

Infusomat® Space

Service Manual



Rx only

B | BRAUN
SHARING EXPERTISE

This Service Manual is valid for:

Designation	Part No.
Infusion Pump Infusomat® Space	8713050/U/US

This Service Manual is available under the following part number:

Designation	Part No.
Service Manual Infusomat® Space 951136

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Important Preliminary Remarks

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Service Work

The present manual is for your information only. The possession of this manual does not authorize the performance of service work. Service tasks may only be executed by persons, who

- have received appropriate training on the system from B. Braun
- are included in the revision service
- possess the necessary test equipment and mechanical aids, and
- fulfill the personal requirements (training and knowledge).

Technical Safety Checks

The user is obliged to perform or to have performed the Technical Safety Checks on those medial products for which these checks have been prescribed by the manufacturer and to carry them out according to the indications of the manufacturer as well as the generally approved technical standards while adhering to the periods stated.

B. Braun also recommends training on the Technical Safety Checks, or to perform at least the steps indicated in the current version of the manual, as:

- the TSC requires that the instructions in the manuals are observed
- the manuals are a reference for measurements
- depending on the unit type, the Service Program must be called which may lead to a dangerous unit condition in case of inappropriate operation. Furthermore, a special service connector may be necessary.

Current Versions

This manual version corresponds to the state when the manual was written. B Braun reserves the right to make technical modifications. The state of the revision is indicated by the index number in the footer of every page.

Revision Service

The possession of this manual does not automatically mean inclusion in the revision service. You will be included in the revision service after:

- technical training by B. Braun

Responsibility of the Manufacturer

The manufacturer, person who assembles, installs or imports the device can only be held responsible for safety, reliability and performance if

- mounting, enhancements, new settings, changes or repairs are carried out by duly authorized persons,
- the electrical installation in the corresponding room meets the requirements of the VDE 0107, VDE 0100 part 710 or IEC 60364-7-710 and the national standards,
- the device is used in accordance with the instructions for use and the Service Manual,
- the Technical Safety Checks are performed at regular intervals,
- a current manual which corresponds to the revision state is used when carrying out maintenance, repair and service,
- the service technician takes part in the revision service,
- the technician has participated in a technical training course for the specific B. Braun unit.

Quality Management

B. Braun is certified in accordance with DIN EN ISO 9001 and ISO 13485. This certification also includes maintenance and service.

The unit has the CE label. The CE label confirms that the device corresponds to the "Directive of the Council for Medical Products 93/42/EC" of June 14, 1993.

Checks and Repair

Training may only be performed by B. Braun. The possession of the manual does not authorize the performance of repairs. The instructions on electrostatic sensitive components (ESD standards) must be observed.

After repair a device check or diagnosis is to be carried out.

Notes on ESD

Semiconductors can be destroyed by electrostatic discharge. Especially MOS components can be damaged by interference from electrostatic fields, even without discharge via contact. This type of damage is not immediately recognizable. Unit malfunctions can even occur after a longer period of operation.

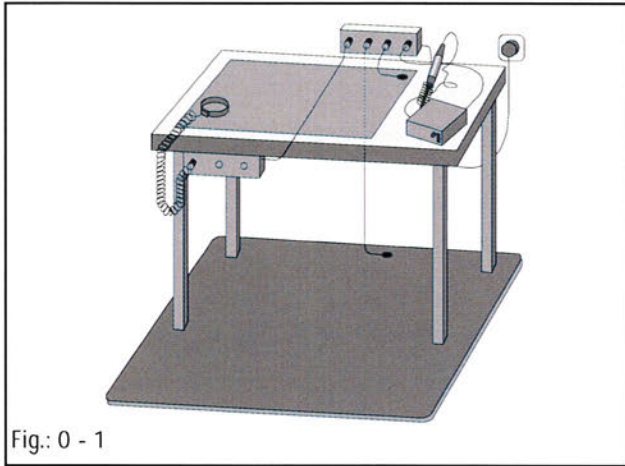


Fig.: 0 - 1

Spare Parts and Test Equipment

Additional notes and warnings are set off as follows:

Each workstation must be equipped according to the recommendations with the necessary static protective measures, if ESD components or boards are handled.

Each workstation must be equipped with a conductive table surface. The conductive surface, the soldering iron or the soldering stations must be grounded via protective resistors.

Chairs must be of antistatic design. The floor or floor mats should be of electrically conductive material.

Personnel must wear conductive wristbands which are connected to a central ground potential via protective resistors, e.g. the ground contact of a wall outlet. Furthermore it is recommended that personnel wear cotton clothing and electrically conductive shoes to prevent electrostatic charge.

Only use original spare parts from the manufacturer. Do not tamper with assembly groups which can only be exchanged completely. The spare parts required are listed in Section 9.

Service personnel are responsible for the calibration of their test equipment. Original test equipment can be calibrated at the works of B. Braun. Further information is available upon request.

Note

Is used for additional or special notes concerning information and working steps.

CAUTION

Is used for working steps which may result in damage to the unit, system or to a connected device.

WARNING

IS USED FOR WORKING STEPS WHICH MAY RESULT IN PERSONAL INJURY.

References to chapters are shown as follows: (EXAMPLE)

(see "Setting Off" ➔ pg. 0 -7)

References to figures and tables are shown as follows: (EXAMPLE)

Fig.: 2 - 3 or Table 2 - 1

References to item numbers in figures are shown as follows

([Fig.: 1 - 1 / Item 1](#))

In this case "Fig.: 1 - 1" is the figure number and "Item 1" the item number within the figure.

When the Service Manual is stored as pdf-file, these references are displayed green. Click with the mouse button on a reference to jump to the corresponding source.

Menu commands are described as:

Menu *File*.

List of Abbreviations

Abbreviations which are not generally known, but are used in this manual, are listed below.

