MERLINmedical®
EXPERIENCE. THE POWER OF INNOVATION.

MC 1 PLUS

OPERATION MANUAL

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

IVD CE

Release 010114

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SAFETY INSTRUCTIONS

Symbols used on the MERLINmedical haemostasis instruments and consumables

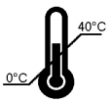
Symbol	Meaning	Used on / in
	Do not reuse	Balls & cuvettes
	In-Vitro Diagnostics Device	Operation manuals
	Biological risks	MC 1^{plus} MC 4^{plus} MC 10^{plus}
	Consult instructions for use	MC 1^{plus} MC 4^{plus} MC 10^{plus}
LOT	Batch code number	Balls & cuvettes
	Manufactured by	MC 1^{plus} MC 4^{plus} MC 10^{plus}
	Use by date: YYYY-MM	Balls & cuvettes
	Temperature limits for storage	Balls & cuvettes
Label ”serial number”	(at the back of the instrument)	MC 1^{plus} MC 4^{plus} MC 10^{plus} Power supply unit

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TABLE OF CONTENTS

Before using the MC 1^{plus} study the instruction manual carefully.
This manual shall convey you an extensive comprehension for the operating mode of the MC 1^{plus} for enabling you to use all functions of the device.

1. Introduction

1.1 Guarantee

The company ABW Medizin und Technik GmbH, called ABW in the following, grants the first buyer that the from 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 (Tel.: +495261 / 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^{plus} 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 ABW 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 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 INSTRUMENTS 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^{plus} is a semi-automatic mechanical and optical detection system which is used for the determination of prothrombin time (PT), activated partial thromboplastin time (aPTT) and fibrinogen concentrations as well as other clotting, chromogenic and clinical chemistry 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 coagulation times / OD values are converted into corresponding results.

1.3 Performance data

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

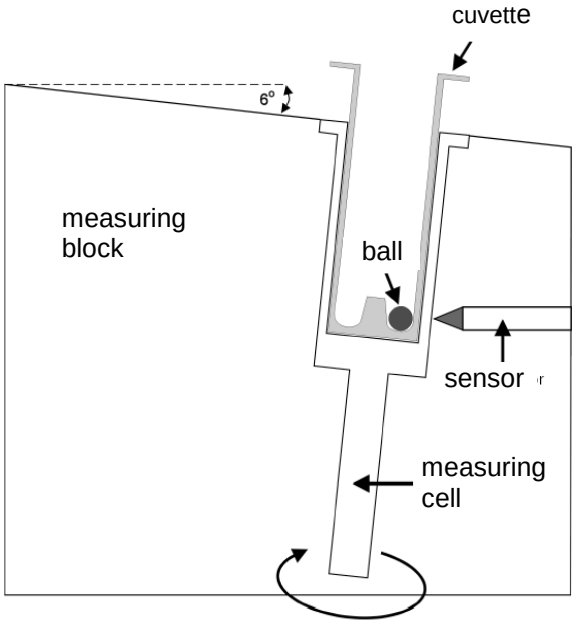
1.3.1 Correlation and precision

An investigation for the evidence of the equivalence of the MC 1^{plus} to another commercial coagulation analyser has been done by a nameable German reagent producer with PT-, aPTT-, Fib-, TZ-, AT3-, D-Dimer and CRP-measurements. Please ask ABW to get more information.

1.4 Measuring principles

1.4.1 Mechanical measuring principle

Special cuvettes with a steel ball inside are placed on the measuring positions in instrument related racks. 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. At first the sample is pipetted into a measuring cuvette, then – if required – the first reagent is added and the incubation is started. The instrument turns the cuvette with the adjusted speed around the longitudinal axis. When the incubation is finished (parameter specific) the start reagent is added and the measurement is started 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.



1.4.2 Optical measuring principle

The photometry is basing on the fact that a part of the passing light (UV-VIS = UV and visible field ca. 200 - 900 nm wave length) is reduced through the liquid test sample. Here the own colouration of the probe or the colouration of the probe by adding suitable reagents is used. The course of the colouration is stored in the MC 1^{plus} and evaluated by special software according the test requirements.

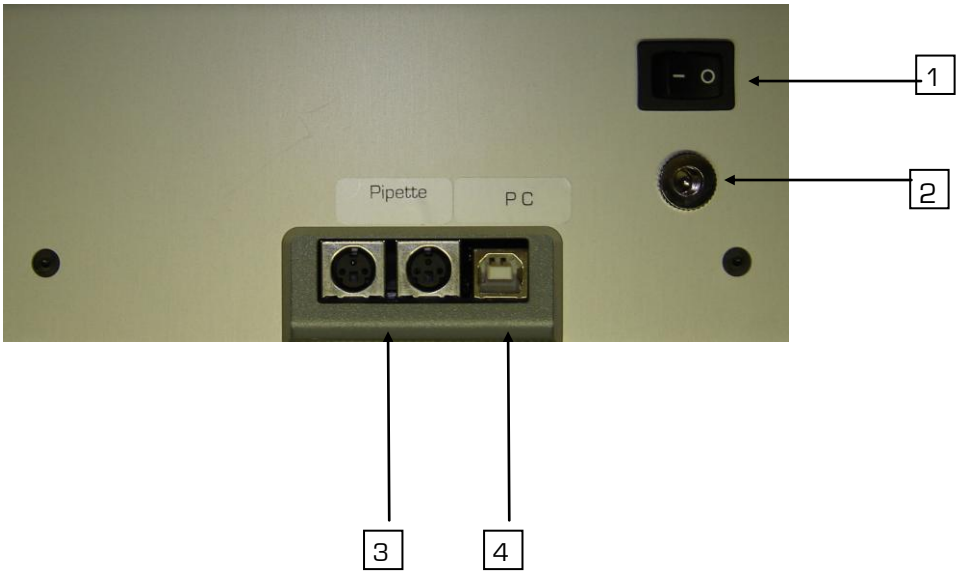
photometer principle: plasma before clot formation — plasma after clot formation

1.5 Specifications

Type	:	Coagulation analyser / bench top device
Connection	:	USB
Measuring principle	:	mechanical + optical measuring method
Number of measuring channels	:	1 + 1
Display	:	PC
Cuvette pre-heating stations (if required also employable as reagent pipetting station)	:	2
Drills 14.5 x 85.0 mm for reagent pre-heating	:	1
Drills 11.5 x 75.0 mm for reagent pre-heating	:	1
Dimensions	:	265 x 187 x 90 mm (L-W-H)
Weight	:	1.8 kgs
Power primary	:	100 VAC - 240 VAC 50 / 60 Hz
Power secondary	:	24V
Power consumption	:	30 VA
Measuring block temperature	:	37.3°C (+/- 0.5°C)
Measuring period	:	4.5 – 999.9 seconds
Measuring period Lyse	:	0 – 999 hours
Motor turning speed	:	MC 1^{plus} micro 50 r.p.m. MC 1^{plus} macro 40 r.p.m.

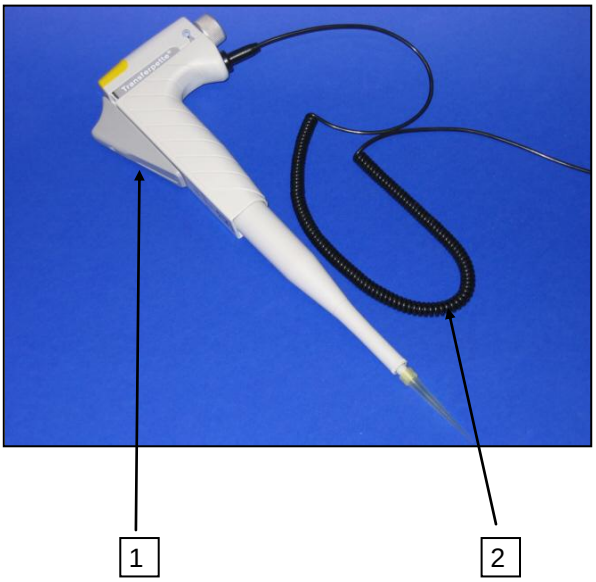
1.6 Views of the MC 1^{plus}

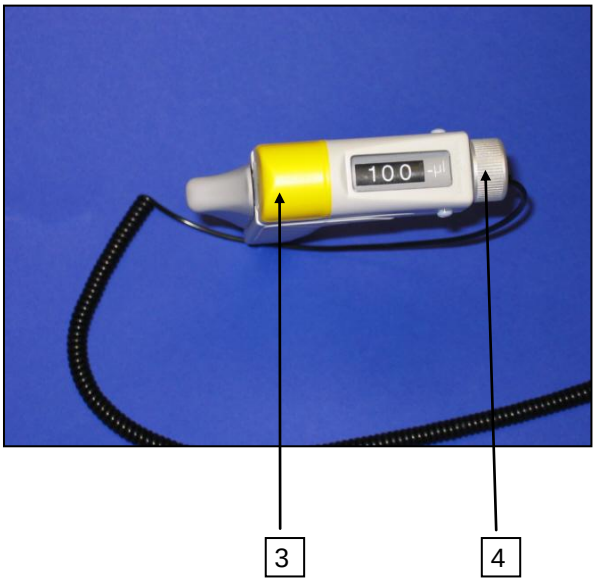
Component	Function / Description
1. Optical Measurement	Measurement of chromogenic and clinical chemistry tests
2. Left key field	for activating and starting the ball measuring station
3. Pre-heating station for samples	2 pre-heating positions for test preparation
4. Pre-heating station for reagent	2 pre-heating positions for reagent
5. Right key field	for activating and starting the optical measuring station
6. Ball measuring station	position, in which the starting reagent is added and the coagulation time is measured
7. Ball dispenser	



Component	Function / Description
1. On / Off switch	Main switch of MC 1^{plus}
2. Low voltage socket	for connection with the external power supply
3. Pipette socket	for connection with automatic pipette
4. USB-port	for connection with PC

1.7 Views of a 3-volume microlitre pipette





Component	Function / description
1. Pipetting key	For filling and dispensing start reagent. If a measuring position activating key has been pressed at the MC 1^{plus} the time keeping can be started by pressing the pipetting key until the first stop.
2. Pipette contact line	For the connection of the automatic pipette with the analyser.
3. Ejector cap	Removing of used pipette tips
4. Switch for volume selection	When the pipetting key (no.1) is pushed down completely the pipetting volume can be adjusted with this switch (50, 100 or 200 µl)

2. Installation

2.1 Unpacking

The MC 1^{plus} 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 ABW-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^{plus} coagulation analyser
Power supply unit
Power cable
USP cable
USB stick with PC software

2.3 Consumables and accessories

Consumables / description	Cat.-No.	Packing unit
MC cuvettes and balls micro	Z05120	1,000
MC cuvettes and balls macro	Z05100	1,000
Reagent tubes plastic (14.5 mm x 80.0 mm)	832158	300
Coagulometer tubes plastic	833118	500

Accessories / description	Cat.-No.	Packing unit
3-Vol-Pipette with start cable	P10000	1
Ball dispenser micro	Z11000	1
Ball dispenser macro	Z10000	1

The in 2.3 Consumables and Accessories mentioned articles are not part of the MC 1^{plus} scope of delivery. The consumables can be ordered according to the user's requirements. An automatic pipette ensures that the time keeping is started simultaneously with adding the start reagent. If the manual start key is used for starting the time keeping the reagent can be dispensed with any pipette which can dispense the correct volume for the according test.

