the system is regulated by Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE), and corresponding national transpositions.

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

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

NOTICE

Pollution by improper waste disposal
Damage to the environment may result
- Do not treat electrical and electronic equipment as unsorted municipal waste.
- Collect waste electrical and electronic equipment separately and return them to RheoMeditech.

To dispose of the system, proceed as follows:

1. Put the system out of operation, see Chapter 3.3.

2. Contact the RheoMeditech Tech Support regarding the disposal of the system.

DESCRIPTION OF THE HARDWARE

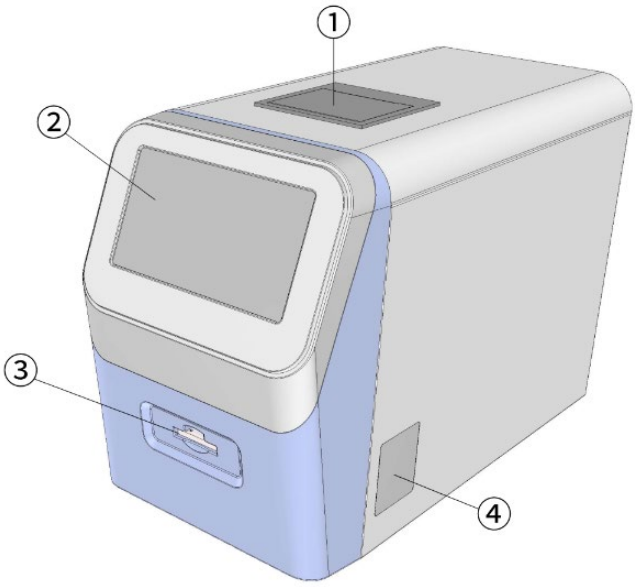
This chapter describes the components of the system and their functions, as well as other materials involved with the components.

4.1 Test Instrument

The instrument consists of the following components:

- Cartridge tray, see Chapter 4.1.1
- Touch screen, see Chapter 4.1.2
- QR / barcode scanner, see Chapter 4.1.3
- Printer / printer paper slot, see Chapter 4.1.4
- Ports for external devices, see Chapter 4.1.6
- Power outlet, power switch, and fuses, see Chapter 4.1.6

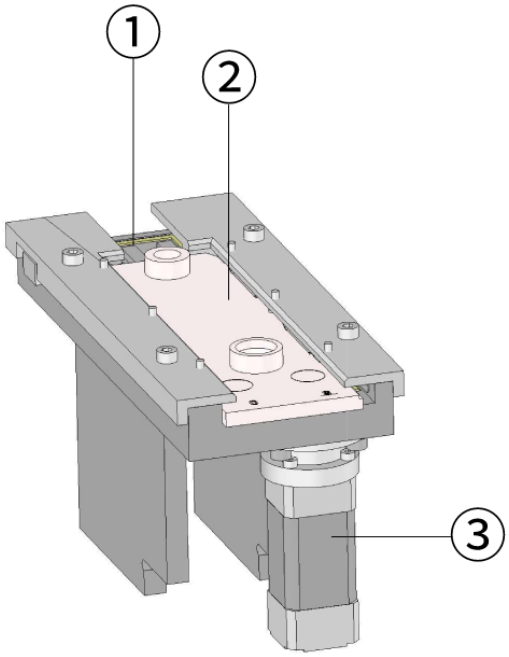
The front and the right-hand side of the instrument are shown below:



1. Printer / printer paper slot
2. Screen
3. Cartridge tray
4. QR / barcode scanner

4.1.1 Cartridge tray

The cartridge tray is located on the lower front of the instrument and can hold a test cartridge for platelet function analysis or quality control testing.



1. Cartridge tray
2. Test cartridge
3. Magnetic agitator

After placing the patient sample in a test cartridge and initiating a test, the cartridge tray inserts a needle into the rubber cap of the test cartridge to create a vacuum. Then, the sample is warmed as it reaches the stirring chamber, and the magnetic agitator initiates stirring of the sample with the pre-applied reagent(s). When the platelet function assay is completed, the cartridge tray automatically pushes out the test cartridge for the removal of the used test cartridge.

4.1.2 Touch screen

The touch screen is located on the upper front of the instrument and displays the software user interface.

4.1.3 QR / barcode scanner

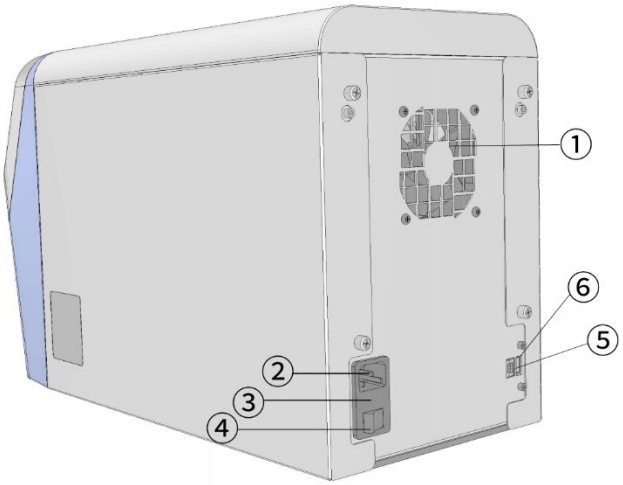
The QR / barcode scanner is located at the right-hand side of the instrument. The operator can utilize this scanner to scan the unique barcode of the test cartridge to automatically enter the cartridge type and lot number or to scan for patient number.

4.1.4 Printer / printer paper slot

The integrated thermoprinter is located on top of the instrument. When the instrument is shipped, 1 roll of printer paper is pre-installed in the printer paper slot.

4.1.5 Ports, power switch, and fuses

All ports are located at the back of the instrument, as well as the power switch and the fan. The following illustration shows the back of the instrument.



1. Fan
2. Power outlet
3. Fuse compartment
4. Power switch
5. RS-232 port
6. USB port

4.2 Connection of External Devices

Laboratory Information System (LIS)

A uni-directional LIS can be connected via the serial RS-232 port. The LIS allows test results to be transmitted from the analyzer to a host computer.

For details on how to connect the LIS, see Chapter X.X.

USB Flash Drive

A USB flash drive can be connected via the USB port. By connecting a USB flash drive, the raw data of test results can be stored.

4.3 Accessories

Instructions for using the accessories are given in the respective procedures.

4.3.1 USB flash drive

The USB flash drive has a PDF copy of this user manual stored. RheoMeditech recommends the operator to fully review the manual prior to using the Anysis™ instrument.

