Thrombotrack™ Select 2

IVD

GB Instruction Manual

CE

Manufacturer: Axis-Shield PoC AS
Oslo, Norway

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CONTENTS

General information

This instruction manual contains information necessary for installation and operation of the Thrombotrack™ Select 2.

Chapter 9 specially covers warnings and precautions. In addition, and in connection with relevant chapters, important information with respect to security and optimum use of Thrombotrack™Select 2 is described. The first indication of such information is:

IMPORTANT! ***The users must conscientiously reads and understand these instructions to fully utilize the capabilities of the Thrombotrack™ Select 2!***

This instruction manual is valid for Thrombotrack™ Select 2 with software versions later than V 2.08.

1 Intended use

Thrombotrack™ Select 2 is a coagulation instrument with processor driven measuring system. Coagulation is detected by the viscosity change that occurs upon clot formation. This patented system enables analyses of all coagulation parameters using whole blood or plasma samples.

Based on input of calibration curves and reagent specific data Thrombotrack™ Select 2 can calculate converted values like coagulation activity in % and INR for PT tests.

2 Installation and environmental conditions

2.1 The package unit

The contents of the package unit for Thrombotrack™ Select 2 , material number 1054880 is:

Thrombotrack™ Select 2	1 unit
Cuvette racks	14 x 8 units
Steel balls	1 x 112 units
Reagent cups, 20 mm	25 units
Dust cover	1 unit
Steel ball dispenser	1 unit
Mains adapter 230 V-12 V	1 unit

2.2 Unpacking of Thrombotrack™ Select 2

Check the packaging for any signs of shipping damage.
Open the packaging and take out the accessories and the instrument.

Check the contents for completeness according to information in chapter 2.1 and sign the Instrument Warranty Card following package unit.

IMPORTANT! ***If packaging or contents is damaged, or anything is missing, contact your local distributor.***

2.3 Placing of Thrombotrack™ Select 2

Select a location where the instrument is not exposed to direct sunlight, excess heat, humidity, dust or vibrations.

To ensure that the measuring block's temperature control (37°C) can work properly, the room temperature should be between 17°C and 28°C.

Place the instrument in a position that allows unhindered access to the power outlet at any time.

IMPORTANT! ***Do not install next to water fittings, baths, sinks, etc.***
Do not place near centrifuges, washers, dishwashers, etc.
Do not install close proximity to radiators or other sources of heat, etc.

Place the instrument on a sturdy, level surface.

2.4 Turn on Thrombotrack™ Select 2

The instruction below is related to figure 2.

1. Set the ON/OFF switch (7) at the rear of the Thrombotrack™ Select 2 to position "0FF".

2. Plug the cord of the AC adaptor into the AC/DC socket (8).

3. Connect the cord for the start pipette to one of the PIPETTE connectors (10) (Start pipette is optional).

4. Connect printer (or host computer) cable to the COM connector (9) (Printer is optional).

5. Check that all cords and cables are properly connected.

6. Plug the AC adaptor into the mains socket outlet.

7. Turn the Thrombotrack™ Select 2 ON with the ON/OFF switch (7).

IMPORTANT! ***Do only use the supplied adapter.***
The mains voltage must coincide with the technical specifications of the instrument.

The mains circuit must have adequate fuse protection.
The instrument must be connected to a properly grounded outlet only.
If in doubt about mains voltage or the circuit in general, contact a qualified electrician.
Do not connect other electrical appliances that may cause interference to the circuit.
Do not set up the instrument near electrical appliances causing electric interference (appliances bearing no CE-label).
Avoid connection to circuits to which other appliances having a high current draw (e.g. centrifuges) or which turn on and off frequently (e.g. refrigerator, water bath, etc.) are connected.
Ensure that the power cord cannot be step on.
All connections to the instrument should be made with the instrument turned OFF.

2.5 Turn off Thrombotrack™ Select 2

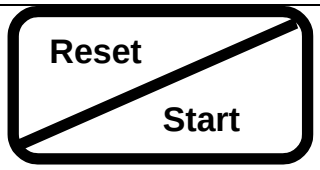
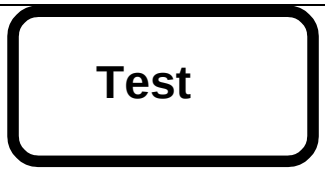
1. Turn the Thrombotrack™ Select 2 off with the ON/OFF switch (7).

2. Remove all used cuvettes and cover the instrument with the supplied dust cover.

3 Functional description of Thrombotrack™ Select 2

3.1 Symbols on Thrombotrack™ Select 2

Two buttons as shown in the table below operate Thrombotrack™ Select 2.

