Service Manual

HumaClot Junior

Cat.-No.: 18680/2

CE

CONTENTS

This page left blank

Warning

Please read this service manual in its entirety prior to servicing the HumaClot Junior. In order to ensure a high level of performance, all warnings and references to technical safety in this service manual must be followed. Repairs to the instrument may only be carried out by trained personnel, and replacement parts must comply with instrument specifications.

The HumaClot Junior is intended for use with human plasma. As there is no known test that can offer complete assurance that product derived from human blood will not transmit hepatitis, AIDS, or other infectious diseases, appropriate precautions should be taken by the instrument operator. In case of plasma spilled on the instrument, clean with a paper towel soaked in 10% bleach.

The **HumaClot Junior** is manufactured for HUMAN GmbH.

Company Address:	HUMAN GmbH Max-Planck-Ring 21 D-65205 Wiesbaden Germany	
Contact:	Phone: Fax: e-Mail: Internet:	+49 (0) 6122 9988-0 +49 (0) 6122 9988-100 (or - 99) human@human.de http://www.human.de

1 REVISIONS

1.1 Software

Rev.	Modification	Remark
C 5.14	Test adaptations For PC/AT3/DD	First release

1.2 Service Manual (Document)

Rev.	Reference Software	Remark
1	C 5.14	First edition

2 INSTRUMENT VIEWS

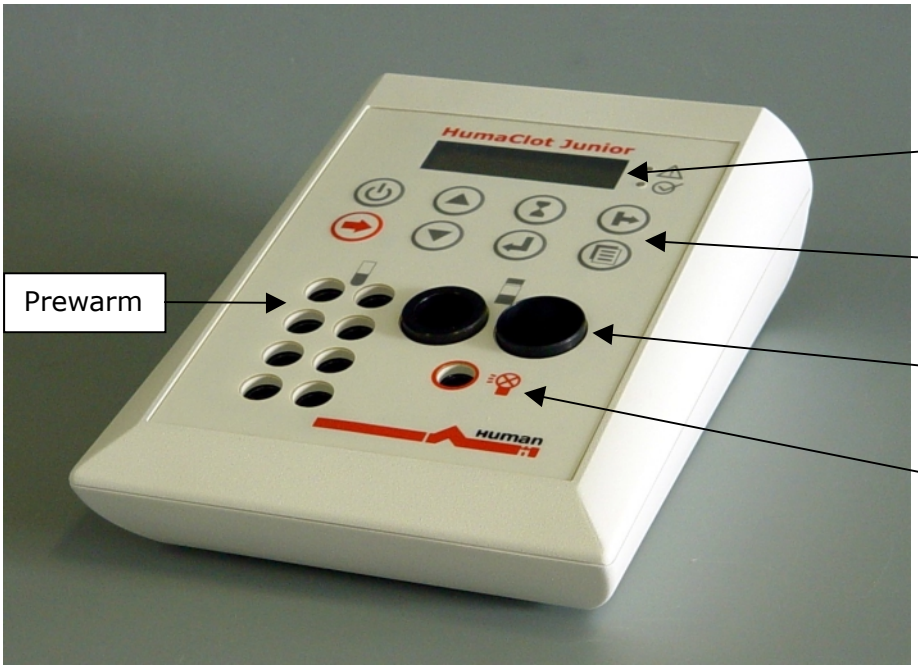


Figure: Front view

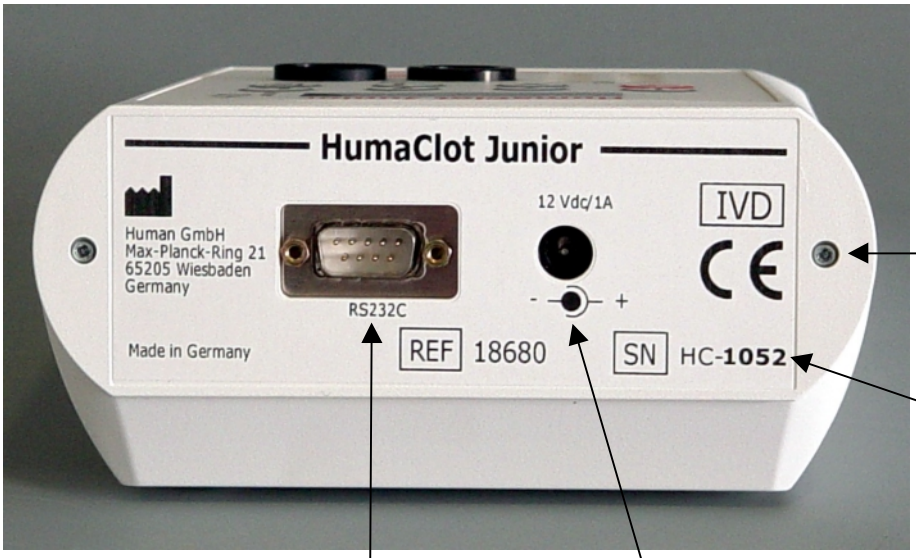


Figure: Rear view

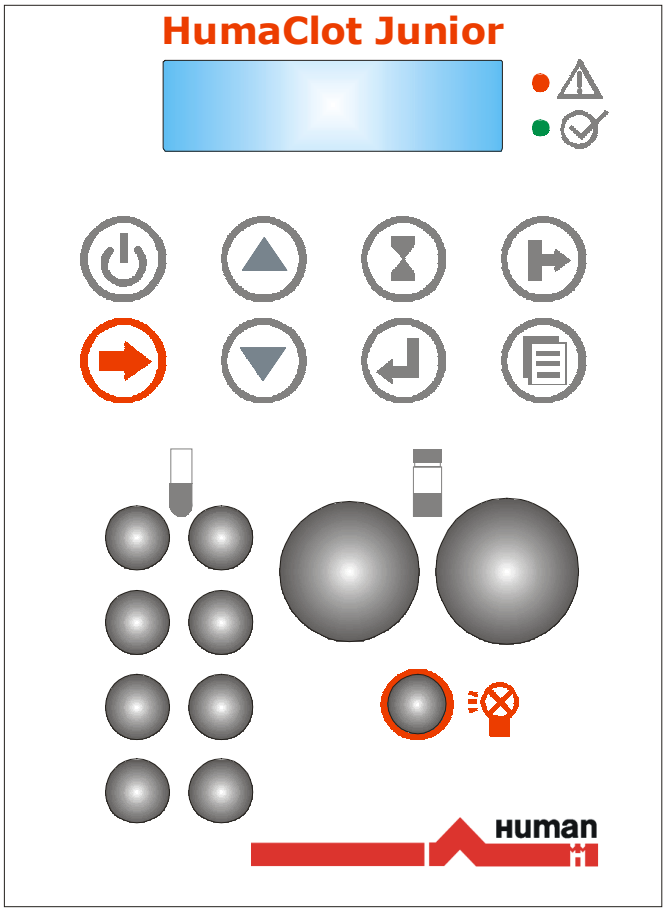


Figure: The Front panel

	On/Off
	Optic start
	Cursor up
	Cursor down
	Timer / Stopwatch
	Enter
	Test
	Menu
	Service / Mailfunction
	Ready to use
	Optic channel