The same flash drive can also be used to store raw data. In order to enable this function, insert the USB flash drive into the USB port prior to testing.

4.3.2 Printer paper

The instrument comes with 1 roll of printer paper installed, and an extra roll is included in the accessories kit.

The Anysis™ instrument uses 57mm X 50 mm X 50 microns (width X diameter X thickness) thermal paper to print test results.

4.4 Test Cartridges

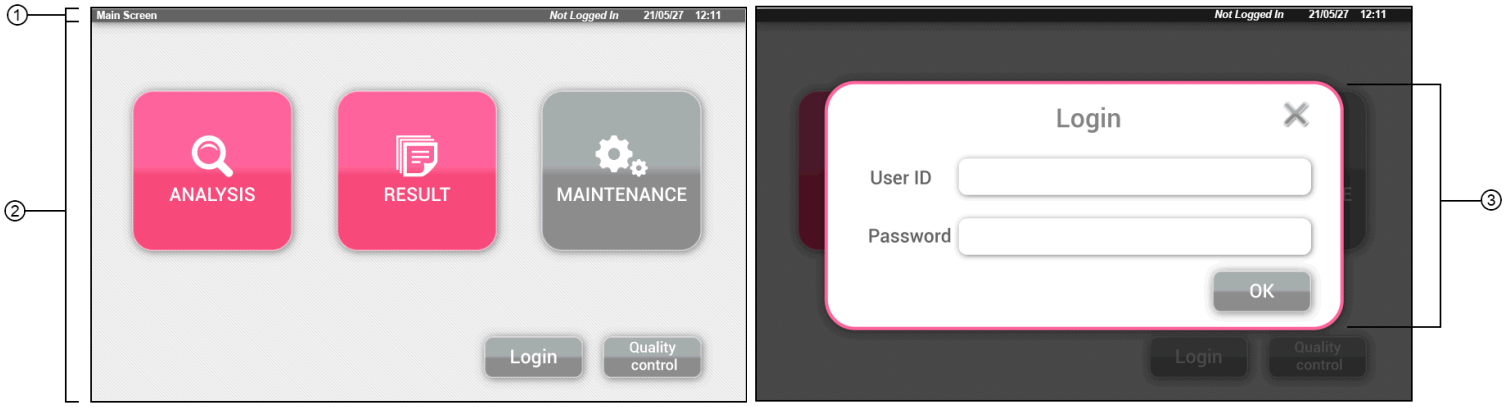
Detailed descriptions of the test cartridges, their handling, applications, and performances are provided in the instructions for use.

DESCRIPTION OF THE SOFTWARE

This chapter describes the structure and the general operation of the software.

5.1 Overview

An overview of the software is shown below:



1. Status bar with screen information, user information, and the current date and time
2. Current screen
3. Dialog

Status Bar The status bar displays the screen information, user account information, and the current date and time.

Screen Information The screen information displays one of four screens available: **Main Screen**, **Analysis**, **Result**, and **Maintenance**. To switch between various screens, the operator must return to the **Main Screen.**

User Information On the right-hand side of the status bar, the User ID of the logged in user is displayed. If the operator has not logged in, the phrase ***Not logged in*** appears in place of the User ID.

Date and Time On the far right, the current date and time are displayed.

Current Screen

Underneath the status bar, the current screen will be displayed. To navigate between screens, the operator must return to the **Main Screen**.

Dialog

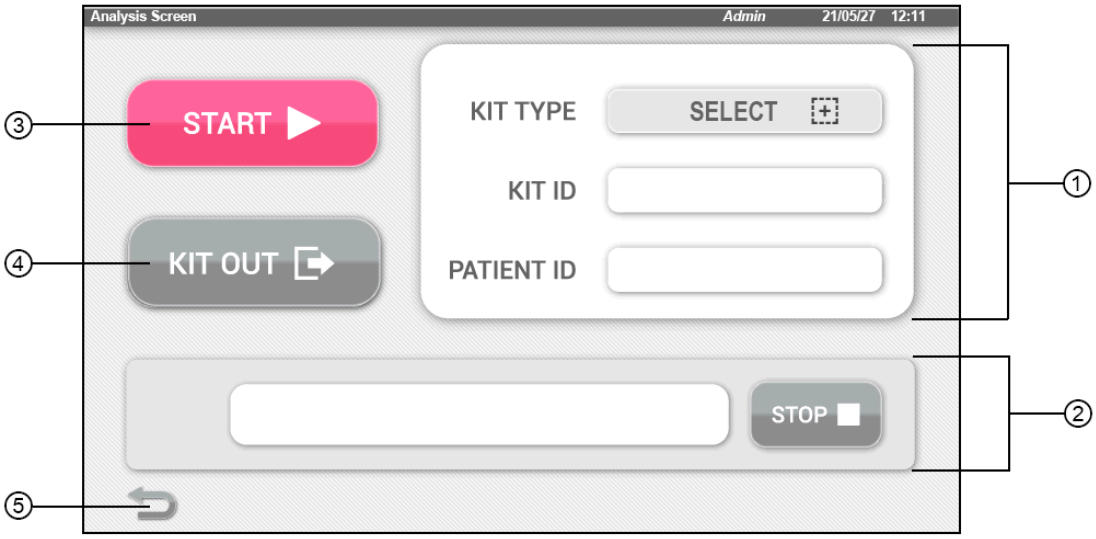
A dialog displayed in three possible situations:

1. When the operator has tapped on a function within the current screen
2. When the system prompts the operator to choose an option
3. When an error message is prompted by the system

In all three possible situations, dialogs can be dismissed by tapping the available tabs on the dialog.

5.2 Analysis Screen

The **Analysis Screen** is displayed below.



1. Test information
2. Progress bar with the **STOP** tab
3. **START** tab
4. **KIT OUT** tab
5. Return tab

Test Information

This section displays the test information, including the cartridge information and the patient information. **KIT TYPE** refers to the type of test cartridge (SIPA / P2Y12 / Aspirin / C/ADP / C/EPI) that will be used. **KIT ID** refers to the cartridge identification number, which can be found on the cartridge package next to LOT. **PATIENT ID** refers to the identification number or code that is specific to each sample.

Progress Bar

Once a test has been initiated, the progress bar will begin to indicate the test process, proceeding from 0% to 100%. Additionally, the **STOP** tab will appear to allow the operator to terminate the test before completion.

Start Tab

The **Start** tab is taped to initiate tests. This function is disabled until the **KIT TYPE** and **KIT ID** are selected. **PATIENT ID** is not necessary to initiate tests.

KIT OUT tab

In case the operator wishes to eject the test cartridge, the **KIT OUT** tab is available. Tapping **KIT OUT** will eject the inserted cartridge out of the instrument.