CAN	Controller Area Network
CE	Communauté Européenne
CS	Calibration Step
DIN	Deutsche Industrie Norm (German Industrial Norm)
EN	European Norm
ESD	Electrostatic Discharge
FuP	Function Microprocessor
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization,
ISP	Infusomat® Space
ISPS	Infusomat® Space (Silicon)
ISPP	Infusomat® Space, (PVC)*
KuP	Monitoring Microprocessor
LCD	Liquid Crystal Display
MOS	Short name of the following company: MOS Technology, Inc. (Commodore Semiconductor Group)
PCA	Patient Controlled Analgesia
PSP	Perfusor® Space
SP	Space (System)
SPC	SpaceCover
SPCC	SpaceCover comfort
SPCS	SpaceCover standard*
SPCO	SpaceCom*
SPCT	SpaceControl*
SPS	SpaceStation
TS	Trouble Shooting
UTS	Unit Test Step
TSC	Technical Safety Check



Important Preliminary Remarks

TEMP
VDE

Temperature
Verband der Elektrotechnik,
Elektronik und
Informationstechnik e.V.
(German Association of
engineers)

* Note: Infusomat® Space (PVC), SpaceCom, SpaceControl and SpaceCover standard are not available in the US or Canada

Contact Persons

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Technical Training

Via local representative.

Entry for Technical Training

Application for a technical training course must be made via the responsible representative.

Ordering of Spare Parts and Test Equipment

Customer Service and Service Hotline

Phone: +1 800 - 627 - PUMP
(+1 800 - 627 - 78 67)

Return of Spare Parts and Test Equipment

BBraun Medical Inc
1601 Wallace Drive, Suite 150
Carrollton, Texas 75006
USA

Generation and Translation

Brückner GmbH, Germany

Product Complaints

Product Complaints can be sent to the Manager of Quality Assurance at the above address. With each complaint, please include serial number or lot number of the product involved, a description of the difficulty experienced, information regarding the type of infusion and settings, type of I.V. solutions in use, the alarms displayed at the time the difficulty occurred and any other information that might aid in the investigation of the complaint.

Description

The Infusomat® Space (ISP) is according to IEC/EN 60601-1 or IEC/EN 60601-2-24 a portable volumetric infusion pump for infusion of small to high volumes with ultimate precision and is suitable for intravenous applications, blood transfusion and enteral nutrition.

The medical specialist must decide on suitability for application on the basis of the warranted properties and the technical data.

System Overview

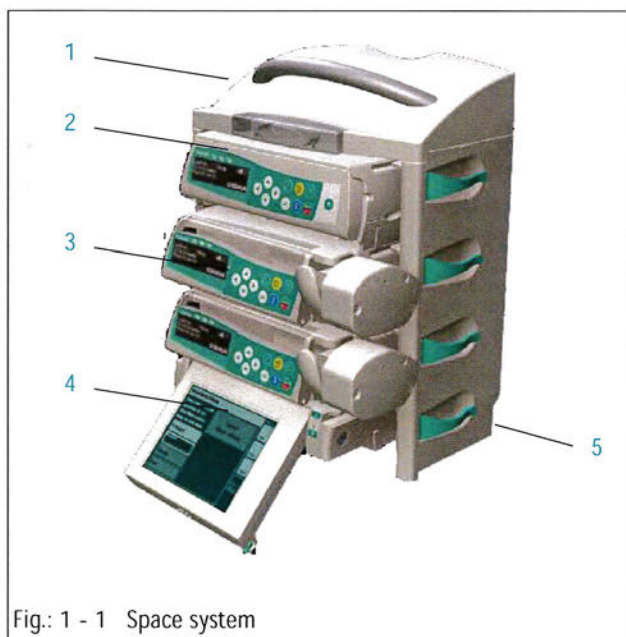


Fig.: 1 - 1 Space system

Legend to fig. 1 - 1:

Item Designation

- 1 SpaceCover
- 2 Infusion pump Infusomat® Space
- 3 Infusion syringe pump Perfusor® Space
- 4 SpaceControl
- 5 SpaceStation

The Space system is a modular design of modern infusion technology for stationary, mobile or private use. The key modules and their connection to the peripheral devices are shown in Fig.: 1 - 1.

All the pump types, Perfusor® Space, Infusomat® Space as well as the other devices of the system are of modular design. Up to three pumps can be connected together using L rails on the bottom of the unit and grooves on the top. They can then be fastened to a drip stand or appropriate rail using the pole clamp.

The SpaceControl module can be used to extend operation. One single pump can be inserted onto this module. The pump is then connected via connectors to the module.

The SpaceStation module allows the set-up of a complete pump system with up to 24 pumps. Up to four pumps can be installed in every SpaceStation. The pumps are supplied with power via the integrated power supply and the built-in connectors. The pumps are connected to the optional SpaceCom via these connectors. SpaceControl can also be integrated into the system.

Up to six SpaceStations can be set-up as a column with a total of 24 pumps. SpaceStation placed next to each other can be connected via special connection cables, if the maximum number of 24 pumps in maximum three columns is not exceeded.

SpaceCover Standard or SpaceCover Comfort forms the top of each column. Alarms are signalled by a row of LEDs and a loud-speaker in the SpaceCover Comfort.

Physical Construction

The Infusomat® Space housing mainly consists of the bottom part, the upper part, the front part and the operating device.

The battery module is inserted in the rear of the housing upper part. The opening is covered by the battery compartment cover.

The operating unit is attached to the front of the bottom part. The thrust bearing of the tube pump (peristaltic pump), the spring-mounted pressure elements for the two pressure sensors and the air inline sensor as well as the shackle for the slide clamp of the Infusomat® Space line are located at the rear of the operating unit. The operating unit is mechanically locked in its closed position via three metal pins. A motor-driven door bolt is used to lock the operating unit. In case of an emergency, the operating device can be opened through an opening on the left side of the housing top. During normal operation this opening is closed with a plug.

According to the line run the following subsystems are installed in the housing front panel, from right to left:

- pressure sensor (upstream, container-side)
- slide guide with 12 slides (mechanically coded, can be dismantled without tool)
coding for ISPS: top left
- air inline sensor
- pressure sensor (downstream, patient-side)
- safety clamp (ISPS).

The slides are moved in the slide guide by pump connecting rods. The connecting rods are mounted on an eccentric shaft and are led outside through a seal diaphragm. The complete pump is flexibly mounted in the inner frame of the device and is moved in combination with the door bolt. The door bolt drive is also installed in the inner frame.

The processor PCB with the external connectors "P2" and "P3" is located at the bottom of the housing bottom part.

