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MC10 PLUS

# OPERATION MANUAL

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

IVD CE

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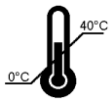
# SAFETY INSTRUCTIONS

## 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<br>MC 4plus<br>MC 10plus |
|  | Consult instructions for use | MC 1<br>MC 4plus<br>MC 10plus |
| LOT | Batch code number | Balls & cuvettes |
|  | Manufactured by | MC 1<br>MC 4plus<br>MC 10plus |
|  | Use by date:<br>YYYY-MM | Balls & Cuvettes |
|  | Temperature limits for storage | Balls & Cuvettes |
| Label<br>"serial number" | Back of instrument | MC 1<br>MC 4plus<br>MC 10plus<br>Power supply unit |

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Before using the MC 10plus study the instruction manual carefully.
This manual shall convey you an extensive comprehension for the operating mode of the MC 10plus 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 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 (Fon: +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 10 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 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 10plus is a semi-automatic mechanical and optical (optionally) 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 and chromogenic 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 are converted into corresponding results.

## 1.3 Performance data

The precision of the tests carried out with the MC 10plus 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.

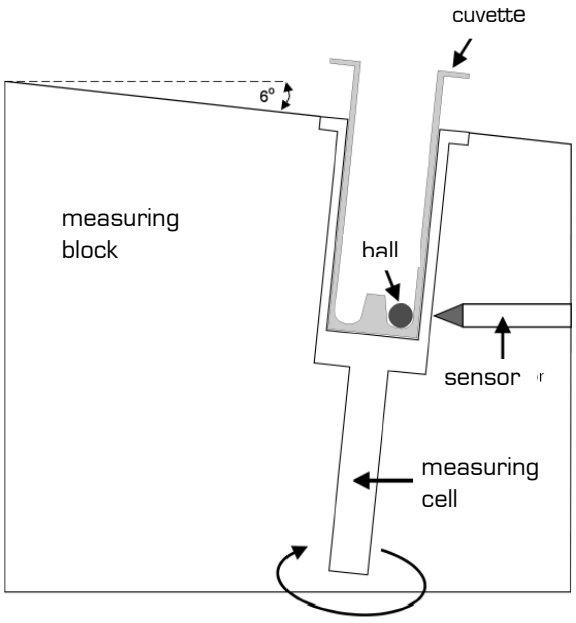
### 1.3.1 Correlation and precision

An investigation for the evidence of the equivalence of the MC 10plus to another commercial mechanical coagulation analyser has been done by a nameable German reagent producer with PT-, aPTT-, Fib-, TZ-, AT3- and D-Dimer 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 place 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 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.




### 1.4.2 Optical measuring principle

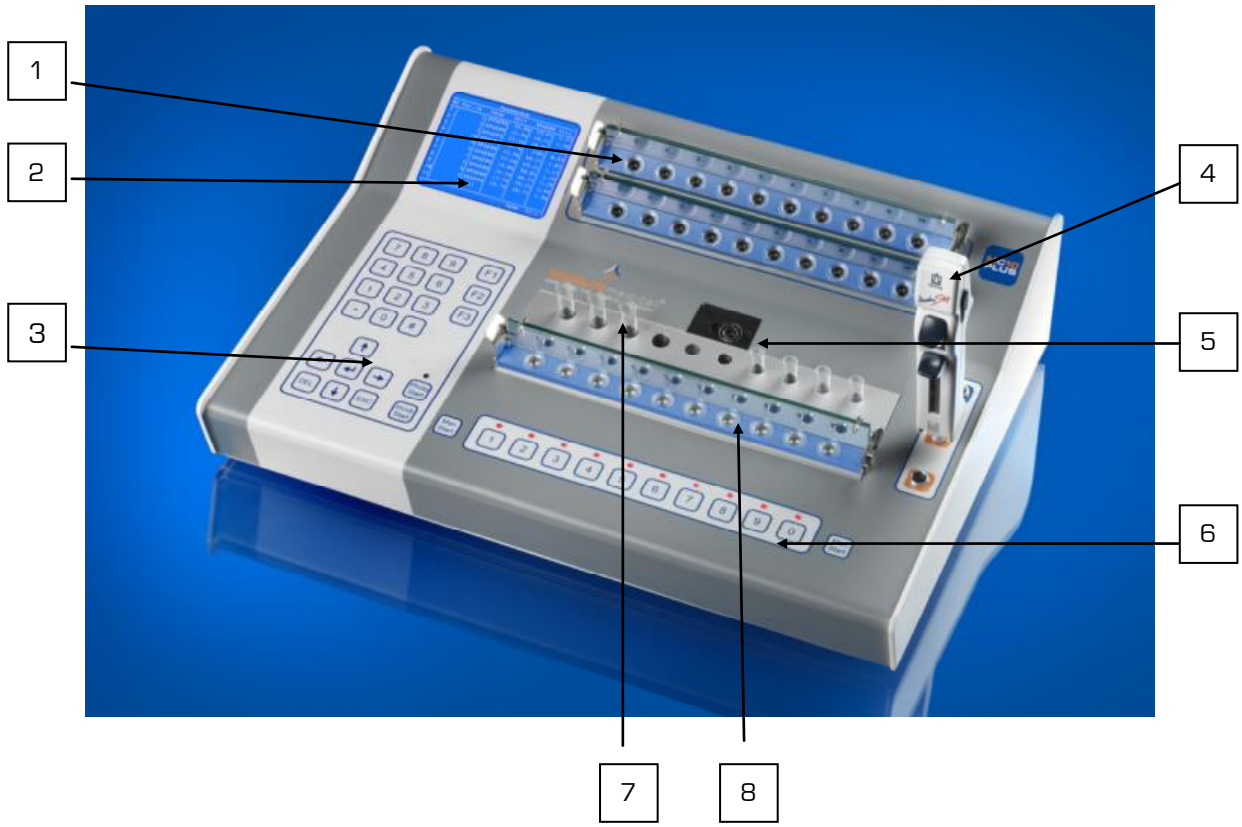
The photometry is basing on the fact that a part of the passing light (UV-VIS = UV and visible field ca. 200 - 900 nm wave length) is reduced through the liquid test sample. Here the own colouration of the probe or the colouration of the probe by adding suitable reagents is used.The course of the colouration is stored in the MC 10$^{plus}$ and evaluated by a special software according the test requirements.

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

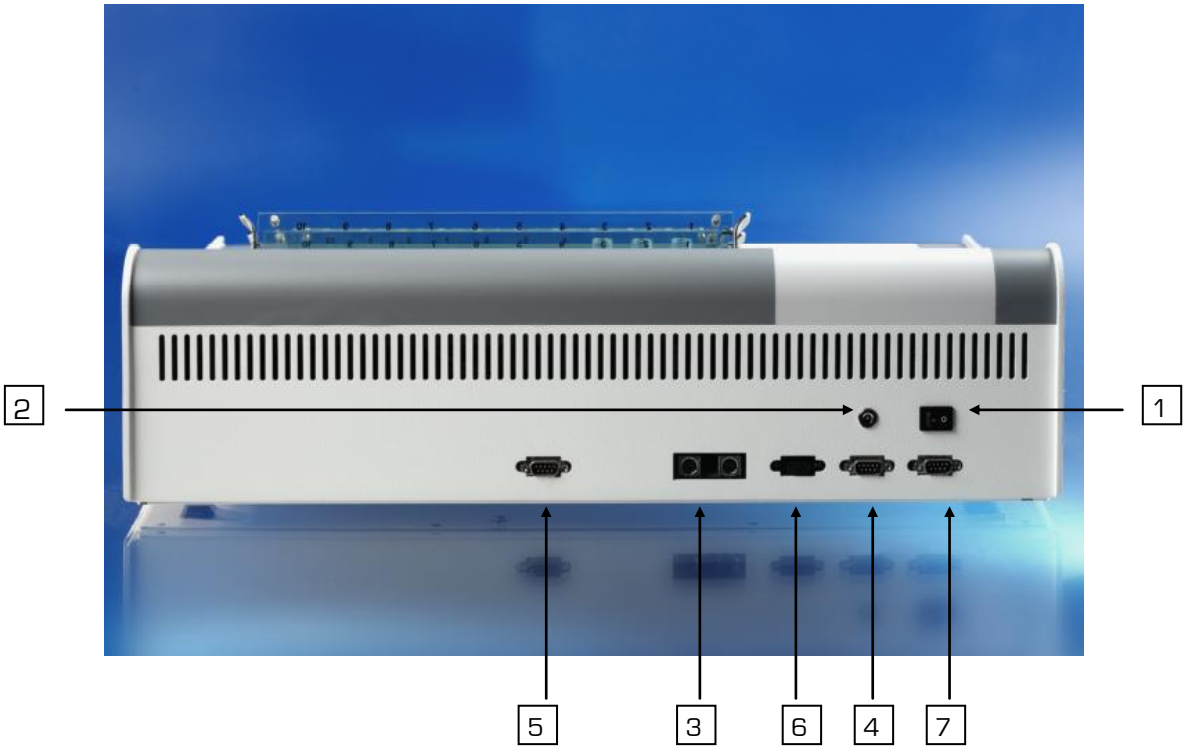
## 1.5 Specifications

| | | |
|---|---|---|
| Type | : | Coagulation analyser / bench top device |
| RS 232 | : | unidirectional |
| Measuring principle | : | mechanical + optionally optical measuring method |
| Number of measuring channels | : | 10 + 1 |
| Display | : | graphic presentation |
| Sample pipetting stations | : | 20 (2 racks with each 10 cuvettes; at room temp.) |
| Cuvette pre-heating stations (if required also employable as reagent pipetting station) | : | 10 (1 rack with 10 cuvettes) |
| Pre-heated storing position for start reagent pipette | : | 2 |
| Pipette storing position at room temperature | : | 1 |
| Drills 14.5 x 85.0 mm for reagent pre-heating | : | 5 |
| Drills 11.5 x 75.0 mm for reagent pre-heating | : | 5 |
| Dimensions | : | 430 x 590 x 170 mm (L-W-H) |
| Weight | : | 15 kgs |
| Power primary | : | 100 VAC - 240 VAC<br>50 / 60 Hz |
| Power secondary | : | 24V |
| Power consumption | : | 70 VA |
| Measuring block temperature | : | 37.3°C (+/- 0.5°C) |
| Measuring period | : | 4.5 – 999.9 seconds |
| Motor turning speed | : | MC 10plus micro 50 r.p.m.<br>MC 10plus macro 40 r.p.m. |