Return Tab

The operator can return to the **Main Screen** by tapping the Return tab.

5.3 Result Screen

An example of the **Result Screen** is shown below.

1. **PRINT** tab
2. Page navigator
3. Result list
4. Return tab

PRINT tab

The **PRINT** tab allows the operator to reprint past results. Tapping **PRINT** will print the selected result.

Page Navigator

The page navigator allows the operator to see additional data prior to or following the current page of data.

Result List

The result list displays the test results in the order of testing. The oldest test is displayed first.

Return Tab The operator can return to the **Main Screen** by tapping the Return tab.

5.4 Maintenance Screen

The **Maintenance Screen** is displayed below.

1. Maintenance list
2. Navigation arrow

Maintenance List The maintenance list displays the various settings the operator can configure. Depending on the user group, user rights vary (see Chapter 5.6).

Navigation Arrow The navigation arrow is used to launch the following page of the maintenance list.

5.5 User Rights

The software has 4 different access levels and corresponding user groups that determine the available user rights, see the table below.

Access Level / User Group	User Rights
Not logged in (**Logoff**)	Displaying the results list
User	All rights except: ♦ Configuring the system except for setting the date and time ♦ Changing factory settings
Administrator	All rights except changing factory settings
Service, RheoMeditech	All rights

Configuring the System

This chapter describes how to configure laboratory- and user-specific settings for the system.

6.1 Setting the Date and Time

In the dialog **Time and Date**, you can:

- Set the time
- Set the date

To set the time, proceed as follows:

1. In the menu **Maintenance**, tap **Time and Date** → The dialog **Time and Date** is displayed.

Set Time

To set the time:

1. Tap **Hour** → A numeric keyboard is displayed.
2. Enter the hour in 24-hour format.
3. Tap **Minutes** → A numeric keyboard is displayed.
4. Enter the minutes.
5. Tap **Save** → Time is set.

Set Date

To set the date:

1. Tap **Year** → A numeric keyboard is displayed.
2. Enter the year.
3. Tap **Month** → A numeric keyboard is displayed.
4. Enter the month.
5. Tap **Date** → A numeric keyboard is displayed.
6. Enter the date.
7. Tap **Save** → Date is set.

6.2 Managing User Accounts (Administrator Mode)

In the dialog **User Manager**, you can manage up to 20 user accounts.

You can:

- Add new user accounts
- Edit existing user accounts
- Delete existing user accounts

To open the dialog, proceed as follows:

1. In the menu **Maintenance**, tap **User Manager** → The dialog **User Manager** is displayed

Add a New User

To add a new user account, proceed as follows:

1. Tap ***Add User ID…*** → The dialog **New User ID** is displayed.
2. Tap **User ID**, and then enter the new User ID.
3. Tap **Password**, and then enter the new password. If you do not want to set a password, skip this step.
4. Tap **Save** → The user account is added.

Edit Existing Users

To edit existing user account, proceed as follows:

1. Tap the User that needs to be edited → The dialog **Edit User** is displayed.
2. Tap **User ID**, and then enter the new User ID.
3. Tap **Password**, and then enter the new password. If you do not want to set a password, remain this slot blank.
4. Tap **Save** → The user account is edited.

Delete Existing Users

To delete an existing user account, proceed as follows:

1. Tap the User that needs to be deleted→ The dialog **Edit User** is displayed.
2. Tap **Delete User** → The dialog **Delete User** is displayed.
3. Tap the User that needs to be deleted → The dialog **Confirmation** is displayed.
4. Tap **Okay** → The user account is deleted.

6.3 Further Configurations

For further configuration of the Anysis™ instrument, contact the RheoMeditech Tech Service.

PREPARING FOR THE ANALYSIS

This chapter describes how to prepare the system before performing the analysis, as well as instructions for collecting and handling the blood samples.

7.1 Sample Collection

Prior to testing, whole blood sample must be obtained and equilibrated. To ensure appropriate and safe collection of the sample, proceed as follows:

1. Whole blood may be collected from venous sites using a 21 gauge or larger (e.g. 18-20 gauge) needle in an appropriate blood collection tube (citrate tube). Blood samples should be obtained from an extremity free of peripheral venous infusions.
2. Collect a discard tube first (approximately 2 mL). The discard tube must not contain EDTA.
3. Gently invert the sample tube 5 times to ensure complete mixing of the contents.
4. Blood must equilibrate at room temperature (18 °C to 25 °C) for a minimum of 30 minutes after collection before testing, but no longer than 4 hours. **Do not** place the sample in a water bath or on a rocker plate.

7.1.1 Sample collection precautions

To ensure safe collection of the blood sample and to prevent inaccurate results due to following an incorrect collection method, the following precautions must be observed:

- **For in-depth instructions on sample collection, consult instructions for use.**
- Use only 21 gauge or larger bore needles for blood collection or transfer.
- Blood samples should be kept upright prior to testing and avoid prolonged contact with the rubber stopper on the blood collection tube.
- Avoid use of a rocker or pneumatic tube transport system.
- Collection of the blood sample must be performed with care to avoid hemolysis or contamination by tissue factors. Samples with evidence of clotting should not be used.

- Fresh whole blood samples must be used within 4 hours of collection.
- Always ensure blood collection tubes are filled to the indicated fill volumes. At altitudes greater than 850 meters above sea level, blood collection tubes may not fill to the specified volume, which results in an incorrect ratio of blood to anticoagulant. Users at these altitudes should refer to their facility's blood collection protocols or blood collection tube manufacturer's recommendations for instructions to properly fill blood collection tubes.
- Do not freeze or refrigerate blood samples.
- All patient samples should be handled as if capable of transmitting disease.
- The first collection tube must be discarded (approximately 2 mL).
- Fresh whole blood samples must be used within 4 hours of collection.

7.2 Preparing Test Cartridges

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

To prepare test cartridges, proceed as follows:

1. Take the test cartridges out of the refrigerator to let them warm up to room temperature. This will take at least 10 minutes.

7.3 Starting the System

To start the system, proceed as follows:

1. Locate the power switch on the back of the instrument. Flick the switch to position **I**. → The instrument will turn on, and **Self-Diagnosis** will automatically initiate. Once the diagnosis completes, main screen will be displayed. If successful, the **Main Screen** will be displayed.

Note: The instrument will need to reach operating temperature to pass the **Self-Diagnosis**. This process will take at least 5 minutes if starting the instrument from cold.