2.4 Location of the instrument

1. Place the MC 1^{plus} 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 to 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 39 cm (width of the instrument: 18,7 cm)
- depth 37 cm (depth of the instrument: 26,5 cm)

2. Position the MC 1^{plus} 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^{plus} 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^{plus}.

Attention!
If the user is electrified a discharge may happen at the MC 1^{plus}.
This discharge has no influence on the function of the MC 1^{plus}.

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 employ the with the MC 1^{plus} supplied suitable external power supply unit, otherwise the analyser could be damaged.

3. It is recommended that all repairs beyond the periodical maintenance and little setting are carried out by the ABW-customer service.

4. If the instrument is not used as advised 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 must not exceed 3 meters.

Warning!
Only the original external power supply (100 VAC – 240 VAC), which is delivered with the MC 1^{plus}, may be used, otherwise the analyser could be damaged.

2.6 Connection of the device

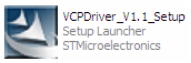
1. Connect the low voltage cable of the power supply unit with the low voltage plug at the back of the instrument.

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^{plus}.

4. Connect the MC 1^{plus} and the PC with the USB cord.

2.7 Software installation

- Turn on the provided PC and wait until it is fully booted.
- Connect the provided USB memory stick to one of the corresponding USB ports of your PC.
- Install the driver for MC 1^{plus} by double clickin on the symbol 

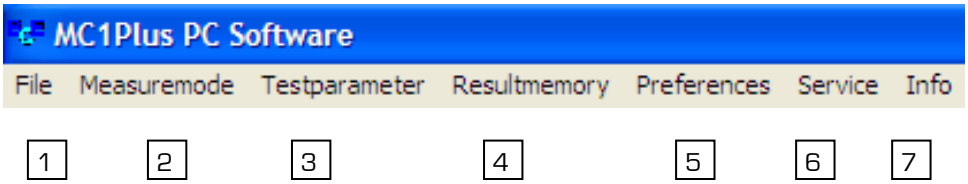
.
- Copy the file MC1 PLUS 

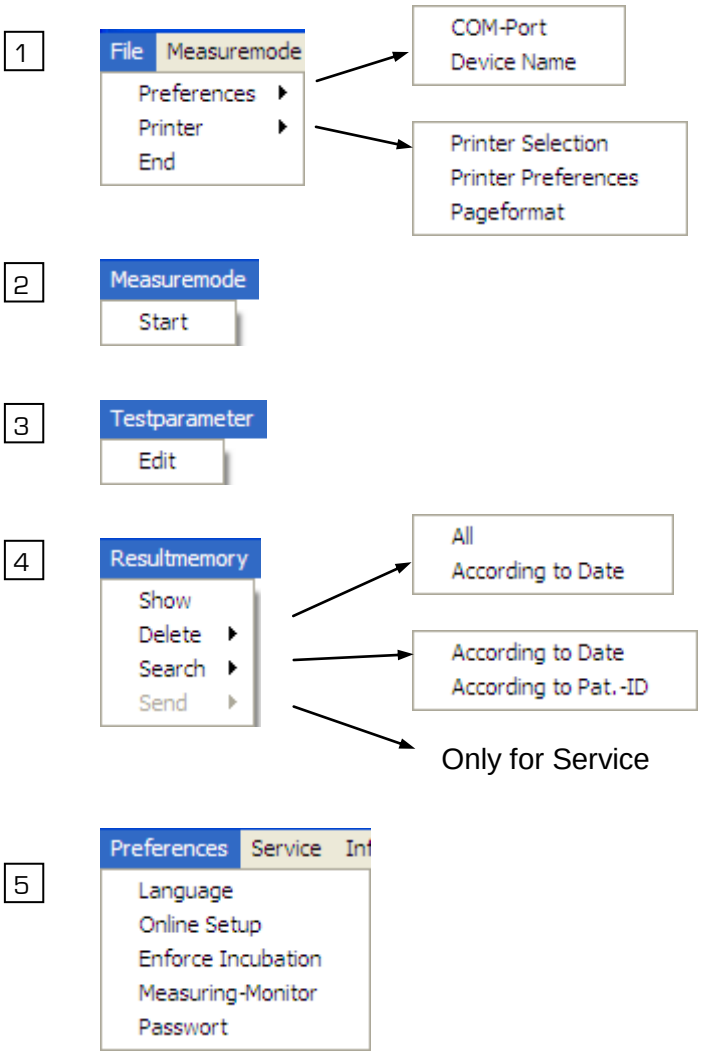
to the hard disk (e.g.. C:\)
- Create a desktop icon from your application program in your MC 1^{plus} folder 

.
- Check which COM port was chosen by your Windows (control panel – system – hardware – device manager – universal serial bus controllers).

3. Function

3.1 Menu structure PC





6 Service Only for service with password

7 Info Software version

3.2 Switch on

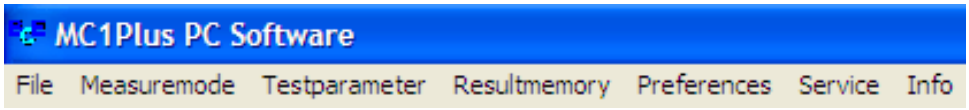
Switching on must always take place in the following order:

1. Switch on the PC and wait until it is booted completely.

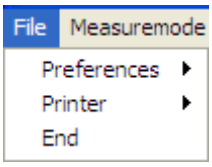
2. Switch on the MC 1^{plus} with the On / Off switch on the back of the instrument. After switching on the equipment accomplishes an initialization with which in the left key field the upper LED shines red and the lower LED green. After the initialization you will hear a sound signal and the upper red shining LED is out. The lower LED continues to shine green.

3. Now the MC1^{plus} program can be started through double-click on the symbol 

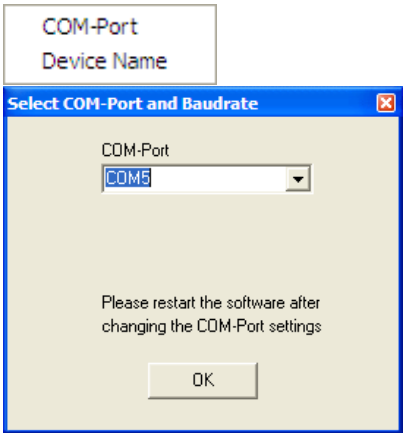
The following window appears:



3.3 File

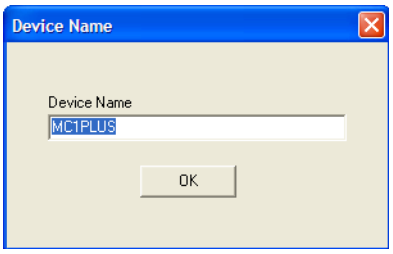


3.3.1 Preferences



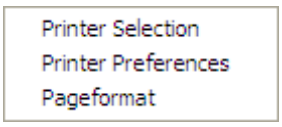
Com-Port Adjust, at which COM-Port the MC 1^{plus} is attached

Device Name Device
name specify, if



several
MC 1^{plus} devices are to be
attached

3.3.2 **Printer**

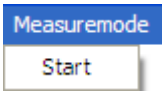


Here you can make all adjustment regarding your printer.

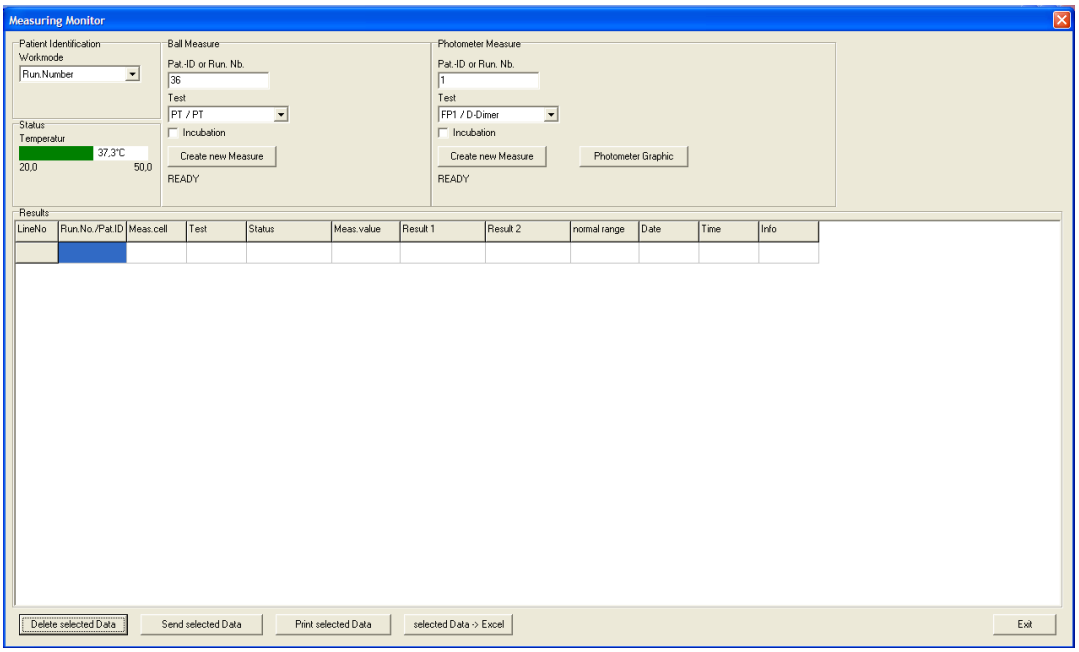
3.3.2 **End**

To exit the software.