3 INSTALLATION

No special precautions are necessary when starting up the **HumaClot Junior**. However, the following is recommended:

- Place on a level surface in an area free from excessive temperature fluctuations.
- Avoid vibration during measurement.
- Protect the instrument from direct sunlight, moisture and dust.
- Check that the voltage and frequency data on the identification plate of the instrument agree with the local power rating before starting the instrument for the first time.

The instrument is connected to the power supply by the mains cable (supplied). If obvious damage has occurred during shipping, **do not use**. Contact your local distributor for replacement or repair.

3.1 Equipment

Standard delivery package

- 1 Pc **HumaClot Junior**
- 1 Pc Power supply
- 25 Pcs Single cuvettes
- 5 Pcs Reagent tubes Ø 22.5 mm
- 5 Pcs Reagent tubes with cap Ø 16.0 mm
- 1 Pc Reagent adaptor Øa 23.4 / Øi 16.0 mm
- 1 Pc Reagent adaptor Øa 24.1 / Øi 22.6 mm
- 1 Pc Operating manual
- 1 Pc Warranty card

Consumables:

Human REF	Product	Content
18690	Single cuvette	500
19120	Pipette, 5 µL – 50 µL	1
19130	Pipette, 20 µL – 200 µL	1
19910/20	Pipette tips 2 - 200 µL	1.000

3.2 Technical Data

Dimensions (LxBxH):	205 x 150 x 75 cm
Weight:	0.51 kg (without power supply)
Ambient Temperature:	18 - 23°C
Power Supply	Input : 90-264 V~ Output : 12 V, 1.0 A
Device:	Micro controller board 14 Bit ADC ; on-chip controlling of LCD, RS232, keyboard, charging, temperature, optic.
Interface:	Serial - 2400 baud, 8 bits, 1 stop, no parity used in print or debug mode.
Optic Cell:	Photometer with pulsed 400 nm LED Variable pulse modulation Variable detector amplification Linear range 0.001 - 1.000 OD
Keyboard:	Foil keyboard with 8 keys and 2 LED's
Display:	2 lines x 16 characters, liquid crystal
Incubation block:	1 measuring, 8 sample, 2 reagent wells; warmed to 37°C.

3.3 Safety Standard Approvals

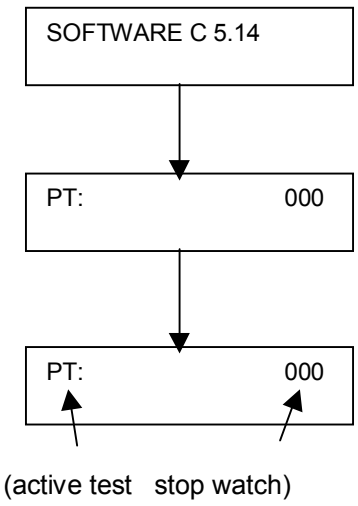
Manufacturer fulfills **EN ISO 9001:2000** and **EN ISO 13485:11/2000**

4 OPERATION INSTRUCTION

This section provides general instructions necessary for the user to achieve maximal use and benefit from the **HumaClot Junior**. For specific test applications refer to sections in the user manual.

4.1 Warm Up

The first visible screen gives the operator the information of the installed software before changing to the warm-up screen.



Info screen:
Software revision
(here: Rev. C 5.14)

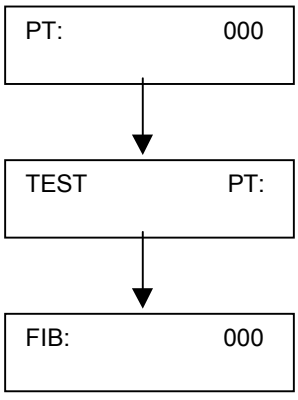
Red LED lights:
It takes approx. 5 minutes
for the instrument to equilibrate to 37°C

Green LED lights:
The **HumaClot Junior** is
ready to operate.

During the warm-up period no functions are available. The hidden service - menu can, however, be activated during the warm-up period (refer to section "SERVICE“). The regular operator should not enter this menu.

4.2 Test Selection

Eight different tests can be performed on the **HumaClot Junior**
(PT, PTT, TT, FIB, FAC, DD, AT3, PC).



Enter test selection with the
key "Test".

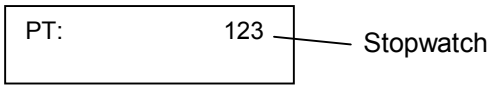
Change active test with the
cursor keys.

Confirm active test with the
key "Enter".

To alternate among the tests, press key **"Test"** to activate test selection, **cursor keys** to change and key **Enter** to confirm**.**