Buttons		Synonymous with
Symbols		<RESET/START>
		<TEST>

3.2 The functional parts of Thrombotrack™ Select 2

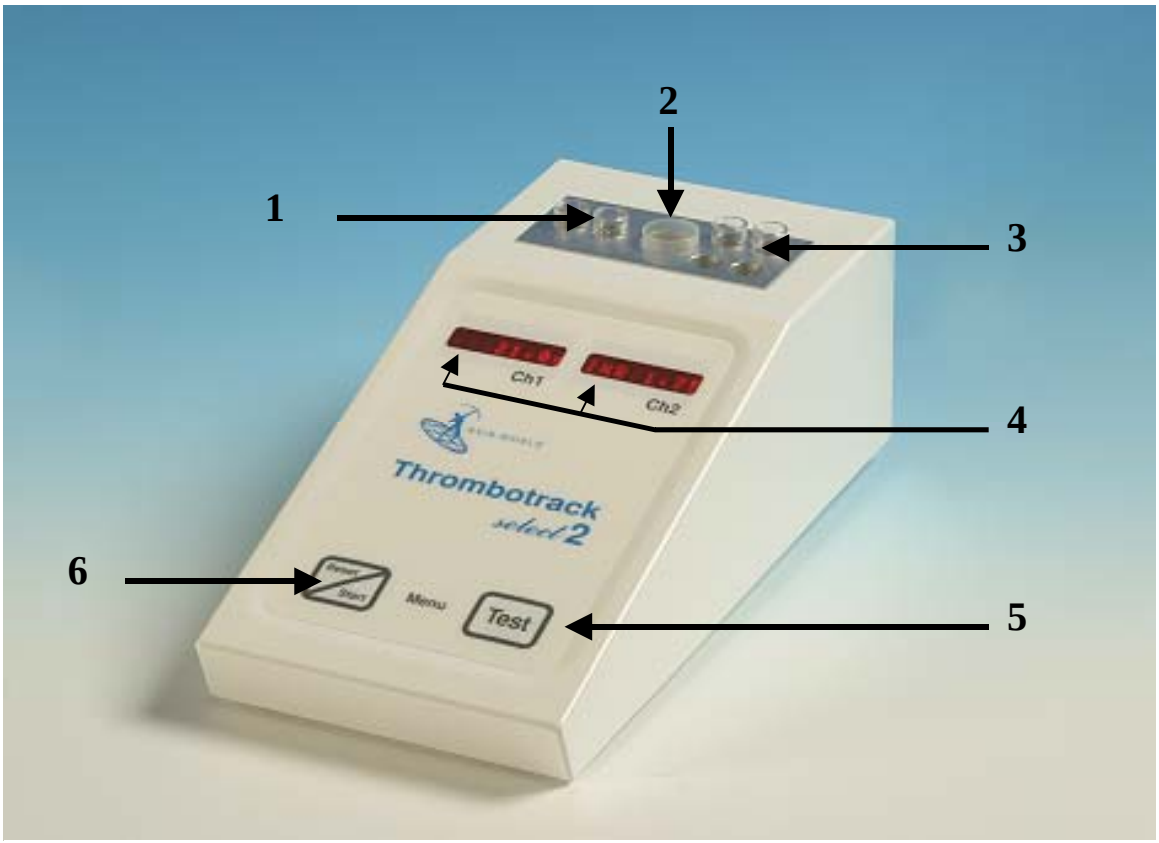


Figure 1

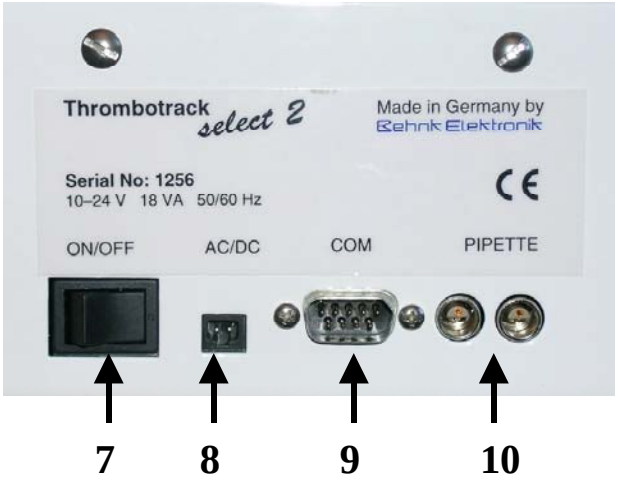


Figure 2

1 Measuring channels
- Two channels are available for measurement

2 Heating position for reagent cup
- One position for heating reagent

3 Heating positions for cuvettes
- Four positions, two integrated with programmable timer for monitoring of the heating time

4 Alphanumeric LED-displays
- Displays measuring results and inform the user of errors.

5 <TEST> button
- See description of buttons in chapter 3.3

6 <RESET / START> button
- See description of buttons in chapter 3.3

7 ON/OFF switch
- For switching ON/OFF

8 AC/DC socket
- For connection of the AC adapter

9 COM connector
- For connection of printer or host computer

10 Pipette connectors
- For connection of start pipette

3.3 Description of <TEST> and <RESET/START > buttons

3.3.1 Main menu

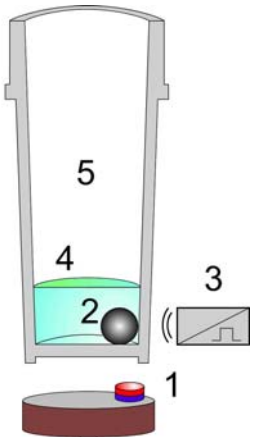
The table below describes the functions of the buttons in the main menu.

Buttons	Function	Description
<TEST>	Select tests	By pressing <TEST> different tests can be selected
	View results	By pressing <TEST> as soon as the measurement is completed, different parameters are displayed, eg. Sec, pat. No.
<RESET/START>	Start the measurement (Without start pipette)	This button activates countdown. Display counts down from 3 seconds. At 0, the measuring time starts. The sample (or start reagent) is added simultaneously
	Reset counters and adjust measuring channels	By pressing <RESET/START> when results are displayed, the instrument is reset and ready for new measurement
	Cancel of measurement	By pressing <RESET/START> when the timer is counting, the measurement is cancelled

3.3.2 Test setting menu

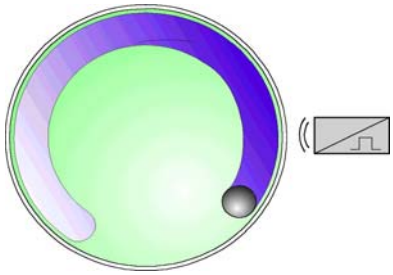
The menu for view and editing of test parameters (calibration data, incubation time, double or single determinations and tolerance) is activated by pressing <RESET/START> and <TEST> at the same time. The description of this menu is given in chapter 7.