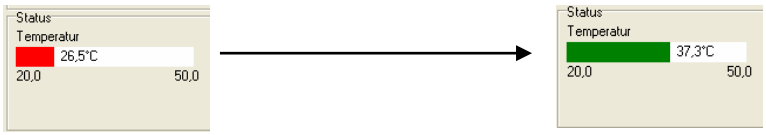
3.4 Measure mode



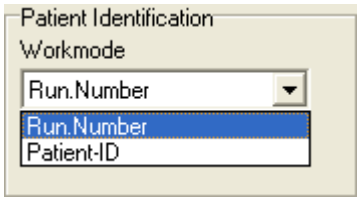
Click **Measuremode** and then **Start**.
The work screen opens.



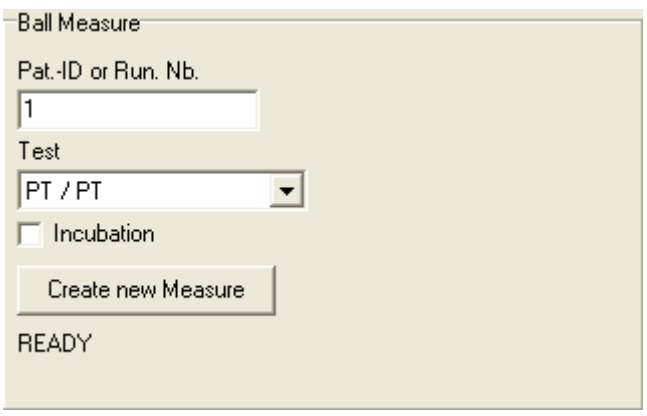
Please wait now until the temperature bar under Status has changed from red to green (37.3°C).



Chose in the field Patient Identification if you want to work with **Run.Number** (running number) or with **Patient-ID** (patient identification).



3.4.1 Measurement of tests with the ball measuring station



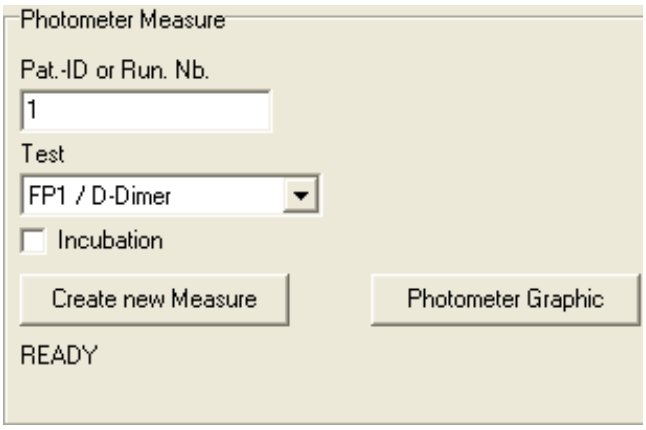
Enter under ***Pat.-ID or Run. Nb.*** the according patient ID or the start number.

Select under ***Test*** the parameter which will be measured.

Activate or deactivate according to the test requirements the field ***Incubation***.

Click on the field ***Create new Measure*** in order to activate the selected test.

3.4.2 Measurement of tests with the optical measuring station



Enter under ***Pat.-ID or Run. Nb.*** the according patient ID or the start number.

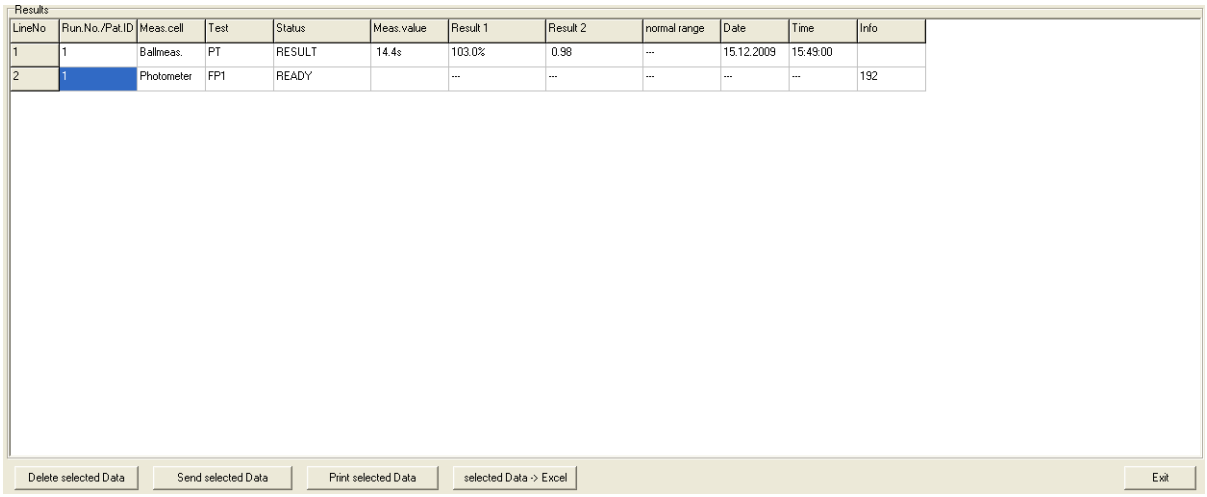
Select under ***Test*** the parameter which has to be measured.

Activate or deactivate according to the test requirements the field ***Incubatio***n.

Click on the field ***Create new Measure*** in order to activate the selected test.

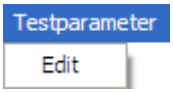
Under Photometer Graphics you can see the according curve of the measurement.

3.4.3 Results

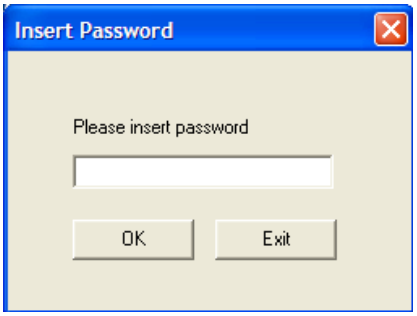


In the field results you see the current conditions of the measurements and the results can read. In order to print results / send results (LIS) / export results to Excel / delete results, mark the according results with the PC mouse before you click on the according button below the results.

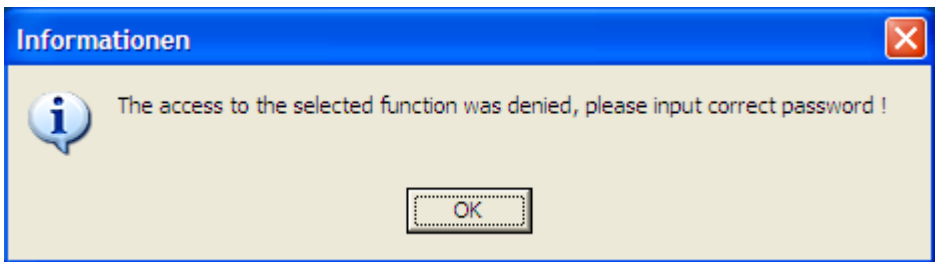
3.5 Test parameter



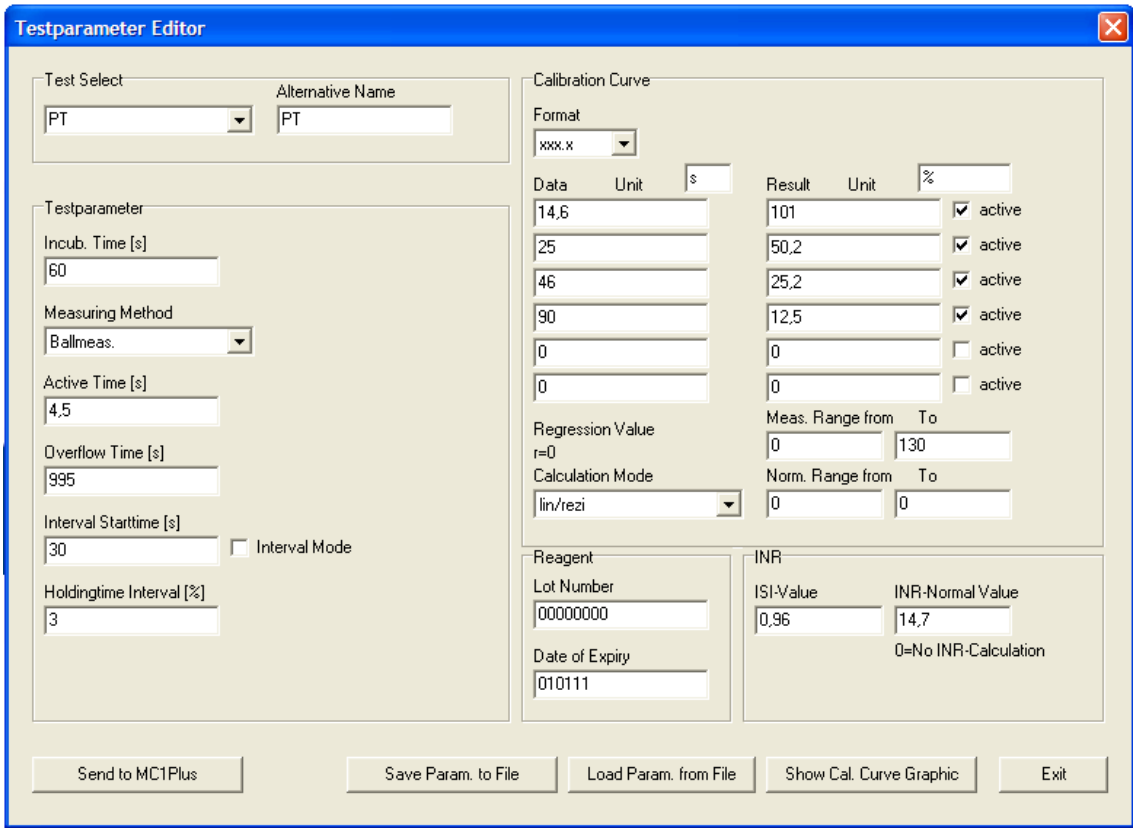
Select ***Testparameter - Edit*** for entering, adapting and changing tests.