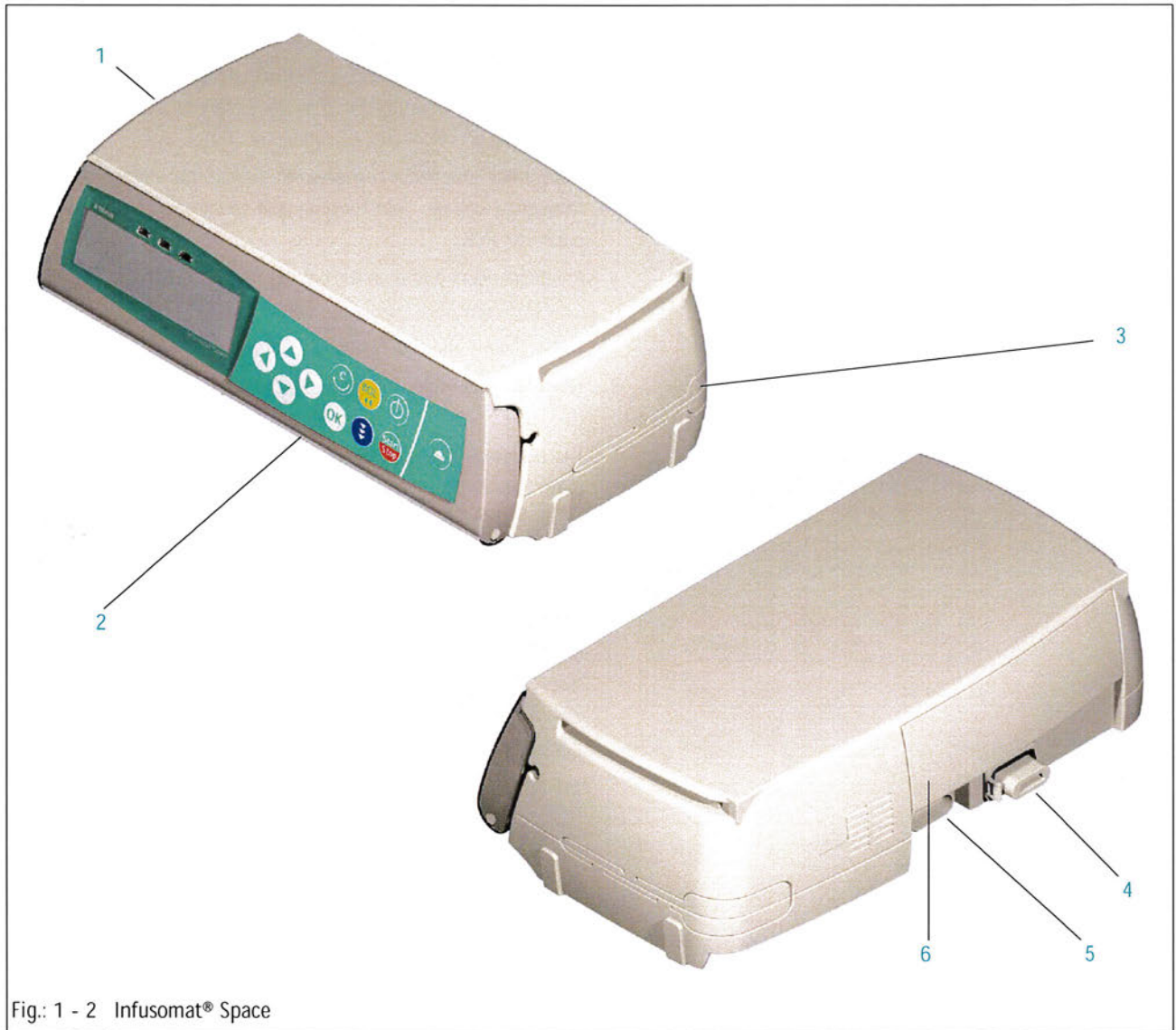


Fig.: 1 - 2 Infusomat® Space

Legend to fig. 1 - 2:

Item Designation

- | | | | |
|---|---|---|--|
| 1 | Infusomat® Space | 4 | Connector "P2" for SpaceStation module, external 12 V DC and accessories |
| 2 | Operating unit | 5 | Connector "P3", connection to SpaceControl module |
| 3 | Cover for drop sensor (not available in US or Canada) | 6 | Battery compartment cover |

Function

There are two power options for the Infusomat® Space :

- via the inserted battery module
- via an external 12 V DC power supply (e.g. SpaceStation, SpaceControl, an external power supply or from an ambulance car) connected to connector "P2"

The voltage supplied is converted to the internal voltages required through a voltage transforming and monitoring circuit on the processor PCB.

An independent circuit in the battery module monitors the battery cells and controls their charge condition.

The keyboard and the display are lighted

The Infusomat® Space is connected to a SpaceControl by connector "P3".

The function processor controls all the functions of the Infusomat® Space. Data is stored in a non-volatile memory which also controls the external data transfer.

The monitoring processor monitors all important responses of the function processor to incoming information. If a response does not correspond with that expected by the monitoring processor, an error message is generated and the device is switched to a safe stop state.

The Infusomat® Space line and its contents is monitored by the sensors listed below:

- optional drop sensor
- pressure sensor, upstream (container-side)
monitors the upstream pressure (negative pressure)
- air inline sensor
monitors the line contents (liquid - air)
- temperature sensor
monitors the temperature of the medium in the line (integrated in the air inline sensor)
- pressure sensor, downstream (patient-side)
monitors the downstream pressure (overpressure)

The pump drive motor is monitored by a detector for speed and direction of rotation.

The motor of the door bolt drive is controlled via the processor PCB. The different positions of the door bolt during operation are monitored by a linear potentiometer.

The safety clamp squeezes the Infusomat® Space line when the operating unit is opened or internal calibration is carried out to protect the patient and prevent an uncontrolled drug flow to the patient. Beside the position monitoring via the door bolt, the "open/closed" state of the safety clamp is monitored by a light barrier. The safety clamp is closed and the Infusomat® Space line is squeezed mechanically when the slide clamp of the Infusomat® Space line is inserted. When the operating device is opened the slide clamp is pulled out of the safety clamp until the Infusomat® Space line is squeezed. The safety clamp is only opened by manual operation of the safety clamp lever and the Infusomat® Space line can be removed.