3.4 The measuring system



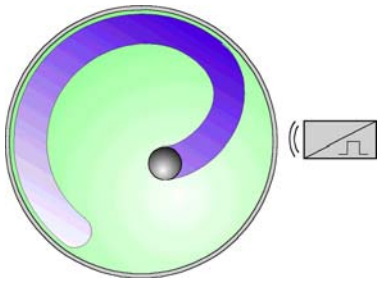
A motor driven magnet (1) beneath a cuvette (5) lets the steel ball (2) rotate in a circular path along the edge of the cuvette's base (Fig. 3). A sensor (3) monitors the continuous rotation of the steel ball. The movement of the ball causes a gentle and optimal homogenizing of the sample (4). Due to this the clotting reaction within the sample takes place in an absolutely synchronous manner.

Figure 3



When the clotting starts the viscosity of the sample changes, affecting the continuous motion of the ball. When a strong clot is formed, the steel ball will stop as shown in figure 4.

Figure 4



A weak clot will deflect the ball towards the center of the cuvette's base (Fig. 5). The sensor detects the clot formation.

Figure 5

In both cases the starting of the clotting is positively detected, irrespective of the sample's cloudiness.

3.5 The functionality of Thrombotrack™ Select 2

The following tests can be performed with the Thrombotrack™ Select 2:

Test order	Test name on display	Test description	Available tests from Axis-Shield PoC
1	PT	Prothrombine time	Thrombotest™, Normotest™, Nycotest® PT, Nycoplastin™
2	PTT / APTT	Activated partial thromboplastin time	Cephotest™
3	TT	Thrombin clotting time	No
4	FIB	Fibrinogen according to Clauss method	No
5	Test A	Free tests, such as factor determination	No
6	Test B	Free tests, such as factor determination	No
7	Test C	Free tests, such as factor determination	No
8	Test D	Free tests, such as factor determination	No
9	Lysis	Thrombolysis test	No

Thrombotrack™ Select 2 has the following functions:

- Automatic start when sample or reagent is added with the start pipette
- Manual start when using a standard pipette
- Input of correlation curves
- Input of reagent-specific data, e.g. ISI
- Calculation of the sample activity
- Serial interface (RS 232) for the connection of a printer or host computer
- Reaction process monitoring
- Notification of critical events

3.6 Consecutive recognition of the tests

Tests are automatically numbered from 1 to 999 consecutively after turning on the instrument. Double determinations are given the same sample number.

4 Preparation prior to operation

The placing conditions and how to turn on Thrombotrack™ Select 2 are described in chapter 2.3 and 2.4.

4.1 Connecting a start-pipette

Two start-pipettes can be connected to the back of the instrument. When adding the start-reagent with a standard laboratory pipette, <RESET/START> has to be pressed simultaneously to start the measuring time.

4.2 Loading the steel ball dispenser

- Unscrew the steel ball dispenser tip.
- Fill steel balls from the steel ball tube into the ball dispenser.
- Screw the steel ball dispenser tip on again.

5 Operating procedures

5.1 Introduction

The operating procedures described in this chapter include the specific procedures for Thrombotest™, Normotest™, Nycotest® PT, Nycoplastin™ and Cephotest™.

It is presuppose that test-settings (calibration data, incubation time, double or single determination and tolerance) and reagent preparation are completed and correct. The test-setting menu is described in chapter 7.

Chapter 6, User guidelines, gives information related to use of reagents, calibration and controls.

5.2 The start up procedure of Thrombotrack™ Select 2

1. Turn on by pressing the ON/OFF switch on the back of the instrument.

   The indicators of the two incubation channels are briefly illuminated and a beep sounds.

   The following text appears: Axis-Shield Thrombotrack™ Select 2 V x.xx

2. The date is displayed (e.g. 20/09/03).

   a) To confirm date, press <TEST>
   b) To change the date:
      Enter the actual number with <RESET/START>. The display flashes, select the right number with <TEST> and confirm with <RESET/START>

The message “TEMP LO” appears and remains until the correct operating temperature is reached.

Note: At a room temperature of approx. 23°C the heating-up time is approx. 10 - 15 minutes.

3. When correct temperature is reached, “ADJUST” flashes in the display, followed by the last measured or selected test. The instrument is now ready for testing.

4. The test is selected by pressing <TEST>

5.3 General information during operation

Before starting the specific operating procedure the following information should be considered:

Cuvettes: It is recommended to use multiple cuvettes (prod. no. 1003386, Cuvette racks + Steel balls).

Dispensing steel balls: When dispensing steel balls, by means of the steel ball dispenser, into each cuvette, the dispenser should be placed on the cuvette in such a manner that the steel ball is kept from ricocheting.

Pre-heating In the operating procedures for Thrombotest™, Normotest™ and Nycotest® PT it is expected that the method specific reagent volume is heated up 37°C in the cuvette heating positions.