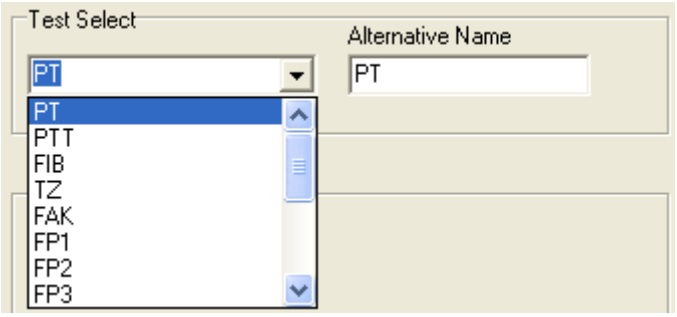
You are requested to enter a password.
The standard adjusted password is: **3103**
You change this password under ***Preferences - Password***.
When an incorrect password has been entered, following message appears:



After entering the correct password the test parameter editor opens.



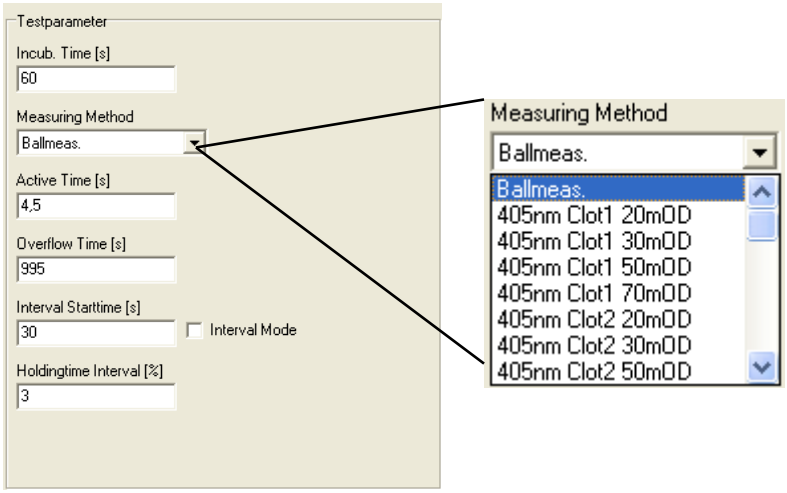
3.5.1 Test Select



In the menu “Test select” select the test which should be changed or generated. 5 tests with PT, aPTT, Fibrinogen, Thrombin time and FAK (factor) are presetted. Compare these adjustments with the package inserts of your reagents and modify if necessary. The tests FP1 to FPB (FP. = free programmable) are intended for free programming.

Under alternative name you enter the description, which appears in the result screen and on the expressions as test description.

3.5.2 Test parameter



Here different parameter-specific inputs can be effected.

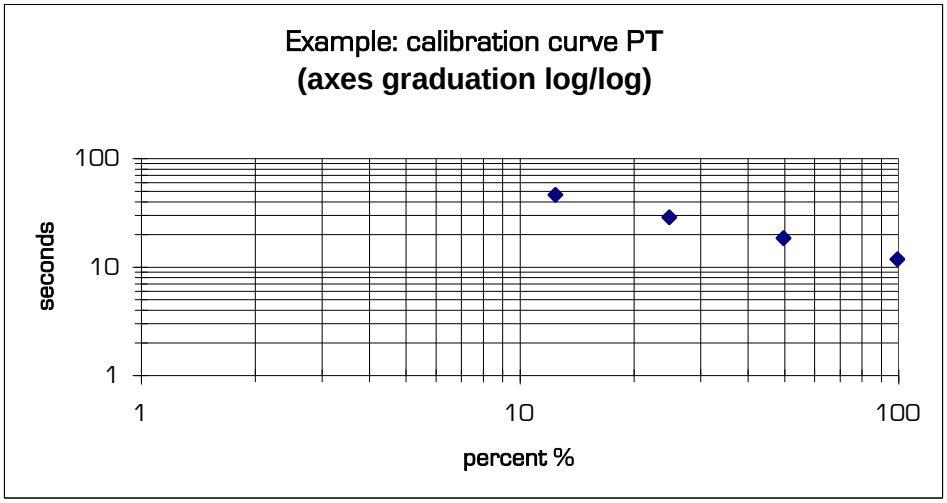
3.5.2.1 Incub. Time (s)

Please enter the incubation period according the package insert of the reagent. Values can be entered between 10 and 999 seconds.

3.5.2.2 Measuring Method

Mechanical measurements (ball method)

The procedure of establishing the test value itself is always the same for all tests which have to be carried out with the mechanical method. The time from adding the start reagent until clot formation, through which the ball is pulled away from its basic position, is measured. In general the measured time is converted into a parameter-specific unit whereas the graduation of the measure axes in the conversion coordinate system can be different.



Furthermore the measured time of the PT can also be converted to the INR-value. Therefore it is necessary to have either the INR-standard value which can be calculated by means of a self-established calibration curve or the by the MC 1^{plus} suggested value which is calculated by means of the entered calibration curve. This value is displayed in brackets in the test parameters after the input for the INR-standard. Also the analyser-specific ISI-value which is stated on the reagent package insert is required for the INR-calculation.

The calculation is carried out as follows:

$$INR = \left(\frac{\text{measured time of the test material}}{\text{INR-standard value}}\right)^{ISI}$$

Optical measurements

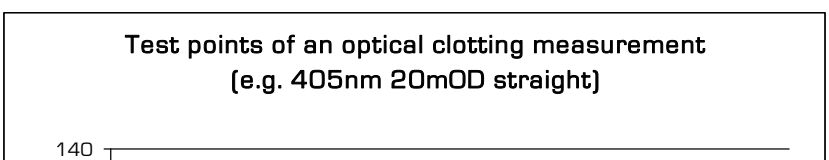
For the optical test method there are five different kinds of detecting a clotting reaction respectively the from this resulting test value determination. Here the test time also always starts by adding the start reagent but the test procedures are different.

General:
For all following test procedures 405 or 650 nm wave length can be selected and for all test methods the start delay and timeout time are freely programmable.
After completion of the measurement the curve can be displayed by pressing the key F2.

Clot 1:
After the start delay time the mean value of the last 10 test values (the determination of all 10 values takes 1 sec.) is calculated. This value is the basic value. After a freely selectable extinction modification of 20, 30, 50 or 70 mOD there is a stop. The concentration is calculated by comparison with a standard curve.

Clot 2:
After the end of the start delay time a straight line (horizontal) is searched. This straight line represents the basic value. After a freely selectable extinction modification of 20, 30, 50 or 70 mOD there is a stop. The concentration is calculated by comparison with a standard curve.

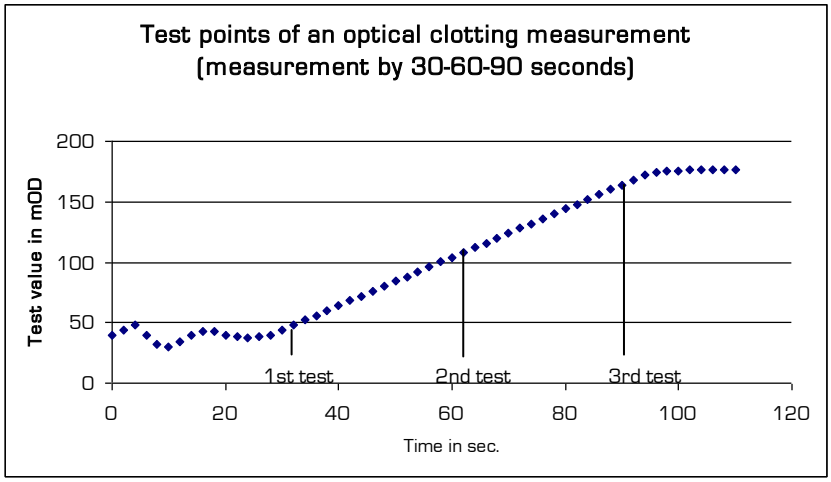
Example for Clot 1



Clot 3:
After the end of the start delay time the mean value is searched at first (as for Clot 1). The course is observed. If this value becomes lower this value is taken as basic value. Always the lowest value is the basic value. After a freely selectable extinction modification of 20, 30, 50 or 70 mOD there is a stop. The concentration is calculated by comparison with a standard curve.

Chromogenic:
After a freely selectable interval (10 / 20 / 30 sec. or 20 / 40 / 60 sec. or 30 / 60 / 90 sec.) the extinction modifications are measured. The modification is calculated in mOD/min. The concentration is calculated by comparison with a standard curve.

