MERLINmedical®
EXPERIENCE. THE POWER OF INNOVATION.

MC1

OPERATION MANUAL

Instrument Manufacturer:
ABW Medizin und Technik GmbH
Lagesche Str.15
32657 Lemgo
Germany

IVD CE

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SAFETY INSTRUCTIONS

Symbols used on the MERLINmedical haemostasis instruments and consumables

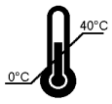
Symbol	Meaning	Used on / in
	Do not reuse	Balls & cuvettes
IVD	In-Vitro Diagnostics Device	Operation manuals
	Biological risks	MC 1 MC 4plus MC 10plus
	Consult instructions for use	MC 1 MC 4plus MC 10plus
LOT	Batch code number	Balls & Cuvettes
	Manufactured by	MC 1 MC 4plus MC 10plus
	Use by date: YYYY-MM	Balls & Cuvettes
	Temperature limits for storage	Balls & Cuvettes
Label “Serial number”	Back of instrument	MC 1 MC 4plus MC 10plus Power supply unit

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TABLE OF CONTENTS

Before use read this operation instruction very carefully!
Be sure to keep this manual for future reference should any questions or problems arise.

1. Introduction

1.1 Guarantee

The company ABW Medizin und Technik GmbH, called ABW in the following, grants the first buyer that the of ABW purchased instruments are free of material and processing failures under normal utilisation.

This guarantee applies for one year as of date of invoice of the first purchase (the "period of guarantee").

Should failures occur within the period of guarantee please contact the ABW-customer service immediately (phone: +49 (0) 5261 / 927 294). When contacting the customer service important information as e.g. the detailed description of the defect as well as instrument type and ID-number of the MC 1 have to be communicated.

The customer service is available for questions concerning guarantee from Monday until Friday from 8:30 a.m. until 5:00 p.m. (public holidays excluded). ABW charges the customer for repair of defects beyond the period of guarantee as well as for the repair of defects which are not covered by the guarantee according to the at that point of time valid costs for work and material.

Following defects which essentially require a repair are excluded from this guarantee:

Defects which are

a) not within the period of guarantee and not communicated within one week after occurring to ABW
b) caused by chemical decomposition or corrosion
c) described in the manual of ABW
d) the consequence of maintenance works, repairs or modifications of not by ABWN authorised staff
e) caused by an application beyond the intended purpose or by an accident.

The liability of the manufacturer for any kind of damages due to the delivery, installation, application, repair and maintenance of the instrument within or beyond this guarantee is - at ABW's own discretion - restricted exclusively to the repair or to the replacement of the instrument. ABW is not liable for the injury of third persons, secondary or consequential damages or losses in profit.

The replaced parts become automatically property of ABW.

The of ABW manufactured instruments may only be used with power supply units which are supplied by the manufacturer and which are expressively intended for this use.

THE ABOVE GUARANTEE IS THE SOLE WARRANTY FOR THE INSTRUMENT OF ABW. ALL OTHER EXPRESSLY OR SILENT PROMISES, INCLUDING PROMISES WITH REGARD TO THE MARKET SUITABILITY OR THE SUITABILITY FOR A CERTIN PURPOSE ARE EXCLUDED.

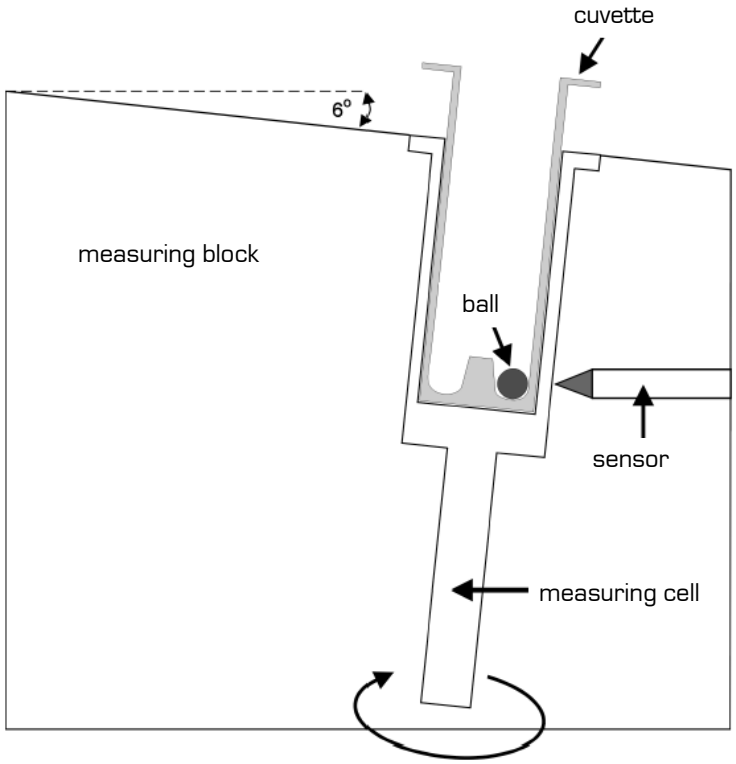
1.2 Purpose of use

The MC 1 is a semi-automatic mechanical coagulation detection system which is used for the determination of prothrombin times (PT), activated partial thrombo plastin times (aPTT) and fibrinogen concentrations as well as other clotting tests whereas the output are measuring results in view of quality. In connection with suitable reagents plasmas and also full blood specimen can be measured.

The sample and also the reagents are added manually with a suitable calibrated pipette. The time keeping until the detection of the coagulation is done automatically. On the base of correct parameters and correct entering of the curves the INR and the proportional results (PT) are calculated with the help of the coagulation time.

1.3 Measuring principle

A special cuvette with a steel ball inside is placed on the measuring point. As the measuring block is sloping slightly the ball always remains due to gravity at the deepest point of the cuvette. In the height of this point there is a magnetic sensor. If the plasma is pipetted into this measuring cuvette the pre-selected incubation time starts and the instrument turns the cuvette with the adjusted speed around the longitudinal axis. When the incubation is finished the start reagent is added and the measurement is start simultaneously. When the coagulation begins the growing clot pulls the ball out of the basic position and the magnetic sensor detects a magnetic impulse which causes the end of the measurement.



1.4 Specifications

Type		:	Coagulation analyser / bench top device
RS 232		:	unidirectional
Measuring principle		:	mechanical measuring method (ball)
Number of measuring channels		:	1
Display		:	graphic presentation
Cuvette pre-heating stations		:	2 (if necessary pipetting stations for reagent)
Reagent pre-heating stations		:	2
Dimensions		:	218 x 125 x 93 mm 88 (L-W-H)
Weight		:	1200 g
Power	primary	:	100 VAC - 240 VAC 50 / 60 Hz
	secondary	:	12 - 15 V
Power consumption		:	14 VA
Measuring block temperature		:	37.3 °C (+/- 0.5 °C) adjustable between 30 and 42°C in the service menu
Measuring period		:	4.5 – 999.9 seconds
Motor turning speed		:	according to version between 25 and 75 r.p.m. (macro or micro res. according sensitivity of the plasma, adjustable in the service menu)

1.5 Performance data

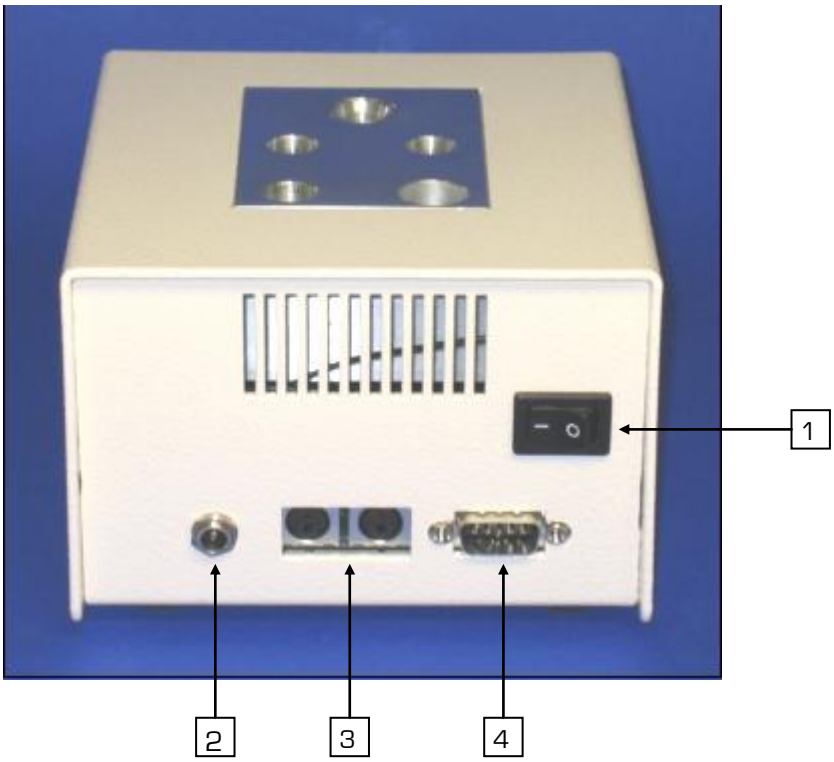
The precision of the tests carried out with the MC 1 is not depending on the instrument but on the sample receipt, sample handling as well as the precision of the employed sample and reagent dispensing system.