7.4 Logging In

To login to a user account, proceed as follows:

1. In the main screen, locate and tap **Login** at the bottom right. → The dialog **Login** is displayed.
2. Tap **User ID** → A keyboard is displayed.
3. Enter the User ID, then tap enter.
4. Tap **Password** → A keyboard is displayed.
5. Enter the password, then tap enter.
6. Tap **Login** → The user is logged in. The logged in User ID is displayed at the top of the screen.

7.5 Performing Quality Control

Before initiating a test session and using a new lot of cartridges, RheoMeditech recommends that quality control measures be taken to ensure consistent performance. RheoMeditech also recommends each lab to keep a hard-copy record of quality control results of the instrument.

1. In the main screen, locate and tap **Quality Control** at the bottom right. → The dialog **Quality Control** is displayed.

Self-Diagnosis

To conduct a Self-Diagnosis, continue as follows:

1. Tap **Self-Diagnosis** → The **Self-Diagnosis** screen is displayed, and immediately begins testing for instrument functions.
2. When the test completes, select **Print** or **Back** → Self-Diagnosis is completed. If **PRINT** is selected, a data sheet containing Self-Diagnosis result is printed.

Wet Quality Control (WQC)

To conduct a Wet Quality Control (WQC), continue as follows:

1. Tap **Wet Quality Control (WQC)** → The **Wet Quality Control** screen is displayed.
2. Tap **Test type** → The dialog **Test type** is displayed.
3. Tap **WQC 1** or **WQC 2**, then tap enter → Test type is selected.
4. Insert the Anysis™ WQC cartridge half-way into the cartridge tray, then carefully pipette 200µL of the WQC solution appropriate to the selected test type, making sure no air bubbles are formed.
5. Fully insert the WQC cartridge into the instrument.

6. Tap **Start** → WQC initiates. The progress bar begins to indicate test progress and the **STOP** tab appears. When WQC completes, the QC result is displayed on the progress bar.
7. Select **Print** or **Back** → WQC is completed. If **PRINT** is selected, a data sheet containing WQC result is printed.

PERFORMING THE ANALYSIS

This chapter describes the methods taken to conduct analyses with patient samples. The steps from entering patient information to viewing test results are explained below.

8.1 Measuring Patient Samples

Prior to performing a test, test cartridge and patient information must be entered. There are two ways to accomplish this:

1. Manually
2. Scanning the information with the scanner

Note: You can conduct the test without entering the patient information. Resulting test file will not contain patient information. However, the test will not be initiated without the cartridge information.

8.1.1 Manually entering the test information

To enter the sample information manually, proceed as follows:

1. Tap **Analysis.** → **The Analysis screen** is displayed.

Kit Type

2. Locate **KIT TYPE**, then press **SELECT** on the right. → The dialog **Test Type** is displayed.
3. Select the test type, then tap **Apply.** → Test type has been selected.

Kit ID

4. Locate the LOT symbol on the cartridge packaging. The last three digits indicate the lot number of the test cartridge. You will need to enter this information as the **KIT ID**. Locate **KIT ID** on the screen, then tap ***Enter kit ID…*** → A numeric keyboard is displayed.
5. Enter the three-digit lot number, then tap **Enter.** → Kit ID is recorded.

Patient ID

6. Now locate **PATIENT ID** on the screen. Tap ***Enter patient ID…*** → An alphanumeric keyboard is displayed.
7. Enter the patient ID, then tap **Enter.** → Patient ID is recorded.

8.1.2 Scanning the test information

To scan the test information, proceed as follows:

1. Tap **Analysis.** → **The Analysis Screen** is displayed.

Kit Type & Kit ID

2. Locate the QR code on the cartridge packaging. This QR code contains information for both the cartridge type and the cartridge ID. Scan the QR code on the scanner located on the right-hand side of the instrument. → **KIT TYPE** and **KIT ID** are automatically entered.

Patient ID

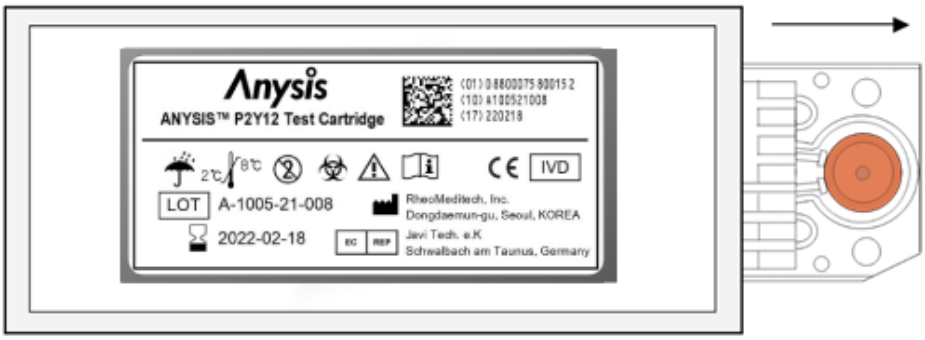
3. Now locate the barcode on the blood collection tube containing the patient sample that will be tested. Scan the barcode on the scanner located on the right-hand side of the instrument. → **PATIENT ID** is automatically entered.

Note: At any point during this process, the scanned information can be manually edited. If either the QR code of the cartridge or the barcode of the blood collection tube malfunctions, follow the steps listed on Chapter 8.1.1.

8.1.3 Loading patient samples

To load patient samples, proceed as follows:

1. Take the test cartridge out of its packaging.



2. Inspect the cartridge for all its expected components (See Chapter 13.1 for a figure of the cartridge):

- Circular tape over the chamber (For Anysis-P2Y12 test cartridge, the tape is present on both top and bottom sides of the chamber)
- Rubber cap

Note: The results obtained with an incompletely constructed test cartridge will result in an error during testing. Do not proceed to testing without correcting the incomplete construction.

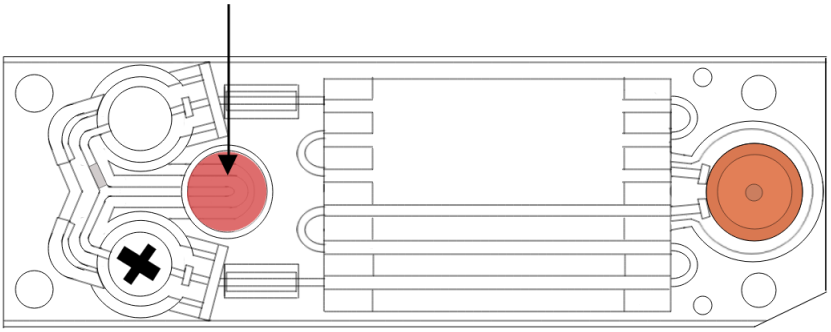
3. Place the cartridge half-way into the cartridge tray, as to leave the sample well revealed.