For Nycoplastin™ and Cephotest™, a sufficient volume of reagent for performing the required number of tests must be pre-heated. In order to reach the required temperature of 37°C in the reagent cup heating position, the volume of the reagent must not exceed 4 mL. The time required depends on the reagent temperature and may take 15-20 minutes.

Incubation timer The heating positions for cuvettes have two integrated positions, located to the right hand side, with programmable timer for monitoring of the heating time. By pressing briefly on the right hand cuvette the incubation timer is started. A beep is sounded and the right-hand cuvette is illuminated in red. 10 seconds before the end of the incubation time the cuvette starts flashing, a beep indicates that the incubation time has lapsed and the illumination is turned off.

The setting of incubation time is described in chapter 7.

5.4 Operating procedure, Thrombotest™

5.4.1 Citrated whole blood method, 50 µL ("diluted method")

Volumes:
Sample volume: 50 µL citrated whole blood
Reagent volume 250 µL

Main steps		Procedure details	
A	***Pre- measurement***	I	Place cuvettes in the 37ºC pre-heating positions and add one ball to each cuvette with the ball dispenser
		II	Pipette 250 µL of the reagent into the cuvette and pre-heat for 5 min. Frozen reagent must be preheated for 15 minutes
		III	Place the cuvette with 250 µL of pre-heated reagent in the measuring position
B	***Auto start***	I	Pipette 50 µL of sample into the cuvette with the start pipette
	Manual start W/count down	II	Press <RESET/START>. The display counts down from 3 seconds. At 0, and signal tone, pipette 50 µL of sample into the cuvette with a standard pipette
C	***End point***	I	Upon clotting, first the value in seconds is shown followed by the coagulation value calculated by the calibration curve. When pressing <TEST>, display of the value in seconds and the sample number can be recalled

5.4.2 Plasma method, 30 µL ("Undiluted method")

Volumes:
Sample volume: 30 µL undiluted plasma
Reagent volume 250 µL

The procedure is the same as for 5.4.1 with exception from the sample volume (5.4.1, step B I or B II).

5.4.3 Capillary blood method

Volumes:
Sample volume: 50 µL capillary blood
Reagent volume 250 µL
The operating procedure is the same as for 5.4.1.

5.5 Operating procedure, Normotest™

5.5.1 Citrated whole blood method, 25 µL ("diluted method")

Volumes:

Sample volume: 25 µL citrated whole blood
Reagent volume 250 µL

Main steps		**Procedure details**	
A	***Pr- measurement***	I	Place cuvettes in the 37ºC pre-heating positions and add one ball to each cuvette with the ball dispenser
		II	Pipette 250 µL of the reagent into the cuvette and pre-heat for 5 min.
		III	Place the cuvette with 250 µL of pre-heated reagent in the measuring position
B	***Auto start***	I	Pipette the 25 µL of sample into the cuvette with the start pipette
	Manual start W/count down	II	Press <RESET/START>. The display counts down from 3 seconds. At 0, and signal tone, pipette 25 µL of sample into the cuvette with a standard pipette
C	***End point***	I	Upon clotting, first the value in seconds is shown followed by the coagulation value calculated by the calibration curve. When pressing <TEST>, display of the value in seconds and the sample number can be recalled

5.5.2 Plasma method, 15 µL ("Undiluted method")

Volumes:

Sample volume: 15 µL undiluted plasma
Reagent volume 250 µL

The procedure is the same as in 5.5.1 with exception from the sample volume (5.5.1, step B I or B II).

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5.6 Operating procedure, Nycotest® PT

Volumes:

Sample volume:	100 µL diluted plasma *
Reagent volume	200 µL

* Plasma must be diluted 1+6 with Nycotest® PT Dilution Liquid

Main steps		**Procedure details**	
A	***Pr- measurement***	I	Place cuvettes in the 37ºC pre-heating positions and add one ball to each cuvette with the ball dispenser
		II	Pipette 200 µL of the reagent into the cuvette and pre-heat for 5 min
		III	Place the cuvette with pre-heated reagent in the measuring position
B	***Auto start***	I	Pipette 100 µL of sample into the cuvette with the start pipette
	Manual start w/count down	II	Press <RESET/START>. The display counts down from 3 seconds. At 0, and signal tone, pipette 100 µL of sample into the cuvette with a standard pipette
C	***End point***	I	Upon clotting, first the value in seconds is shown followed by the coagulation value calculated by the calibration curve. When pressing <TEST>, display of the value in seconds and the sample number can be recalled

5.7 Operating procedure, Nycoplastin™

Volumes:

Sample volume:	100 µL undiluted plasma
Reagent volume	200 µL

Main steps		**Procedure details**	
A	***Pre-measurement***	I	Pre-heat sufficient amount of reagent to 37ºC in the plastic cup heating position
		II	Place cuvettes in the 37ºC pre-heating positions and add one ball to each cuvette with the ball dispenser
		III	Pipette 100 µL of plasma into a cuvette in the pre-heating position and incubate for 60 sec.
		IV	When incubation of plasma is completed, move the cuvette to the measuring position
B	***Auto start***	I	Pipette 200 µL of pre-heated reagent into the cuvette with the start pipette
	Manual start W/count down	II	Press <RESET/START>. The display counts down from 3 seconds. At 0, and signal tone, pipette 200 µL of pre-heated reagent into the cuvette with a standard pipette
C	***End point***	I	Upon clotting, first the value in seconds is shown followed by the coagulation value calculated by the calibration curve. When pressing <TEST>, display of the value in seconds and the sample number can be recalled