## 1.6 Views of the MC 10plus

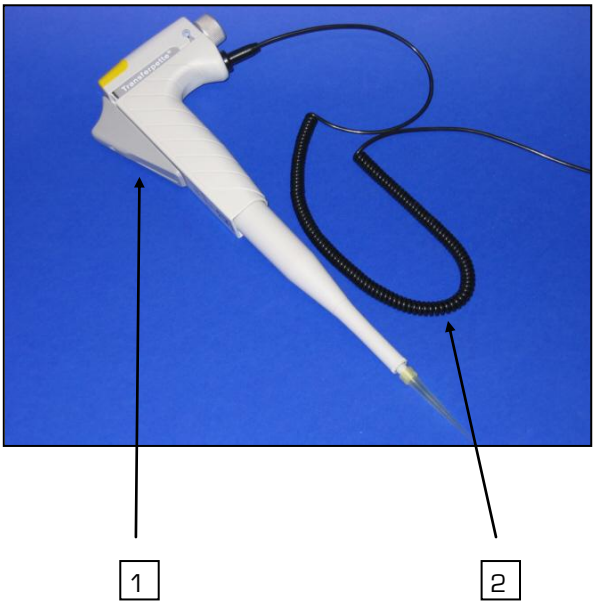


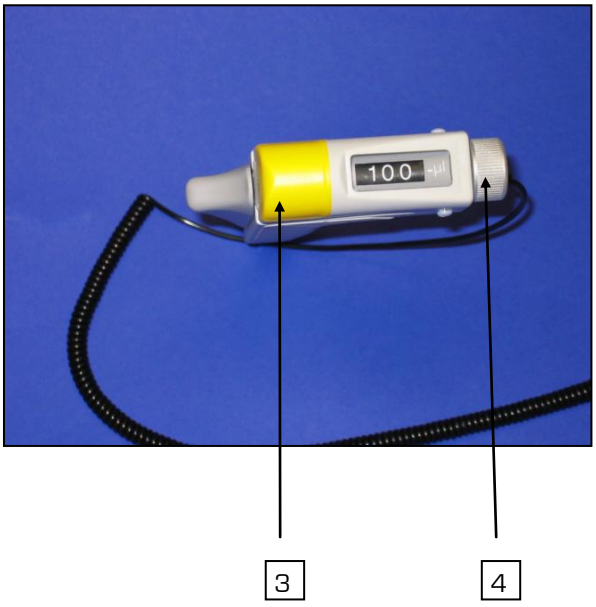

| Component | Function / Description |
|---|---|
| 1. Sample pipetting | pre-pipetting for further measurements |
| 2. Graphic display | display of the keyboard layout, programme and result display |
| 3. Function keys | keys for data entering, their functions are shown in the display above |
| 4. Start pipette | different kinds of start pipettes can be used (red storing position = heated). |
| 5. Optical measuring position | (as option) for diverse chromogenic tests |
| 6. Signal lamps with activating keys | depending on the condition of the system respectively of the measuring positions above green, yellow or red |
| 7. Reagent and cuvette pre-heating station | reagent pre-heating positions for reagent and cuvettes and for the preparation of the intended tests |
| 8. Measuring positions | position in which the start reagent is added and which the clotting time is measured |




| Component | Function / Description |
|---|---|
| 1. On- / off-switch | main switch of the MC 10plus |
| 2. Low voltage socket | for connecting the instrument with the external power supply unit |
| 3. Pipette sockets | for the connection of automatic pipettes with contact line |
| 4. RS 232 interface | plug-in for external printer |
| 5. Barcode scanner connection | for external barcode scanner |
| 6. PC | online-connection for the purpose of Software Updates |
| 7. LIS | online-connection for external laboratory EDP Laboratory Information System |

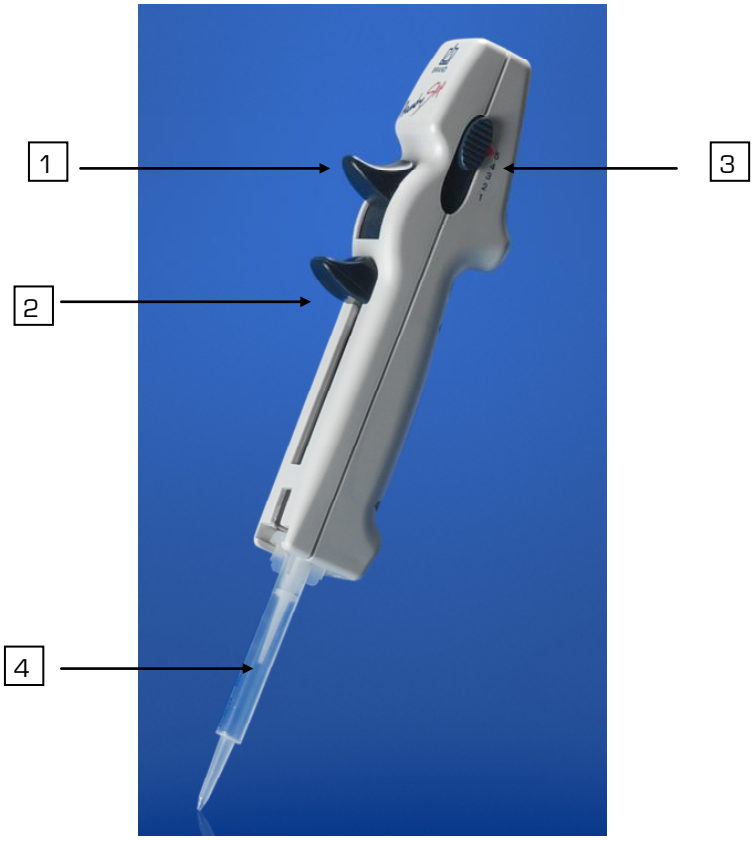
## 1.7 Views of a 3-volume microlitre pipette




| Component | Function / description |
|---|---|
| 1. Pipetting key | For filling and dispensing start reagent. If a measuring position activating key has been pressed at the MC 10plus 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) |

## 1.8 Views of a Handystep pipette




| Component | Function / description |
|---|---|
| 1. Dispensing lever | For dispensing reagent. If start reagent has been absorbed and a measuring position activating key has been pressed at the MC 10plus the time keeping can be started by pressing the dispensing lever (automatic pipette). |
| 2. Locking / Filling lever | For absorbing reagent. For inserting a combitips pull down |
| 3. Sliding switch for volume selection | For adjusting the pipetting volume (please see pipette back) |
| 4. Combitip | Adjust volume of the combitips and adjust the sliding switch for volume selection (no. 3) to pipetting volume |

# 2. Installation

## 2.1 Unpacking

The MC 10plus 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 10plus coagulation analyser |
| Power supply unit |
| Power cable |
| 2 Sample racks |

## 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 |
| Thermo paper | 851057 | 5 |

| Accessories / description | Cat.-No. | Packing unit |
|---|---|---|
| Automatic pipette Handystep® with start cable | P20010 | 1 |
| Ball dispenser micro | Z11000 | 1 |
| Ball dispenser macro | Z10000 | 1 |
| Printer | H10000 | 1 |
| Sample holder MC 10 | C00300 | 1 |
| CoagView®-Software (for data transmission) | S20000 | 1 |
| Lysis-Programme (for Lysis-evaluation) | S10000 | 1 |
| Barcodescanner | 240001 | 1 |

The in 2.3 Consumables and Accessories mentioned articles are not part of the MC 10plus scope of delivery. The comsumables 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 10plus 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 79 cm (width of the instrument: 59 cm)
   - depth 53 cm (depth of the instrument: 43 cm)

2. Position the MC 10plus 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 10plus 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 10plus.

**Attention!**
If the user is electrified a discharge may happen at the MC 10plus. This discharge has no influence on the function of the MC 10plus.

## 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 10plus 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 may not exceed 3 meters.

**Warning!**
Only the original external power supply (100 VAC – 240 VAC) which is delivered with the MC 10plus 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 10plus.