⚠WARNING

Infection by contact with infectious samples
Death or serious illness may result

- Treat all blood samples as if capable of transmitting disease; avoid contact with samples.
- Wear appropriate protective wear.
- Handle the patient samples with universal precautions.

4. Gently mix the samples by slowly inverting the collection tube 4-5 times.
5. Once the sample has been resuspended, slowly pipette 200µL of the sample into the sample well as to prevent injecting air bubbles.



6. Now fully push the test cartridge into the cartridge tray. Do not apply excessive pressure and avoid contact with the sample well.

8.1.4 Performing the test

To perform the test, proceed as follows:

1. Tap **START.** → The test initiates. The progress bar begins to indicate test progress. **STOP** tab appears. After the test has been initiated, each test can take up to 10 minutes to complete. In case there is an error, error dialog will appear on the screen (See Chapter 12.3) Once the test completes, the MD result will be displayed on the progress bar and on the printed data sheet. The used test cartridge will be automatically ejected from the instrument.

8.1.5 Stopping a test

To terminate a test during testing, proceed as follows:

1. Tap **STOP.** → The dialog **Confirmation** is displayed.
2. Tap **OK.** → Test is terminated, and the test cartridge is ejected out of the instrument.

Note: Do not reuse test cartridges.

8.1.6 Removing used cartridges with samples

To remove used cartridges with tested samples, proceed as follows:

⚠WARNING

Infection by contact with infectious samples
Death or serious illness may result
- Treat all blood samples as if capable of transmitting disease; avoid contact with samples.
- Wear appropriate protective wear.
- Handle the patient samples with universal precautions.

1. After completing a test, the instrument will automatically eject the test cartridge. Once the cartridge is fully ejected, carefully remove the cartridge by holding the corner of the cartridge.
2. Discard the used cartridge in an appropriate biohazard waste container.

8.2 Managing Results

To manage test results, proceed as follows:

1. Tap **Result.** → **Result Screen** is displayed.

In the **Result Screen**, you can:
- View test results
- Reprint test results

View Test Results

To view test results, proceed as follows:

1. The result list is organized in the order of recentness**.** The most recent test result will be displayed first, with the oldest test result last. Tap the tested date of the result you wish to view. → All tests conducted on the selected date is displayed in the order the tests were conducted. The last test conducted on the selected date will be displayed last on the list.

Reprint Test Results

To reprint test results, proceed as follows:

1. The result list is organized in the order of recentness**.** The most recent test result will be displayed first, with the oldest test result last. Tap the tested date of the test result you wish to reprint. → All tests conducted on the selected date is displayed in the order the tests were conducted. The last test conducted on the selected date will be displayed last on the list.
2. Locate the test result that you wish to reprint, then tap **Print** → The test result is reprinted.

FINISHING THE ANALYSIS

This chapter describes how to log off and turn off the instrument after a test session.

9.1 Logging Out

To log out, proceed as follows:

1. In the **Main Screen**, tap **Logout** → The dialog **Confirmation** is displayed.
2. Tap **OK** → You are logged out.

9.2 Shutting Down the System

To shut the instrument off, proceed as follows:

1. Locate the power switch on the back of the instrument. Flick the switch to position **O**. → The instrument is shut down.

CLEANING THE SYSTEM

This chapter describes how clean and disinfect the system.

NOTICE

Damage to the touch screen due to incorrect cleaning methods
The touch screen may begin to malfunction
- Only use isopropanol or ethanol to clean the touch screen.
- Only use special screen disinfectant to disinfect the touch screen.
- Do **not** wipe the touch screen with a rough material that can create scratches.

NOTICE

Damage to the instrument
The instrument may begin to malfunction
- **Never** sterilize the instrument.

10.1 Cleaning the System

⚠WARNING

Electric shock due to spilled liquid
Death or serious injury may result
- Do not completely immerse the instrument into liquid.
- Do not pour liquid onto the instrument.
- Do not place liquid containers on top of the instrument.

To clean the touch screen, gently wipe it with a soft cloth moistened with ethanol or isopropanol. Once completed, dry the touch screen with a microfiber cloth.

All other surfaces can be cleaned with a cloth or a light-duty wiper moistened with ethanol, isopropanol, or commercial disinfectant. You can effectively remove blood stains by wiping the area with a cloth moistened with water. Dry the cleaned area with a cloth once completed.

PERFORMING MAINTENANCE

This chapter describes when RheoMeditech recommends the operator to perform various maintenance and repairs, as well as how to perform them.

Note: If the operator chooses to carry out improper maintenance measures that are not described in this chapter of the Anysis User Manual, the resulting damage to the Anysis™ System will void the warranty, resulting in service charges.

11.1 Periodic Maintenance

Recommended intervals for each maintenance types are described below:

Interval	Action	Reference
Daily, beginning of each test shift	Perform a Self-Diagnosis	Chapter 7.5
Daily, end of each test shift	Clean the instrument, other used parts, and worktop	Chapter 10.1
Prior to using a new lot of cartridges	Perform a Wet Quality Control (WQC)	Chapter 7.5

11.2 Printer

11.2.1 Reloading printer paper

You will need:

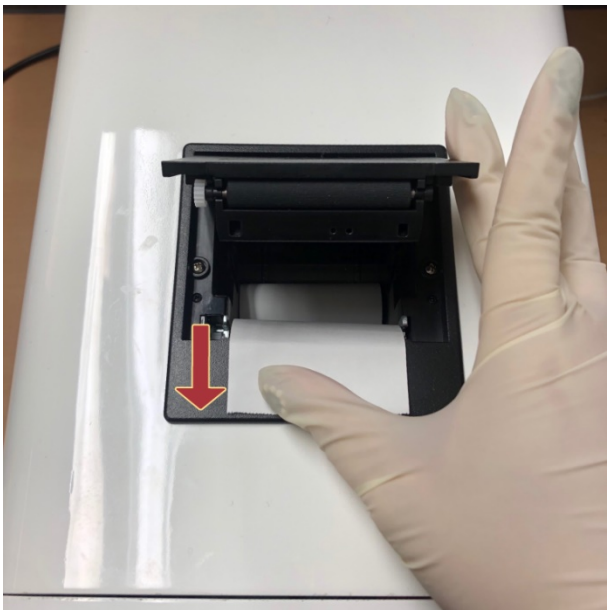
- 1 Roll of printer paper

Reload Printer Paper

To reload printer paper, proceed as follows:

1. Open the printer cover at the top of the instrument by lifting the tab.

2. Remove the empty paper roll.
3. Load the new paper roll into the printer paper trough, with the loose end pulled to the front.