5.8 Operating procedure, Cephotest™

Volumes:
Sample volume: 100 µL undiluted plasma
Cephotest reagent: 100 µL
$CaCl_2$, 20 mM: 100 µL

Main steps		**Procedure details**	
A	***Pre- measurement***	I	Pre-heat sufficient amount of $CaCl_2$ to 37ºC in the plastic cup heating position
		II	Place cuvettes in the pre heating positions and add one steel ball to each cuvette with the ball dispenser
		III	Pipette 100 µL of plasma into a cuvette in the pre-heating position
		IV	Pipette 100 µL of Cephotest™ reagent into the cuvette with 100 µL plasma and incubate for 6 min.
		V	When incubation of plasma and reagent is completed, move the cuvette to the measuring position
B	***Auto start***	I	Pipette 100 µL of pre-heated $CaCl_2$ into the cuvette with the start pipette
	Manual start w/count down	II	Press <RESET/START>. The display counts down from 3 seconds. At 0, and signal tone, 100 µl of pre-heated $CaCl_2$ is pipetted into the cuvette with a standard pipette
C	***End point***	I	Upon clotting, the timer stops and the value in seconds is shown

6 User guidelines

6.1 Use of reagent

The package inserts for reagents from Axis-Shield PoC provides all information necessary for reagent preparation and use. The same applies to the respective controls or calibrators.

Always follow this instruction; improper use may lead to incorrect results.
In case various ways of performing a test are described (e.g. for automated instruments), the instructions concerning manual performance of the test are prevailing.

When using less volume than stated in the reagent package inserts, it is important to reduce all pipetting volumes by same percentage. Make sure that the total sample volume is not less than 150 µL.

6.2 Calibration and interpretation of results

The measured time is the time from adding the sample (or start reagent) until the occurrence of coagulation. The value in seconds is the basis for calculation and interpretation of the result.

Reagent packages for PT tests from Axis-Shield PoC contain inserts with reagent- and batch specific calibration data (Correlation tables). If there is uncertainty regarding use of calibration data on Thrombotrack™ Select 2 contact your local distributor.

The specific inserts from Axis-Shield PoC provide information on how to interpret results obtained.

The description of how to enter and edit calibration data on Thrombotrack™ Select 2 is given in chapter 7.1.

6.3 Quality Control

To control the instrument, reagents and test methods, special control plasmas are used. In the package inserts from Axis-Shield PoC recommendation for use of controls are included.

The package inserts for the control plasmas give all necessary information for preparation and use. The control kits also include needed data-keys with recommended values. Control plasmas available from Axis-Shield PoC are listed in the table below.

Control plasmas	**Thrombotest™**	**Normotest™**	**Nycotest® PT**	**Nycoplastin™**	**Cephotest™**
Control Plasma Normal		R	R	R	R
Control Plasma AK	R	R	R	R	
Control Plasma Abnormal	R	R	R	R	R
Control Plasma Heparin					R

R means recommended values that are stated in the data-keys.

6.4 Operational Check of the Thrombotrack™ Select 2

- Start an analysis without placing a twin cuvette in the measuring channels. After approx. 1.1 seconds both displays will show "*NO BALL"*, i.e. no ball was detected in none of the measuring channels.

- Dispense one ball each into a twin cuvette and fill both with at least 150 µL distilled water or buffer. Place the cuvette in the measuring channel and start an analysis by pressing <RESET/START>. After a time longer than 1.1 seconds, remove the cuvette from the measuring channels. The displays will stop and show the corresponding "measuring result".

7 Test setting menu

The tests stored in Thrombotrack™ Select 2 (see chapter 3.5) are selected by pressing <Test> in the main menu.

This chapter describes how to enter the test-setting menu for editing calibration data and test parameters. The test parameters which can be edited are; calibration data, incubation time, double or single determinations and tolerance.

Chapter 7.1 uses the PT function to give examples on how to set up calibration curves in order to obtain calculation of % and INR. Chapter 7.2 explains the procedure for calculation of INR only. Chapter 7.3 gives explanations related to other tests on Thrombotrack™ Select 2.

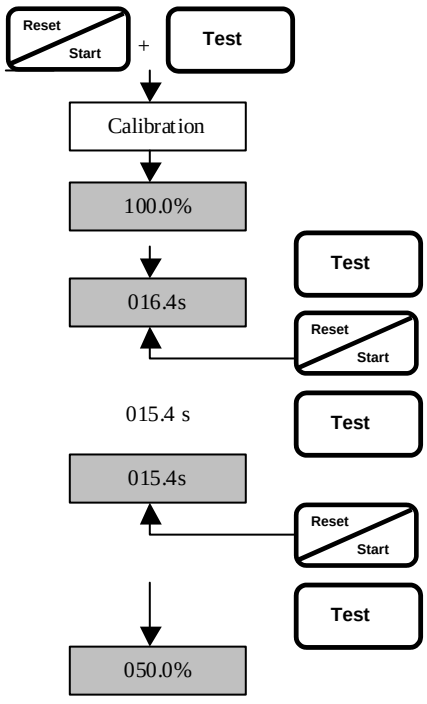
7.1 Editing calibration data and test settings for PT tests

Select the PT test with <TEST> and press <RESET/START> and <TEST> at the same time as shown on the figure below. "Calibration" appears for a short moment followed by the first calibration value. If no value is to be changed, scroll with <TEST> until "SAVEDATA" appears.

To obtain a measuring result in %

- A time value (calibration value) must be assigned for each calibration point.
- At least 2 calibration points must be entered.