4.3 Stop Watch

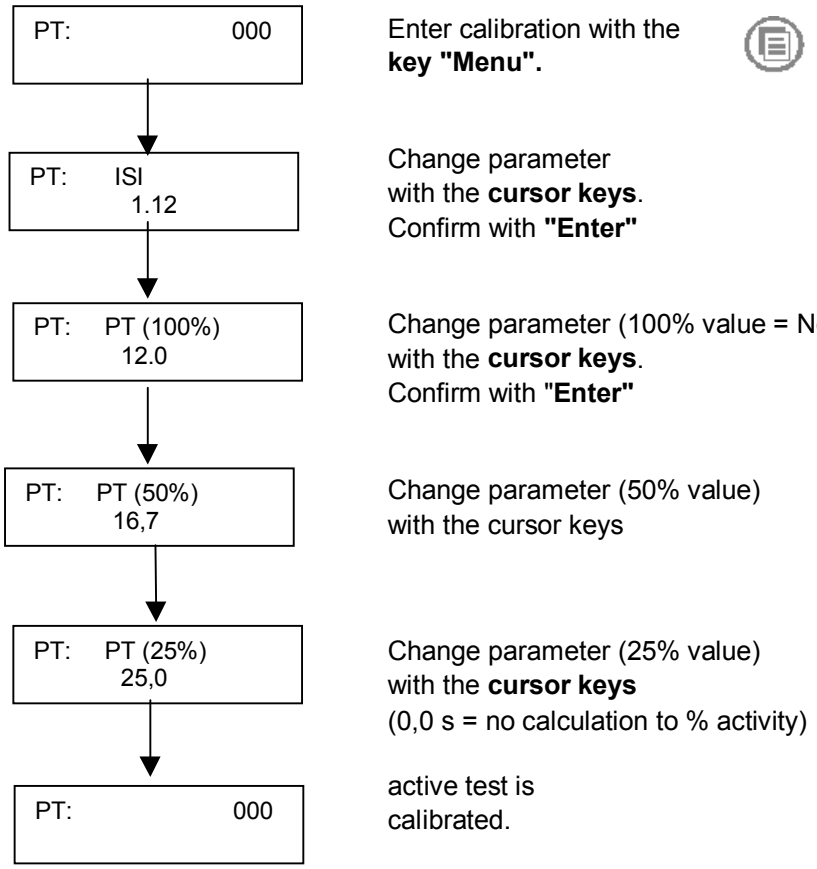
A stop watch function helps the operator to control the correct incubation times.



To start the stopwatch press the **key "Timer".**
To stop and reset press the **key "Timer"** again.

4.4 Calibration

The specific parameters for the tests can be entered into the **HumaClot Junior** and stored.



Remark: The input of values is done by pressing the up/down keys, first in steps of 10 and then with change of direction in steps of 1

4.5 Default Test Values

PT: ISI = 1.10
(1) 100% (Normal) = 12.8 s (2) 50% = 16.7 s (3) 25% = 25.0 s

PTT: Normal = 30.0 s

TT: Normal = 15.0 s

FIB: (1) 300 mg/dL = 12.0 s (2) 150 mg/dL = 23.0 s (3) 75 mg/dL = 36.0 s

FAC: (1) 100% = 32.5 s (2) 10% = 60.0 s (3) 5% = 70.0 s

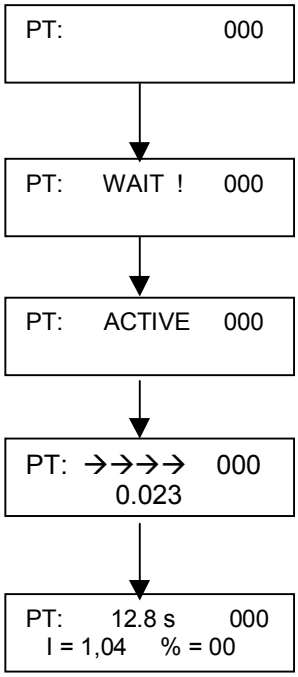
DD: (1) 1600 ng/ml = 150 mE (2) 200 ng/ml = 30 mE (3) 0 ng/ml = 0 mE

AT: (1) 100% = 400 mE (2) 50% = 800mE (3) 1% = 1100 mE

PC: (1) 100% = 62 mE (2) 50% = 23 mE (3) 1% = 3 mE

4.6 Measurement

Reconstitute reagent according to the reagent description and pre-warm (if required) in the reagent positions of the instruments. Insert the cuvettes in the incubation area (6 positions) and pipette the required volume of plasma into the cuvettes. To start a measurement, place the specific cuvette in the “Optic” position.



Activate the optic with the **key "Optic".**

This screen appears only for a few seconds and switches automatically to next screen

the measurement starts automatically with the addition of reagent. In case of problems: press the key **"Optic“** to start

The measurement is running.
Don’t touch the cuvette during a run!
The value in the second line shows the optical density [OD].

If a clot is found, the result is displayed and printed (if printer is connected)
(% = 00, if 25% value is set as zero !!!)

Note: Once started a faint beeping sound is followed by a scrolling arrow. The current light absorbance (OD) can be read on the display. Avoid contact with the cuvette while this message is shown. A beeping sound will be heard again if a clot-reaction was detected and the result will be displayed. If a printer is attached, the result will be also printed. If the clot reaction takes more than the maximum reading time of 300 s, the optic will stop and display „+++.+“, which means „no clot detected“.

4.7 Measurement Stop

The measurement can be canceled at any time by pressing the key **"Optic“** again.

4.8 Autostart

The measurement will start automatically when the reagent is added, if the optic is set to active. For the some tests (i.e. fibrinogen, thrombin) this feature does not work properly because the change in the signal is too small. In this case, inject the reagent quickly and with more force into cuvette and/or press the key **“optic”** again.

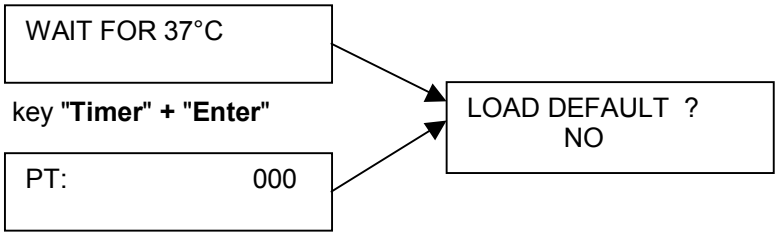
5 SERVICE

WARNING

Please read this section in its entirety prior to operating on the HumaClot Junior. In order to ensure accurate and reliable performance of the instrument, only authorised personnel, should perform any service functions on the HumaClot Junior instrument.

5.1 Service Functions

To enter the hidden service submenu, press **key "Timer"** and **key "Enter"** simultaneously.



The following service procedures can be performed on the **HumaClot Junior:**

Reset to default values
Temperature adjustment
OD-correction
Coag.-correction
Optic check
Set RS232

Use the **cursor keys** to change and the **key "Enter"** to confirm !

Incorrect adjustments will influence the measurement significantly! Before changing anything, be aware of the consequences!

5.2 Total Default Values

The **HumaClot Junior** can store test and system parameter permanent on board.