To ensure patient safety the operating unit is automatically locked. For this purpose, the operating unit is manually pressed in the door bolt with the three locking pins. The resistance of the linear potentiometer which is monitored by the controller is changed when the position of the door bolt changes. The locking process is started and can take up to 10 seconds. During the locking process several calibrations are carried out automatically, e.g.:

- occlusion test
to check, for example, the function of the safety clamp
- pressure calibration of the two pressure sensors.

The operating unit is also unlocked automatically via the door bolt. In case of a power failure or malfunction, the operating unit can be unlocked manually by a small emergency unlocking crank. To do so, move the door bolt manually with the crank to the open position as described hereafter.

Opening the Operating Unit Manually

1. Press the locking of the battery compartment cover using a pointed tool and remove the battery compartment cover from the housing.
2. Remove the emergency unlocking crank out of the battery compartment cover.
3. Press the emergency unlocking crank carefully in the emergency unlocking plug on the left side of the housing until stop.

Note

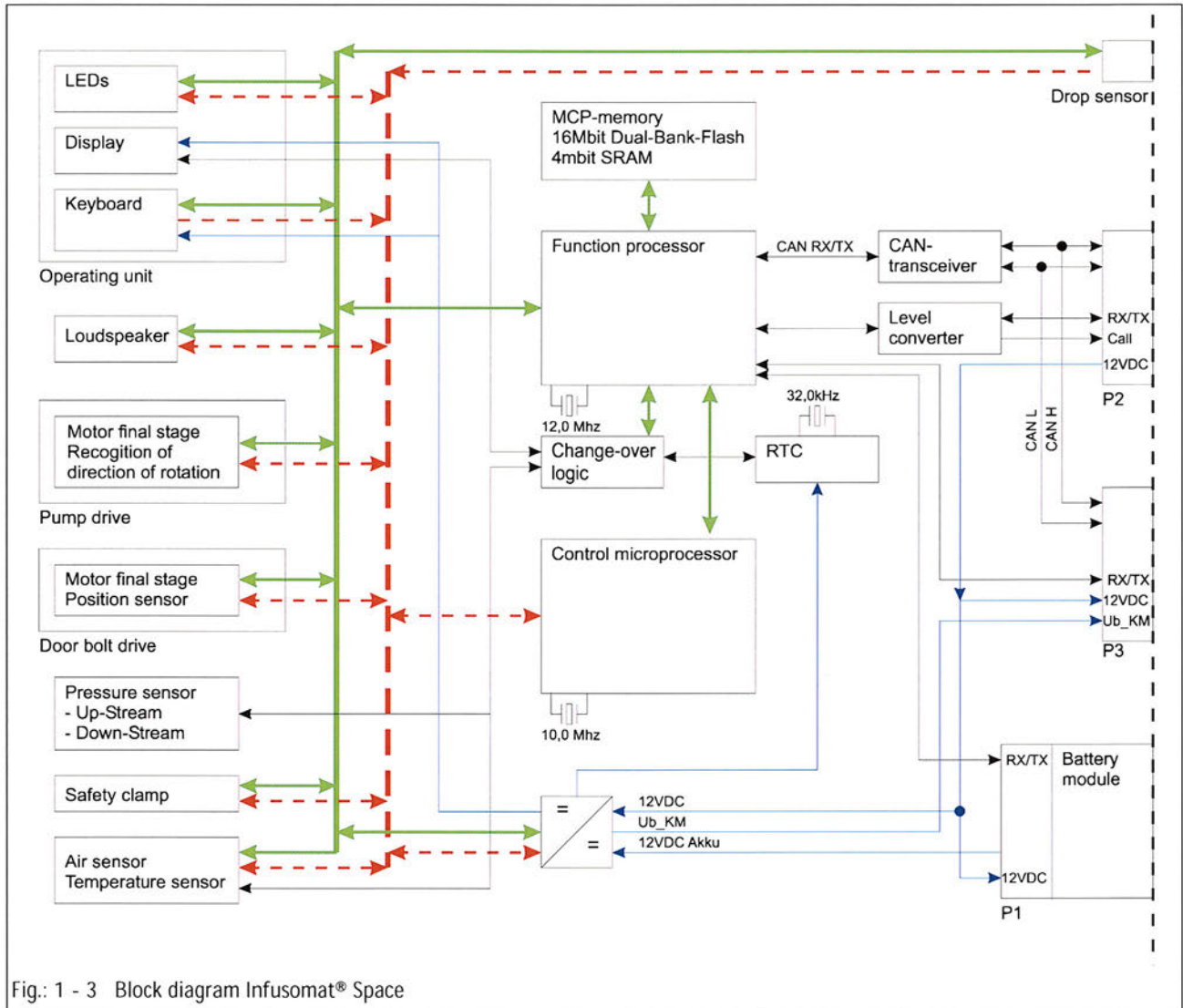
The hexagon socket of the emergency unlocking plug is tapered to the inside. If the emergency unlocking crank is not inserted until stop, the hexagon socket may be damaged.

4. Turn the emergency unlocking plug carefully with the emergency unlocking crank through 90° to the right (clockwise in arrow direction) until stop and remove the plug out of the housing.
5. Insert the emergency unlocking crank in the housing opening. The crank must be pushed in the hexagon socket of the door bolt drive.

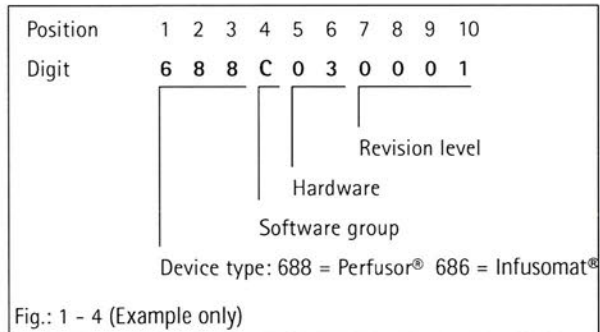
CAUTION

Make sure that the emergency unlocking crank is not turned beyond the stop by force.

6. Turn the emergency unlocking crank to the right (clockwise according to arrow direction) until the operating unit is released and opens.