4. If an additional printer is used connect the data line of the printer with the RS-232 interface (chapter 1.6).

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

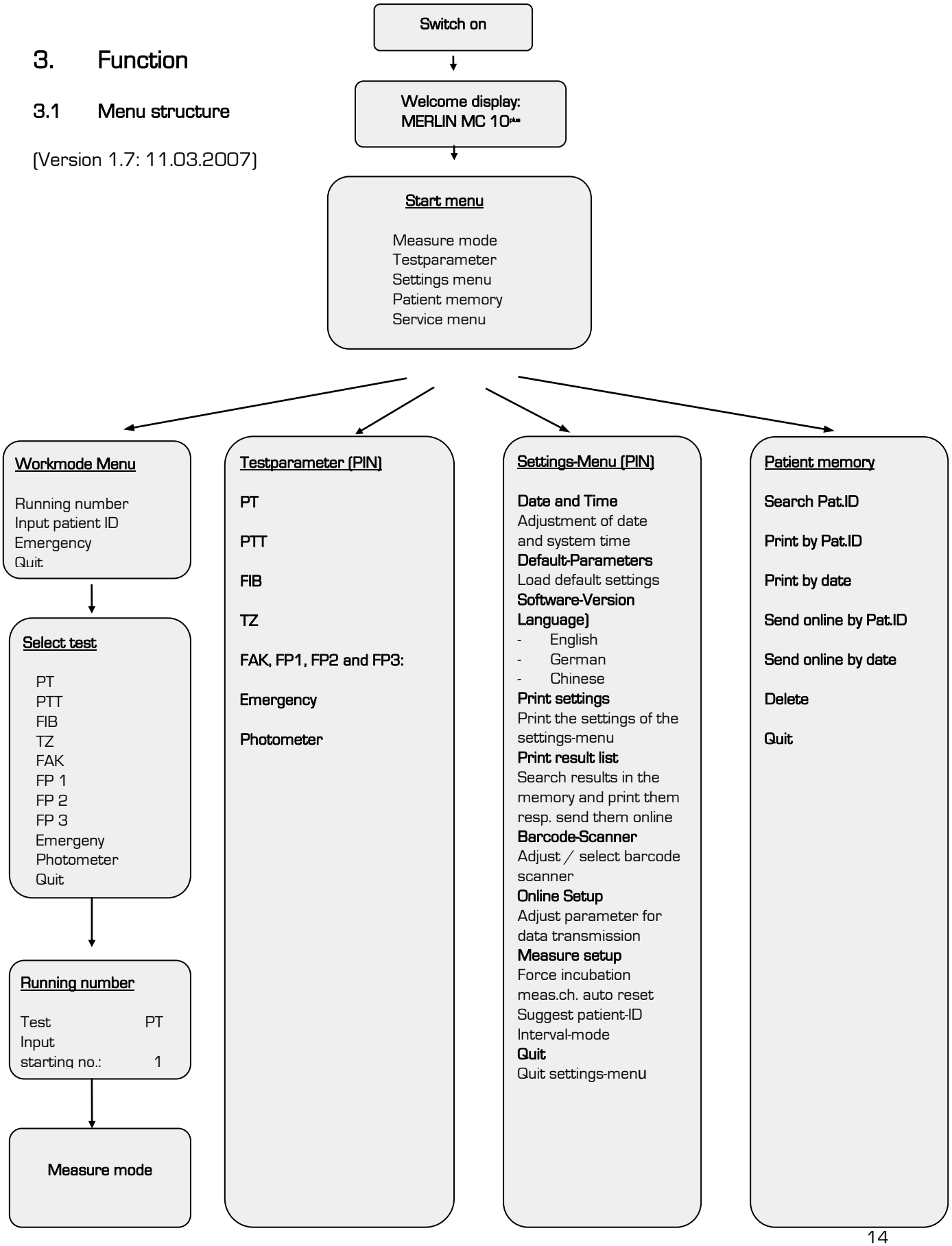
5. The data line for the external printer or for the online connection may not be longer than 3 meters.

6. If an external barcode scanner shall be used connect the contact line of the scanner with the socket for the scanner (chapter 1.6).

# 3. Function

## 3.1 Menu structure

(Version 1.7: 11.03.2007)



## 3.2 Performance test

The correct operation of the instrument should be examined by means of a performance test prior to the intended use of the analyser.

All functions of the MC 10plus are called up with the control keys below the display.

Ensure that no used cuvette is in the optical measuring position.

Switch on the MC 10plus at the on / off-switch at the back side.

The MC 10plus makes a signal tone and the display is lighted up and the signal lamps under the measuring positions light up yellow-orange. Watch the display.


After approx. 15 sec. the display changes automatically from the welcome display to the start menu. The signal lamps do no longer light up.

| Start menu |
|---|
| Measure mode<br>Test parameter<br>Settings-menu<br>Patient memory<br>Service menue |

Select „Measure mode“ by means of the arrow keys and confirm by pressing the ENTER-key. You have to communicate the MC 10plus now in the work mode menu whether a running number or a Pat.-ID shall be used for the sample test result identification.
In addition to these possibilities an urgent sample can be defined as “Emergency“, for which two parameters have been defined before (chapter 3.3) in order to ensure a quickest possible measurement.

| Workmode menu |
|---|
| Running number<br>Input Pat.-ID<br>Emergency<br>Quit |

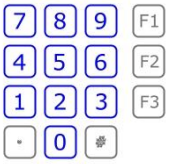

Select the required patient definition with the arrow keys and confirm with ENTER.

Now defined which test shall be carried out. You can select the according parameter with the arrow keys and confirm your selection with the ENTER-key.

| Select test |
|---|
| PT |
| PTT |
| FIB |
| TZ |
| FAK |
| FP 1 |
| FP 2 |
| FP 3 |
| Quit |


If you wish to work with a running number for the sample identification you have to enter a start number for the first sample to be measured. The MC 10plus suggests number one. (if an identification via Pat.-ID is required skip the next display).

| Running number | |
|---|---|
| Test: | PT |
| Input starting no.: | 1 |




Confirm the input with the ENTER-key. Then you get automatically to the measuring programme. Here the signal lamps light up green constantly.

| Measuring mode TEMP = 37.3°C | | | | | |
|---|---|---|---|---|---|
| MZ | Pat.-ID | PROG | TIME | RESULT | INFO |
| 1 | STOP | | | | |
| 12 | STOP | | | | |
| 13 | STOP | | | | |
| 14 | STOP | | | | |
| 15 | STOP | | | | |
| 16 | STOP | | | | |
| 17 | STOP | | | | |
| 18 | STOP | | | | |
| 19 | STOP | | | | |
| 20 | STOP | | | | |
| 21 | INIT | | | | |
| F1 = AUTO | | | F3 = DELETE | | |

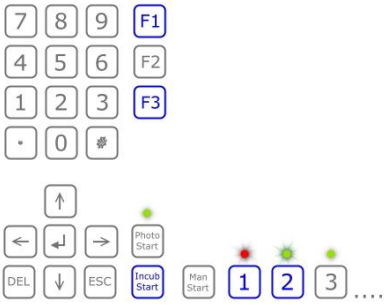

A measurement can not be started before the measuring block has reached the programmed temperature. If the temperature is not yet reached then “TEMP” will flash in the upper right corner when you try to start a measurement.

### 3.2.1 Testing of a measurement resp. of an incubation

Before patient samples are measured the procedure of such measurement should be simulated. If a patient-ID is required for the sample identification, every ID has to be entered before the measurement in the according measuring channel and confirmed with ENTER (when using a running number this input has to be skipped). For a measurement test load one rack with new balls and cuvettes and insert the cuvettes with the rack into the measuring positions. The MC 10plus can process the in the test parameters (chapter 3.3) stored test-specific incubation time in two different ways:

a) **Force incubation time** (chapter 3.5.9): a measurement can only be started if the test-specific incubation time has been carried out before in this measuring position resp. in the inserted cuvette with sample and reagent. Activate the according measuring position (signal lamp below the measuring position constantly lighting up green) by pressing the according activation key and start the incubation time by pressing the key "Incub Start"; now the signal lamp of this measuring channel lights up yellow-orange. **PLEASE NOTE – in this mode an incubation is obligatory, i.e. an abort is not possible**. 5 seconds before the end of the adjusted incubation time (chapter 3.3) the MC 10plus gives acoustic signals. When the incubation is finished the according measuring position can be prepared for the test start with the key below. The start reagent has to be added within the next 5 seconds which is shown by blinking of the related display line and by the assigned now green blinking signal lamp. When a measurement has been started in a measuring channel (by using an automatic start pipette this happens automatically) the green signal lamp below this measuring position changes its colour and blinks red. After a test period of ca. 5 seconds the clotting reaction can be simulated by slightly lifting the cuvette, the signal lamps constantly lights up red after the clotting result detection. If a further measurement shall be done in a measuring position in which already a measurement has been carried out before this measuring position has to be reset by repressing the according measuring position key. By pressing the key F3 on the keyboard all measuring positions can be reset simultaneously.

b) ***Not* force incubation time** (chapter 3.5.9): Here you also have the possibility to work with a test-specific incubation time, but this incubation time is not obligatory. Activate the




according measuring position (signal lamp below the measuring position constantly lighting up green) by pressing the according activating key and start the incubation time with the key "Incub Start"; the signal lamp of this measuring channel now light up yellow-orange. In this mode it is possible to abort the incubation time by pressing again the according activating key and then to start the measurement, but for precision reasons this is not recommended. 5 seconds before the end of the adjusted incubation time (chapter 3.3) the MC 10plus gives acoustic signals. When the incubation is finished or has been aborted the according measuring position can be prepared for the test start with the key below the

measuring channel. The start reagent has to be added within the next 5 seconds which is shown by blinking of the related display line and by the assigned green signal lamp. When a measurement has been start in a measuring channel (by using an automatic start pipette this happens automatically) the green signal lamp below this measuring position changes its colour and flashes up red. After a test period of ca. 5 seconds the clotting reaction can be simulated by slightly lifting the cuvette, the signal lamps constantly lights up red after the clotting result detection. If a further measurement shall be done in a measuring position in which already a measurement has been carried out before this measuring position has to be reset by repressing the according measuring position key. By pressing the key F3 on the keyboard all measuring positions can be reset simultaneously.