Calibration PT:	ISI = 1.10		
	(1)	100% (Normal)	= 12.8 s
	(2)	50%	= 16.7 s
	(3)	25%	= 25.0 s
Calibration PTT:	Normal = 30.0 s		
Calibration PT:	Normal = 15.0 s		
Calibration FIB:	(1)	300 mg/dL	= 12.0 s
	(2)	150 mg/dL	= 23.0s
	(3)	75 mg/dL	= 36.0 s
Calibration FAC:	(1)	100%	= 32.5 s
	(2)	10%	= 60.0 s
	(3)	5%	= 70.0 s
Calibration DD:	(1)	1600 ng/ml	= 150 mE
	(2)	200 ng/ml	= 30 mE
	(3)	0 ng/ml	= 0 mE
Calibration AT3:	(1)	100%	= 400 mE
	(2)	50%	= 800 mE
	(3)	1%	= 1100 mE
Calibration PC:	(1)	100%	= 62 mE
	(2)	50%	= 23 mE
	(3	1%	= 3 mE

Temperature	°C=370 (9040)
OD Correction PT:	100
OD Correction FIB:	100
OD Correction FAC:	100
OD Correction PTT:	100
OD Correction DD:	100
OD Correction TT:	100
OD Correction AT3:	100
OD Correction PC:	100
Coag Correction PT:	100
Coag Correction FIB:	100
Coag Correction FAC:	100
Coag Correction PTT:	100
Coag Correction DD:	100
Optic check (mw):	mw = approx. 11500 (range from 10xxx to 13xxx) Integration time: approx 013 (from 011 to 020)
RS 232 Print Results	(Data->RS232 = NO)

5.3 Temperature Adjustment

The incubation block of the **HumaClot Junior** should maintain a temperature of 37,2 °C.
When the green LED is on, fill a reagent tube with 1 ml water and place it in a reagent position. Place a (digital thermometer in the reagent tube and allow to warm up for approx. 10 min. before reading the temperature.

SET TEMPERATURE °C=371 (9085)

Example: The current temperature is 37,1°C and the digital target value is 9085.

Compare the temperature displayed by the system and the thermometer. If the temperature is different, adjust the temperature on the **HumaClot Junior** by pressing the Up/Down cursor keys

Wait until a stable temperature of 37.0°C is displayed on the **HumaClot Junior**. Check and correct the system temperature if not equivalent to the external thermometer.

Use the Up / Down keys to increase or decrease of temperature

5.4 Optic Adjustment

5.4.1 OD Correction

OD-CORRECTION
PT = **100**

The optical density measured by the instrument can be corrected by a factor for each test. Therefore it is possible to adapt other reagents.

(OD-Correction = 100 → optical density * 1.00 -> no effect)
(OD-Correction = 120 → optical density * 1.20)

OD-CORRECTION **below 100** will cause:
- longer clotting times
- reduce sensitivity of the method (more results will showas +++.+ s)

OD-CORRECTION **above 100** will cause:
- shorter clotting times
- increase sensitivity of the method, which can cause wrong results (short-time results !!!!)

WARNING : OD-CORRECTION should be within 50 - 150

special : OD-CORRECTION for fibrinogen test

Run a 300 mg/dL calibrator. The result should be close to 10 s. If it is above/below 10 s, in-/decrease the OD-CORRECTION slightly.

5.4.2 COAG CORRECTION

With the COAG CORRECTION the instrument can correct the result for better correlation to other systems or reagents.

Example: On another instrument a plasma sample measures with PT = 12.1 seconds; on the HumaClot Junior the result is 11.0 seconds. To get equal results, the result has to be corrected by factor of 1.10 (+10%).
This can be done by entering COAG CORRECTION = 110 (Factor 1.10).

COAG-CORRECTION
PT = **100**

5.4.3 OPTIC CHECK

The OPTIC CHECK is recommend, if problems with measurements arise. Remove the cuvette from optic.

```
OPTIC CHECK
mw = 11323        014
```

The HumaClot Junior has adjusted this optic value (mw) to 11323 at an amplification (amp) of level 14.

Control range:
(ensure that no cuvette is placed in the optic)

mw: 10000 – 13000
amp: 10-18

Press key “menu” to repeat the optic check, or the up/down keys to change the amplification.

5.4.4 Interface RS232

The interface can used in two ways:

Print Mode → Results are printed
Debug Mode → Reaction curve can be portrayed on a PC

```
DATA → RS232
       NO
```

(NO → Print Mode ; YES → Debug Mode)

The interface port is set to 2400 Baud, 8 Bits, 1 Stop, No parity
Protocol: **M1** tab **NR** tab **TEST** tab **SEC** tab **mOD** tab **%** tab **INR** tab **Unit** **LF**

Example of a results printout:

```
01      PT:
   12.5 s
   I = 1.03

02      PT:
   13.2 s
   I = 1.35

03      PT:
   12.8 s
   I = 1.22

04      PT:
   12.6 s
   I = 1.04
```

run #01

run#02

run#03

run#04

6 TROUBLESHOOTING GUIDE

Note : Always verify instrument performance by testing appropriate control samples

System Error Message	Interpretation and corrective action
Optic Failure !	The **HumaClot Junior** is not operating in accordance with its optical specifications. This can happen, if - there is not sufficient light (i.e. with very turbid reagents or lipemic samples). Change to HUMAN reagent . Avoid extreme samples. - there is too-intense light (i.e. direct sunlight). Protect against sunlight. - LED is burned out. Replace device.
Measurement does not start automatically	The change in the signal is too small. This can happen with very clear reagents (ie. fibrinogen, thrombin). Try to pipette forcefully and quickly or start measurement by pressing the key **"OPTIC"** after adding the reagent.
Measurement starts incorrectly	Signal noise and temperature drift can start the measurement incorrectly. Stop the measurement and activate the optic shortly before starting.
Red Service LED is on	Electrical power is not sufficient. Use original power supply. Charge battery pack, if used.
Green Ready LED is off	Temperature is out of range. Wait a few minutes. If the error persists, contact technical service
Temperature not correct	Adjust the temperature.
+++.+ s **"No Clot Detect"**	Always repeat the sample to verify the result Possible reasons include the following Clotting time is longer than 300 secs Clotting time is shorter than 8 secs Incorrect reagent Fibrinogen level of sample is below 100 mg/dL (i.e. sample dilutions) Air bubbles Debris in cuvette Sample improperly collected OD-Correction is set to zero
Clotting time too short	Always repeat the sample to verify the result. Possible reasons include the following: Incorrect reagent Air bubbles Debris in cuvette Sample improperly collected Optic is incorrectly adjusted Action: Use recommended materials Decrease OD Correction slightly Increase OD Range