1.5.1 Correlation and precision

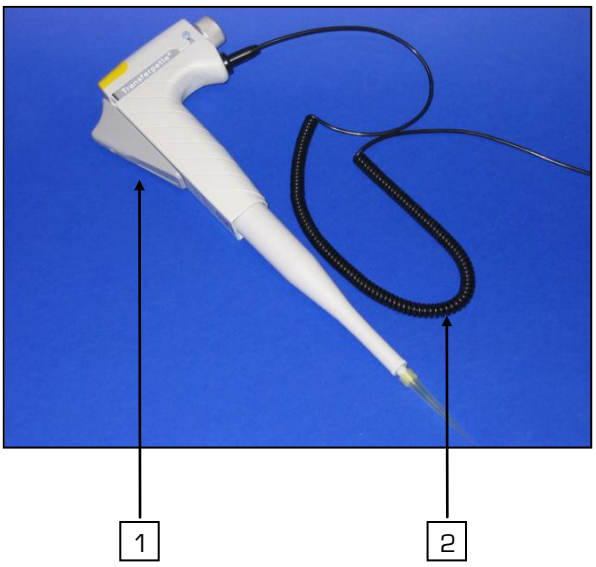
An investigation for the evidence of the equivalence of the MC 1 to another commercial mechanical coagulation analyser is done by a nameable German reagent producer for prothrombin times (PT), activated partial thrombo plastin times (aPTT), fibrinogen (Fib) and thrombin time (TT). Please ask ABW to get more information.

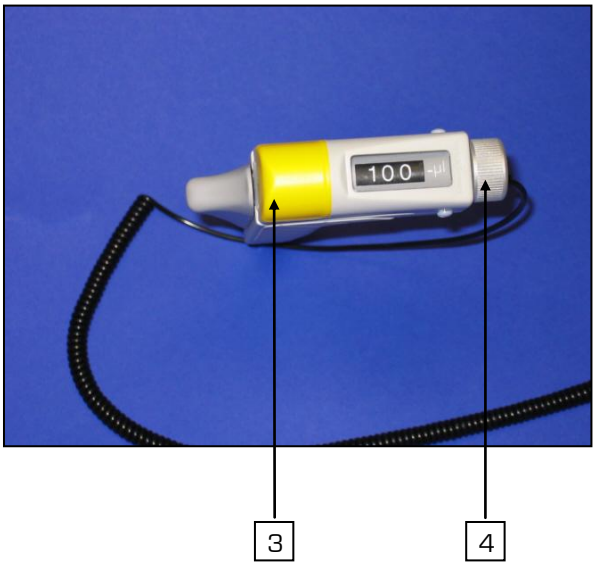
1.6 Views of the MC 1

Component	function / description
1. Reagent pre-heating station	heated stations for pre-heating the reagents
2. Cuvette pre-heating stations	heated station for pre-heating the cuvettes and also for pipetting the first reagent (chapter 4.3 res. 4.4)
3. Rotating measuring cell	position, where the plasma and the start reagent is added and where the coagulation time is measured
4. Graphic display	display of the key plan programme and result presentation
5. Keys	entering keys of the MC 1; the function of the keys is shown in the above display



Component	function / description
1. On-/off-switch	main switch of the MC 1
2. Low voltage socket	for connecting the instrument with the external power supply unit
3. Pipette sockets	for the connection with automatic pipettes
4. RS 232 interface	connection for external printer or an online-connection





Component	function / description
1. Pipetting key	for absorbing and dispensing of start reagent. If the measurement start key of the MC 1 is pressed the time keeping can be started by pressing the pipetting key until the first “click”.
2. Pipette contact line	for connecting the automatic pipette with the analyser
3. Throw-off cover	for the rejection of used pipetting tips
4. Volume adjustment key	If the pipetting key (no. 1) is pressed down completely this wheel serves for the adjustment of the pipetting volume (50, 100 or 200µL)

2. Installation

2.1 Unpacking

The MC 1 is transported in a cardboard which shall protect the instrument from transport damages. Remove the analyser and the accessories carefully from the cardboard. If you detect any obvious damages you have to record them on the delivery note. The carrier and your MERLIN-contact person have to be informed accordingly and immediately.

2.2 Content / Scope of delivery

Please take care that following items have been delivered:

	MC 1 coagulation analyser
	Power supply unit
	Power cable

2.2.2 Starter kit

MC cuvettes and balls	100	pieces
Ball dispenser	1	piece
Reagent tubes plastic (14,5mm x 80mm)	10	pieces
Coagulometer tubes plastic	10	pieces

2.3 Consumables and accessories

Consumables	Cat.-No.	Qty.
MC cuvettes and micro balls	Z05120	1,000
MC cuvettes and macro balls	Z05100	1,000
Reagent tubes plastic (14.5 mm x 80 mm)	832158	300
Coagulometer tubes	833118	500

Accessories	Cat.-No.	Qty.
Thermo printer	H10000	1
Thermo paper	851057	5
3-Volume automatic pipette	P10000	1

The in chapter 2.3 (Consumables and Accessories) additionally listed items are not part of the MC 1 starter kit. Repeat orders of consumables have to be places on demand. An automatic start pipette (accessory) makes sure that the time keeping starts simultaneously with the adding of the start reagent. If the manual start key is used for the start of the time keeping the reagent can be dispensed with any pipette which can dispense the for the according test required volume.

2.4 Location of the instrument

1. Place the MC 1 on a plane, stable, vibration- and dust-free work surface which is deep and wide enough to ensure the air circulation of the instrument. For ensuring a sufficient cooling of the analyser the distance between instrument and wall respectively another object has to be at least 10 cm. The instrument should not be placed next to centrifuges or other instruments which could cause vibrations.

   Minimum space requirements:
   - width 34 cm (width of the instrument = 14 cm)
   - depth 37 cm (depth of the instrument = 27 cm)

2. Position the MC 1 in an area with low humidity and little variations in temperature. The device should not be placed directly under ventilation shafts which cause strong draughts.

3. Place the MC 1 in an area which is protected from direct sun light.

4. The distance between the analyser and the socket may not exceed 3 m. Other instruments with high power consumption and which are frequently switched on and off as e.g. centrifuges, air conditionings or refrigerators should not be connected to the same circuit. When switching on and off such instruments the voltage drop can be strong enough to have a negative effect on the proper operation of the MC 1.

Attention!
If the user is electrified a discharge may happen at the measuring / pre-heating block. In this case a reset of the instrument will be carried out automatically. After that the user can continue as usual.

2.5 Connection demands

1. Before the electrical installation is carried out it has to be ensured that the operating voltage of the supplied power supply unit corresponds with the existing mains voltage (100 VAC – 240 VAC).

2. Only the with the MC 1 supplied suitable external power supply unit should be used, otherwise the analyser could be damaged.

3. It is recommended that only the ABW-customer service carries out repairs beyond the periodical maintenance and little settings.

4. If the instrument is not used in accordance with the advises in the manual the safe operation is not granted and the guarantee expires.

5. The instrument may not be connected to an extension lead.

6. The total length of the mains connection may not exceed 3 meters.

Warning!
Only the with the MC 1 supplied suitable external power supply unit (100 VAC – 240 VAC), otherwise the analyser could be damaged.

2.6 Connection of the device

1. Connect the low voltage cable of the power supply unit with the low voltage plug at the back of the instrument.

2. Insert the plug of the power supply unit into a socket.

3. If an automatic pipette is used connect the pipette contact line to one of the according sockets at the back of the MC 1.