Note: A maximum of 5 calibration points can be set. If, for example, only 4 points are to be set, enter the time value 000.0 seconds for calibration point 5 (see example).



Press <TEST> to choose the calibration value.

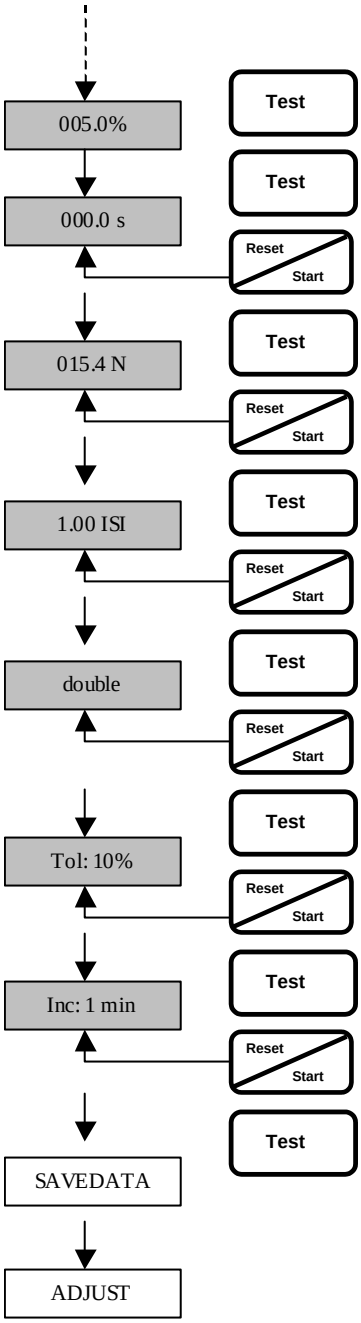
Press <RESET/START> to select the digit to be changed. The selected digit will start to flash.

Press <TEST> to change the selected digit.

Press <RESET/START>to select the next digit, or Press <RESET/START> until no more digits are flashing.

Continue to press <TEST> to choose the next calibration point to be edited.

In this example the curve is suppressed by entering 000.0 sec. to the corresponding calibration point (005.0%)



Press <TEST> to select the second value belonging to 005.0%.

Press <RESET/START>, select the digits and set to 000.0 sec. by pressing <TEST>.

By pressing <TEST> the display of normal time appears. By digit selection with <RESET/START> and changing with <TEST> the normal time is set.

Press <TEST> and ISI value is displayed. Select the digits to be changed by <RESET/START> and change by the <TEST> button.

The next display is double (or single) determination. Pressing <RESET/START> makes the selection.

If double is selected the next display is the Tolerance. As above the digit to be changed is selected by the <RESET/START> button. Pressing the <TEST> button makes the changing.

The next display is Incubation. The time will flash and is changed by pressing the <RESET/START> button.

The last pressing of <TEST> is followed by a short display of SAVEDATA and ADJUST. The display moves back to the test selected.

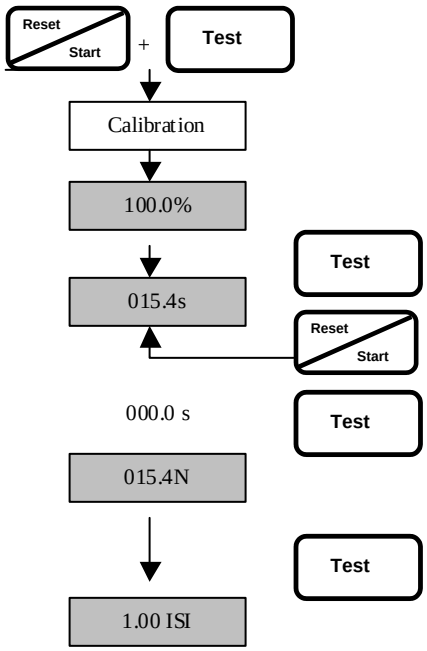
Note: All the calibration points (%, mg/dL or g/L) are edited in the same way as described above.

IMPORTANT! ***When entering calibration curves that have an increasing or decreasing trend, it is important to ensure that calibration values in seconds always increases from the first to the last calibration point. Only the quantity information (%, mg/dL, g/L) may show an increase or decrease.***

If a calibration value smaller than the previously entered value is entered, this will be indicated by an alarm tone and the message "ERROR 20" in the display. By pressing <TEST> the error message is cleared and the system returns to the first calibration point to correct the entries.

7.2 Setting up PT for calculation of INR only

The previous chapter described how to set up a calibration curve for calculation of % and INR. Assumed that calculation of only INR is needed, the procedure is as follows.



The menu is entered as described in chapter 7.1 and "Calibration" will appear shortly before the first calibration point (100%) is seen on the display.

When pressing <Test> the second value corresponding to 100%, 15.4 seconds is seen on the display.

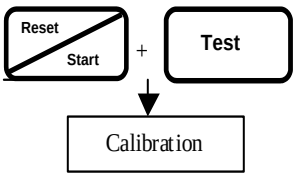
By selection of digits by the <RESET/START> button and changing by the <Test> button, the time is set to 000.0 second.

Coming up next on the display after pressing <Test> is the normal time (15,4 second).

The rest of the procedure is the same as described in chapter 7.1

7.3 Editing test settings for other tests

7.3.1 PTT/APTT (Cephotest™)



Select the PTT test with <TEST> and press <RESET/START> and <TEST> at the same time as shown on the figure. "Calibration" appears for a short moment followed by normal time (displayed as xxx.xs N).