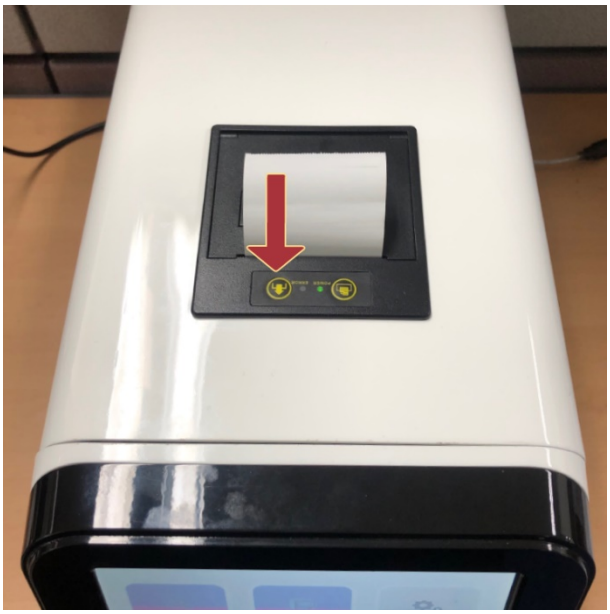


4. Close the printer cover.

11.2.2 Advancing printer paper

To advance the loaded printer paper, proceed as follows:

1. Make sure that the Anysis™ System is turned on, and printer paper is loaded.
2. Print the advance button at the top of the instrument.



TROUBLESHOOTING

12.1 Installing Fuses

To install a fuse that is included in the accessory kit or an additional purchase, contact RheoMeditech representative or RheoMeditech Tech Service.

NOTICE

Damage to the instrument
The instrument may break down

- Do not use fuses that are purchased from a third-party seller. Only use RheoMeditech-approved parts to troubleshoot.

NOTICE

Damage to the instrument
The instrument may break down

- **Do not** attempt to replace the fuse without the guidance of a RheoMeditech personnel.

12.2 Other Hardware-Related Troubleshooting

To reduce complications involved with the hardware, RheoMeditech does not allow the operator to neither troubleshoot hardware-related problems nor perform instrument calibrations. To calibrate the Anysis™ Instrument (including, but not limited to concerns regarding the touch screen, vacuum system, motor system, thermoregulation, etc.), contact RheoMeditech Tech Service.

Note: If the operator chooses to carry out improper troubleshooting measures, the resulting damage to the Anysis™ System will void the warranty, resulting in service charges.

12.3 Error Messages

12.3.1 Attention messages

The following lists the attention messages commonly encountered during testing. Explanations and solutions for such errors are described below.

12.3.1.0 Invalid permissions

Error Code	**Attention 00**
Explanation	The logged in user account does not have permissions to access the selected function.
Causes	♦ Not logged into the system ♦ The logged in account does not have permissions to access the function.
Solutions	♦ Log into a user account in the user group **Administrator**.

12.3.1.1 Expired test cartridge

Error Code	**Attention 01**
Explanation	The scanned test cartridge has past the manufacturer expiration date.
Causes	♦ The test cartridge has not been used before its expiration date.
Solutions	♦ Test with a new, unexpired test cartridge.

Note: Do not use expired test cartridges. The test results obtained by testing with expired test cartridges are incorrect in relation to the result ranges defined by RheoMeditech.

12.3.1.2 Sample not detected

Error Code	**Attention 02**
Explanation	The system has failed to detect the presence of the whole blood sample.
Causes	Methodology-Related ♦ No sample in the sample well Hardware-Related ♦ Camera malfunctioning
Solutions	♦ Ensure that the sample was pipetted to the sample well (without air bubbles) ♦ If sample was pipetted onto the sample well, but the problem persists, perform a Self-Diagnosis. If the Self-Diagnosis fails: ♦ Contact the RheoMeditech Tech Service. If the Self-Diagnosis passes, but the problem persists: ♦ Contact the RheoMeditech Tech Service.

Note: Do not use the test result if **Attention 02** was displayed during testing.

Note: Do not reuse the test cartridge that has had sample pipetted for the erred test.

12.3.1.3 Malfunctioning needle motor

Error Code	**Attention 03**
Explanation	The system has detected an error in prompting the motor required to move the needle.
Causes	♦ Motor system malfunctioning
Solutions	♦ Perform a Self-Diagnosis. If the Self-Diagnosis fails: ♦ Contact the RheoMeditech Tech Service. If the Self-Diagnosis passes, but the problem persists: ♦ Contact the RheoMeditech Tech Service.

Note: Do not use the test result if **Attention 03** was displayed during testing.

Note: Do not reuse the test cartridge if **Attention 03** was displayed during testing.

12.3.1.4 Malfunctioning syringe motor

Error Code	**Attention 04**
Explanation	The system has detected an error in prompting the motor required to move the syringe.
Causes	♦ Motor system malfunctioning
Solutions	♦ Perform a Self-Diagnosis. If the Self-Diagnosis fails: ♦ Contact the RheoMeditech Tech Service. If the Self-Diagnosis passes, but the problem persists: ♦ Contact the RheoMeditech Tech Service.

Note: Do not use the test result if **Attention 03** was displayed during testing.

Note: Do not reuse the test cartridge if **Attention 03** was displayed during testing.

12.3.1.5 No sample in the stirring chamber

Error Code

Attention 05

Explanation

The system has failed to detect any movement of the whole blood sample into the stirring chamber.

Causes

Methodology-Related

- Incomplete cartridge construction
- Sample has begun coagulating due to various reasons (e.g., 4+ hours elapsing since collection, incomplete mixture of the sample with citrate)

Hardware-Related

- Vacuum system malfunctioning
- Camera malfunctioning

Solutions

- Ensure that the test cartridge is completely constructed with all its components (See Chapter 8.1.3).
- Ensure that the sample has not begun coagulating prior to use.
- Perform a Self-Diagnosis.

If the Self-Diagnosis fails:

- Contact the RheoMeditech Tech Service.

If the Self-Diagnosis passes, but the problem persists:

- Contact the RheoMeditech Tech Service.

Note: Do not use the test result if **Attention 05** was displayed during testing.

Note: Do not reuse the test cartridge if **Attention 05** was displayed during testing.

12.3.1.6 Insufficient sample in the stirring chamber

Error Code

Attention 06

Explanation

The system has detected that the stirring chamber has been insufficiently filled with the whole blood sample.