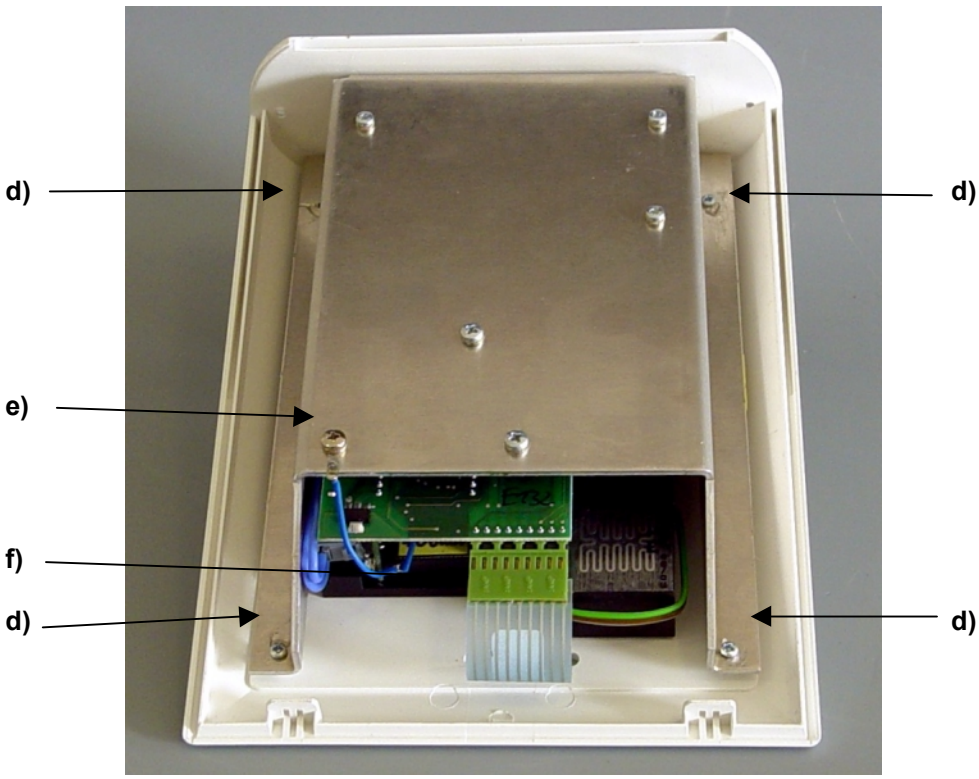
System Error Message	Interpretation and corrective action
Clotting time too long	Always repeat the sample to verify the result. Possible reasons includes the following: Incorrect reagent Air bubbles Debris in cuvette Low fibrinogen level Sample improperly collected Optic is incorrectly adjusted Action: Use recommended materials Increase OD-Correction slightly Decrease OD-Range

7 DISASSEMBLY / ASSEMBLY

Tools required: Phillips screwdriver, medium / small

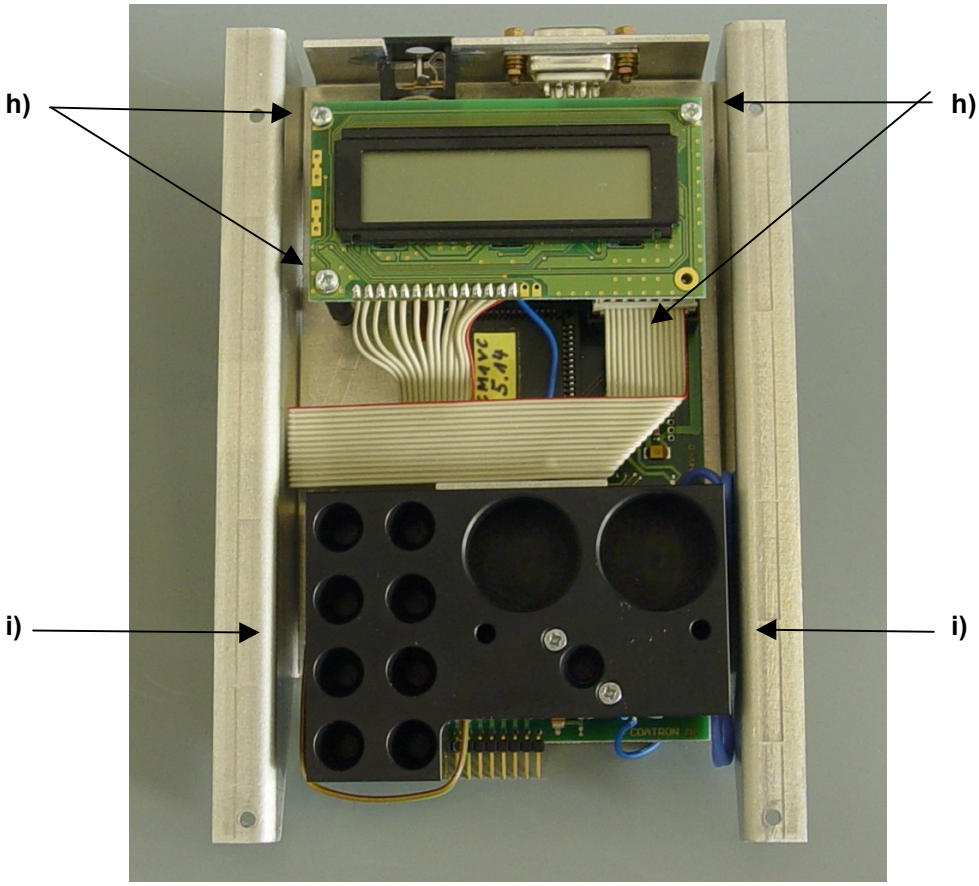
7.1 Disassembling the Instrument

a) Remove the two EJOT screws M2,5x8 with screwdriver on the rear of the instrument
b) Move upper part towards the front against the base
c) The parts are now separated