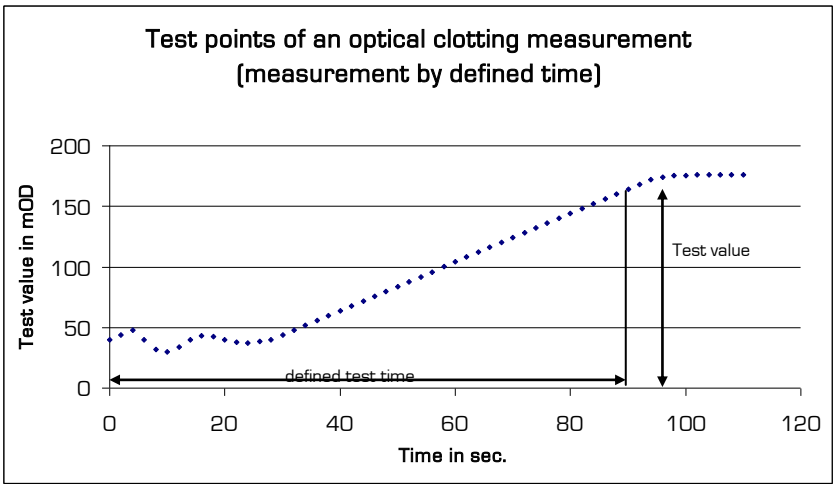
Example for chromogenic measurement



Delta E:

The first test value is established after the end of the start delay time as for Clot 1. The second value is established after the timeout time. The modification is displayed in mOD. The concentration is calculated by comparison with a standard curve.

Example for time measurement Delta E



Ensure the correct kind of calculation resp. measurement when entering the test parameters. The correct test method is stated on the reagent package insert. For questions please approach your contact person, the reagent supplier or the company ABW.

3.5.2.3 Active Time (s)

Active Time with ball method: Time between start reagent addition and activation of the sensor.

Active Time with optical method: After Active Time the first measuring point is seized.

3.5.2.3 Overflow Time (s)

Overflow Time with ball method: Maximum measuring time.

Overflow Time with optical method: Maximum measuring time.

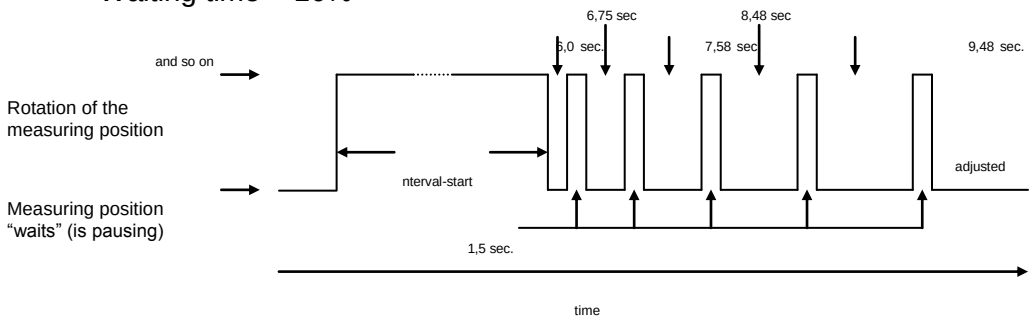
3.5.2.3 Interval Mode

In order to test also very unstable clots with lowest fibrin concentrations the MC 1^{plus} can also be operated in a switchable **interval mode**. If the interval mode is switched

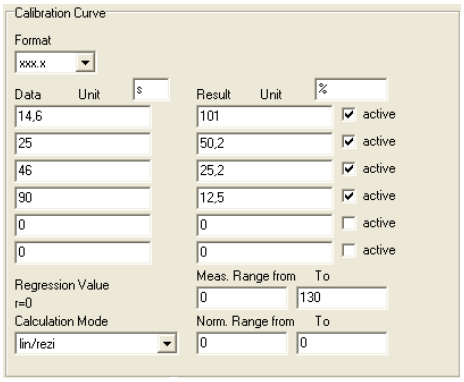
on (interval start greater than zero), the operation changes from the continuous rotation of the measuring position to an interval mode after the previously adjusted start time. The interval start can be hold up and accelerated whereas the according adjustment has to be made before. The pulse time is always 1.5 sec respectively one rotation.

The stop time depends on the up to now measured time and on the adjusted percentage increase „waiting time“. During the waiting times no measurements are possible and the CV of the expected test results increases proportionally to the input of the percentage increase of the waiting time whereas the probability of detecting also lowest fibrin concentrations is increasing.

Example: Interval start = 60 Sek.
Waiting time = 10%



3.5.3 Calibration curve



Here you enter the calibration curve parameters.

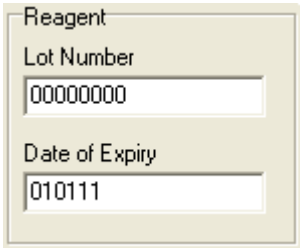
Under format you specify the result format (decimal places).

Units can be defined freely.

Measured value and result always form a pair per column and must be set if necessary actively. Under result you enter the calibrator value and under measured value the second or mOD value.

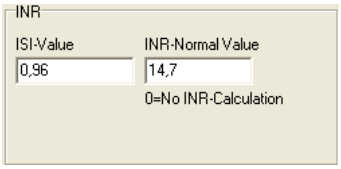
Corresponding to the test regulations computation mode, measuring range and normal range are entered.

3.5.4 Reagent



Here you can enter the lot number and the date of expiry.

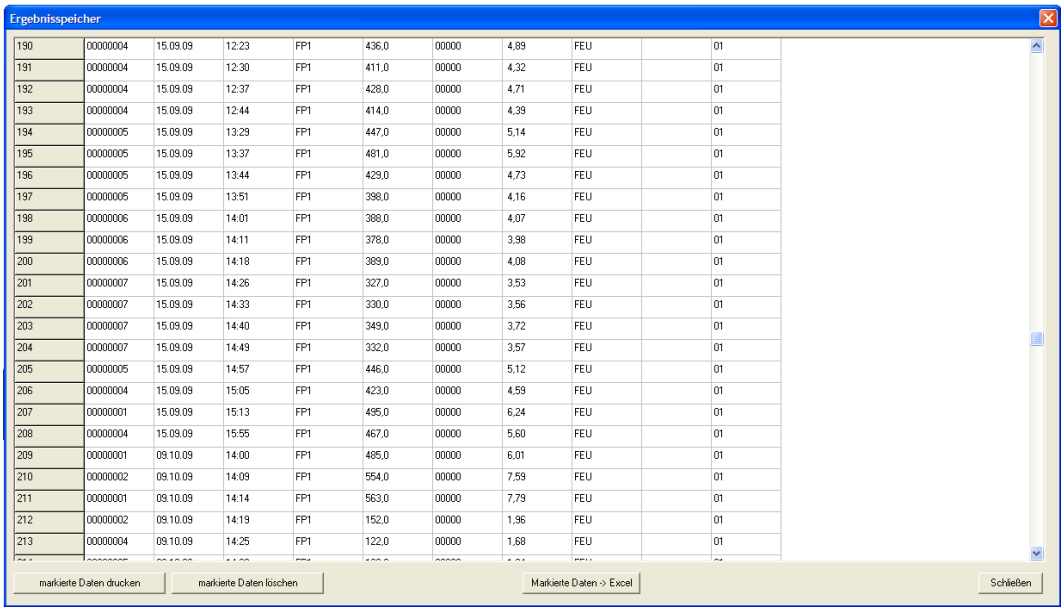
3.5.5 INR



Here you enter the ISI-Value and the normal clotting time.

3.6 Result memory

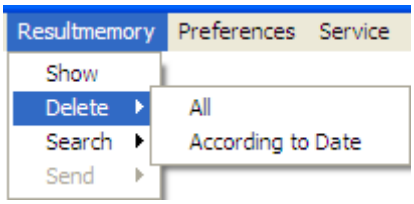
3.6.1 Show



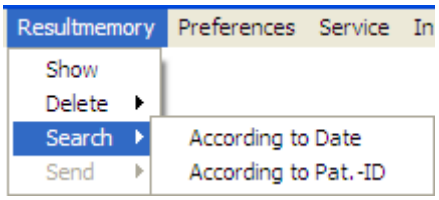
190	00000004	15.09.09	12:23	FP1	436,0	00000	4,89	FEU		01
191	00000004	15.09.09	12:30	FP1	411,0	00000	4,32	FEU		01
192	00000004	15.09.09	12:37	FP1	428,0	00000	4,71	FEU		01
193	00000004	15.09.09	12:44	FP1	414,0	00000	4,39	FEU		01
194	00000005	15.09.09	13:29	FP1	447,0	00000	5,14	FEU		01
195	00000005	15.09.09	13:37	FP1	481,0	00000	5,92	FEU		01
196	00000005	15.09.09	13:44	FP1	429,0	00000	4,73	FEU		01
197	00000005	15.09.09	13:51	FP1	398,0	00000	4,16	FEU		01
198	00000006	15.09.09	14:01	FP1	388,0	00000	4,07	FEU		01
199	00000006	15.09.09	14:11	FP1	378,0	00000	3,98	FEU		01
200	00000006	15.09.09	14:18	FP1	389,0	00000	4,08	FEU		01
201	00000007	15.09.09	14:26	FP1	327,0	00000	3,53	FEU		01
202	00000007	15.09.09	14:33	FP1	330,0	00000	3,56	FEU		01
203	00000007	15.09.09	14:40	FP1	349,0	00000	3,72	FEU		01
204	00000007	15.09.09	14:49	FP1	332,0	00000	3,57	FEU		01
205	00000005	15.09.09	14:57	FP1	446,0	00000	5,12	FEU		01
206	00000004	15.09.09	15:05	FP1	423,0	00000	4,59	FEU		01
207	00000001	15.09.09	15:13	FP1	495,0	00000	6,24	FEU		01
208	00000004	15.09.09	15:55	FP1	467,0	00000	5,60	FEU		01
209	00000001	09.10.09	14:00	FP1	485,0	00000	6,01	FEU		01
210	00000002	09.10.09	14:09	FP1	554,0	00000	7,59	FEU		01
211	00000001	09.10.09	14:14	FP1	563,0	00000	7,79	FEU		01
212	00000002	09.10.09	14:19	FP1	152,0	00000	1,96	FEU		01
213	00000004	09.10.09	14:25	FP1	122,0	00000	1,68	FEU		01

In the result memory you see the last 1000 results. You can mark the results with the cursor and print, delete or export them to Excel.