Causes

Methodology-Related

- Sample has begun coagulating due to various reasons (e.g., 4+ hours elapsing since collection, incomplete mixture of the sample with citrate)
- Stirrer has blocked the sample from completely filling the allotted space in the stirring chamber.

Hardware-Related

- Motor system malfunctioning
- Vacuum system malfunctioning
- Camera malfunctioning

Solutions

- Ensure that the sample has not begun coagulating prior to use.
- Perform a Self-Diagnosis.

If the Self-Diagnosis fails:

- Contact the RheoMeditech Tech Service.

If the Self-Diagnosis passes, but the problem persists:

- Contact the RheoMeditech Tech Service.

Note: Do not use the test result if **Attention 06** was displayed during testing.

Note: Do not reuse the test cartridge if **Attention 06** was displayed during testing.

12.3.1.7 Sample intrusion into the bead section.

Error Code	**Attention 07**
Explanation	The whole blood sample has migrated past the stirring chamber into the bead section prior to mixing with the agonist(s).
Causes	♦ Camera malfunctioning
Solutions	♦ Perform a Self-Diagnosis. If the Self-Diagnosis fails: ♦ Contact the RheoMeditech Tech Service. If the Self-Diagnosis passes, but the problem persists: ♦ Contact the RheoMeditech Tech Service.

Note: Do not use the test result if **Attention 07** was displayed during testing.

Note: Do not reuse the test cartridge if **Attention 07** was displayed during testing.

12.3.1.8 Sample migration distance below the measurable range

Error Code

Attention 08

Explanation

The distance travelled by the sample is below the measurable MD range.

Causes

Methodology-Related

- Sample has begun coagulating due to various reasons (e.g., 4+ hours elapsing since collection, incomplete mixture of the sample with citrate)

Hardware-Related

- Vacuum system malfunctioning
- Camera malfunctioning

Solutions

- Ensure that the sample has not begun coagulating prior to use.
- Retry the test with a new cartridge.
- Perform a Self-Diagnosis.

If the Self-Diagnosis fails:

- Contact the RheoMeditech Tech Service.

If the Self-Diagnosis passes, but the problem persists:

- Contact the RheoMeditech Tech Service.

Note: Do not use the test result if **Attention 08** was displayed during testing.

Note: Do not reuse the test cartridge if **Attention 08** was displayed during testing.

12.3.1.9 Pressure out of range

Error Code	**Attention 09**
Explanation	Pressure has been detected to be out of the appropriate range set by the System.
Causes	Methodology-Related ♦ Incomplete cartridge construction Hardware-Related ♦ Vacuum system malfunctioning
Solutions	♦ Ensure that the test cartridge is completely constructed with all its components (See Chapter 8.1.3). ♦ Perform a Self-Diagnosis. If the Self-Diagnosis fails: ♦ Contact the RheoMeditech Tech Service. If the Self-Diagnosis passes, but the problem persists: ♦ Contact the RheoMeditech Tech Service.

Note: Do not use the test result if **Attention 09** was displayed during testing.

Note: Do not reuse the test cartridge if **Attention 09** was displayed during testing.

12.3.1.10 Cartridge release error

Error Code	**Attention 10**
Explanation	Upon the completion of a test, the used test cartridge has failed to be pushed out of the cartridge tray.
Causes	♦ Needle failed to raise after completing the test ♦ Motor system malfunctioning
Solutions	♦ Turn off the system and turn it back on. ♦ If the problem persists after restarting the system, **DO NOT** forcefully pull the cartridge out of the tray. Contact RheoMeditech Tech Service for help.

Note: If the operator chooses to forcefully pull the cartridge out of the cartridge tray, the operator becomes reliable for the resulting damage to the instrument and the service fees associated with the damage.

12.3.2 Warning messages

The following lists the warning messages that are prompted in more serious situations that can cause permanent damage to the instrument and / or the operator. Explanations and solutions for such errors are described below.

12.3.2.5 Abnormal temperature detection

Error Code **Warning 01**

Explanation The system has detected a prolonged abnormality in the thermoregulation system of the instrument, which can lead to permanent damage to the system.

Causes

- Thermoregulation system malfunctioning
- Inadequate environment to test
- System malfunctioning

Solutions

- Check the surrounding environment of the instrument. If you can sense the exceedingly high temperature or a burning smell, immediately turn the system off and let it cool for at least 10 minutes. After the 10 minutes, turn the system back on and run a Self-Diagnosis to ensure that the instrument logistics are properly functioning.

If the Self-Diagnosis fails:

- Contact the RheoMeditech Tech Service.

If the Self-Diagnosis passes, but the problem persists:

- Consult with the recommended testing environment (Chapter 13.2) and correct any incompetent conditions of the laboratory.
- Contact the RheoMeditech Tech Service if there are no incompetent conditions present.

- If the operator cannot detect any abnormalities regarding the temperature of the system at the time of the warning, it is possible that the thermoregulation system is malfunctioning. Perform a Self-Diagnosis.

If the Self-Diagnosis fails:

- Contact the RheoMeditech Tech Service.

If the Self-Diagnosis passes, but the problem persists:

- Contact the RheoMeditech Tech Service.

12.3.3 Additional alerts

The following lists the alert messages that are not prompted by the instrument but are necessary for the operator to be aware of. Explanations and solutions for such errors are described below.

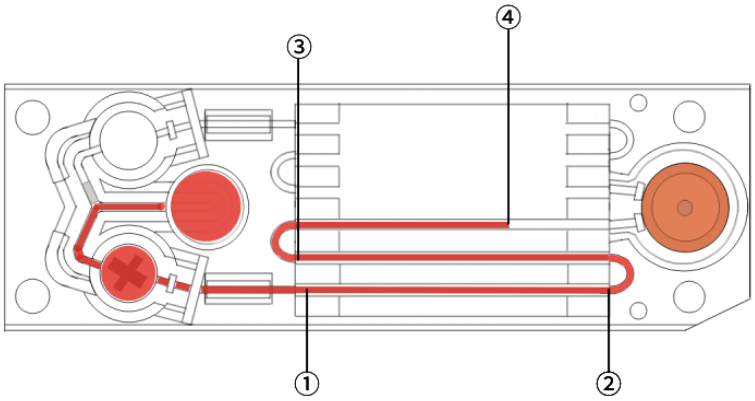
12.3.3.5 Measured MD distance differs from the actual distance

Error Code

Alert 01

Explanation

The MD travelled by the sample is incorrectly read by the instrument. The diagram displaying actual MDs at various points in the migration tube.



1. MD 110
2. MD 158
3. MD 218
4. MD 268

Causes

- Defective cartridge
- Camera malfunctioning

Solutions

- Perform a Self-Diagnosis.