The calibration/test settings data that can be edited for the PTT/APTT are:
- Normal time
- Double (or single) determination
- Tolerance
- Incubation time

For selection and editing of parameters see the example for PT test described in chapter 7.1.

If normal coagulation time is entered, RATIO between measured coagulation time and normal coagulation time is calculated and displayed. In order to display second values only, the normal time is set to 000.0 second.

When setting up for Cephotest™, the incubation time shall be set to 6 minutes.

7.3.2 Fibrinogen

Select FIB (Fibrinogen test) with <TEST> and press <RESET/START> and <TEST> at the same time. The first data coming up after the message "Calibration" is the concentration unit. Thrombotrack™ Select 2 express the results in mg/dl or g/l. To press the <RESET/START> button makes the selection.

When pressing <TEST>, the first calibration point appears. To set up the curve the same procedure as for PT can be followed; a time value is assigned for each calibration point.

As for PT the maximum of calibration points is 5. At least 2 calibration points must be entered. When only 2 calibration points are needed, enter 0.000mg/dl for the 3.calibration point.

When the calibration curve is completed, the dilution factor decided by the fibrinogen method is entered. Thereafter, double (or single) determination, tolerance and incubation time are entered.

7.3.3 Test A, B, C and D

Select test A, B, C or D by the <TEST> button. The procedure described in chapter 7. 1 can be followed.

8 Printer DPU 414 (optional)

To the <COM> port of the Thrombotrack™ Select 2, an Epson® compatible printer with a serial input port can be connected. We offer a suitable printer as optional accessory (DPU 414, Cat. No 012 224).
For communication the Thrombotrack™ Select 2 parameters are preset as below:
Baud rate: 19200 Format: 8 Bit Parity: No Stop bit: 1

8.1 Installing the DPU 414 Printer

For instructions regarding installation and operation of the DPU 414, refer to the Instructions for Use supplied with the printer. Turn both printer and Thrombotrack™ Select 2 off. The printer cable supplied is connected to the <COM> port of the Thrombotrack™ Select 2 and to the port marked “SERIAL” of the DPU 414.
Turn the printer on first, then the Thrombotrack™ Select 2.

8.1.1 Printer Logs

```
Axis-Shield Thrombotrack Select-2 V2.08

**  Test arrangement 1  **
Date              01/07/02
Channel  Pat  Test
1+2      A      PT double
--------------------------
```

After turning the Thrombotrack™ Select 2 ON, the manufacturer, the instrument's designation and the program version are printed.

When the date is confirmed or corrected, the current date and the last selected test are printed. In this example PT - repeat determination.

```
Date              01/07/02
Result                   1
Channel 1+2 PT
Time 1     14.6s
Time 2     13.8s
Average    14.2s
Activity              54.9%
INR                   1.18
```

The illustration on the left shows the log of a PT double determination.

```
Date                01/07/02
Result                     1
Channel 1+2 PT
Time 1      14.6s
Time 2      13.8s?
Average     14.2s
Activity               54.9%
INR                     1.18
```

If the measuring is uncertain, the respective measuring time (in this case Time 2) is flagged with a question mark.

```
TOLERANCE  OUT OF  RANGE!
Date              01/07/02
Result                   6
Channel 1   PT
Time 1     19.1s
Activity              40.7%
INR                    1.59

Result                   6
Channel 2   PT
Time 2     15.3s
Activity              49.1%
INR                    1.28
```

If the single time values are outside tolerance no mean value will be calculated. In this case the single time values are treated like single determinations.

8.1.2 Printing the Test Parameters

```
**  PT-PARAMETERSET  **
Date              01/07/02
Point     Activity  Time
1         100.0%    10.0s
2         50.0%     15.0s
3         25.0%     34.0s
4         12,5%     56.8s
Normal time         :12.0s
ISI                 :1.00
Tolerance           :10%
Determination       :double
Incubation time     :2min
```

Once all test parameters have been edited, the message "*SAVEDATA"* is displayed. They are stored in the Thrombotrack™ Select 2 and simultaneously printed out.

Would you like to print existing test parameters, select the respective test and proceed as detailed in section "Editing the Calibration Values". Confirm all items with the <TEST> button until the message "*SAVEDATA"* appears in the display.

9 Warnings and precautions

- All biological substances should be regarded as a potential source of infection!
- Wear gloves when handling blood, blood samples and objects contaminated by blood!
- Strictly follow the existing regulations pertaining to the handling and manipulation of reagents for laboratory use and blood samples
- Trained specialists shall only operate this instrument. The user must be familiar with the instruction manual and be able to work accordingly in order to fully utilize the capabilities of the Thrombotrack™ Select 2
- This product generates and uses high-frequency energy and may radiate such energy if the product is not installed and operated as detailed in these instructions.
- We recommend that you observe the different error messages displayed by the instrument.
- Intervention in and modification of the product, not explicitly approved by the manufacturer, may result in inoperativeness. The costs for necessary repairs are to be borne by the user.
- The manufacturer is not liable for any damage resulting from disregard of the specifications stated in these instructions, damage caused by handling of reagents and biological fluids or other action with the product not in conformity with these instructions.
- Data processing equipment connected to the instrument, such as personal computers or printers, must conform to the EN 60950 or UL 1950 standard, respectively.