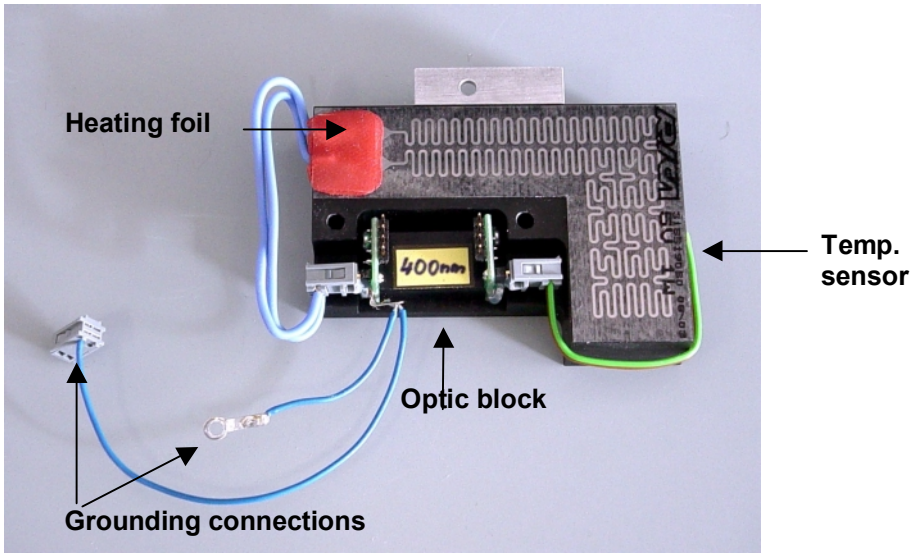


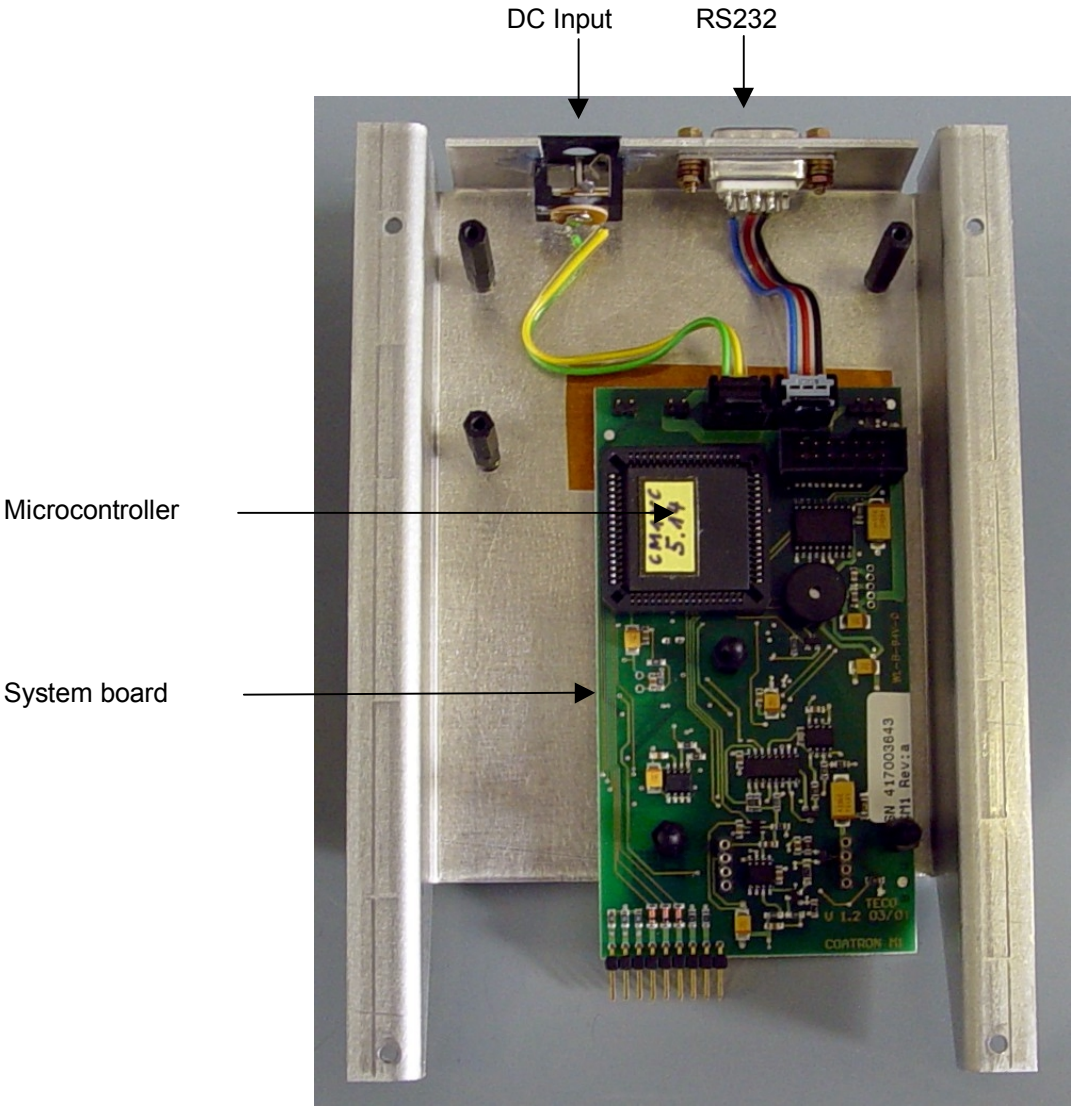
d) Remove the four EJOT screws with the screwdriver
e) Remove the M3x6 screw with the ground cable
f) Unplug the keyboard cable from system board connector
g) Lift up the complete inner assembly from the top case