If the Self-Diagnosis fails:

- Contact the RheoMeditech Tech Service.

If the Self-Diagnosis passes, but the problem persists:

- Contact the RheoMeditech Tech Service.

12.3.3.6 Sample found to have travelled past the touchdown point

Error Code	**Alert 02**
Explanation	The test was not terminated when the sample reached the touchdown point, which is MD 268.
Causes	♦ Camera malfunctioning ♦ Software malfunctioning
Solutions	♦ Perform a Self-Diagnosis. If the Self-Diagnosis fails: ♦ Contact the RheoMeditech Tech Service. If the Self-Diagnosis passes, but the problem persists: ♦ Contact the RheoMeditech Tech Service.

APPENDIX

This chapter describes the principle of the system and technical specifications.

13.1 Principle of the System

Instrument Operating Principles

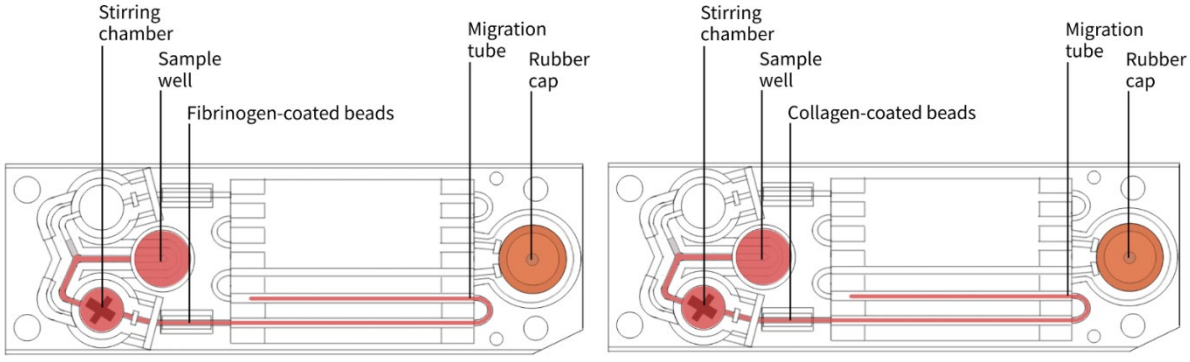
The Anysis™ System measures platelet aggregation-induced occlusion and provides a migration distance (MD) as a result. The Anysis™ system consists of the test instrument and disposable test cartridges. Quality control measures are internally included in the test instrument. The instrument controls all test sequencing, temperature, reagent-sample mixing, and performs self-diagnostics.

Each single-use test cartridge contains a lyophilized preparation of human fibrinogen- or collagen-coated beads and platelet agonist(s). After loading an anticoagulated (citrated) blood sample, the remained process of the testing is automatically conducted, and the degree of platelet aggregation as a result is displayed.

The Anysis™ test is based on platelet aggregation-induced occlusion mechanism. Activated platelets tend to bind to fibrinogen-coated microparticles, which are densely packed in a microtube and subsequently recruit additional activated platelets. Accumulated platelet aggregation in the microbeads section leads to occlusion of blood flow. Then, Anysis™ determines the final migration distance (MD) of blood flow in a microtube. The MD decreases with increasing number of activated platelets. The instrument measures and reports the final MD in a millimeter unit, which does not require any calculations or conversions. The platelet adhesion and aggregation to thousands of microbeads packed in a microtube result in rapid and reproducible results if the platelets are activated.

Testing Principles

Principles for individual test cartridges are described in their respective instructions for use.



13.2 Technical Specifications

Physical	Dimensions (L x W x H):	44.8cm X 21.4cm X 29.7cm
	Required space for ventilation:	5cm on all sides
	Recommended workspace (L x W x H):	55cm X 32cm X 60cm
	Weight:	10 kg
	Required load capacity of worktop:	50 kg
Electrical	Operating voltage, frequency:	100 to 240VAC, 50/60Hz
	Current:	1A @ 220VAC
	Power consumption:	220W
	Fuse:	2.0A/250V, 5 X 20mm
Environmental	Operating temperature:	18 to 29°C
	Non-operating storage and: transportation temperature	-29 to 50°C
	Operating humidity:	20 to 90%RH, non-condensing
	Non-operating storage and: transportation humidity	0 to 95%RH, non-condensing
	Pollution degree:	2
	Degree of protection (according to IED 60529):	IP20
	Altitude (maximum):	2000m
General	Installation category:	II
	Incubation well temperature:	28°C
	Incubation well warm-up time (room to operating temperature):	Up to 20minutes
	Incubation time:	30 sec
	Maximum sample volume:	300µL
	Vacuum set point:	40mBar
Printer	Type:	thermal printer paper
	Compatible Printer Paper:	57mm wide, standard 5-year readable life

External I/O Ports	RS-232 Use:	LIS
	USB-2 Use:	Software updates, data storage, user manual
Software	Stored Patient ID:	Maximum of 20 User Accounts
	Stored results:	Last 5000 results

Explanation of Symbols

ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements			
5.1.1 	**Manufacturer**	5.1.3 	**Date of manufacture**
5.1.4 	**Use by date**	5.1.5 LOT	**Batch code**
5.1.6 REF	**Catalogue number**	5.1.7 SN	**Serial number**
5.3.7 	**Temperature limits**	5.4.1 	**Biological risks**
5.4.2 	**Do not re-use**	5.4.3 	**Consult instructions for use**
5.4.4 	**Caution**	5.5.1 IVD	**In-vitro diagnostic medical device**
5.5.5 	**Contains sufficient for < n > tests**		

13.3 Manufacturer Catalog

Manufacturer Catalog Number	Description
30001	ANYSIS™ System
30005	ANYSIS™ Instrument
30010	ANYSIS™ Wet Quality Control (WQC), kit of 6 control solutions (3 WQC 1, 3 WQC 2 solutions)
30020	ANYSIS™ C/EPI Test, kit of 20 C/EPI test cartridges
30030	ANYSIS™ C/ADP Test, kit of 20 C/ADP test cartridges
30040	ANYSIS™ Aspirin Test, kit of 20 Aspirin test cartridges
30050	ANYSIS™ P2Y12 Test, kit of 20 P2Y12 test cartridges

13.3.1 Spare parts and accessories

Manufacturer Catalog Number	Description
30080	ANYSIS™ thermal printer paper
01001	Power cord, US
01002	Power cord, Continental Europe
01003	Power cord, United Kingdom
01004	Fuse, 1A/250V, 5x20mm SLO-BLO type
30081	ANYSIS™ Test Cartridge rubber cap, compatible with all cartridge types