10 Troubleshooting

10.1 Error Description

Problem	Possible cause	Corrective actions
Early stop or poor viscosity	Pipetting too forceful Sample preparation Volume error	This may cause bubbling, which disturbs the movement of the ball and thus the measuring. Check the preparation of the sample. Check the volume.
Message *"NO BALL"*	No ball in the cuvette Cuvettes are incorrectly seated in the measuring channel A ball may be present in the measuring channel	No ball dispensed into the cuvette. Cuvette is not pushed all the way down into the measuring channel. A ball in the measuring channel prevents the cuvette from being seated correctly. Remove the ball from the measuring channel. Discard the ball removed from the measuring channel as it has become magnetized.
Message *"Time out"* Excessive measuring times Measuring does not stop	Sample preparation Volume error	The maximum measuring time of 599s has been exceeded. The system does not detect any clotting. In this case the sample preparation should be checked. With Fibrinogen too much dilution of the plasma may also be the cause.
Message *"? XX.Xs"*	Extremely small blood clot Disturbance of the ball's rotational movement	The automatic ball monitoring indicates a problem with the ball's rotational movement by a question mark "?". The cause may be an extremely small blood clot formation or small particles in the sample. The analysis should be repeated or, if the values are within tolerances when performing a repeat determination, the value may be accepted.
Message*"TEMP HI"*	The temperature of the measuring block is too high	One reason may be exposure to direct sunlight or installation close to a heater/radiator, which provides additional heating of the measuring block. In this case the location should be changed. Another reason may be too high room temperature (> 30°C).
Message*"TEMP LO"*	The temperature of the measuring block is too low	The instrument is exposed to a cold draft or placed near an opened window. The instrument should be relocated.
The display remains dark	Instrument not turned ON The AC adaptor is not connected	Check the following: - "ON/OFF" switch at the rear of the instrument turned ON? - Is the power cord from the AC adaptor properly plugged into the "AC/DC" socket at the rear of the instrument? - Is the AC adaptor plugged into a mains socket outlet? - Is the mains socket outlet ok? ***IMPORTANT! Have the outlet checked by a qualified electrician!*** If all of the above is found to be in order, please contact your local distributor or service.
Printer does not print	Printer not online Printer out of paper Incorrect parameter setting of the printer	Set the printer online. Install a fresh roll of paper. Check installation and parameter settings of the printer (see Instructions for Use).

10.2 Error messages

Message	Meaning	Corrective actions
"ERROR 00"	Software error	Turn instrument OFF, then ON again
"ERROR 01"	Software error	Turn instrument OFF, then ON again
"ERROR 10"	Print buffer overflow	Turn instrument OFF, then ON again
"ERROR 20"	Calibration curve not constant	Correct calibration values (Enter measuring times in ascending order)
"ERROR 21"	Checksum error	Check test data entries
"ERROR 30"	Unknown transmission format	Update EPROM version * (Devices are not compatible)
"ERROR 31"	Data transmission error	Update EPROM version * (Devices are not compatible)

* These messages may appear when the software is updated. Service engineer carries out a software update.

11 Cleaning

To clean the Thrombotrack™ Select 2 use an absorbent paper moistened with an alcoholic solution or wiping disinfectant with a pH-value between 7.4 and 9.0. Any other detergents having a higher pH-value may cause damage to the housing, measuring block or other components.

IMPORTANT! ***Do not use cleaners containing ammonium chloride or chlorine, as normally their pH-value is higher than 9.0!***

To protect the measuring channels we advise always to leave empty cuvettes in the measuring channels when the instrument is not being used.

12 Maintenance

The Thrombotrack™ Select 2 does not require periodic maintenance or adjusting. The instrument is maintenance-free. The instrument's software permanently monitors all functions. Changes in the system (e.g. aging of the sensor) are automatically compensated.

13 Warranty

Axis-Shield PoC guarantees a warranty period of 12 months from the date of delivery to the user. For this period it is guaranteed that the Thrombotrack ™ instrument works within quality requirements valid on the date of manufacture release.

Axis-Shield PoC is prepared to compensate for faulty material or malfunctions within the limitations of the warranty.

Tampering with the internal components, damage due to operating errors, misuse and overlooking essential information with respect to warnings and precautions described in this User Manual will invalidate the warranty.

The acknowledgment of claims shall immediately be reported to your local supplier.

14 Technical data

Specifications		
	Thrombotrack™ Select 2	
Protection class	I	
Working voltage	12 - 24VDC or 10 / 20VAC	
Power input	16W	
	AC adaptor	
Protection class	II	
Working voltage	230V AC ± 10% / 50 - 60 Hz	
Power output	20VA	
Dimensions		
	Thrombotrack™ Select 2	Thrombotrack™ Select 2 with packing
L x W x H	20.7cm x 11.3cm x 6.8cm	40cm x 30cm x 18cm
Weight	1.1kg	3.1kg
	Space required	
L x W x H	40cm x 50cm x 50cm	
Ambient Conditions		
Operating temperature	+17°C - +28°C	
Storage temperature	+10°C - +40°C	
Rel. humidity	80% at 31°C - 50% at 40°C	
Maximum heat output	20W	
Over voltage class According to Annex J, EN 61010-1:1993	II	
Usage environment	Indoor use in residential areas, commercial dwellings and light industrial environments	
Test Volume (sample + reagent)		
Minimum	150µl	
Maximum	400µl	
Accessories		
	Product number	
Start Pipette 20 - 200µl	1114960	
Cuvette racks+ Steel balls, 1000 pcs	1003386	
Reagent cups, 100 pcs.	1054881	
Printer DPU 414	1111506	
Thermal paper (5 rolls/pack)	1054878	