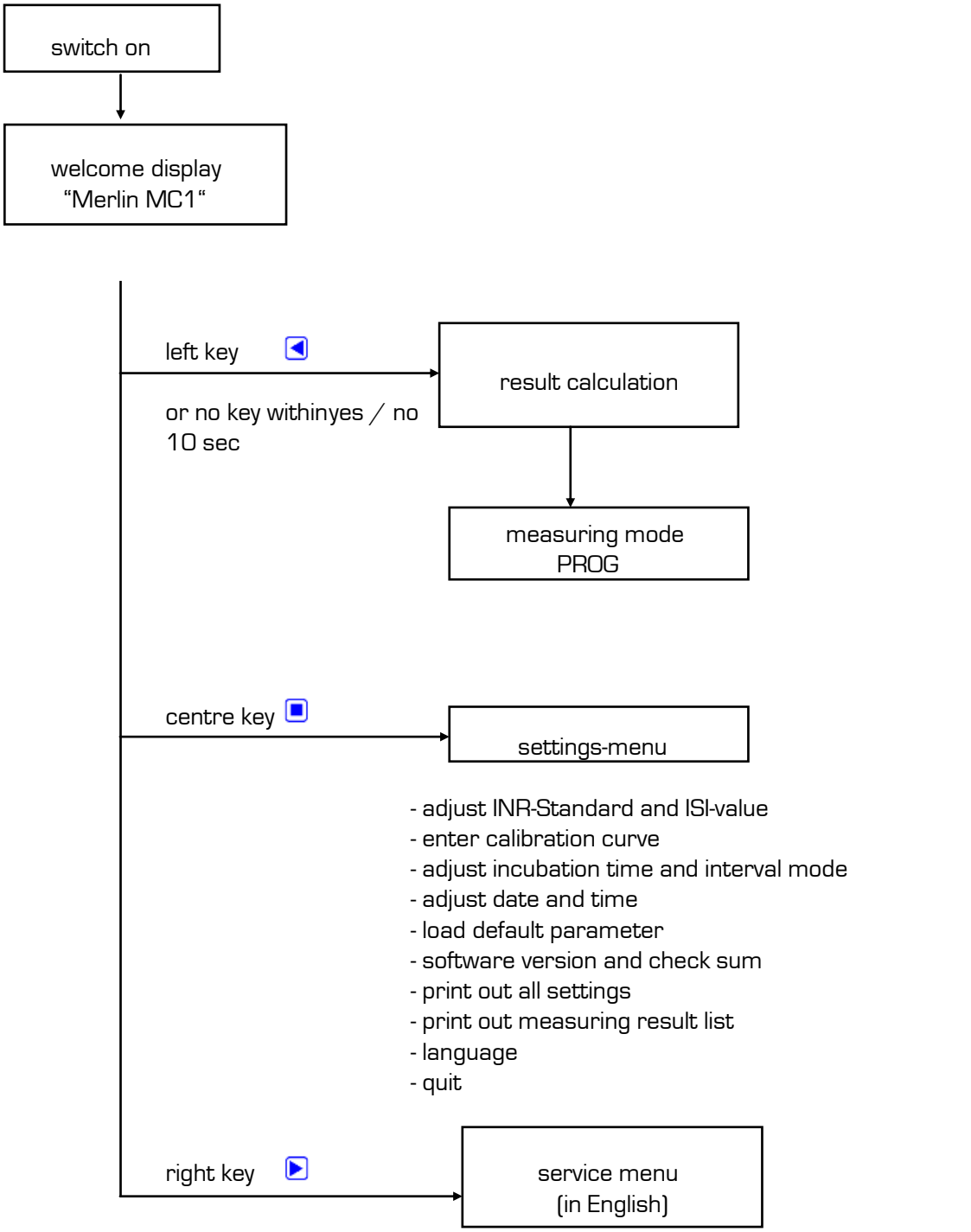
4. If an additional printer is used connect the data line of the printer with the RS-232 interface.

or If you require an online connection then the EDP-data line has to be connected with the RS-232 interface.

5. The data line fort he external printer or fort he online connection may not be longer than 3 meters.

2.7 Function

2.7.1 Menu structure



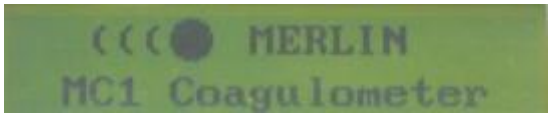
2.7.2 Performance test

The correct operation of the instrument for the measurement of patient results should be examined by means of a performance test.

All functions of the MC 1 are called up with the control keys below the display.

Switch on the MC 1 at the on / Off-switch at the back side.

The MC 1 makes a signal tone and the display is lighted up. Watch the display.



After approx. 12 sec. The display changes automatically from the welcome display to the main menu. It has to be entered whether a result calculation (PT / INR / %) is required or whether only results in seconds (aPTT, Fib, TT ...) should be reported. Before continuing you have to confirm this.

	with result calculation	(PT)
	without result calculation	(aPTT, Fib, TT...)

Now the MC 1 is in the main menu. On the right side of the display the measuring block temperature appears. If you try to start a measurement as long as the entered rated temperature (chapter 2.9.2) is not reached "TEMP" will flash, i.e. the instrument does not allow a measurement.

If the measuring has reached the programmed temperature a measurement can be started.

Testing an incubation

At first an incubation should be simulated. Place a new cuvette with ball in the measuring cell and activate the measuring programme with the left key ◀ "Result / 0.0" will flash for approx. 5 sec. Within this time an incubation can be started by pressing the centre key ■ on the operating panel. 5 sec before the end of the adjusted incubation time (chapter 2.8.3) the MC 1 gives an acoustic signal.

The display switches back to the main menu after the end of the incubation time.

Testing a measurement

Thereafter a measurement should be tested. Activate the measuring programme with the left key ◀ and start the measurement within the next 5 seconds either by pressing the right key ▶ or by using the automatic pipette (if existing and connected).The formation of a clot respectively the start of a coagulation reaction can be simulated by slightly shifting the measuring cuvette. The measurement time counter stops automatically and the result will be displayed. If the result output with calculated results has been selected before these results will also be displayed.

After finishing a measurement the MC 1 stops after 60 sec unless a new measurement is started

By pressing the left key ◀ again you will come back to the main menu.

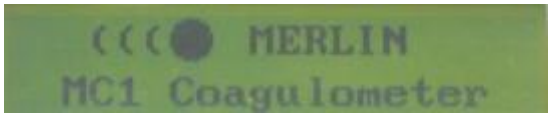
Please note that the measuring / pre-heating block will not be heated before the instrument is in the main menu. The measuring cell only turns on demand.

2.8 Settings menu

All functions of the MC 1 can be selected by means of the keys on the operating panel below the display.

Switch on the MC 1 at the on-/Off-switch at the backside of the instrument.

The MC 1 gives a signal tone and the display is lit up. Watch the display.



If you press the centre key on the operating panel within 10 seconds behind the second signal tone after switching on the instrument you will come into the settings-menu of the MC 1. Here you have the possibility to make different parameter-specific inputs:

- adjust INR–standard and ISI-value
- enter calibration curve (PT)
- adjust incubation time an interval mode
- adjust date and time
- load default parameter
- software version and check sum (view)
- language
- print out all settings
- print out measuring result list
- quit

For exchanging the parameters please press the left res. the right key on the operating panel. Please press the centre key of the three keys for modifying the selected parameter.

2.8.1 Adjusting INR-standard value and ISI-value

The INR-standard value is stated on the package insert of the PT-reagent. This value can be increased with the left key ◀ and decreased with the right key ▶ . The input is finished by pressing the centre key ■ .

The ISI-value is also stated on the package insert of the PT-reagent. Please confirm the input with the centre key ■ .

2.8.2 Entering the calibration curve (PT)

Input of a calibration curve for PT: at first you have to enter the standard value in % of your calibrator. The actual value can be increased with the left key ◀ and decreased with the right key ▶ . The input has to be confirmed by pressing the centre key ■ .

After the confirmation the software switched automatically to the line where the before measured time for this standard has to be entered. The actual value can be increased with the left key ◀ and decreased with the right key ▶ . The input has to be confirmed by pressing the centre key ■.

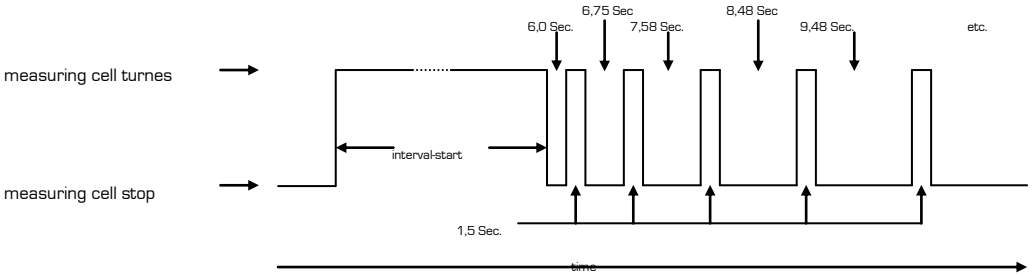
For entering the diluted standard values please proceed as for the input of the values of the undiluted calibrator.

2.8.3 Adjusting incubation time and interval mode

You can select the incubation time (standard = 60 seconds). With the left key ◀ the time can be increased, with the right key ▶ the time can be decreased. The input has to be confirmed by pressing the centre key ■ .