By pressing the F1 key you can switch on an automatic activation for the mechanical measuring positions. After pipetting with an automatic pipette the next free measuring position will then be prepared / activated for the measurement start. This automatic activation can also be switched on by keeping the activation key of the mechanical measuring position, which is the next position to be pipetted, pressed down until all following measurements have been started.

By pressing the key ESC measurement and incubations can be aborted. Confirm the abort with the ENTER-key.


For quitting the measure mode press once again the ESC-key.

When leaving the measure mode the signal lamps will keep the actual colour. The signal lamps also keep their colour during the following operations until you re-enter the measure mode.

## 3.3 Test parameters

After switching on the analyser select the menu test parameter in the start menu by using the arrow keys and confirm your selection by pressing ENTER. (The test parameter menu is protected by a PIN and can only be entered by instructed staff).

| Start menu |
|---|
| Measure mode |
| Test parameter |
| Settings menu |
| Patient memory |
| Service menu |


Here different parameter specifications can be determined. By selecting the parameter to be modified via the arrow keys and by confirming with ENTER you get into the display of the according parameter. Depending on the parameter following settings can be done:

| | PT | PTT | FIB | TZ | FAK |
|---|---|---|---|---|---|
| Test name | PT, NT or TT | PTT | FIB | TZ | FAK |
| Incubation time | 30, 40, 50, 60,... | | | | |
| Result format | number of digits before and after decimal point | | | | |
| Calibration | several values[1)] | - | several values[1)] | - | sev. values[1)] |
| Calculation | lin/rezi | - | log/log | | log/lin |
| Result unit | % | sec. | g/L. | sec. | sec. |
| Calibration value | max + min | - | max + min | - | max + min |
| INR-Calculation | YES / NO | - | - | - | - |
| INR-Std.-Value | value[2)] | - | - | - | - |
| ISI-Value | value[3)] | - | - | - | - |
| Ball or optical method | ball (mechanical) | | | | |
| Single or double | single / double | | | | |
| Deviation (VC) | freely adjustable | | | | |
| Start delay | freely adjustable between 3,5 and 30 seconds | | | | |
| Timeout time | freely adjustable (depending on result format) | | | | |

| | FP 1 | FP 2 | FP 3 | Emergency | Photometer |
|---|---|---|---|---|---|
| Test name | freely programmable | | | this parameter reverts to two other parameters | this parameter reverts to one other parameter |
| Incubation time | 30, 40, 50, 60,... | | | | |
| Result format | number of digits before and after decimal point | | | | |
| Calibration | several values[1)] | | | | |
| Calculation | several calculation formulas | | | | |
| Result unitt | freely programmable | | | | |
| Calibration value | max + min | | | | |
| INR-calculation | YES / NO | | | | |
| INR-Std. | value[2)] | | | | |
| ISI-value | value[3)] | | | | |
| Ball or optical method | ball (mechanical) or optical | | | | |
| Single or double | single / double | | | double | |
| Deviation (VC) | freely adjustable | | | (6%) | |
| Start delay | freely adjustable between 3,5 and 30 seconds | | | | |
| Timeout time | freely adjustable (depending on result format) | | | | |

1) These values have to be determined by the operator himself by means of suitable calibration material

2) These values have to be calculated by the operator resp. the MC 10plus suggests this value
3) These values have to be taken from the package insert of the reagent Packungsbeilage

For modifying these settings please press the left arrow key. Select the parameter setting which you wish to modify by pressing ENTER and change the setting with the arrow or numerical keys. By pressing the ENTER-key you confirm your input. By pressing the DEL-key the last input is deleted.


The MC 10plus automatically calculates the INR-standard value by means of the programmed calibration curve and suggests the calculated value (in brackets).

The parameters which have been programmed as emergency are alway carried out in double determination in the emergency mode. A test result can only be released when then deviation of both single measurements does not exceed 6 % as it is fixed in the regulations of the Federal Medical Association (RILIBÄK). If a parameter is carried out in general in double determination and if it has been programmed as emergency parameter, then the deviation, which has been defined in the test parameter setting, will bet he basis for the double determination of the emergency results.

The input screen for the test parameters is always the same. If a parameter does not require a certain point (as e.g. the INR-data input the PTT) then this input field is hidden respectively skipped. This means that this point can not be modified (e.g. the measurement method for PT, PTT, FIB, TZ and FAK). If nevertheless such a modification should be required then this test has to be set up as freely programmable test (FP1, FP2 or FP3).

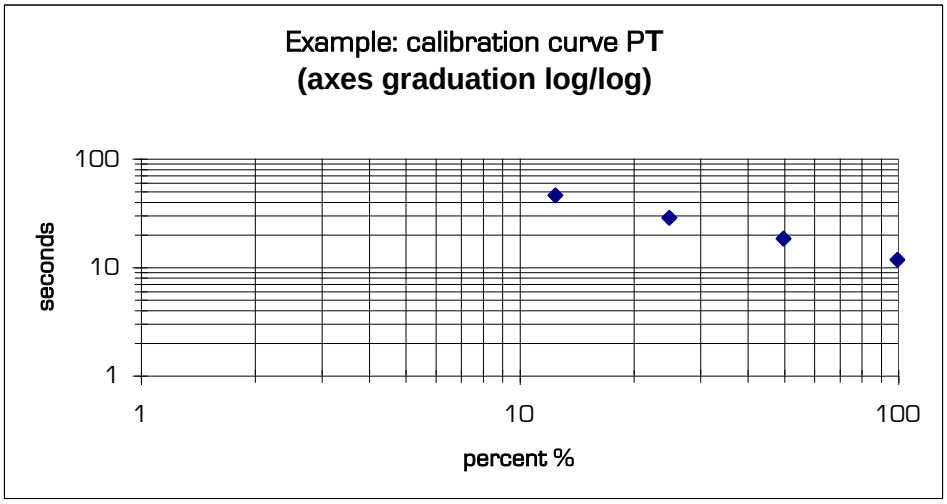
The selected parameter can be printed by pressing the key F1.

By pressing the ENTER-key after the last input the modification of the test parameter programming is saved. You call up the test parameter with the left arrow key again for modifying it or you leave this screen with the right arrow key.

## 3.4 Test evaluation / calculation

### 3.4.1 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 10plus 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:

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

### 3.4.2 Optical measurements

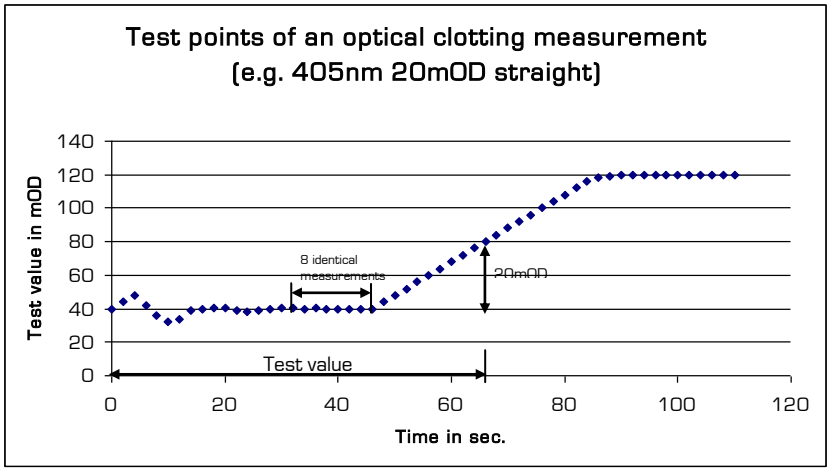
For the optical test method there are five different kinds of detecting a clotting reaction respectively the from that resulting test value determination. Here the test time also always starts by adding the start reagent but the test procedures are different.

**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

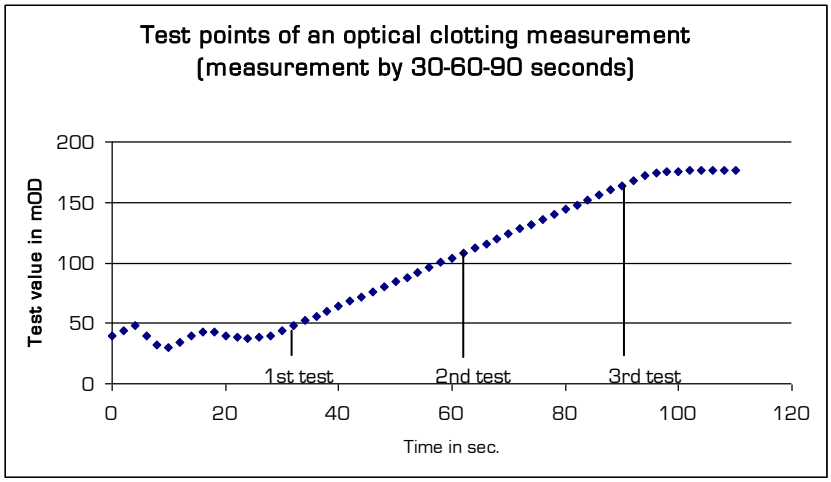



**Clot 3:**
After the end of the start delay time the mean value is searched at first (as for Clot 1). The course is observed. If this value becomes lower this value is taken as basic value. Always the lowest value is the basic value. After a freely selectable extinction modification of 20, 30, 50 or 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.