3.6.2 Delete



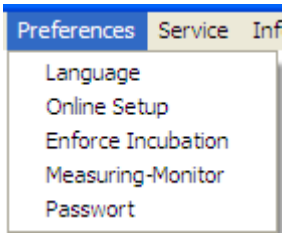
3.6.3 Search



3.6.4 Send

Send results to LIS

3.7 Preferences



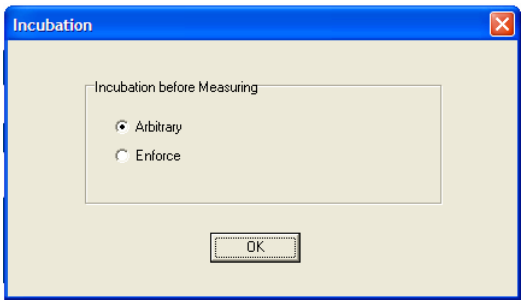
3.7.1 Language

Select your language

3.7.2 Online Setup

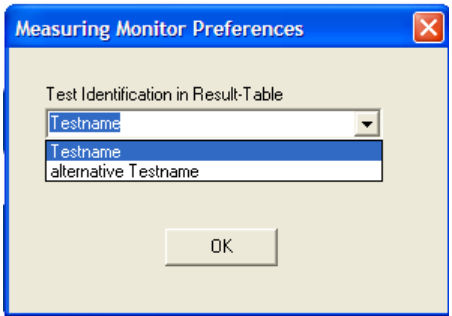
Select the LIS

3.7.3 Enforce Incubation



Here you have the possibility of forcing the incubation in the measuring program according the adjustment in the test parameters, i.e. an incubation must take place at the appropriate measuring point prior to a started measurement.

3.7.4 Measuring-Monitor



Here you specify which test description (see 3.4.1 test selection) is indicated with the results.

3.7.5 Password

Here you can change the preinstalled password (3103).

3.8 Service

Only for authorized and trained technicians.

3.9 Info

The current version of the PC software is indicated

4. Pipetting technique

4.1 Precision and correctness

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

4.2 Pipetting with a microlitre pipette

Tests can either be carried out with manual micro litre 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 microlitre pipette the time keeper has to be started simultaneously by pressing one of the two manual start keys which are located next to the activating keys for the measuring channels.

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 removed. Bent or otherwise damaged pipette tips should also be disposed of. The tip opening must 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 absorption 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 most usual pipettes which have a button on top of the pipette (chapter 1.7). For pushing the switch place your thumb over the switch and press it down. The pipette has the two above described positions.

In order to avoid a contamination of reagent (if the same pipette is used for both sample and reagent) the tip has to be exchanged between the dispense of sample and reagent. The automatic microlitre pipette is equipped with an ejector cap at the upper end. For disposing the tip just press the yellow cap.

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.

4.2.1 Volume selection on automatic microlitre 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.

4.3 Sample absorption (microlitre pipette)

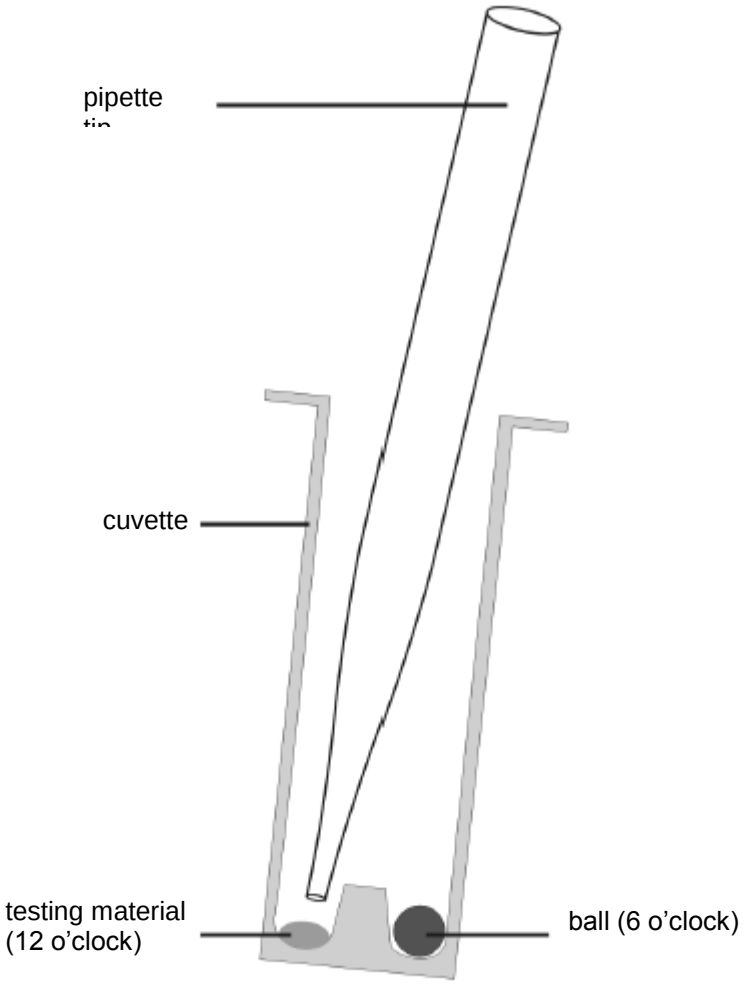
Press down the pipetting key until the first stop. Hold it and immerse the tip ca. 2 - 3 mm into the sample resp. the reagent. If plasma is pipetted directly from a centrifuged sample tube it has to be granted that the tip does not get into touch with the cruor. So you ensure that the aspiration of erythrocytes or blood platelets is avoided. If a reagent in the form of particles is pipetted, the reagent should be mixed up very well before the pipetting procedure.

Let the pipetting key slide back slowly in order to let the sample / reagent flow constantly into the pipetting tip. A slow absorption ensures that the correct volume gets into the tip. A sudden release of the pipetting key may cause the absorption of a wrong volume. Furthermore a certain part of the sample / reagent may get into the pipette piston which may cause a contamination of the following samples / reagent. If liquid has been aspirated into the pipette piston the pipette has to be unscrewed and cleaned. Otherwise the pipette blocks and does not aspirate reliably.

If the tip is filled no drops may leak. If this happens anyhow either the tip is not connected correctly or he pipette has to be serviced. In this case exchange the tip. If the problem is not sorted out the pipette may not be used before it has been inspected.

4.4 Sample dispense (microlitre pipette)

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 over 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 down until the second stop. 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 distribution 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 pipetting key until the second stop. For the sample distribution 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.