Unit Software



Approved Software Versions

- **686E030003** - Initial Release
- **686F030005** - Enhanced display features.
- **686F030007** - Enhanced display features.

Software Update of the Unit

The instructions for updating the software are supplied with the software itself.

CAUTION

If the device is disconnected while the software is being updated or the device or PC is switched off, a component of the software may be seriously damaged so that repairs are no longer possible. In such a case the software cannot be updated via the PC and the device must be returned to B. Braun.

Service Program

Approved Version

Note

Please note that text and / or functions of the Service Program may change depending on the software version. The following screen illustrations are only examples and represent the state when the manual was printed.

- HiBaSeD 3.1.0 - for 686E030003
- HiBaSeD 4.0.0 - for 686F030005
- HiBaSeD 4.0.1 - for 686F030007

HiBased Service and Update CD.....FZ8912

Starting the Service Program

Note

Installation and further operation of the Service Program is described in its separate instructions for use.

1. Start the "HiBaSeD.exe" program (History, Barcode, Service, Drug list) on the PC. The Service Program is loaded and started and the initial window of the Service Program is displayed.
2. Read the notes carefully.
3. Mark the field "I accept all conditions" and then the field "Yes" to confirm that you have read the notes.

Note

Click the field "English" to switch the language of the notes over to English.

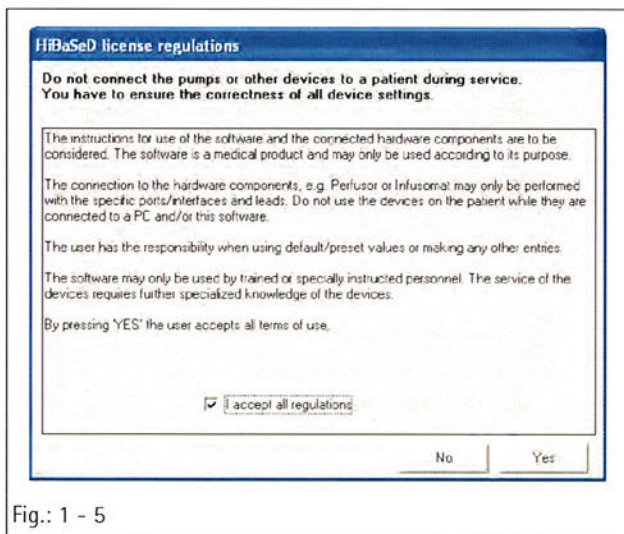
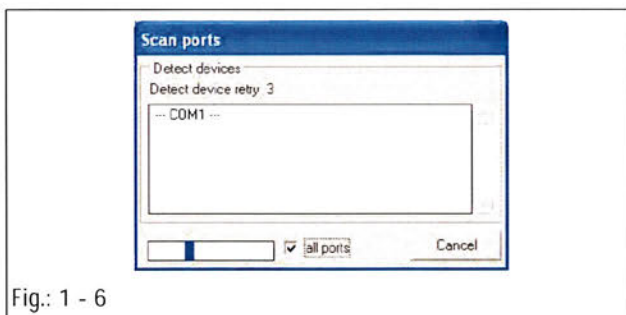
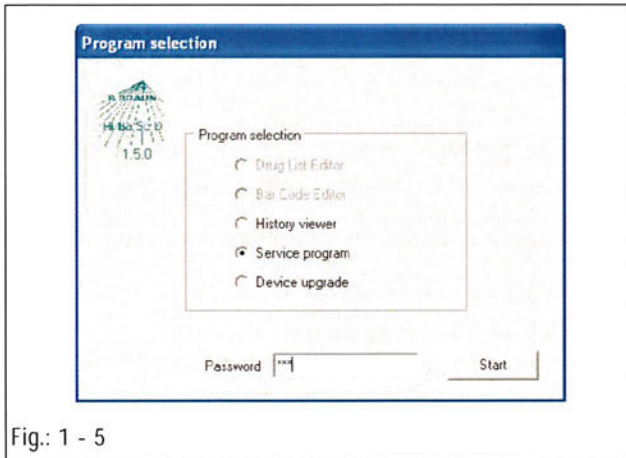


Fig.: 1 - 5

4. Enter the password and confirm it by clicking the field "Start".



The Service Program checks the PC interfaces for connected devices of the Space system. Units that were found are displayed for a short moment on the screen.

The work window of the Service Program appears on the screen. All devices recognized are listed in the left column.