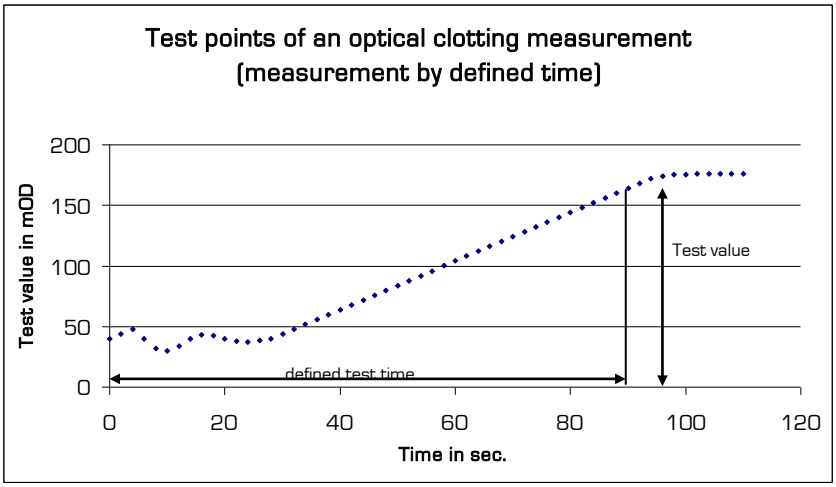
Example for chromogenic measurement




**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 Settings menu

After switching on the analyser select the menu settings menu in the start menu by using the arrow keys and confirm your selection by pressing ENTER. (The settings menu is protected by a PIN and can only be entered by instructed staff).

| Start menu |
| --- |
| Measure mode |
| Test parameter |
| Settings menu |
| Patient memory |
| Service menu |


In this menu different user-specific system settings can be made. If the settings menu has been selected following screen appears:

| Settings menu |
| --- |
| Date and time |
| Default-Parameters |
| Software-Version |
| Language |
| Print settings |
| Print result list |
| Barcode Scanner |
| Online-Setup |
| Measure set-up |
| Quit |


### 3.5.1 Date and time

After selection of this point with the arrow keys and after confirming the selection by pressing ENTER you reach the mask where the system date and time can be modified. The actual system date is displayed in the upper line. In the lines below you can modify date, month and year by using the arrow and numerical keys. Every input has to be confirmed with the ENTER-key.

The actual time is displayed below the date settings. You can modify the time also with the arrow and numerical keys. Every input has to be confirmed with the ENTER-key.

You can quit the date and time setting mask via the ESC-key.

### 3.5.2 Default parameters

In the MC 10plus some basic settings as e.g. a calibration curve for PT, incubation times and so on are programmed. Through these settings the instrument can be reset to the starting values.

**Please note: If you confirm this point with the left arrow key then all your parameter inputs are deleted**

### 3.5.3 Software-Version

In this mask the actual software version is displayed. After confirmation the checksum of all inputs is checked and displayed. By pressing the ESC-key you get back to the settings menu.

### 3.5.4 Language

It is possible to programme the MC 10plus with the required language of a country. For the time being following languages can be adjusted with the arrow keys:

English
German
Chinese

Further languages can be programmed after consulting the manufacturer.

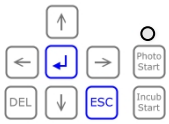
### 3.5.5 Print settings

The user-specific settings as e.g. calibration curves and other parameter settings can by printed with an external printer. For printing these settings please select this point with the arrow keys and confirm the print-out by pressing the left arrow key. By pressing the ESC-key you return to the settings menu.

### 3.5.6 Print result list

The MC 10plus has a test value memory in which the last 1,000 test values can be saved. If you select this point with the arrow keys, the patient-ID resp. The running number can be entered via the keyboard. By this the entry in question can be called up, printed or sent online once again. For calling up a test result block or for resending or printing is the first and last patient-ID has to be entered and confirmed with the ENTER-key. By pressing the ESC-key you return to the settings menu.

### 3.5.7 Barcode Scanner




In this menu the available barcode scanner and the barcode settings are programmed. The according scanner and the settings can be selected with the arrow keys. Then confirm the input by pressing the ENTER-key. For this setting please contact your responsible IT-manager.

Operation breakdown with the barcode scanner:

When all adjustments for the barcode scanner have been effected in the settings menu the measurement procedure can be started:

At first the counter has to be activated by pressing the according preselection key. Then the barcode has to be entered with the barcode scanner or manually within the next 5 sec. Thus all IDs are assigned resp. the working list is established. If a wrong ID-number has been entered then it can be selected directly and deleted with the key DEL.

### 3.5.8 Online setup

For the online connection of the MC 10plus the settings for the data communication with the host (LIS) can be adjusted in this menu. If you have any questions concerning these settings please contact your responsible IT-manager, ABW (Fon: +495261_927294) or a person in charge who has been instructed by the manufacturer.

### 3.5.9 Measure setup

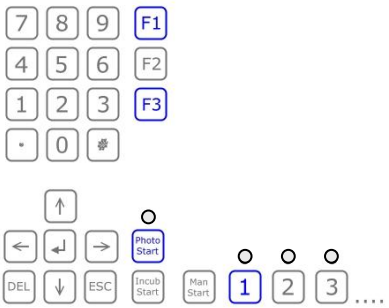
When „Suggest patient ID“ is displayed you can choose YES or NO. If you choose YES the instrument suggests the last patient ID + 1, if you choose NO no ID will be suggested.

#### 3.5.9.1 Forced incubation

In this menu you can *force* the *incubation* which is programmed for the measure mode. This means an incubation must take place before a measurement can be carried out in the according measurement position (chapter 3.2.1).

#### 3.5.9.2 Channel autoreset

Furthermore you can reset the measuring positions in this menu point by pressing the according measure channel selection key once only under *measure channel autorest.* Thereby this measuring position is activated for a new measurement the keys F1 (autom. measure channel activation) and F3 (measure channel reset of all measure channels) are not active in this case.



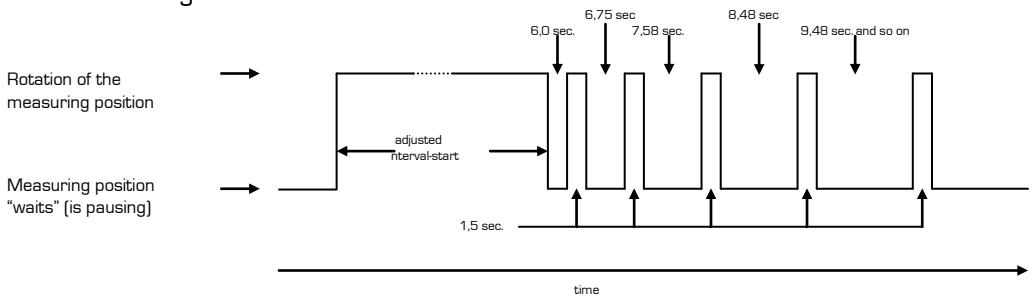
#### 3.5.9.3 Interval mode

In order to test also very unstable clots with lowest fibrin concentrations the MC 10 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 holded up and accelerated whereas the according adjustment has to be made before. The pulse time is always 1.5 sec respectively one rotation.

##### 3.5.9.3.1 Waiting time

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%




## 3.6 Patient memory

In the patient memory you can revert to the patient-ID-numbers as well as to the individual test results.

**Search patient-ID:**
For calling up a certain patient-ID you can enter it directly via the numerical keys, count up and down with the arrow key ↑ and ↓ or read in via the barcode scanner.
The first test result of the patient in questions is displayed und you have following options:

| | |
|---|---|
| Print patient: | press F1 |
| send online: | press F2 |
| continue searching: | press → |
| input patient-ID: | press ↑ |

With the →-key the next result of this patient can be displayed. In this way all results of a patient can be called up one after another.

**Print by patient-ID:**
With this menu item the patient results can be printed.
Before the printout the patient-ID can be entered via the numerical keys, counted up and down with the arrow keys ↑ and ↓ or read in with the barcode scanner. Then the print command can be given with the ENTER-key ↵.

**Print by date:**
All results of all patients of a defined date are printed.

**Send online by patient-ID:**
With this function you can send the patient date to the connected PC.

**Send online by date:**
With this function you can send the data of a prior defined date to the connected PC.

**Delete:**
With the delete function the memory of the instrument is deleted completely (all test results). The moment of deletion depends on the internal laboratory organisation. It is recommended to carry out the deletion procedure every morning before start of work.

Altogether up to 1,000 results can be stored whereby the storing procedure is basing on the FIFO-principle (first-in-first-out). When result no. 1,001 is stored the result no. 1 is deleted automatically from the memory.

## 3.7 Service-menu

After switching on the analyser select the menu service menu in the start menu by using the arrow keys and confirm your selection by pressing ENTER. (The service menu is protected by a PIN and can only be entered by instructed staff).

In this menu you can - with the support of the manufacturer - you can modify instrument specific parameters as e.g. measuring block temperature, measuring channel turning speed etc. The service menu can only be opened after prior consultation with the manufacturer.

# 4. Pipetting technique

## 4.1 Precision and correctness

The accuracy of the MC 10plus depends on the correctness and precision with which sample and reagents are pipetted.

### 4.1.1 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.

### 4.1.2 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.

### 4.1.3 Pipetting with a Handystep dispenser

Tests can either be carried out with a manual or an automatic Handystep dispenser which are equipped with a contact line or which are wireless. If an automatic Handystep pipette is used for dispensing the start reagent the time keeper is started automatically as soon as the reagent is dispensed. If a manual Handystep pipette is used for dispensing the start reagent 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 important that only combitips which are suitable for the Handystep pipette are employed. Only combitips which are recommended for the according Handystep pipette should be employed.

Combitips with out of shape connection pieces should be removed. Bent or otherwise damaged combitips should also be disposed of. The tip opening must not be blocked.