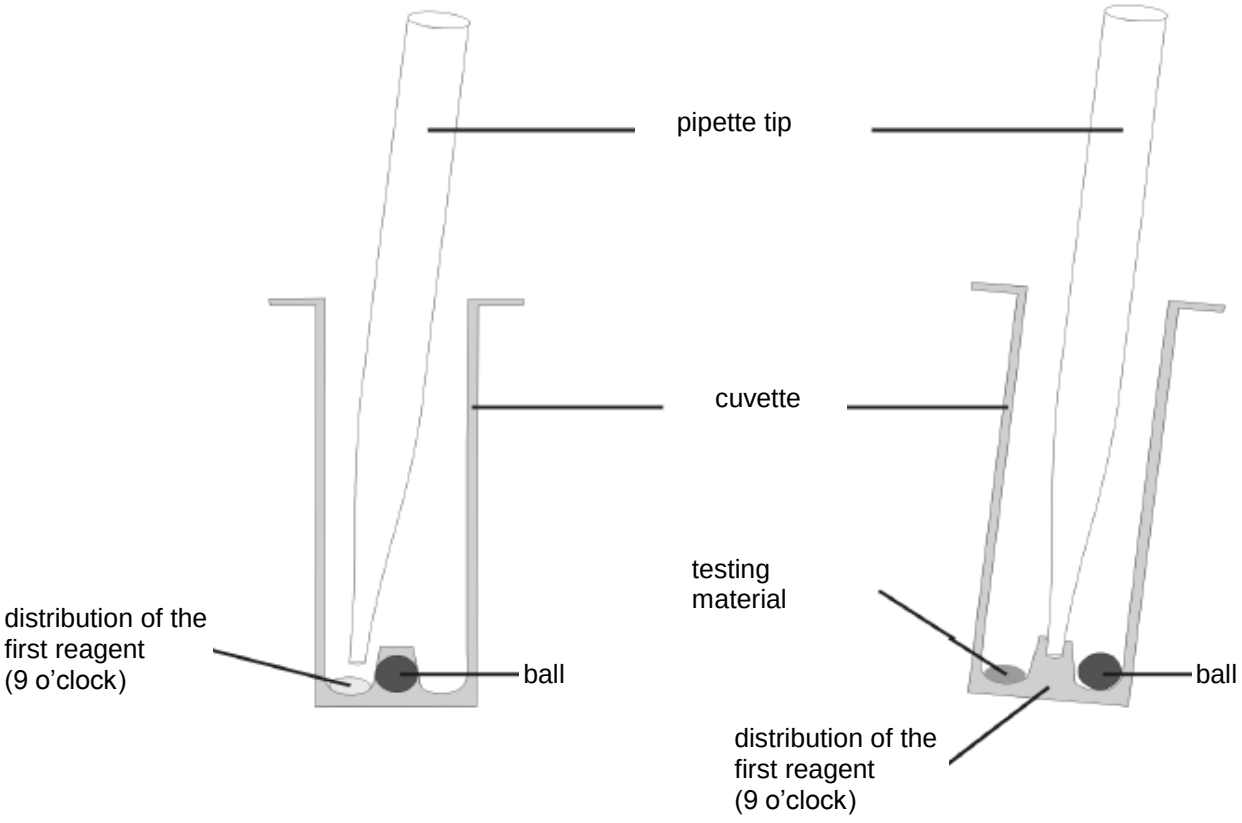


4.5 Dispense of reagent 1 (microlitre pipette)

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

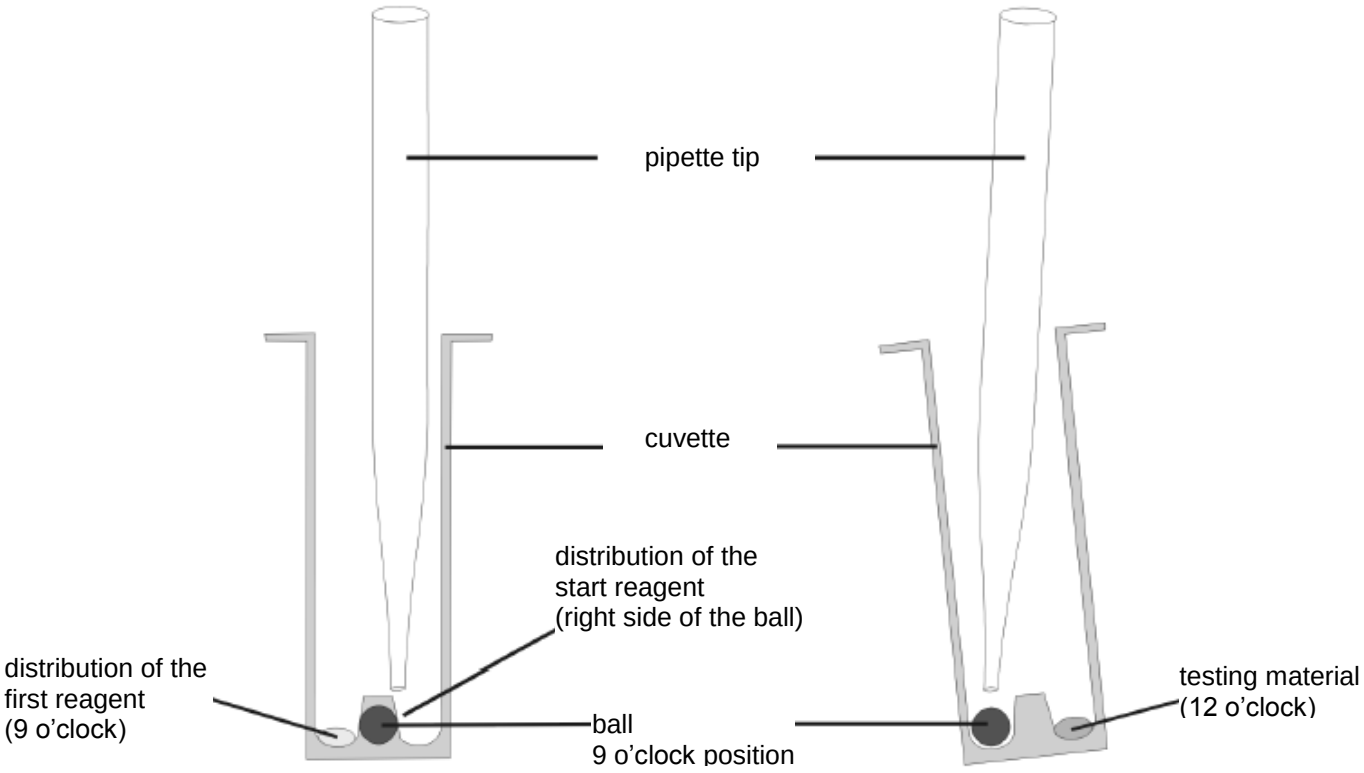
During tests for which more than one reagent is used the first reagent should be dispensed in the 9 o'clock position of the cuvette (please see picture). Go with the pipette into the 9 o'clock position. Position the tip 2 – 3 mm above the bottom of the cuvette.

Press down the pipetting key until the first stop and hold it down for 1 –2 seconds in order to let 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 distribution 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 pipetting key slowly until the first stop. Wait 1 – 2 seconds and press then the pipetting key down to the second. 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).



4.6 Dispense of start reagent (microlitre pipette)

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 pipetting key into until the last stop. The distribution 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 reagent pipetting procedures 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 possible automatic pipettes in chapters 1.7 and 1.8.



5. Operation

5.1 Switch on PC

Switch on the PC and wait until it is booted completely.

5.2 Switch on the instrument

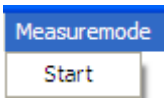
Switch on the MC 1^{plus} with the On / Off switch on the back of the instrument.
The MC 1^{plus} gives an audio signal and on both key fields the red and green LEDs light up briefly (the red LED in each case. During the initialization only the LEDs of the left key field shine. After approximately 10 seconds the MC 1^{plus} gives a double audio signal and only the green LED on the left key field lights up. The MC 1^{plus} is now ready for use.

5.3 Start MC 1^{plus} Software

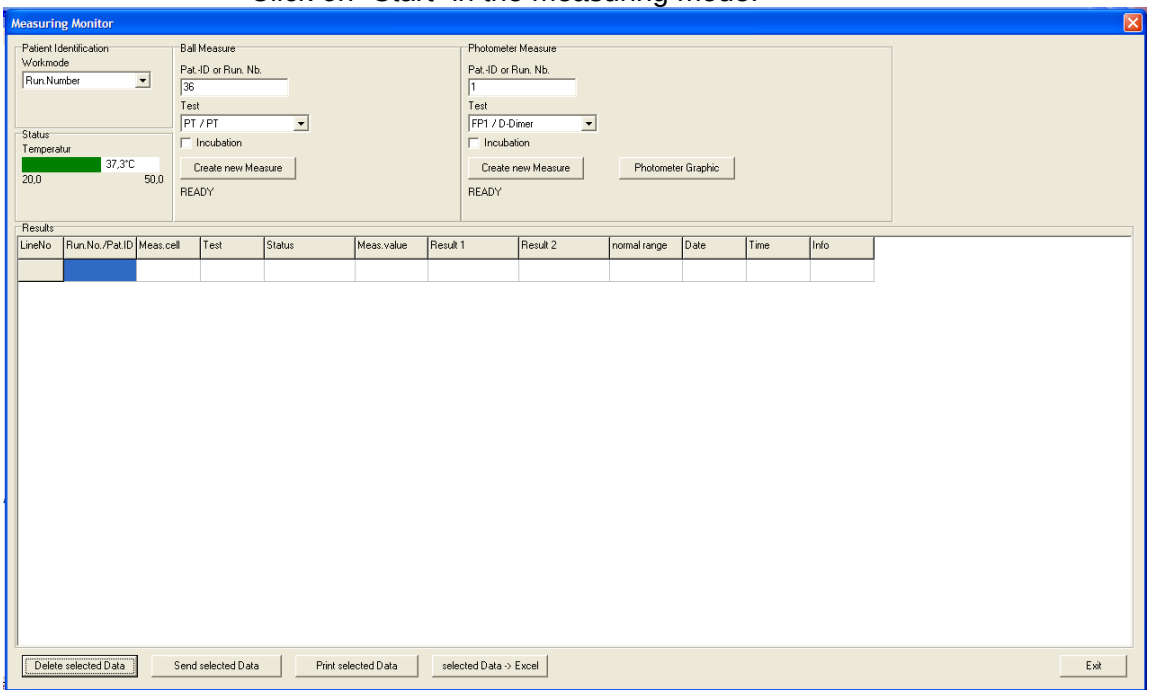
With doubleclick on the symbol 

you start the MC 1^{plus} software.

5.4 Start Measuring Mode

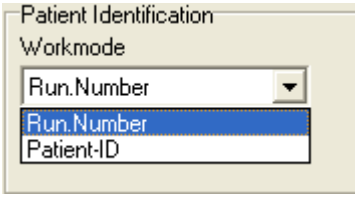


Click on “Start” in the measuring mode.

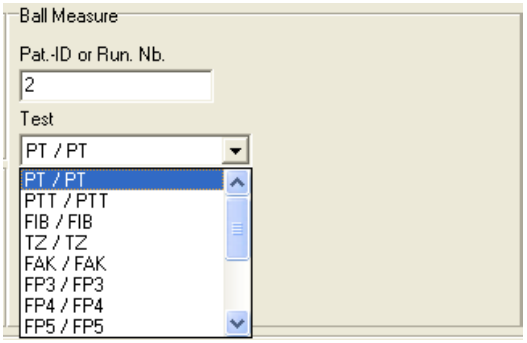


Wait until in the status of the temperature indication is green.

Select under “patient identification” whether you want to work with sequential number or patient identification number.



5.4.1 Ball Measure

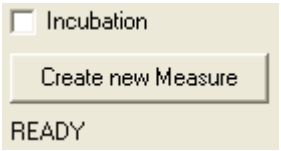


Enter either the starting number or the first patient identification number.

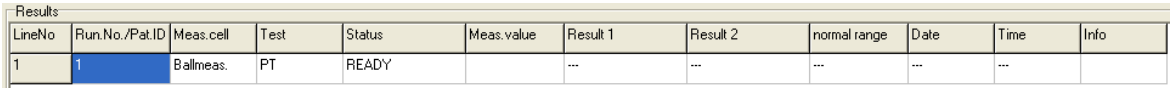
Select the test which to be measured.

The respective test specifications must be stored before under test parameters (please see chapter 3.4).

Select whether you want to work with or without incubation.
The adjustment cannot be changed if prior to the measurement following setting has been effected: Preferences - Incubation – Arbitrary.



Press Create new Measure



Measurement with incubation

The instrument uses a special cuvette with a steel ball. Before a measurement can take place such a cuvette is placed in one of the preheating places for cuvettes (above the ball measuring station). In cuvettes which were placed in these preheating positions reagent is pipetted only if the parameter consists of two reagent substances (e.g. aPTT). If a measurement has to be carried out, the preheated cuvette has to be put into the measuring station.

Activate the measuring station by pressing the upper key on the left key field. This program is now 5 seconds active, which is indicated by the lower flashing green LED. Within this time the sample is to be pipetted and at the same time the incubation has to be started by pressing the lower key on the left key field.

The MC 1^{plus} acoustically signals 5 seconds before the end of the in the test parameter menu (chapter 3.4.2.1) preselected incubation time the end of this work

procedure in order to prepare you to pipette the start reagent and thus to start the measurement. Subsequently the measuring program has to be activated by pressing the upper key on the left key field again. The measurement can be started within the next 5 seconds (LED flashes green). This is done via simultaneously pressing the lower key on the left key field and pipetting the (start-) reagent. If an automatic pipette is attached to the equipment, this constitutes a facilitation of the measurement start, i.e. the lower key on the left key field doesn't need to be pressed at the same time with the test addition. During the measurement the upper LED on the left key field flashes. The instrument will stop the measurement automatically when the clot is detected, the upper LED stops shining and the lower LED shines green again.