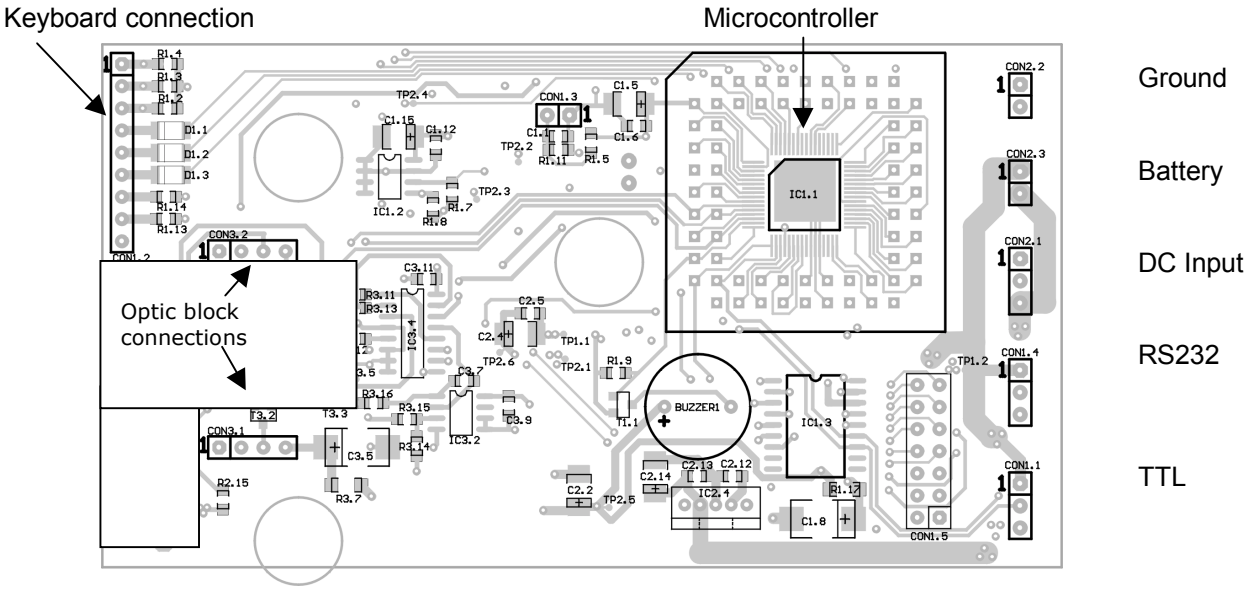
h) Remove the four screws from the display and unplug the cable



i) Lift up the complete heating block away from the system board sockets and spacers.




DC Input
RS232
Microcontroller
System board


Keyboard connection
Microcontroller
Optic block connections
Ground
Battery
DC Input
RS232
TTL

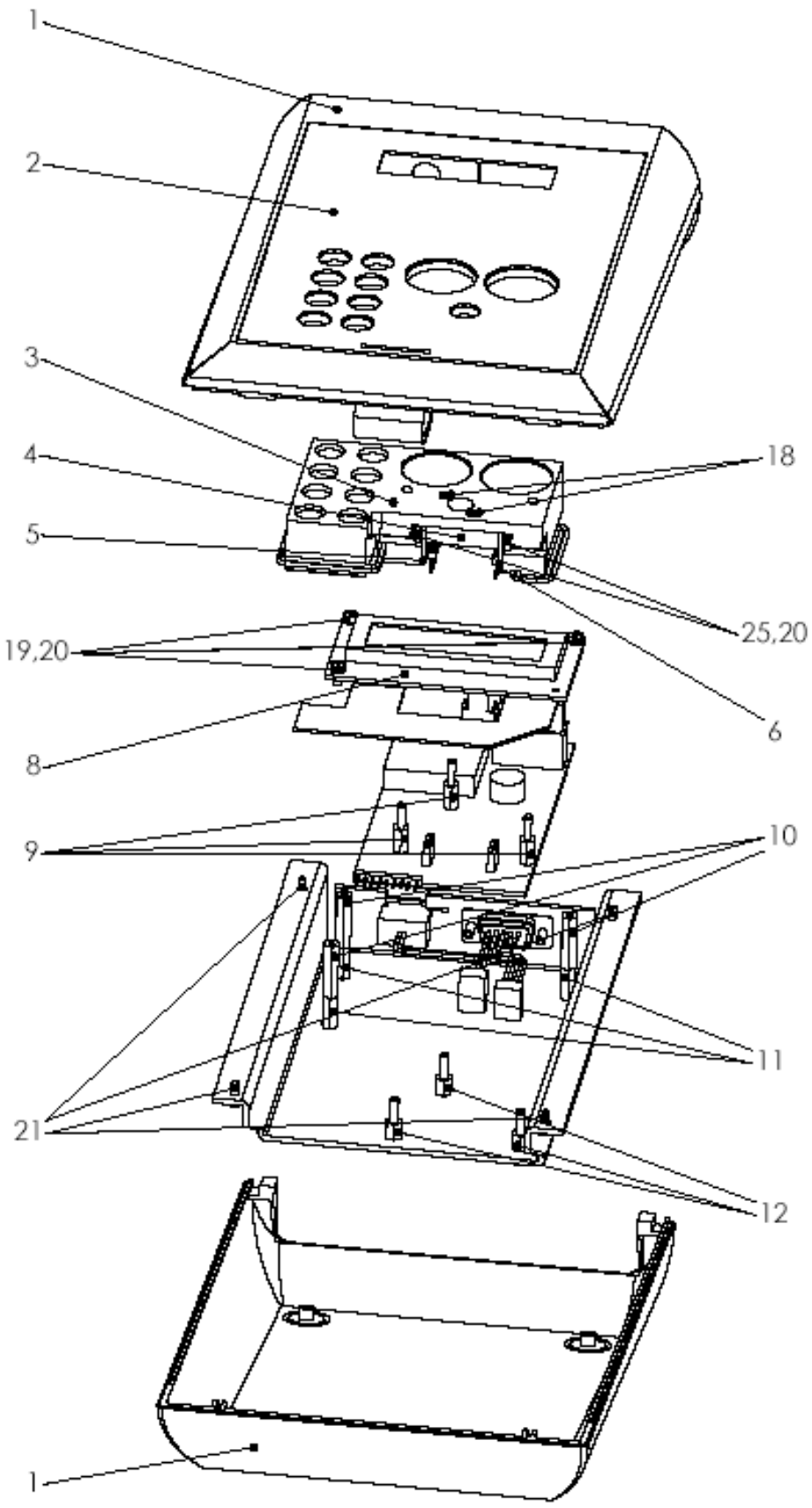
7.2 Assembling the Instrument

- Assembling of the instrument is the reverseof disassembly.
- Carefully put together the components, fixing (tightening them firmly.
- After complete assembly of all components, connect the external power supply and switch on the instrument.
- Run basic function tests (checking dialogue).
- Simulate measurement without reagent. Start the optic and stop after approx. 15 seconds with a pencil inserted into the optic channel. This will stop the measurement and show the virtual result.
- If the system board, heating components or microcontroller has been changed, a temperature check should be done before the final QC (Quality Control) procedure.