For mounting a combitip push down the locking / filling lever of the Handystep pipette to the lower stop. Pull out the locking / filling lever slightly and swing it out. Then insert the tipp and swing the locking / filling lever back to lock the tip. If you dip not the tip 3 – 10 mm into the start reagent the liquid can be absorbed by raising the locking / filling lever slowly to prevent cavitation.

### 4.1.4 Volume selection on the Handystep dispenser

Adjust the Handystep pipette with the sliding switch for volume selection according to the inserted combitip respectively the required dispense quantity of the start reagent (therefore regard the chart on the back of the Handystep pipette). For the reason of precision the first start reagent dispense should be discarded.

**No matter which type of pipette is employed: the pipetting precision is proportional to the correctness and precision of the test results.**

## 4.2 Sample absorption (microlitre pipette)

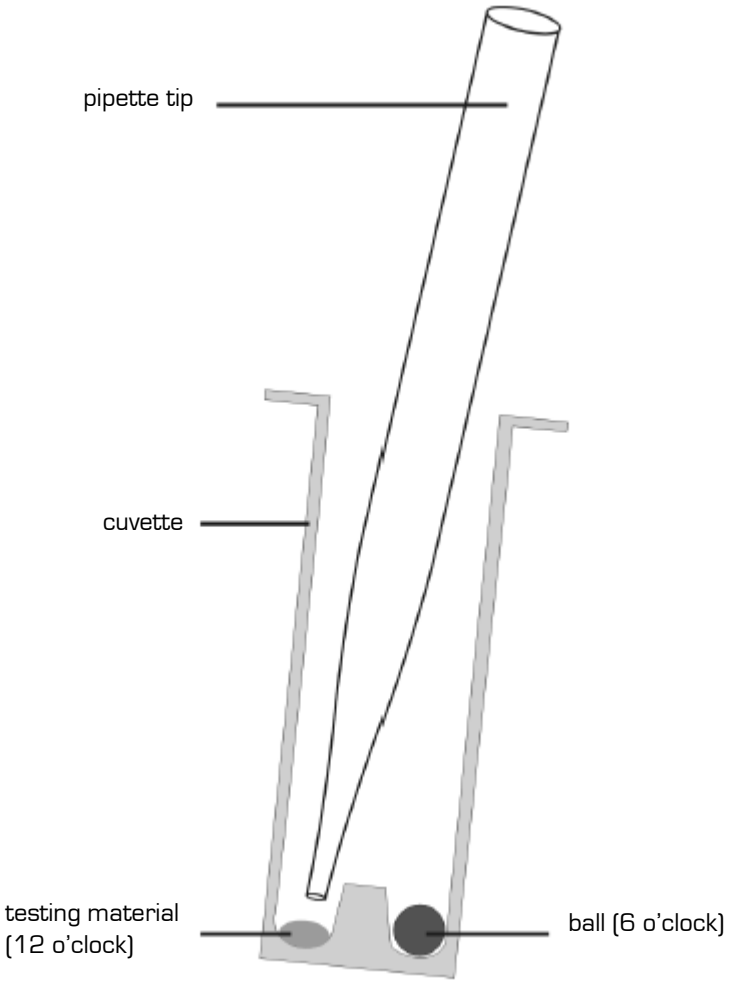
Press down the pipetting key until the first stop. Hold it and immerse the tip ca. 2 - 3 mm into the sample resp. the reagent. If plasma is pipetted directly from a centrifuged sample tube it has to be granted that the tip does not get into touch with the cruor. So you ensure that the aspiration of erythrocytes 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.

## 4.3 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.

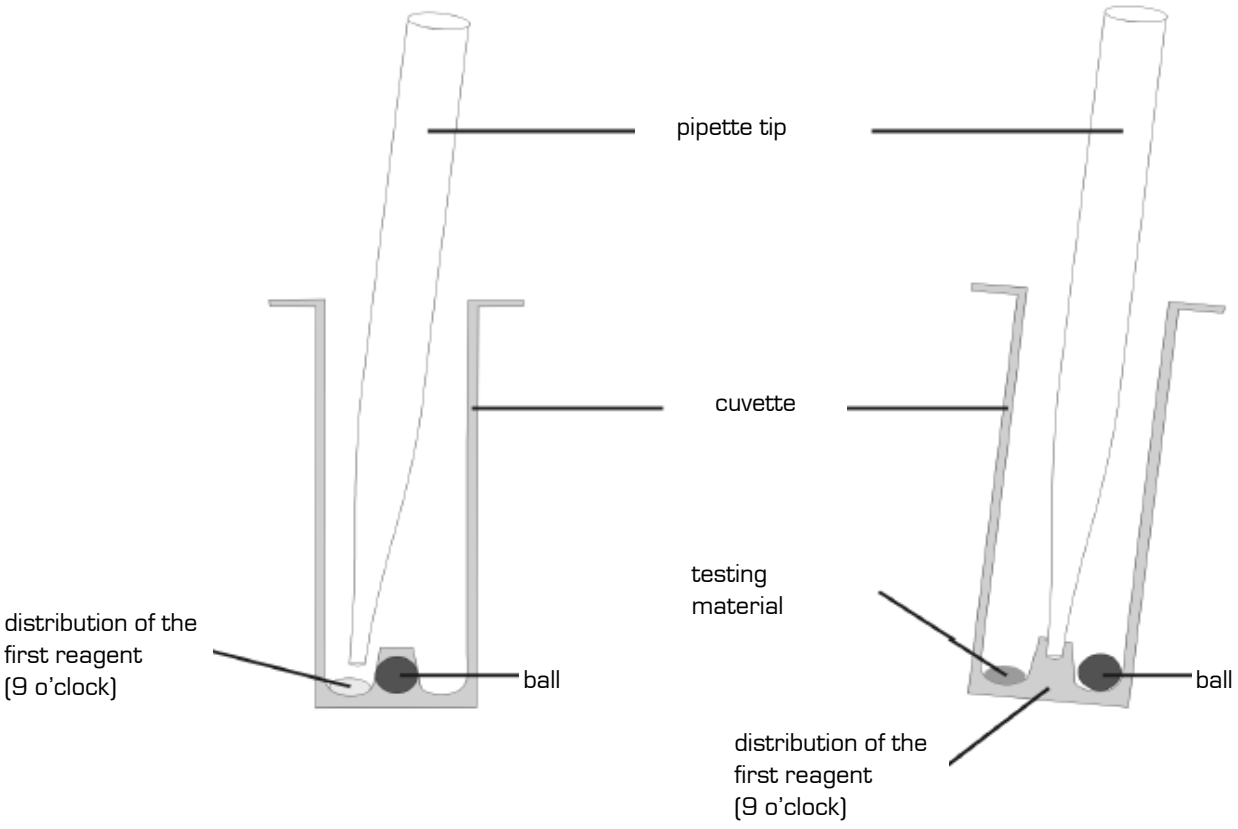


## 4.4 Dispense of reagent 1 (microlitre pipette or Handystep pipette)

(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).

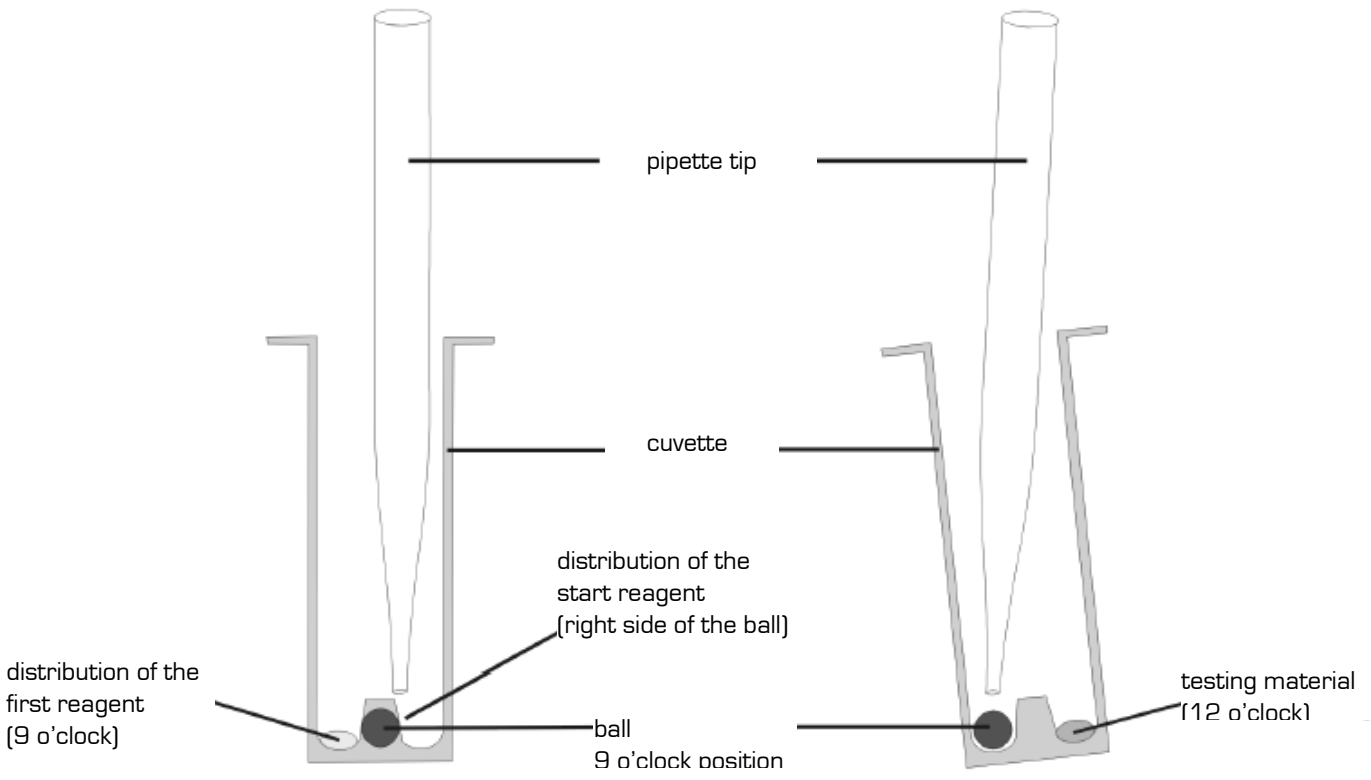



view from the front

view from the side

## 4.5 Dispense of start reagent (microlitre pipette or Handystep 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.




view from the front

view from the side

# 5. Operation

## 5.1 Keyboard layout

All functions of the MC 10plus can be called up with the keyboard (under the display)

## 5.2 Switch on the instrument

Switch on the MC 10plus with the ON-/Off-switch on the back of the instrument.