Example: You have a patient sample and want to determine a PT. Place a cuvette into one of the two preheating stations for cuvettes (see chapter 1.6). Prepare the reagent according to its regulation and position it in a 14.5 x 85 mm plastic tube in the measuring/preheating station above the cuvette preheating places. Place the preheated cuvette into the measuring position. Now you must activate the measuring program by pressing the upper key on the left key field. Note that this program remains only 5 seconds active. Pipette the plasma (100µl with MC 1^{plus} macro, 50µl with MC 1^{plus} micro, you can also consult the manufacturer regarding the possibility of further reducibly) and start simultaneously the incubation timer by pressing the lower key on the left key field. 5 seconds before the incubation ends the MC 1^{plus} gives 5 acoustic audio signals in a 1-second pulse. Within these 5 seconds you can take up the preheated reagent (200µl with MC 1^{plus} macro, 100µl with MC 1^{plus} micro) with the pipette. At the end of the incubation the measuring program has to be activated again by pressing the upper key on the left key field. Again the program remains active only 5 seconds. Start the measurement by adding the start reagent with the cuvette within these 5 seconds. The measurement is stopped automatically when a coagulation reaction starts respectively when a clot is formed. The measuring station will however continue to turn in order to make a visual control function possible. The result is indicated on the PC in the result screen.

Results

LineNo	Run.No./Pat.ID	Meas.cell	Test	Status	Meas.value	Result 1	Result 2	normal range	Date	Time	Info
1	1	Ballmeas.	PT	RESULT	14.4s	103.0%	0.98	---	15.12.2009	15:49:00	

For further measurements you have to press again new measurement.

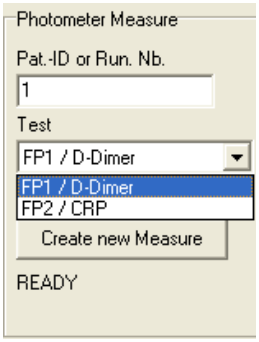
Parallel to an active ball measuring an optical measurement can be started.

Measurement without incubation

For measurements without incubation you activate the measuring program by pressing the upper key on the left key field and start the measurement within the next

5 seconds (LED flashes green). This is done via simultaneously pressing the lower key on the left key field and the adding of the (start) reagent. If an automatic pipette is attached to the equipment this constitutes a facilitation of the measurement start, i.e. the lower key on the left key field doesn't need to be pressed at the same time with the test addition. During the measurement the upper LED on the left key field flashes. The measurement is stopped automatically when a coagulation reaction starts respectively when a clot is formed. The measuring station will however continue to turn, in order to make a visual control function possible. The result is shown on the PC in the result screen.

5.4.2 Photometer Measure

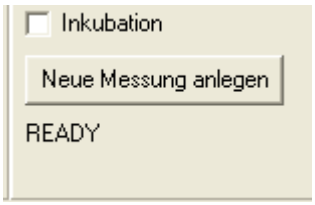


Enter either the starting number or the first patient identification number.

Select the test which to be measured.

The respective test specifications must be stored before under test parameters (please see chapter 3.4).

Select whether you want to work with or without incubation.
The adjustment cannot be changed if prior to the measurement following setting has been effected: Preferences - Incubation – Arbitrary.



Press Create new Measure

Results

LineNo	Run.No./Pat.ID	Meas.cell	Test	Status	Meas.value	Result 1	Result 2	normal range	Date	Time	Info
1	1	Ballmeas.	PT	RESULT	14.4s	103.0%	0.98	---	15.12.2009	15:49:00	
2	1	Photometer	FP1	READY		---	---	---	---	---	192

Measurement with incubation

In cuvettes which were placed in these preheating positions reagent is pipetted only if the parameter consists of two reagent substances (e.g. aPTT). If a measurement has to be carried out, the preheated cuvette has to be put into the measuring station.

Activate the measuring station by pressing the upper key on the left key field.

The instrument uses a special cuvette with a steel ball. Before a measurement can take place such a cuvette for preheating it in the optical measuring point. Activate the measuring station by pressing the upper key on the right key field This program is now 5 seconds active, which is indicated by the lower flashing green LED. Within this time the sample is to be pipetted and at the same time the incubation has to be started by pressing the lower key on the right key field. The MC 1plus gives an acoustic sign at the end of this work procedure 5 seconds before expiration of the in the test parameter menu (chapter 3.4.2.1) preselected incubation period in order to prepare you to pipette the start reagent and to start the measurement. Thus the measuring program has to be started by pressing the upper key on the right key field again and the measurement can be started within the next 5 seconds (LED flashes green). This is effected by simultaneously pressing the lower key on the right key field and the adding (start) of the reagent. If an automatic pipette is attached to the equipment this constitutes a facilitation of the measurement start, i.e. the lower key on the right key field doesn't need to be pressed at the same time with the test addition. During the measurement the upper LED on the right key field flashes. The measurement is stopped automatically when a coagulation reaction starts respectively when a clot is formed. The upper LED stops shining and the lower LED shines green again.

Example: You have a patient sample and want like to determine D-dimer. Place a micro cuvette into the optical measuring position. Prepare the reagent according to the test guide. Pipette reagent 1 into the cuvette. Now you must activate the measuring program by pressing the upper key on the right key field. Note that this program remains active only 5 seconds. Pipette the sample and start at the same time the incubation timer by pressing the lower key on the right key field. Briefly take the cuvette and oscillate it gently in order to enable the ball to reagent and sample by rotation well. Place the cuvette again into the optical measuring point. 5 seconds before the incubation ends the MC 1^{plus} gives 5 acoustic audio signals in a 1-second pulse. Within this time you can take up the reagent 2 with the pipette. At the end of the incubation the measuring program must be activated again by pressing the upper key on the right key field. The program remains active again only 5 seconds. Start the measurement by adding reagent 2 of the cuvette within these 5 seconds. Briefly take the cuvette and oscillate it gently in order to enable the ball to mix reagent and sample by rotation well. Place the cuvette again into the optical measuring point.

Attention, this procedure may not exceed the length of time of the preselected Active Time.

After termination the result is indicated on the PC in the result screen, the upper LED stops shining and the lower LED shines green again.

For further measurements you must press again new measurement.

Measurement without incubation

For measurements without incubation you activate the measuring program by pressing of the upper key on the left key field and then start the measurement within the next 5 seconds (LED flashes green). This is done by pressing simultaneously the lower key on the right key field and by adding the (start) reagent. If an automatic pipette is attached to the equipment this constitutes a facilitation of the measurement start, i.e. the lower key on the right key field doesn't need to be pressed at the same time with the test addition During the measurement the upper LED on the right key field flashes red. After the measuremant the result is indicated on the PC in the result screen, the upper LED stops shining and the lower LED shines green again.

5.5 Switch off the instrument

Before you switch off the equipment, you first must close the MC1^{plus} software. Afterwards you switch off the equipment by on-off switch on the back out. Now you can also close down and switch off the PC.

6.0 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^{plus} supplied suitable external power supply unit (100 VAC – 240 VAC) 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 must not exceed 3 m.

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

ATTENTION!
The cuvettes are disposable items which may not 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.

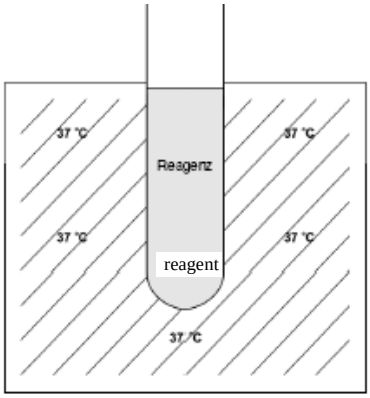
ATTENTION!
This instrument is classified as an in-vitro-diagnostic device!

ATTENTION!
If the operator is electrified a discharge may happen at the measuring / pre-heating block of the MC 1^{plus}. This discharge does not influence the functions of the MC 1^{plus}.

7. Hints for the handling

7.1 Handling of the reagents

The reagent in questions has to be prepared exactly according the instructions of the reagent supplier. Therefore please see the package insert. All reagents which have to be pre-heated, should be dispensed into a reagent tube (14.5 x 85 mm), the tube should be stored in the reagent pre-heating station prior to the pipetting. The liquid level in the tube should not exceed the upper edge of the reagent station. It takes approximately 15 minutes to heat up the reagent to the required working temperature. All reagents should be used prior to their stated expiry date.



7.2 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 balls in the cuvettes are made of special 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.

The correct performance of **cuvettes** and **balls of other manufacturers** can not be granted. Therefore **cuvettes** and **balls of other manufacturers** may not be employed.

7.3 Handling of the testing material

The taking of the blood from a patient has a decisive influence on quality and precision of the results. Here it is imperative to use 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.

8. 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 10.1 “Analytical errors”.

9. Maintenance

9.1 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^{plus} 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^{plus}.

Balls that fell erroneously into the station can be removed easily by means of a magnet.

9.2 System self-test

9.2.1 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) Then printer and scanner are initialised and the welcome message is printed out. The procedure is displayed in the lower left corner of the display

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

4) 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 10.2)

5) When changing into the measuring mode the ball sensors are inspected, they have 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 10.2).

9.2.2 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 10.2).

2) The actually measured temperature is surveyed. If it exceeds 50°C the heating is switched off and the message „Error found, Temp = VALUE“ is displayed. The error number 1100 is stored in the error list (chapter 10.2).

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 10.2).

10. Errors

10.1 System 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^{plus} 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 higher (>55%) or lower (<21%) haematocrit.
	Pre-analytical error Clot in the sample	Samples containing micro or macro clots should not be taken 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.

10.2..Analytical errors

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^{plus} is delivered with manual. Please practise the pipetting technique. The instructions for the correct pipetting technique are in chapter 4 (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 4 (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.

Error type	Possible causes	Troubleshooting
Analytical error	None or more balls than one have been added.	Use one ball per cuvette.
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.

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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