8 SPARE PARTS

Human REF	Product description	Position on drawing
18681/1	Power supply 90-264 Vac/12 Vdc - EU	n/a
18681/2	Power supply 90-264 Vac/12 Vdc - US	n/a
18681/3	System board	7
18681/4	LCD display cpl.	8
18681/5	Spacer M2,5 L12	11
18681/6	Spacer M3 L9 (for system board, top)	9
18681/7	Optic block cpl.	4
18681/8	Temperature sensor cpl.	27
18681/9	Cable RS232	17
18681/10	Cable DC-Input	16
18681/11	Cable ground	n/a
18681/12	Heating foil 5V, 1W	14
18681/13	Casing cpl.	1
18681/14	Type label	26
18681/15	Mounting plate	15
18681/16	Fastening angle	13
18681/17	Heating block	3
18681/18	Foil keyboard	2
18681/19	Reagent adapter da=23,4 di=16,0	n/a
18681/20	Reagent adapter da=24,1 di=22,6	n/a
18681/21	Spacer M3 L6 (for system board, bottom)	12
18681/22	Spacer M2,5 L32 (for display) (L12+L20)	10/11
18681/23	Fixation package	n/a
18681/24	Cardboard, white	n/a
18681/25	Cardboard, inlay	n/a
18680/1	User manual, english	n/a
18680/4	Warranty card, english	n/a
18680/2	Service manual, english	n/a

9 TECHNICAL DRAWING (3D-EXPLOSION)



1 = Casing cpl.

2 = Foil keyboard

3 = Heating block

4 = Optic block cpl.

5 = Receiver board

6 = Transmitter board

8 = LCD display cpl.

9 = Spacer M3 L9

10 = Spacer M2,5 L20

11 = Spacer M2,5 L12

12 = Spacer M3 L6

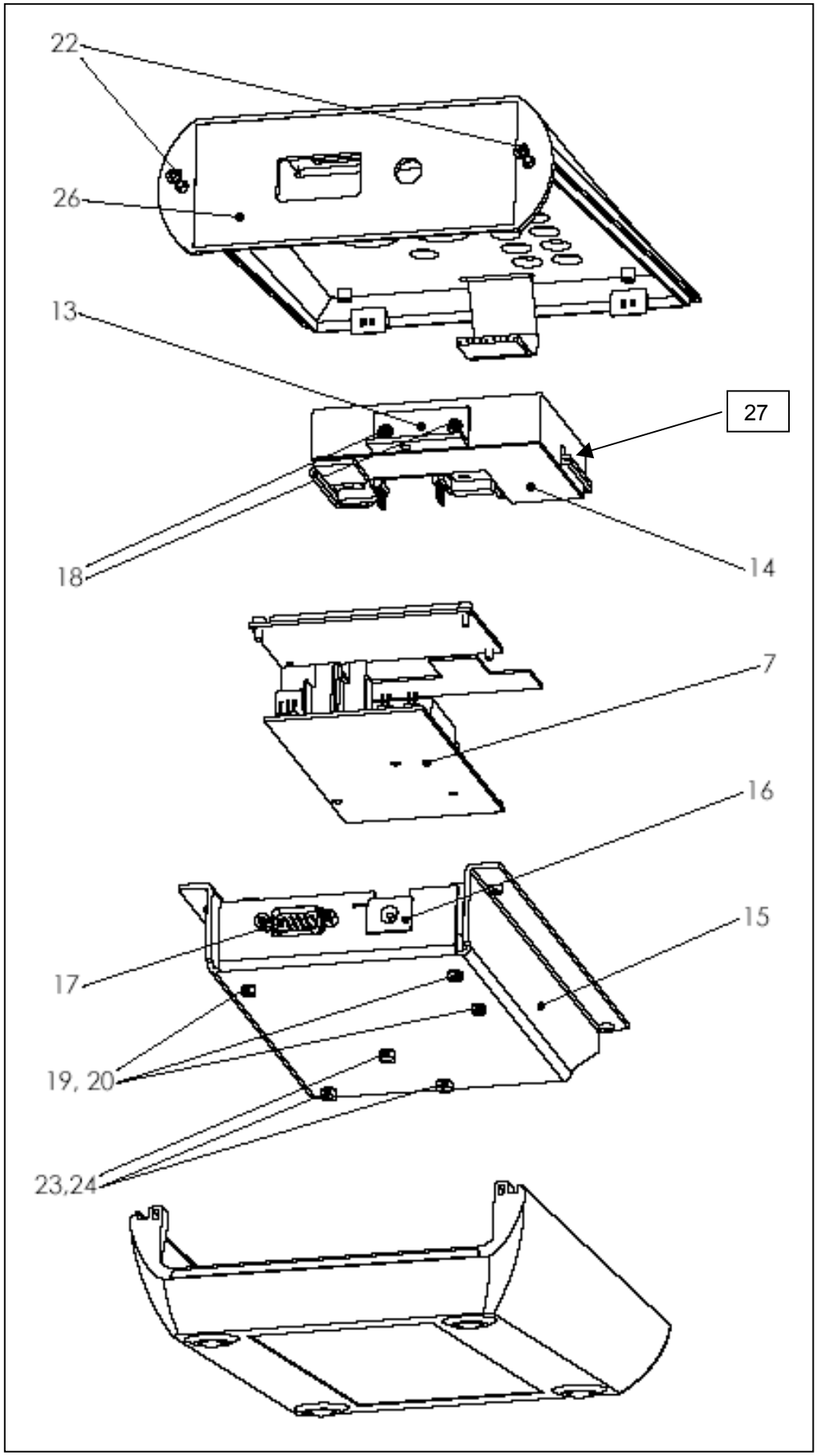
18 = Screw M2,5x8

19 = Screw M2,5x6

20 = Washer M2,5

21 = Ejot screw 2,5x8

25 = Screw M2,5x5



7 = System board

13 = Fastening angle

14 = Heating foil

15 = Mounting plate

16 = Cable DC-Input

17 = Cable RS232

18 = Screw M2,5x8

19 = Screw M2,5x6

20 = Washer M2,5

22 = Ejot screw 2,5x6

23 = Screw M3x6

24 = Washer M3

26 = Type label

27 = Temp.sensor cpl.

Human
Gesellschaft für Biochemica
und Diagnostica mbH
Max-Planck-Ring 21 • D-65205 Wiesbaden
Germany
Telefon: +49 6122 9988 0
Telefax: +49 6122 9988 100

eMail: human@human.de
Internet: http://www.human.de

01/2004-12