For also measuring very instable clots with lowest fibrinogen concentrations the MC 1 is equipped with a part time **interval mode**. If this is switched on (interval-start higher than zero) then, after the adjusted start time, the continuous measuring cell turning changes over to the interval mode. The interval time can be increased with the left key ◀ , with the right key ▶ it can be decrease. The process has to be confirmed by pressing the centre key ■ . The pulse time is always 1.5 seconds respectively one round. The pause time depends on the up to the now measured time and the adjusted percentage increase "interval wait state". As during the breaks no measurement is possible the CV of the expected measuring results increases proportionally to the input of the percentage increase of the pause length whereas the probability of detecting also lowest fibrinogen concentrations enhances.

Example: interval-start = 60 seconds
Interval wait state= 10 %



For the adjustment of the „interval wait state“ please proceed as for the adjustment of „interval start“

2.8.4 Entering date and time

Here you can enter the actual date and time for the correct data transmission to the external printer. By pressing the left key ◀ the day, month etc. can be increased, and by pressing the right key ▶ they can be decreased. The inputs have to be confirmed with the centre key ■.

2.8.5 Loading default parameters

The instrument has a basic „default“ setting for all parameters in the settings-menu, i.e. there is also a standard calibration curve for PT saved which always enables you to reset the calculated results to the initial values.

Attention: If you confirm this by pressing the left key ◀ the of you saved calibration curve will be deleted.

If you are mistakenly in this point and if the present curve shall remain actual please press the right key ▶ .

2.8.6 Software version

Here the actual version of the software is stated. After pressing the centre key ■ the check sum of all entered values is verified and displayed. By pressing the centre key ■ a second time you get back to the settings-menu.

2.8.7 Language

Following languages are actually programmed in the device:

- English
- German
- Chinese

Please contact the manufacturer for additional languages.

The language can be selected by pressing the left key ◀ and the right key ▶ . Please confirm with the centre key ■ .

2.8.8 Printing out all settings

Here you have the possibility to print out all in the settings menu saved inputs. If you want to print out these inputs confirm this with the centre key ■ .

2.8.9 Printing out measuring result list

The MC 1 has a patient memory where the results (time and – if existing – INR and % with measuring date and time) of the last 15 measurements can be stored. This memory can be printed out by pressing the centre key ■.

2.8.10 Quit (leaving settings menu)

For leaving the settings menu select „**Quit**“ and confirm this by pressing the centre key ■ .

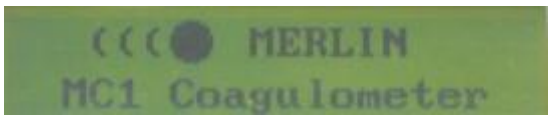
ATTENTION: The measuring / pre-heating block is not heated during any procedures in the settings menu.

2.9 Service menu

All functions of the MC 1 can be called up by means of the keys below the display.

Switch on the MC 1 with the on-/off-switch at the backside of the instrument.

The MC 1 makes a signal tone and the display is lighted up. Watch the display.



If you press the right key on the operating panel within 10 seconds behind the second signal tone after switching on the instrument you will come into the service menu of the MC 1. With the support of the manufacturer (phone +49 (0)5261 927 294) you have the possibility to enter diverse instrument-specific inputs (this menu is always in English and protected by a PIN).

- turning speed
- temperature
- set PIN
- print out fault list
- quit

For changing the parameter please press the left key respectively the right key on the panel. For changing the selected parameter please press the centre key .

2.9.1 Turning speed (changing the turning speed of the measuring cells)

The setting of the turning speed can be adjusted in accordance with the MC 1-version (macro 40 rpm/min – micro 50 rpm/min). By means of this speed the stability respectively precision of sensitive plasma can be influenced (e.g. veterinary medicine). By pressing the left key the turning speed can be increased, by pressing the right key it can be decreased. By pressing the centre key the input can be confirmed.

2.9.2 Temperature (changing the pre-heating block temperature)

The operating temperature of the measuring / pre-heating block can be adjusted in this menu (standard value = 37.3°C). The temperature can be increased by pressing the left key ◀ , by pressing the right key ▶ it can be decreased. By pressing the centre key ■ the input can be confirmed.

2.9.3 Adjusting the PIN

The service menu is protected with a password. With the support of the manufacturer (phone +49 (0)5261 927 294) you have the possibility to enter diverse instrument-specific inputs.

2.9.4 Printing out the error list

The MC 1 has an error memory which saves he last 15 system errors. This memory can be printed out with the support of the manufacturer – phone +49 (0)5261 927 294 (chapter 9.2).

2.9.5 Quit (leaving the service menu)

For leaving the service menu please select "**Quit**" and confirm this by pressing the centre key ■ .

3. Pipetting technique

3.1 Precision and correctness

The accuracy of the MC 1 depends on the correctness and the precision with which the sample and the reagents are pipetted.

Tests can either be carried out with manual microlitre pipettes or with automatic pipettes which are equipped with a contact line. If an automatic pipette is used for dispensing the start reagent the time keeper will be started automatically as soon as the reagent is dispensed. If the start reagent is dispensed with a manual micro litre pipette the time keeper has to be started simultaneously by pressing the right key ▶ on the panel.

No matter which pipette type is used: the pipetting accuracy is absolutely proportional to the correctness and precision of the test results.

It is imperative that a suitable pipette tip is used for the pipette. Only the for the according pipette recommended tips should be used.

Pipette tips with out of shape connection pieces should be thrown away. Bent or otherwise damaged pipette tips should also be disposed of. The tip opening may not be blocked.

Place a pipette tip on the pipette cone. For fixing the tip push it slightly to the top and turn it to the right. If the tip is not fixed at the pipette the precision can be affected negatively. For fixing the tip on the automatic pipette (accessory item) the tip has to be turned to the right (clockwise) in order to avoid that the shaft tip loosens.

Most of the pipettes have 2 dispense positions. The first position is the calibrated volume for the pipette and is used for the aspiration of the sample respectively the reagent. The second position is used for the dispense in order to ensure the complete dispense of the tip content. The automatic pipette (available as accessory item) is equipped with a lateral pipette switch. In contrast to this most of the usual pipettes have a button on top of the pipette. For pushing the switch place your thumb over the switch and press it down. The pipette has the two positions as described above.

In order to avoid a contamination of reagent (if the same pipette is used for the sample and the reagent) the tip has to be exchanged between the dispense of sample and reagent. The Automatic pipette is equipped with a dispose button at the upper end. For disposing the tip just press the yellow part of the top.

In order to avoid a cross contamination of samples a new tip should be used for every sample. For pipetting citrated whole blood this procedure is stipulated.

3.2 Choice of volume (automatic pipette)

Press down the lateral grey pipette switch into the first position and keep it pressed.

Turn the silver adjusting button until the requested volume appears in the window at the top of the pipette. The pipette can be adjusted for absorbing and dispensing 50, 100 or 200 µl.

3.3 Sample absorbing

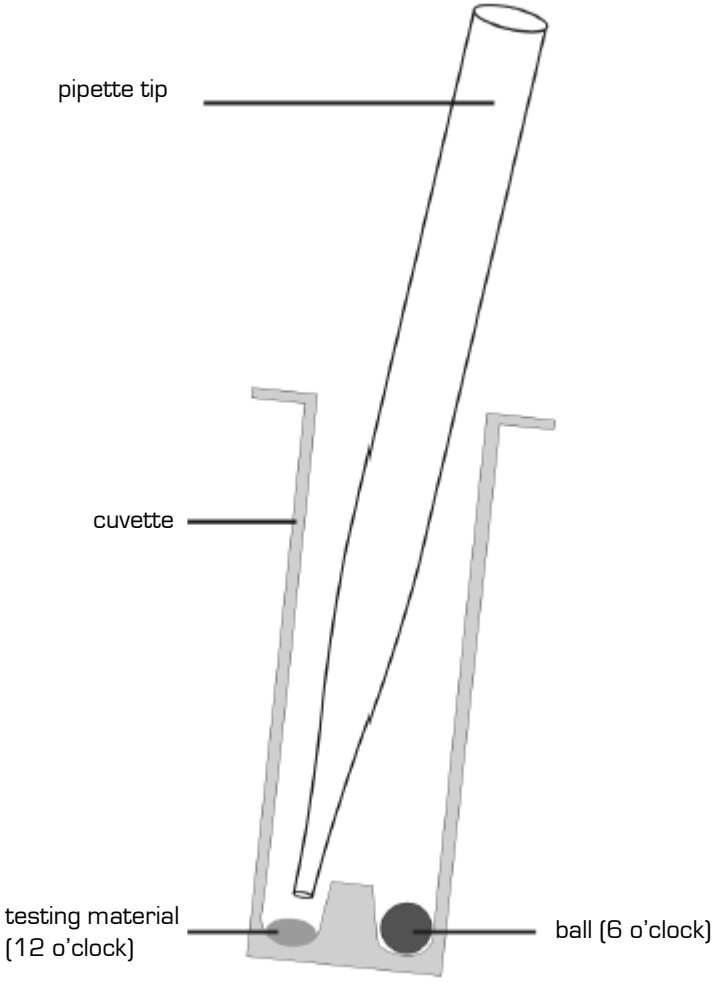
Press down the switch until the first position. Keep it pressed and dip the tip approximately 2 – 3 mm into the sample respectively the reagent. If the plasma is pipetted directly from a centrifuged blood tube the tip may not get into the blood / plasma border zone. Hereby it is ensured that not erythrocytes or platelets can be absorbed into the tip. If a reagent particle is pipetted the reagent should be mixed very well before the pipetting procedure.