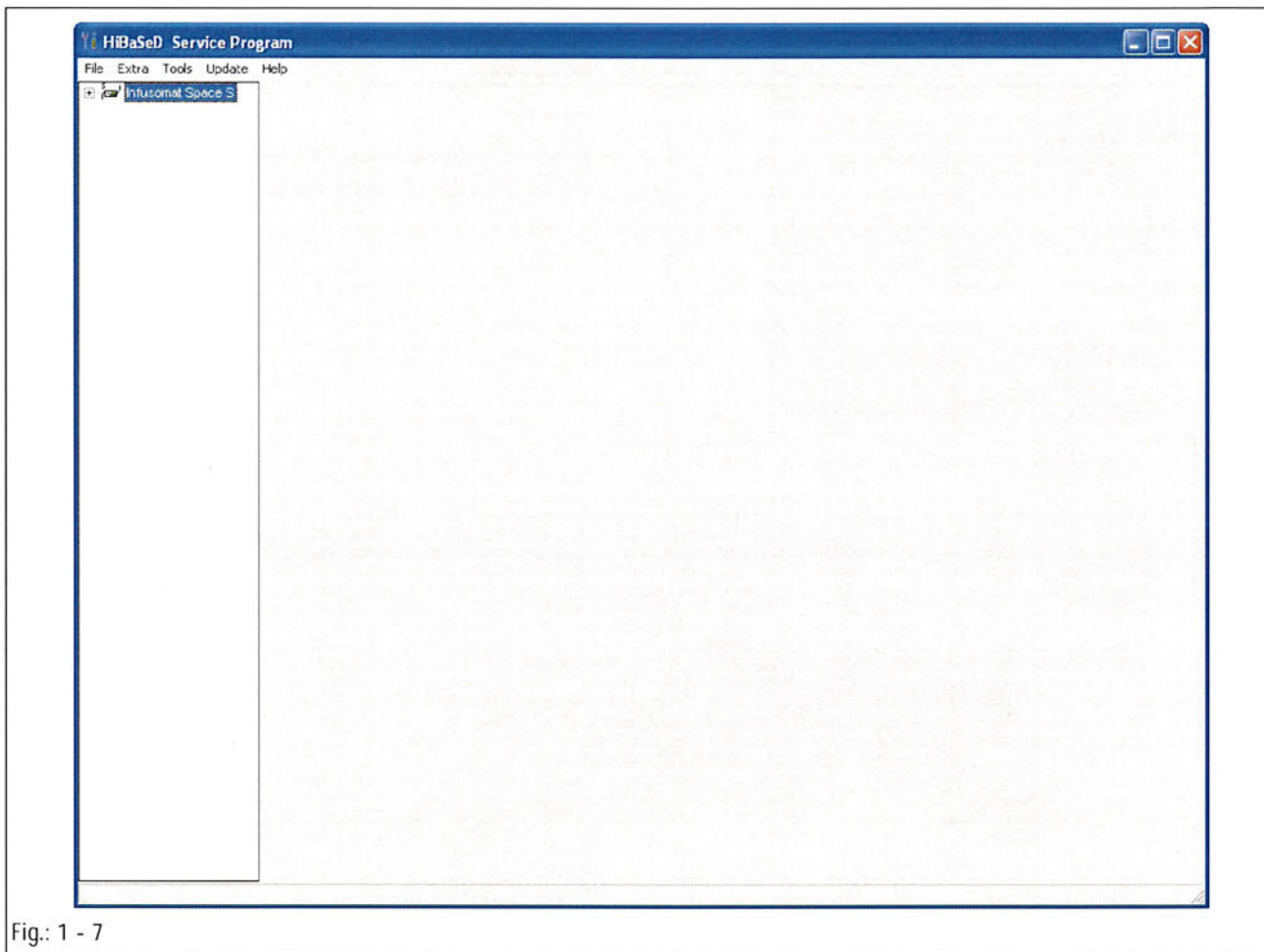


Fig.: 1 - 7

5. Activate the desired device from the list on the left in the work window with a double-click. The device data is then displayed below the device name.

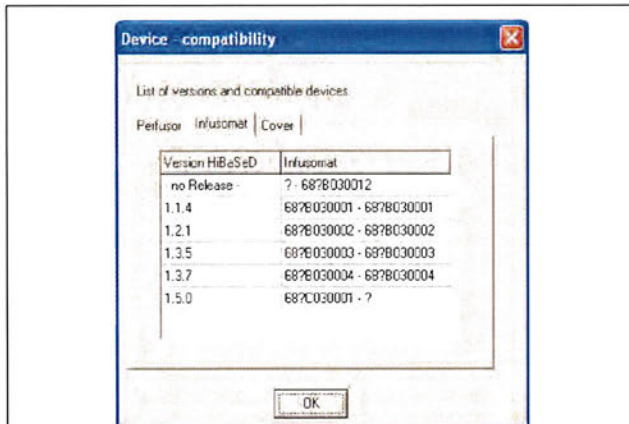


Fig.: 1 - 8

If the unit software version is not compatible with the Service Program version, a window opens prompting the operator to change the Service Program version. This window displays a compatibility list of the Service Program- and unit software versions.

If Service Program- and unit software versions are compatible, all the Service Program functions are activated.