The MC 10plus makes a signal tone and the display is lighted up and the signal lamps under the measuring positions light up yellow-orange. Watch the display.


After approx. 15 sec. the display changes automatically from the welcome display to the start menu. The signal lamps do no longer light up.

| Start menu |
|---|
| Measure mode<br>Test parameter<br>Settings-menu<br>Patient memory<br>Service menu |

Select „Measure mode“ by means of the arrow keys and confirm by pressing the ENTER-key. You have to communicate the MC 10plus now in the work mode menu whether a running number or a Pat.-ID shall be used for the sample test result identification.
In addition to these possibilities an urgent sample can be defined as “Emergency“, for which two parameters have been defined before (chapter 3.3) in order to ensure a quickest possible measurement.

| Workmode menu |
|---|
| Running number<br>Input Pat.-ID<br>Emergency<br>Quit |

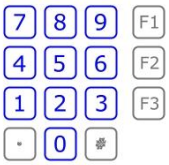

Select the required patient definition with the arrow keys and confirm with ENTER.

Now define the test to be carried out. You can select the according parameter with the arrow keys and confirm your selection with the ENTER-key.

| Select test |
|---|
| PT |
| PTT |
| FIB |
| TZ |
| FAK |
| FP 1 |
| FP 2 |
| FP 3 |
| Quit |


If you wish to work with a running number for the sample identification you have to enter a start number for the first sample to be measured. The MC 10plus suggests number one. (if an identification via Pat.-ID is required skip the next display).

| Running number | |
|---|---|
| Test: | PT |
| Input stsarting no.: | 1 |




Confirm the input with the ENTER-key. Then you get automatically to the measuring programme. Here the signal lamps light up green constantly.

A measurement can not be started before the measuring block has reached the programmed temperature. If the temperature is not yet reached then “TEMP” will flash in the upper right corner when you try to start a measurement.

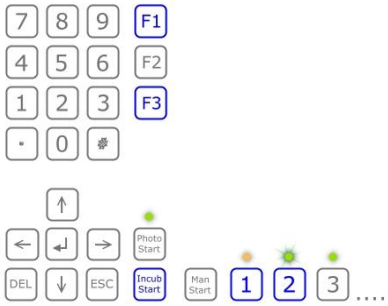
| Measuring mode TEMP = 37.3°C | | | | | |
|---|---|---|---|---|---|
| MZ | Pat.-ID | PROG | TIME | RESULT | INFO |
| 1 | STOP | | | | |
| 12 | STOP | | | | |
| 13 | STOP | | | | |
| 14 | STOP | | | | |
| 15 | STOP | | | | |
| 16 | STOP | | | | |
| 17 | STOP | | | | |
| 18 | STOP | | | | |
| 19 | STOP | | | | |
| 20 | STOP | | | | |
| 21 | INIT | | | | |
| F1 = AUTO | | | F3 = DELETE | | |

## 5.3 Measurement of parameters with one reagent component

The instrument employs especially manufactured cuvettes and steel balls. Load a rack with new cuvettes and balls and insert the rack with the cuvettes and balls into the pre-heating stations for cuvettes above the measuring positions. Into cuvettes which has been positioned in these pre-heating stations only then reagent is pipetted if the parameter consists of two reagent substances (e.g. aPTT). The MC 10plus can process the test-related incubations time which is programmed in the test parameters (chapter 3.3) in two different ways:

a) **Force incubation time** (chapter 3.5.9): if a measurement shall be carried out the rack with the pre-heated cuvettes has to be positioned in the measuring channel row and the measurement respectively the measuring channel has to be activated by pressing the according activating key which is located under the measuring position. The activation for this measuring channel is now active for 5 seconds which is indicated by flashing of the according display line and the assigned greed signal lamp. The sample has to be pipetted within this period of time and the incubation time keeper has to be started by pressing the key "Incub Start" (on the left side of the activation keys) simultaneously. **PLEASE NOTE – in this mode an incubation is obligatory, i.e. an abort is not possible**. When a measurement has been start in a measuring channel the green signal lamp below this measuring position changes its colour and flashes up constantly yellow-orange. 5 seconds before the end of the in the settings menu selected incubation time (chapter 3.3) the MC 10plus signalizes acoustically the end of this step in order to remind to pipette the start reagent and to start the measurement. Then the measuring programme has to be activated again by pressing the activating key under the measuring position. The activation for this measuring position is now active for 5 seconds which is indicated by of the according display line and the assigned greed signal lamp. The measurement can be started within these 5 seconds (assigned display line and according green signal lamp). This happens automatically by adding the (start) reagent (f no automatic pipette is used for adding the start reagent the measurement has to be started by pressing one of the two manual start keys which are left and right from the measuring position activating keys). The signal display changes its colour and flashed red. The instrument automatically stops the measurement as soon as a clot is formed. The signal display now lights up constantly red. For preparing a new measurement press the activating key under the according measuring position or reset all measuring positions simultaneously by pressing the F3-key (reset of all measuring positions with the F3-key is not supported during automatic channel reset (chapter 3.5.9)).

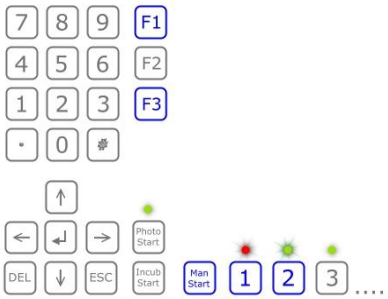
Please ensure that the start reagent to be pipetted has been pre-heated to 37°C in order to avoid incorrect results. The pre-heating happens (according to the employed start pipette) either in the tip of the Handystep pipette (if the Handystep pipette has been stored in the according pre-heating position) or in a reagent tube which has been placed in a reagent pre-heating position.



b) ***Not*** **force incubation time** (chapter 3.5.9): If a measurement shall be carried out the rack with the pre-heated cuvettes has to be inserted in the measuring position row and the measurement respectively the measuring position has to be activated by pressing the activating key under the measuring position. The activation for this measuring position is now for 5 seconds active which is indicated by flashing up of the assigned display line and the according green signal lamp. Within this period the sample has to be pipetted and the incubation time keeper has to be started with the key "Incub Start" (on the left side of the activating keys). If an incubation starts in a measuring position the green signal lamp under this measuring position starts its colour and lights up constantly yellow-orange. In this mode the incubation can be aborted by pressing once again the according measuring position activating key. For the reason of precision a premature incubation abort is not advised. 5 seconds before the end of the in the settings menu selected incubation time (chapter 3.3) the MC 10plus signalizes acoustically the end of this step in order to remind to pipette the start reagent and to start the measurement. If the incubation is finished or has been aborted the measuring programme has to be activated again by pressing the activating key under the measuring position. The activation for this measuring position is now active for 5 seconds which is indicated by of the according display line and the assigned greed signal lamp. The measurement can be started within these 5 seconds (assigned display line and according green signal lamp). This happens automatically by adding the (start) reagent (f no automatic pipette is used for adding the start reagent the measurement has to be started by pressing one of the two manual start keys which are left and right from the measuring position activating keys). The signal display changes its colour and flashed red. The instrument automatically stops the measurement as soon as a clot is formed. The signal display now lights up constantly red. For preparing a new measurement press the activating key under the according measuring position or reset all measuring positions simultaneously by pressing the F3-key (reset of all measuring positions with the F3-key is not supported during automatic channel reset(chapter 3.5.9)).

**Example:** You wish determine the PT of a patient sample. Therefore load a rack with new cuvettes and balls and place these cuvettes with the rack into the cuvette pre-heating stations above the measuring position (see chapter 1.6 Views). Prepare the reagent according to the package insert and aspirate it with the Handystep pipette respectively position the reagent in a 14.5 x 85 mm plastic tube in the measuring / pre-heating position above the cuvette pre-heating positions. Insert the rack with the pre-heated cuvettes into the measuring positions. Then activate the measuring programme with the activating key under the measuring position of the sample which has to be tested. Please note that the programme remains active only for 5 seconds. Pipette the plasma (50 µl for the MC 10plus micro, the volume may probably be reduced – please consult the manufacturer) and start the incubation time keeper by pressing the key "Incub Start" which is on the left side of the activating keys, simultaneously. 5 seconds before the end of the incubation time MC 10plus gives 5 acoustic signals ( 1 per second). Within this period of time (5 seconds) the pre-heated reagent (100 µl for the MC 10plus micro) can be aspirated with the pipette. If a Handystep pipette is used the reagent is pre-heated directly in the pipette as the pipette is pre-heated in the according pipette storing position. After the end of the incubation the measuring programme has to be activated again by pressing the activating key under the measuring position. Again the programme remains active for only 5 seconds. Start the measurement by adding the start reagent with these 5 seconds into the cuvette (if no automatic start pipette is used one of the two manual start keys on the right and left side of the activating keys have to be pressed simultaneously with the dispense of the start

reagent). The measurement is stopped automatically when a coagulation reaction starts respectively when a clot is formed.