Take your finger slowly off the switch for letting the sample or reagent flow steadily into the pipette tip. A slow absorbing makes sure that the exact quantity gets into the pipette tip. If you let the switch snap back it is possible that the wrong volume is absorbed. Furthermore a part of the sample or of the reagent can get into the pipette piston. This could result in a contamination of the following samples or reagents. If liquid has been absorbed erroneously into the pipette piston the pipette has to be taken apart and cleaned. Otherwise the pipette could be blocked and a proper absorbing process could be interfered.

If the tip is filled no drops may come out. Should this happen nevertheless either the tip is not positioned correctly or the pipette has to be maintained. In this case replace the tip. If the problem can not be solved with this the pipette should not be used until it has been inspected carefully.

3.4 Sample dispensing

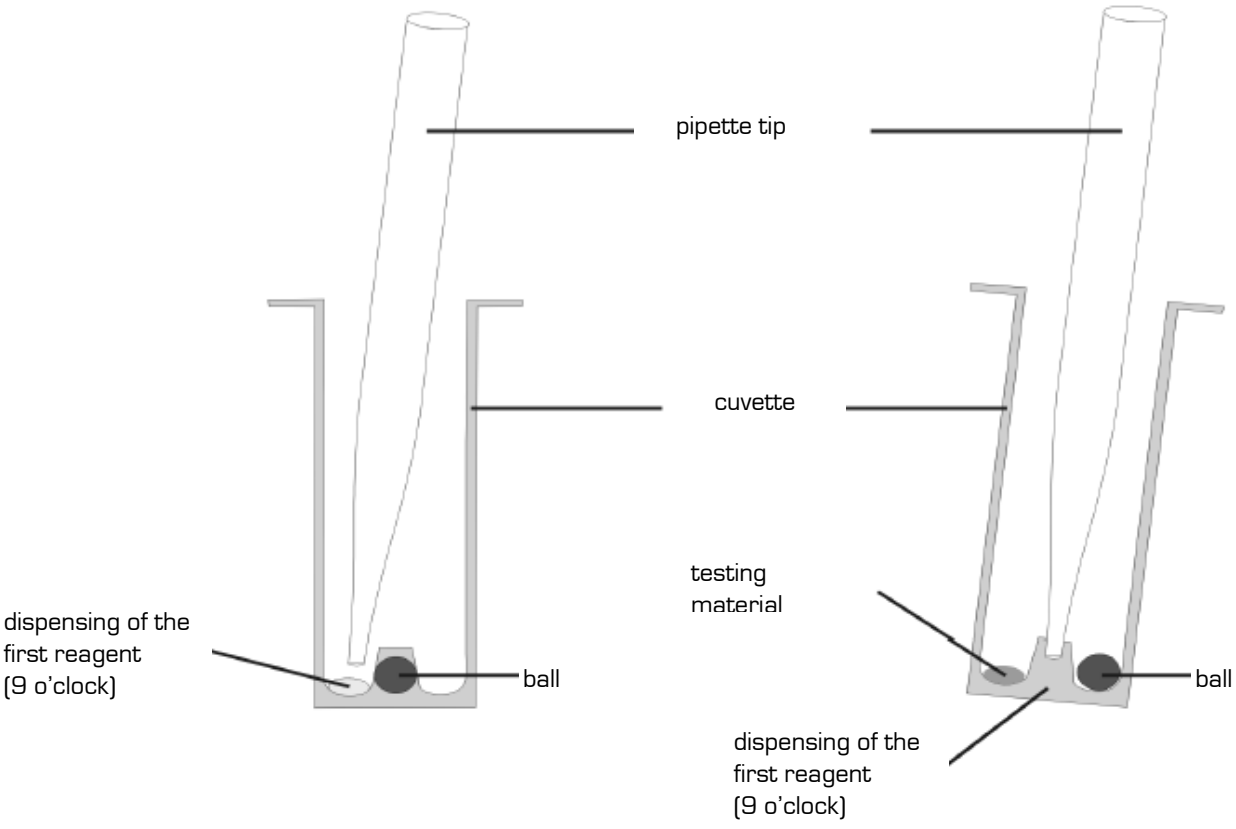
The sample should be dispensed in the 12 o'clock position of the cuvette (please see picture). Aim with the pipette at the 12 o'clock position. Position the tip approximately 3 – 4 mm above the bottom of the cuvette. Press down the pipette switch until the first position and keep it pressed 1 – 2 seconds for letting the remaining content accumulated down in the tip. Press the switch into the second position. By this the sample residuals in the pipette are dispensed. In order to avoid bubble formations and splashes the tip has to be positioned in such a distance to the bottom of the cuvette that it is in the sample at the end of the dispensing procedure. Alternatively you can hold the tip to the side wall of the cuvette approximately 3 – 4 mm above the bottom of the cuvette and you then press down the switch slowly into the first position. Wait 1 – 2 seconds and press then the switch into the second position. For the sample dispensing the tip should not touch the upper part of the side wall of the cuvette. Any part of the sample that sticks at the upper part of the side wall of the cuvette is not involved in the coagulation reaction.



3.5 Dispensing of reagent 1

(can be pipetted in the measuring cell and as well in the cuvette pre-heating station)

During tests for which more than one reagent is used the first reagent should be dispensed in the 9 o'clock position of the cuvette (please see picture). Go with the pipette into the 9 o'clock position. Position the tip 2 – 3 mm above the bottom of the cuvette.
Press down the pipette switch into the first position and keep it pressed for 1 –2 seconds for letting the remaining content accumulate down in the tip. Press down the pipetting key until the second stop. In order to avoid bubble formations and splashes the tip has to be positioned in such a distance to the bottom of the cuvette that it is not in touch with the test material of the dispensing procedure. Alternatively you can hold the tip to the side wall of the cuvette approximately 3 – 4 mm above the bottom of the cuvette and then you press down the switch slowly into the first position. Wait 1 – 2 seconds and press then the switch into the second position. In order to avoid a contamination of the reagent during the following pipetting procedures of the reagents it has to be taken care that the tip does not touch the already dispensed sample (not if this reagent has already been added in the cuvette pre-heating station).

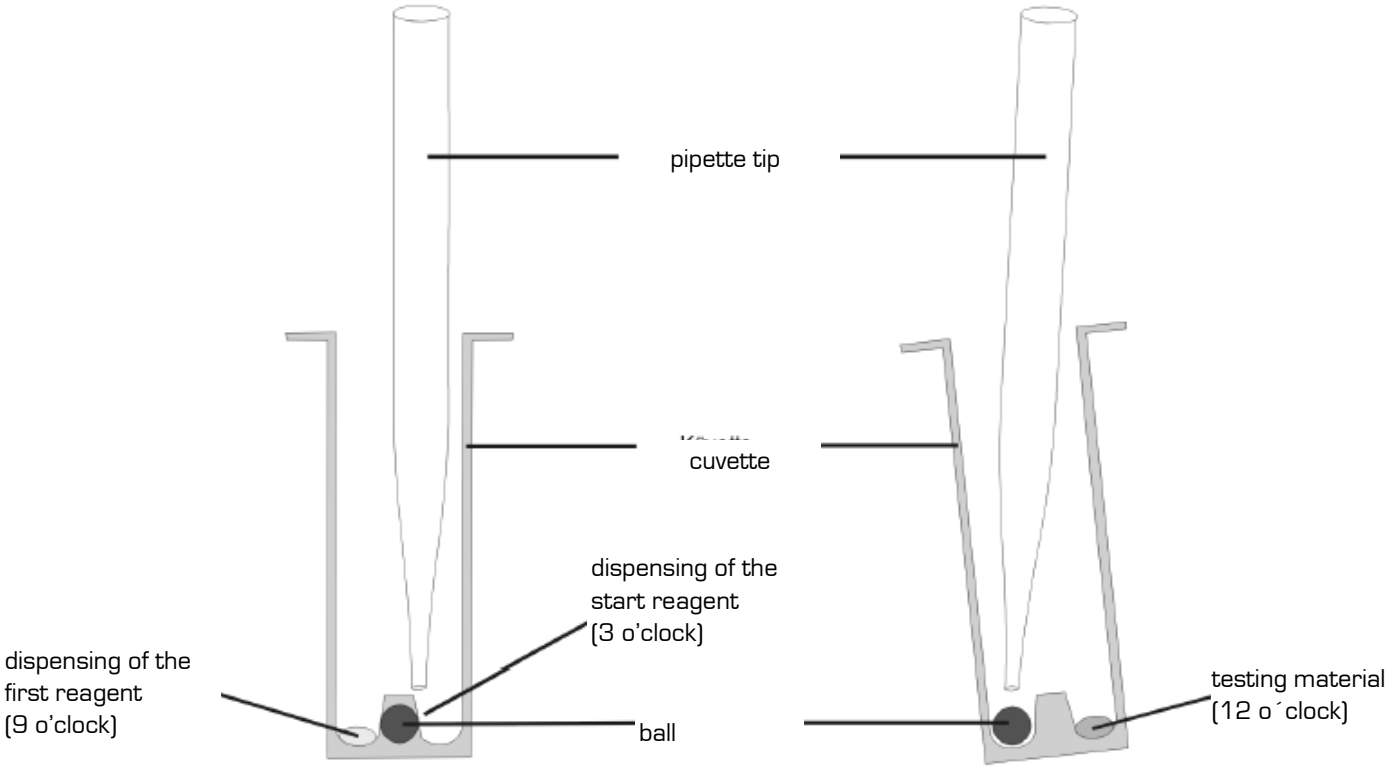


view from the front

view from the side

3.6 Dispensing of start reagent

The start reagent sets off the coagulation reaction as soon as it is added. It should be dispensed directly to the right of the ball. Through this positioning it is ensured that the reagent and the other components of this mixture are mixed immediately. Hold the pipette obliquely from the right and aim with the pipette tip at the right side of the ball. Position the tip approximately 5 – 6 mm above the ball and press the pipette switch into the last position. The dispensing should not be carried out so fast that the reagent splashes out of the cuvette. In order to avoid a contamination of the reagent during the following pipetting procedures of the reagent it has to be taken care that the tip does not touch the already dispensed sample and / or the already dispensed reagent. You can find a detailed illustration of the automatic pipette with contact line in chapter 1.6 (Automatic pipette) on page 13.



view from the front

view from the side

4. Operation

4.1 Service keys

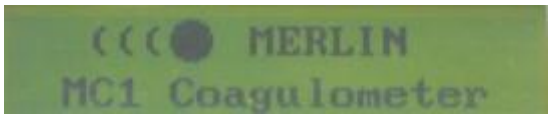
The keys on the service key panel are arranged in one line. Each key has several functions and has to be pressed solely or in combination with other keys for carrying out the according functions.

The according key function is indicated above the keys in the display.

4.2 Switching on the device

Switch on the MC 1 at the main switch on the backside of the instrument.

The MC 1 makes a signal tone and the display is lighted up. Watch the display.



If the left key  or none of the three keys is pressed within the first 10 seconds the display changes automatically from the welcome display to the main menu. It has to be entered whether a result calculation (PT / INR / %) is required or whether only results in seconds (aPTT, Fib, TT ...) should be reported. Before continuing you have to confirm this.

with result calculation (PT)
without result calculation (aPTT, Fib, TT,...)

The MC 1 is now in the main menu and starts to heat the measuring / pre-heating blocks. The measuring cell does not turn up to now. As long as he adjusted rated temperature (chapter 2.9.2) is not reached „TEMP“ will flash if you try to start a measurement, i.e. a measurement can not be started.

If the programmed measuring block temperature is reached the measurement can be started.

4.3 Measurement of parameters with one reagent component

The instrument uses an especially manufactured cuvette with a steel ball. Before a measurement such a cuvette is placed in one of the pre-heating stations above the measuring position. Into cuvettes which are placed in these pre-heating stations only then reagent is pipetted if the parameter consists of 2 reagents substances (e.g. aPTT). If then a measurement shall be carried out a pre-heated cuvette has to be changed over into the measuring cell and the measuring programme has to be started with the left key ◀ on the service panel. This programme is active for 5 seconds which is displayed by flashing "Result / 0.0". Within this period of time the sample has to be pipetted and the incubation counter has to be started simultaneously by pressing the centre key ■ on the panel. 5 seconds before the end of the in the service menu pre-selected incubation time (chapter 2.8.3) the MC 1 signals the end of this step acoustically for making you ready to pipette the start reagent and to start the measurement. For stopping the incubation counter earlier you have to press the centre key ■ once again. Thereafter the measuring programme has to be re-activated by pressing the left key ◀ and the measurement can be re-started with the next 5 seconds ("result / 0.0" is flashing). For this the right key ▶ has to be pressed and simultaneously the (start) reagent has to be added. If an automatic pipette is connected with the instrument the pipette releases the start of the measurement, i.e. it is **not** necessary to press the right key ▶ simultaneously with the adding of the reagent. The instrument stops the measurement automatically when the coagulation starts, but the measuring cell continues to turn for the optical monitoring. In order to prepare a new measurement press again the left key ◀ on the panel.

Example: You want to determine the PT of a patient sample. Place a cuvette into one of the two pre-heating stations for cuvettes (please see chapter 1.6 "Views"). Prepare the reagent in accordance with the instructions and position it in a 14.5 x 85 mm plastic tube on the measuring / pre-heating station above the cuvette pre-heating station. Change over the pre-heated cuvette into the measuring cell. Now you have to active the measuring programme by pressing the left key ◀ . Please note that this programme remains active for only 5 seconds. Pipette the plasma (100µl for MC 1-macro, 50µl for MC 1-micro, please contact the manufacturer for the possibility of smaller volumes) and start the incubation timer simultaneously by pressing the centre key ■ . 5 seconds before the incubation ends the MC 1 makes 5 acoustic signals by the second. Within this period of time you can absorb the pre-heated reagent (200µl for MC 1-macro, 100µl for MC 1-micro) with the pipette. By pressing the left key ◀ the measuring programme has to be re-activated after the end of the incubation. again the programme only remains active for the next 5 seconds. Start the measurement by adding the start reagent in the cuvette within these 5 seconds. The measurement is stopped automatically when the coagulation starts respectively the measurement stops when a clot is formed. The measuring cell carries on to turn for the continuance of the visual control function.

If the result calculation has been activated when the instrument was switched on the results will also be displayed. Should this not happen the instrument has to be switched off and on. Before the measurement is repeated the calculation has to be selected during the instrument start. If calculated results are displayed although they should not be calculated just ignore these values respectively switch the instrument off and on. Before the measurement is repeated the calculation must not be selected during the instrument start.

Please note the instruction (chapter 3.3 to 3.6) for the pipetting of plasma and reagent.

For carrying out a new measurement please press the left key ◀ on the panel.

4.4 Measurement of parameters with two reagent components

Basically there is no difference in the measurement of parameters with 2 reagent components (e.g. aPTT) and in the measurement of parameters with one reagent component. You have to pipette the first reagent into the measuring cuvette when it is still on the pre-heating chancel above the measuring cell i.e. before the cuvette is changed over into the measuring cell. Then please carry on as described in chapter 4.3.

4.5 Stopping of an incubation time

If the incubation counter has been started erroneously it can be reset by re-pressing the centre key ■ .

4.6 Stopping after a mistakenly start of a measurement

If the measurement has been started by mistake or it the time counter has not been stopped automatically it can be stopped at any point of time by inserting a new cuvette with ball into the measuring cell. Let the cuvette turn around for approximately 4 seconds and lift it slightly respectively remove this cuvette.

The MC 1 can be reset by pressing the left key ◀ on the service panel.

4.7 Switching off the device

If the instrument is not used for a longer period of time it is recommend to switch it off by pressing the main switch into the off-position at the backside of the instrument.

5. Warning hints for the operation

ATTENTION!
Used cuvettes are highly bio-hazardous and should be handled in compliance with the in the laboratory valid safety instructions for the dispose of bio-hazardous material.

WARNING!
Only the with the MC 1 supplied suitable external power supply unit (110V or 240V) should be used, otherwise the analyser could be damaged.

WARNING!
The length of the power lead and of the data cable to the online computer respectively to the external printer may not exceed 3 m.

ATTENTION!
The instrument may not be connected to an extension lead.

ATTENTION!
The cuvettes are disposable which are not allowed to be reused.

ATTENTION!
After positioning the cuvettes in the instrument the operator is obliged to ascertain that a ball is in the cuvette.

CAUTION!
After opening the cuvette packing the cuvettes and balls have to be protected against dust, moisture and other pollutions. They have to be kept dry and stored in a suitable and safe place.

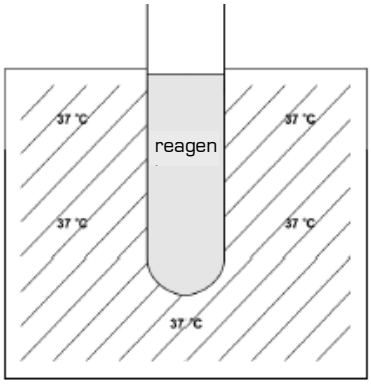
ATTENTION!
This instrument is classified as an in-vitro-diagnostic device.