According to the parameter and the settings the result can be converted to another result unit.

Please regard the instructions (chapter 4) for pipetting plasma and reagent.

For preparing the next measurement press the activating key below the according measuring position or reset all measuring positions simultaneously by pressing the F3-key (reset of all measuring positions with the F3-key is not supported during automatic channel reset(chapter 3.5.9)).

## 5.4 Measurement of parameters with two reagent components

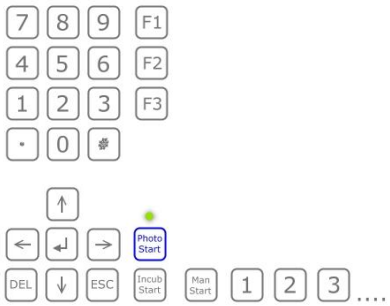
On the whole measurements of parameters with two reagent components (e.g. aPTT) do not differ from measurements of parameters with one reagent component. Nevertheless you can pipette the first reagent into the measuring cuvettes when these are still in the pre-heating positions above the measuring positions, i.e. before the cuvette is changed over to the measuring position. Please regard the parameter-related incubations time and then proceed as described in chapter 5.3.

## 5.5 Measurement of parameters in the optical measuring position

If optical tests have to be carried out it has to be ensured that no used cuvette is in the optical measuring position of the MC 10plus when it is switched on. If this can not be granted switch off the instrument once again for the reason of security, remove the cuvette from optical measuring position and switch on the analyser again.

The measurement of parameters in the optical measuring differs from measurements in the mechanical measurement positions as follows:

a) The activating key of the measuring position is not located directly under the measuring position but in the keyboard right from the right arrow key.



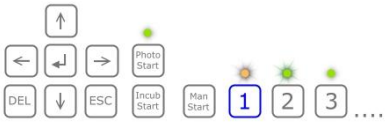

b) A total sample / reagent volume of at least 300 µl has to be reached ifor ensuring a correct measurement.

Before a photometrical test can be carried out it has to be programmed as freely programmable test (FP1, FP2 or FP3) in the test parameters (chapter 3.3). It is possible to select a freely programmable test as photometrical test which can be run parallel to to mechanical tests. Please ensure the correct input of the calculation formula (chapter 3.4 when programming the test.

The measuring position activating key F1 is not activated for the photometrical measuring position. The automatic measuring position reset has full function when this feature has been adjusted accordingly in the settings menu.

## 5.6 Stopping of an incubation time

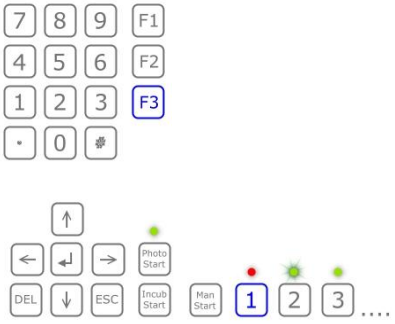
If the incubation time keeper of a measuring position has been started by mistake an abort can be caused by pressing the measuring activating key once again. By doing so this measuring position is prepared for the measurement start simultaneously. If the user has entered “Yes” for the point “Force incubation time” in the settings menu prior to the measurement an abort of the incubation is not possible.




## 5.7 Stopping after a mistakenly start of a measurement

If the measurement has been started mistakenly or the time keeping has not been stopped automatically for other reasons the measurement can be stopped at any time by inserting a new cuvette with ball into the measuring position. Let the cuvette turn approximately 5 seconds, then lift it slightly respectively remove this cuvette.

For preparing a new measurement press the activating key below the measuring position in question or reset all measuring positions simultaneously by pressing the F3-key.




## 5.8 Switching off the device

If the analyser is not employed for a longer period of time it is recommended to switch off the instrument by pressing the on-/off-switch at the back off the housing.

## 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 10plus 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 may 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.

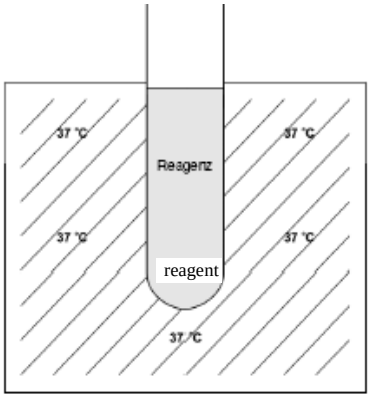
**ATTENTION!**
This instrument is classified as an in-vitro-diagnostic device!


**ATTENTION!**
If the operator is electrified a discharge may happen at the measuring / pre-heating block of the MC 10plus. This discharge does not influence the functions of the MC 10plus.

# 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 10plus 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 10plus.

Ball 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 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**<br>The MC 10plus 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**<br>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.**<br>Unexpected result of patient samples. | **Pre-analytical error**<br>Sample tube under- or overfilled. | Commercial vacuum tubes have to be filled completely to ensure the correct blood-/ anticoagulant relation. |
| | **Pre-analytical error**<br>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**<br>Wrong relation of anticoagulant and blood. | Citrate volume has not been adjusted for patients with higher (>55%) or lower (<21%) haematocrit. |
| | **Pre-analytical error**<br>Clot in the sample | Samples containing micro or macro clots should not be taken for tests. |
| | **Pre-analytical error**<br>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**<br>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.**<br>Unexpected result of patient samples. | **Pre-analytical error**<br>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**<br>Contact with glass. | Transfer the plasma by means of plastic transfer pipettes into a plastic storage tube. |
| | **Sample-related**<br>Loss of factors V and VIII. | Don't warm up the sample longer than 5 minutes at 37°C. |
| | **Sample-related**<br>Wrong volume has been selected. | Follow the manufacturer's instructions. |
| | **Reagent-related**<br>Contaminated reagent. | Reconstitute a new reagent or open a new bottle. |
| | **Reagent-related**<br>Wrong reagent has been used. | Follow the manufacturer's instructions. |
| | **Reagent-related**<br>Wrong reagent volume has been used. | Follow the manufacturer's instructions. |
| | **Reagent-related**<br>Reconstitution with the wrong diluent volume | Follow the manufacturer's instructions. |
| | **Reagent-related**<br>Reconstitution with another diluent than the recommended diluent. | Follow the manufacturer's instructions. |
| | **Reagent-related**<br>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.**<br>Unexpected result of patient samples. | **Reagent-related**<br>Reagent disintegration. | Is this the first of this delivery employed reagent? Is the storage temperature correct? |
| | **Reagent-related**<br>Reagent disintegration. | Don't employ the reagent if the reconstituted storage life of the non-reconstituted reagent is expired. |
| | **Reagent-related**<br>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**<br>Contaminated reagent. | Don't touch the already dispensed samples / reagents with the pipette tip. |
| | **Controls-related**<br>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**<br>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.**<br>Unexpected result of patient samples. | **Analytical error**<br>Wrong incubation time | Follow the manufacturer's instructions. |
| | **Analytical error**<br>Wrong test sequence. | Follow the manufacturer's instructions. |
| **Irregular results within the test.**<br>Controls may be within or out of the reagent range. | **Analytical error**<br>Imprecise manual pipetting of sample and reagent. | The pipette has to be maintained. The as accessory available automatic pipette of the MC 10plus is delivered with manual. Please practise the pipetting technique. The instructions for the correct pipetting technique are in chapter 4 (pipetting).<br><br>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).<br><br>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.<br><br>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.**<br>Controls may be within or out of the reagent range. | **Reagent-related**<br>Irregular or imprecise reconstitution of the reagent or control material. | Reconstitute a new reagent and / or control material. |
| | **Reagent-related**<br>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**<br>Reagent concentration due to vaporizing | Reagent container has to be closed when it is not used. |
| | **Sample-related**<br>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.<br>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**<br>No sample has been added. | Ensure that the sample has been added. |
| | **Sample-related**<br>Fibrinogen deficiency | Due to fibrinogen deficiency the results of many clotting tests are retarded essentially. |
| | **Reagent-related**<br>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**<br>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**<br>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**<br>A clot is formed within less than 4.0 seconds. | For fibrinogen tests use the next higher dilution.<br>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 instrument 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 |
| | |
| | |
| | |
| | |
| | |

# 11. Additional printer

It is possible to connect the MC 10plus with an external printer (available as accessory) via 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 10plus with the supplied cable. Switch on the printer with the main switch. When it is switched on the POWER lamp lights up.

The data are transmitted to the printer (when it is switched on) after the determination is finished.

When the printer is switched off the data are not printed (they are also not printed when the printer is switched on afterwards), but they can be printed later out of the printer buffer of the MC 10plus (settings menu chapter 3.5).

The 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. For all other tests the result is converted according the settings in the test parameters or the measured time is printed out as sole result.

If the printer is in the OFF-status during the test procedure no data are transmitted. They can be printed out from the printer buffer of the MC 10plus (see settings menu chapter 3.5) 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.

# 12. Barcode scanner

For the connection of a barcode scanner, its settings and handling please see chapter 3.5.7.

# 13. Appendix I

## Verification document

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

| | | |
|---|---|---|
| Instrument type | : | MC 10plus |
| 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<br>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*<br>*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*