ATTENTION!
If the operator is electrified a discharge may happen at the measuring / pre-heating block. In this case a reset of the instrument will be carried out automatically. After that the user can continue as usual.

6. Handling hints

6.1 Handling of the reagents

The reagent for the required test has to be prepared according to the manufacturer's instructions. Please see the application instructions of the manufacturer for exact instructions concerning preparation and handling of the reagent. All reagents which have to be pre-heated have to be dispensed into a 14.5 x 85 mm tube which has to be placed into the reagent pre-heating station before the pipetting. The liquid level in the tube may not exceed the upper edge of the reagent station. It takes approximately 15 minutes to heat up the reagent to the working temperature. All reagents should be used before the indicated expiry date.



6.2 Handling of the cuvettes

The cuvette packing is created in such a way that the cuvette can be picked up at the long paper strip and then inserted directly in the measuring station. Pull off the paper protector after the insertion into the station.

The correct size and surface structure of the cuvettes are decisive for the proper test performance. For achieving correct values the cuvettes have to be kept absolutely clean. The **cuvettes** are designed for just one **single use**. The correct performance of **other cuvettes** can not be granted, thus other cuvettes may **not be employed**. The balls in the cuvettes are made of a special stainless steel. Purity, weight, size surface structure and magnetic properties of the balls are decisive for the proper test performance. The balls which are part of the scope of delivery have been tested with regard to their compatibility with the test method of the analyser as well as to their chemical neutrality under the employment with plasma and coagulation reagent. Rust, little impurities and oil residues may have a strong impact on the coagulation test results.

6.3 Handling of the testing material

The taking of the blood from a patient has a decisive influence on the quality and the precision of the results. Here it is imperative to use the according special syringes. Furthermore it has to be ensured that the procedure of taking the blood is not carried out too fast, i.e. the blood may not be pulled into the syringe too fast as otherwise the for the clotting analysis important parts could be destroyed.

7. Quality control

A regularly carried out quality control is the best monitoring system for reliable test results. For making sure that the results of the control probe and of the unknown probe are evaluated under the same test conditions the control material should be included in every test run. The recommendations of the reagent manufacturer concerning the quality control should serve as a guideline for the quality control report. If the control results are out of the stipulated ranges this could be a hint for a system error of which the cause should be investigated immediately. Frequent sources of error and instructions for the troubleshooting are listed in chapter 9.1 “Analytical errors”.

8. Maintenance

8.1 Maintenance by user

The rotation speed, the power of the magnet sensor and the temperature of the analyser have been calibrated by the manufacturer before delivery. It is recommended to check the temperature of the measuring / pre-heating block periodically with a usual calibrated thermometer. The turning speed of the measuring cell can as well be checked from time to time with a calibrated (stop) watch.

A general cleaning is the only maintenance procedure that has to be carried out regularly. It is recommended to clean the instrument from time to time with a damp cloth for removing dust and other materials. Blood, serum and reagent residues should be removed immediately. Reagents can cause corrosion. Liquids that have been spilled over the pre-heating station or the measuring cell must be removed at once. Spilled samples have to be considered as potentially bio-hazardous and must be removed immediately in strict compliance with the appropriate safety precautions for avoiding a contamination of the personnel. If a decontamination of the MC 1 is required wipe off the area in question with a paper cloth which is moistened with a mild disinfectant.

In addition to this there are no routine maintenance procedures for the MC 1.

Ball that fell erroneously into the station can be removed easily either by turning round the instrument or by means of a magnet.

8.2 System self-test

8.2.1 Automatic self-tests after switching on the device:

1) After switching on the main memory (RAM) of the controller is checked at first. Should an error be detected „XRAMERR“ appears in the LCD-display.

2) After that the **R**eal-**T**ime-**C**lock is checked. If non-plausible data are read the RTC is reset to time 00:00:00 and date 01.01.00.

3) A signal tone can be heard and the welcome display appears.

4) The printer is initialised and the welcome message is printed out.

5) The check sum of all resident adjusted parameters is checked. If this is not ok the default parameters are loaded. This is always the case when the instrument is switched on the first time after it has been built. Thereafter the error message “Default parameter loaded” appears for indicating that among others the calibration curve is active again! The error number 2000 is stored in the error list (chapter 9.2).

6) When changing into the measuring mode the ball sensor is inspected, it has to be inactive then. If this is not the case the error message „Error : Ball-Sensor is not OK !“ appears. The error number 2100 is stored in the error list (chapter 9.2).

8.2.2 Cycle tests during measuring mode:

1) The communication via the I2C-bus (internal data management) is surveyed. If an error occurs the message „Error found, I2CErr“ is displayed and the error number 1000 is stored in the error list (chapter 9.2).

2) The actually measured temperature is surveyed. If it exceeds 50°C the heating is switched off and the message „Error found, Temp = WERT“ is displayed. The error number 1100 is stored in the error list (chapter 9.2).

3) The communication with the LCD-display is surveyed. If an error occurs the message „Error found, LCDErr“ is displayed and the error number 1200 is stored in the error list (chapter 9.2).

9. Errors

9.1 Analytical Errors

Error type	Possible causes	Troubleshooting
Display is not lighted after switching on the instrument with main switch on the backside of the device.	**Instrument error** The MC 1 is not connected with the power supply unit resp. power supply unit is not plugged into the power outlet.	Make sure that the power lead is fixed in the socket of the power supply unit. Make sure that the power lead of the power supply unit is plugged in a suitable power outlet.
After switching on the instrument with the main switch on the backside the temperature does not stabilize at 37.3°C.	**Instrument error** Temperature sensor is out of order or thermostat is overheated.	Check the temperature of the incubation stations with a suitable thermometer. Read the temperature after approx. 10-15 minutes. Contact the technical customer service of ABW.
Controls within the reagent range. Unexpected result of patient samples.	**Pre-analytical error** Sample tube under- or overfilled.	Commercial vacuum tubes have to be filled completely to ensure the correct blood-/ anticoagulant relation.
	Pre-analytical error Wrong volume, wrong sample material (e.g. EDTA, heparin), wrong concentration or too less anticoagulant	Anticoagulant has to be applied according to the reagent manufacturer's instructions.
	Pre-analytical error Wrong relation of anticoagulant and blood.	Citrate volume has not been adjusted for patients with too high (>55%) or with lower (<21%) haematocrit.
	Pre-analytical error Clot in the sample	Samples containing micro or macro clots should not be used for tests.
	Pre-analytical error The mixing of the samples has been carried out either not at all or insufficiently or too hard.	Turn round gently and mix very well, avoid mechanical trauma.
	Pre-analytical error Contamination with heparin.	Blood should not be taken by the heparin-lock-method or by a heparinised tube.

Error type	Possible causes	Troubleshooting
Controls within the reagent range. Unexpected result of patient samples.	**Pre-analytical error** Delay of transport or processing resp. the use of not standardised methods for transport, processing, storage or analysis of the sample.	Follow the instructions of the manufacturer. Centrifuge the specimen and keep the correct relative centripetal force and time. Don't store samples for more than 4 hours at room temperature or in the refrigerator.
	Pre-analytical error Contact with glass.	Transfer the plasma by means of plastic transfer pipettes into a plastic storage tube.
	Sample-related Loss of factors V and VIII.	Don't warm up the sample longer than 5 minutes at 37°C.
	Sample-related Wrong volume has been selected.	Follow the manufacturer's instructions.
	Reagent-related Contaminated reagent.	Reconstitute a new reagent or open a new bottle.
	Reagent-related Wrong reagent has been used.	Follow the manufacturer's instructions.
	Reagent-related Wrong reagent volume has been used.	Follow the manufacturer's instructions.
	Reagent-related Reconstitution with the wrong diluent volume	Follow the manufacturer's instructions.
	Reagent-related Reconstitution with another diluent than the recommended diluent.	Follow the manufacturer's instructions.
	Reagent-related New reagent batch with different reactivity.	It is quite usual that slight differences in reactivity exist between different batches. Reverify the reference range and establish – if required – a reference curve

Error type	Possible causes	Troubleshooting
Controls within the reagent range. Unexpected result of patient samples.	**Reagent-related** Reagent disintegration.	Is this the first of this delivery employed reagent? Is the storage temperature correct?
	Reagent-related Reagent disintegration.	Don't employ the reagent if the reconstituted storage life of the non-reconstituted reagent is expired.
	Reagent-related Reagent disintegration due to too long heating in the reagent station.	The reagent should not be stored in the analyser. When the test is completed remove the reagent from the instrument, close and store the reagent in compliance with the manufacturer's instructions.
	Sample-related Contaminated reagent.	Don't touch the already dispensed samples / reagents with the pipette tip.
	Controls-related Disintegrated or contaminated material.	Dissolve new controls. Incorrect reconstituted control materials(s)! Reconstitute the controls according to the manufacturer's instructions. Only freshly deionised water may be used for the reconstruction.
	Analytical error Wrong reagent temperature.	A suitable tube has to be used. Please note that only such a reagent volume may be dispensed into the tube that the filling height is not higher than the pre-heating station. Let the reagent come slowly to room temperature (within 15 – 20 minutes). Some reagents (thrombin reagent for fibrinogen) may not be warmed up, but they should be brought to room temperature before use. Please follow the instructions of the reagent manufacturer.

Error type	Possible causes	Troubleshooting
Controls within the reagent range. Unexpected result of patient samples.	**Analytical error** Wrong incubation time	Follow the manufacturer's instructions.
	Analytical error Wrong test sequence.	Follow the manufacturer's instructions.
Irregular results within the test. Controls may be within or out of the reagent range.	**Analytical error** Imprecise manual pipetting of sample and reagent.	The pipette has to be maintained. The as accessory available automatic pipette of the MC 1 is delivered with manual. Please practise the pipetting technique. The instructions for the correct pipetting technique are in chapter 3 (pipetting). Wrong dispensing position: it is very important that the reagent is always dispensed from the same position. Please find the instructions for the correct pipetting technique in chapter 3 (pipetting). Reagent in particle form has not been mixed before employment. Close the opening of the tube with a cap or with Parafilm™, turn round the tube and mix it gently. Sample and first reagent have not been mixed. After sample and reagent have been dispensed take the cuvette out of the pre-heating station and sway it gently 5 or 6 times for dispensing the mixture constantly on the bottom of the cuvette.
Analytical error	None or more balls than one have been added.	Use one ball per cuvette.

Error type	Possible causes	Troubleshooting
Irregular results within the test. **Controls may be within or out of the reagent range.**	**Reagent-related** Irregular or imprecise reconstitution of the reagent or control material.	Reconstitute a new reagent and / or control material.
	Reagent-related Disintegrated reagent caused by too long pre-heating procedure in the reagent station.	Remove the reagent from the instrument when the analyses are completed.
	Reagent-related Reagent concentration due to vaporizing	Reagent container has to be closed when it is not used.
	Sample-related Wrong taking and handling of the samples.	Check the integrity of the sample. Inspect it with regard to micro clots, haemolysis or other problems. Ensure that the relation of anticoagulant to sample is correct (filled completely). Take a new sample. If the results are irregular again, check the clinical condition of the patient. The results of patients with disseminated intravasal coagulation (DIG) are usually erratic. Take care that the recommended storage guidelines are followed.
	Sample-related No sample has been added.	Ensure that the sample has been added.
	Sample-related Fibrinogen deficiency	Due to fibrinogen deficiency the results of many clotting tests are retarded essentially.
	Reagent-related No reagent or wrong reagent added.	Make sure that the correct reagents are employed.

Error type	Possible causes	Troubleshooting
A clot is formed but not detected resp. timer does not stop.	**Analytical error** No ball in the cuvette.	Make sure that the ball does not fall out of the cuvette before you position the cuvette in the measuring cell.
	Analytical error Incorrect cuvette position	The ball is positioned above the sensor. Make sure that the bottom of the measuring cell is not blocked by a ball or other materials.
	Sample-related A clot is formed within less than 4.0 seconds.	For fibrinogen tests use the next higher dilution. For stopping the timer insert a new cuvette with a new ball into the measuring cell. Take the cuvette out of the measuring position after 10 seconds.

9.2 System error

If the instrument detects an error during its self-test the error is indicated on the LCD-Display. The device turns into a sleep mode and can only be waked up by switching it off and on.

The MC 1 stores an error list with the last 15 errors. Every of the last 15 errors is stored with date, time and error code. For printing out this list please contact the ABW–Hotline (phone: +49 (0)5261 / 927 294).

Error-code	Meaning
1000	I2C-Bus communication not OK (internal data management)
1100	Temperature of the measuring block exceeds 50°C
1200	LCD-display not OK
2000	Check sum adjusted value are not OK, default values are loaded
2100	After switching on the ball sensor was still active

10. Additional printer

The MC 1 analyser allows to connect an external printer (available as accessory) to the serial 9-pole RS 232 interface. Please see the printer manual for detailed settings of the printer.

Only the power supply unit which is delivered with the printer should be used.

The printer is connected to the MC 1 with the supplied cable. Switch on the printer with the main switch [ON(I)].

When the green ON-LINE lamp lights up the data are transmitted to the printer after the determination is finished.

When the red ON-LINE lamp does not light up the data are stored in the printer buffer until the printer is switched to ON LINE. The green lamp flashes when the butter contains data. The data are printed out as soon as the ON-LINE key is pressed.

The red lamp flashes when paper has to be reloaded.

The selected test determines what is printed out. If PT has been selected the INR-value and the percentage result are printed out in addition to the measured time. For all other tests only the measured time is printed out.

If the printer is switched on during a test and if it is online, the data are transmitted automatically to the printer when the determination is finished. After this the data are printed out.

If the printer is switched on during a test procedure but is OFF LINE, the data are transmitted automatically to the printer buffer when the determination is finished. The data are printed when the printer is switched to ON LINE.

If the printer is in the OFF-status during the test procedure then the data can neither be transmitted nor be printed out at a later point of time.

More detailed description and instructions for the use of the Thermal Printer can be found in the Thermal Printer instruction booklet.

11. Appendix I

Verification document

The analyser to which this operation instruction is added
has been test as described in the following:

Instrument type	:	MC 1
Version	:	_____
Serial number	:	_____
Temperature measuring / pre-heating block	:	_____
Speed measuring cell	:	_____
Test location	:	_____
Test date	:	_____
Tester	:	_____

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EC Konformitätserklärung
EC Declaration of Conformity

Produktspezifikation / *Product specification*	
Produktklassifikation / *Product classification*	In-vitro-Diagnostika / *In-vitro diagnostics*
Typ / Type	MC 1 / MC 1 plus / MC 4plus / MC 10 plus

Wir / *We*

ABW Medizin und Technik GmbH
Name des Anbieters / *Supplier's name*
Lagesche Str. 15e, D-32657 Lemgo
Anschrift / *Address*

erklären in alleiniger Verantwortung, dass das oben genannte Produkt
declare under our sole responsibility that the product mentioned above

auf das sich die Erklärung bezieht, mit der / den folgenden Norm(en) oder normativen Dokument(en) übereinstimmt:
to which this declaration related is in conformity with the following standard(s) or other normative document(s):

nach folgenden Richtlinien und unter Anwendung der harmonisierten Normen entwickelt, konstruiert und produziert worden ist:
to which this declaration relates, is in conformity with the following requirements:

Titel und / oder Nummer sowie Ausgabedatum der Norm(en) oder der anderen normativen Dokumente

1.	Sicherheit:	EN 61010-1: Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel und Laborgeräte: Allgemeine Anforderungen EN 61010-2-101: Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte: Besondere Anforderungen an In-vitro-Diagnostik (IVD)-Medizingeräte
	Safety:	*EN 61010-1: Safety requirements for electrical equipment for measurement, control and laboratory use: General requirements for safety* *EN 61010-2-101: Safety requirements for electrical equipment for measurement, control and laboratory use: Particular requirements for in-vitro-diagnostic (IVD)*
2.	EMV:	EN 61326-1: Elektromagnetische Verträglichkeit - Anforderungen
	EMC:	*EN 61326-1: Electromagnetic compatibility – Requirements*
3.	Risikomanagement:	DIN EN ISO 14971:3/2001: Medizinprodukte - Anwendung des Risikomanagement auf Medizinprodukte
	Risk management:	*DIN EN ISO 14971:3/2001: Medical devices - Application of risk management to medical devices*
4.	Informationen:	DIN EN 1041:4/98: Bereitstellung von Informationen durch den Hersteller eines Medizinproduktes
	Information:	*DIN EN 1041:4/98: Information supplied by the manufacturer with medical devices*

Title and / or number and date of issue of the standard(s) or other nomative document(s)

(falls zutreffend) gemäß den Bestimmungen der Richtlinie(n) / *(if applicable) following the provisions of the directive(s)*

1.	Anhang 1 der Richtlinie 98/79/EG über In-Vitro-Diagnostika Geräte gem. Anhang III mit Ausnahme Abs. 6	Annex 1 of Directive 98/79/EC on in-vitro diagnostic medical devices according Annex III exept Point 6
2.	Deutsches Medizinproduktegesetz	German medical product law
3.	Richtlinie 80/181/EWG über die Einheit im Messwesen	Directive 80/181/EEC relating to units of measurements
4.	Richtlinie RoHS 2011 / 65 / EU	Directive RoHS 2011 / 65 / EU

Lemgo, April, 06th 2016

Ort und Datum der letzten Änderung
Place and date of issue of last amendment

Unterschrift der Geschäftsleitung
Signature of Managing Director