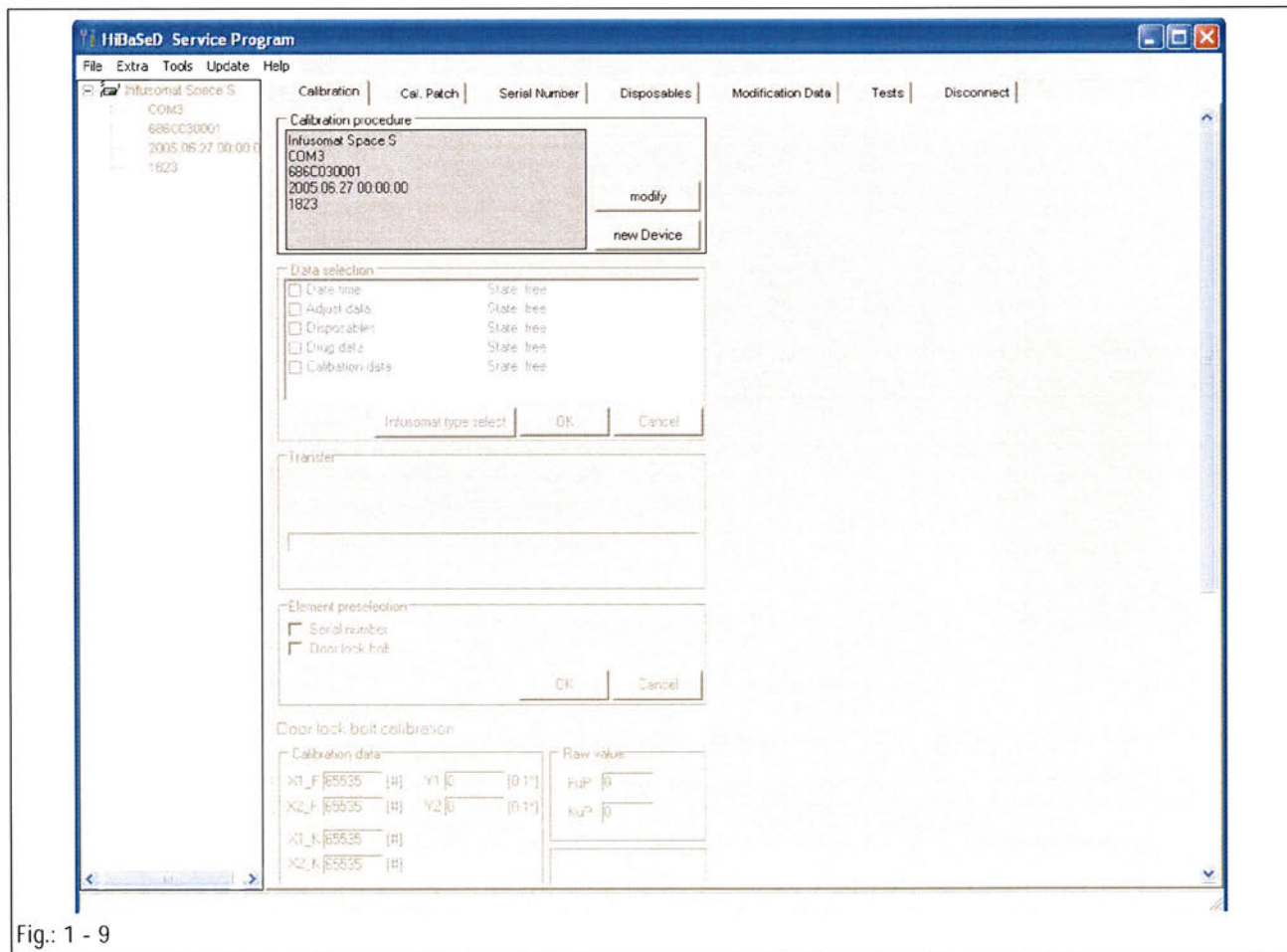


Fig.: 1 - 9

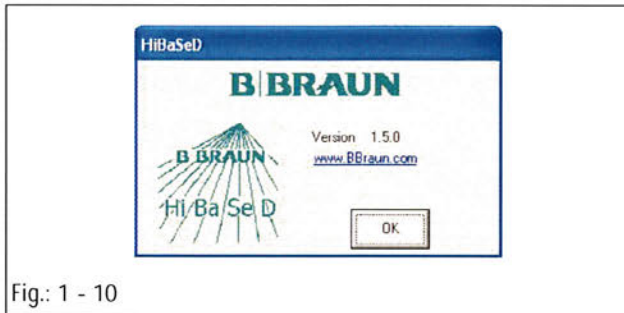


Fig.: 1 - 10

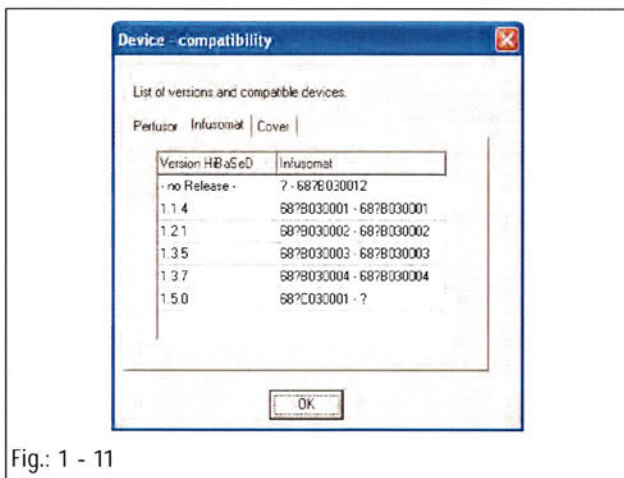


Fig.: 1 - 11

Service Program Version

1. Open the "HiBaSeD" window via **Help** ➔ **Info ...**. The current version of the Service Program is shown in this window.
2. Close the window by clicking "OK".

Compatibility List

1. Open the "Unit - Compatibility" window via **Help** ➔ **Com-
patibility**. This window displays the compatibility of the Hi-
BaSeD-version and the unit software version.
2. Close the window by clicking "OK".

Quit the Service Program

1. Exit the Service Program via **File** ➔ **Exit**.
2. Disconnect a power supply which might be connected from the unit.
3. Switch off the unit.
4. Remove the battery module.
5. The device can be restarted after appr. 10 seconds.

Technical Data

All technical data is indicated in the instructions for use.

Options

The functions of the individual options are detailed in the instructions for use.

Infusomat® Space

Designation	Part No.:
Power supply USA /	0871 3112A

Accessories

Designation	Part No.:
Charger SP	0871 3170
battery charging station	
Connection cable staff call SP.....	0871 3232
Power supply cable 12 V	0871 3231
for ambulance cars	
CombiLead SP 12 V	0871 3133
connection cable, pump - pump	
InterfaceLead SP	0871 3230
interface cable CAN SP	
Drop Sensor SP	0871 3175
PoleClamp SP	0871 3130
The PoleClamp is a holder for one or several Space system pumps.	
Short stand SP	0871 3135

General

WARNING

WHILE TESTING THE UNIT AND TROUBLE SHOOTING THE OPERATOR/SERVICE TECHNICIAN MUST WORK WITH VOLTAGES OF UP TO 115 / 230 V AC. THESE VOLTAGES MAY CAUSE INJURIES WHICH ARE DANGEROUS TO LIFE AND LIMB. THE NATIONAL AND INTERNATIONAL SAFETY REGULATIONS ARE TO BE ADHERED TO.

Before each disassembly and assembly of a unit subsystem check the connectors, plug contacts and connections for corrosion and tight fit. These fault types are not described again in the following trouble shooting list.

The following equipment and gauges are necessary for testing the unit and/or performing troubleshooting:

- PC
- Service connector Space
- Service Program HiBaSeD
- Interface cable

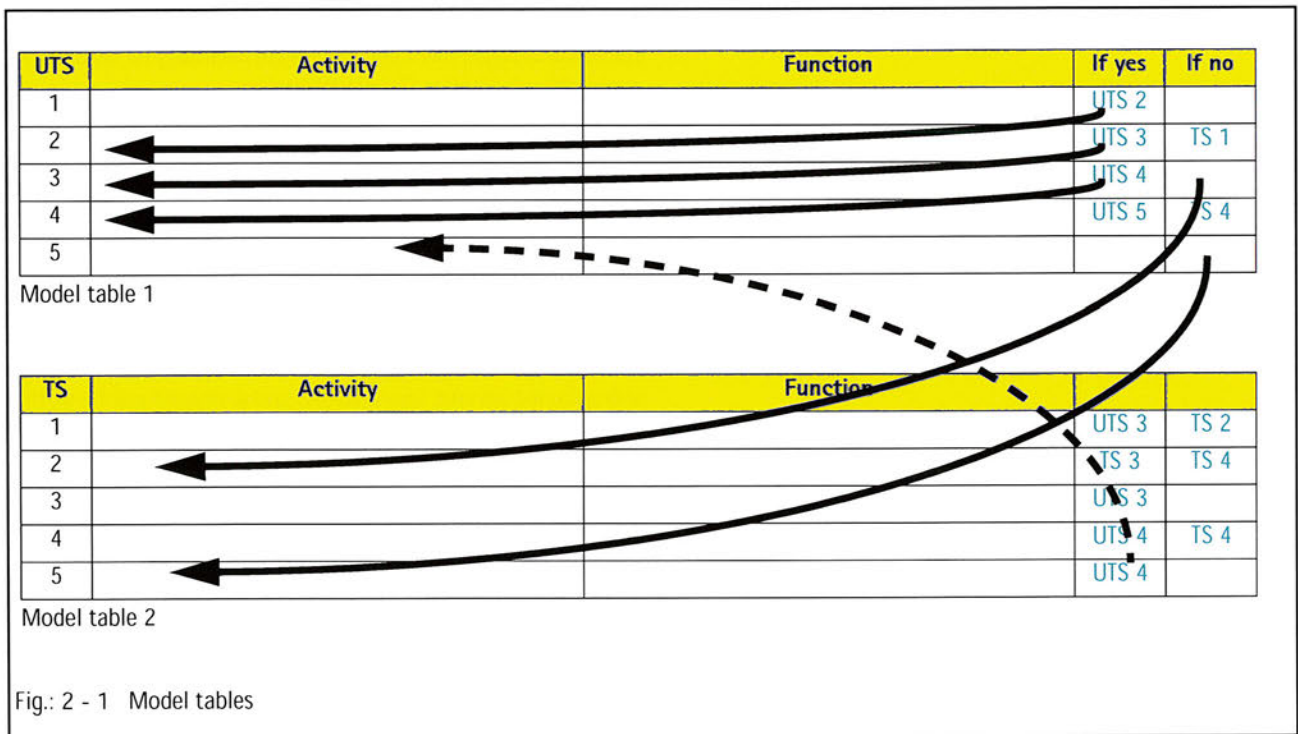
CAUTION

Take special care when carrying out measurements on an open and switched-on unit. Short circuits and wrong measuring methods can cause serious damage to or destroy the subsystems of the device.

The unit check, calibration and trouble shooting are subdivided into numbered working steps (Unit Test Step UTS, Calibration Step CS, Trouble Shooting TS) and are based on each other.

Beginning with UTS 1 the operation described here has to be executed. The consequences of the steps performed are listed in the "Function" column. If the result corresponds to the consequence, the working step must be carried out to which reference is made in the column "If yes". If the result does not correspond with the function described, the working step in column "If no" is to be executed.

One example is given in Fig.: 2 - 1.



Steps for which additional information is required are described after the table in detail.

Alarms and Error Codes

The alarms of the Infusomat® Space are classified in 5 categories. These categories are listed hereafter according to their importance.

- Alarm advice
In case of unacceptable inputs corresponding messages are displayed (e.g. "Caution! Rate out of range", "The parameter cannot be changed") and a beep sounds.
- Pre-alarm
Pre-alarms are triggered several minutes (depending on the service settings) before the operating alarms.
- Reminder alarm
A reminder alarm is triggered if the device is not operated for two minutes when input or operation was not finished.
- Operating alarm
In case of an operating alarm the infusion is stopped. An audible signal is released, the red LED flashes and a staff call is triggered. The message "Alarm" and the cause of the alarm appear on the display.
- Device alarm

The most important alarms and error codes as well as their meaning and possible fault clearance are specified in the following lists.

Note

The device should be checked after every repair or service (see „Device Check“ ➔ p. 2 - 9).

Alarms

	Alarm	Possible Cause	Fault Clearance
1	Battery nearly discharged (type: pre-alarm)	The device was not connected to the mains long enough	Connect device to the supply voltage via the AC adaptor plug. Start battery maintenance by pressing "OK", if this message is displayed when the device is switched off.
		Battery module defective or too old	<p>WARNING</p> <p>THE FOLLOWING ACTIVITY MUST NOT BE CARRIED OUT WHEN A PATIENT IS CONNECTED TO THE UNIT.</p> <hr/> <p>Operate the device with battery until the message "Battery discharged" is displayed and the unit is switched off. Then connect the unit to the mains for at least 6 hours.</p>
2	Battery discharged (type: operating alarm)	The device was not connected to the mains long enough	Connect the unit to the mains for at least 6 hours
		Battery module defective	Replace battery module
3	Battery cover open (type: operating alarm)	<input type="checkbox"/> The battery compartment cover is not correctly closed	Insert the battery compartment cover correctly
		<input type="checkbox"/> The magnet in the battery compartment cover is missing	Exchange the battery compartment cover
		<input type="checkbox"/> The battery compartment cover is not recognized by the battery module	Replace battery module
4	Device alarm (type: device alarm)	A serious internal fault was detected in the system	Carry out a device check (see "Device Check" ➔ p. 2 - 9)

Table 2 - 1 Alarms

Device Alarms of the Function Processor

	Error Code	Definition	Possible Cause	Fault Clearance
1	2001 ... 2013	Internal Error		
2	2014	Loudspeaker not off	Loudspeaker connector Loudspeaker	Check the loudspeaker connector Check the loudspeaker
3	2015	Loudspeaker lost	Loudspeaker connector Loudspeaker	Check the loudspeaker connector Check the loudspeaker
4	2016	Loudspeaker shorted	Loudspeaker connector Loudspeaker	Check the loudspeaker connector Check the loudspeaker
5	2017	KUP no work	Software defective or obsolete	Update software, change ISP processor PCB if necessary
6	2018	FUP-KUP OS Cycle Timeout	Software defective or obsolete	
7	2019	FUP Flash Memory Error	Software defective or obsolete	
8	2020	FUP different version KuP to FuP	Software defective or obsolete	
9	2021	FUP UPSTREAM TOO HI	Upstream pressure sensor defective	Replace sensor
10	2022	FUP UPSTREAM TOO LOW	Upstream pressure sensor defective	
11	2023	FUP DOWNSTREAM TOO HI	Downstream sensor defective	
12	2024	FUP DOWNSTREAM TOO LOW	Downstream sensor defective	
13	2025	FUP EA key closed to long	Keyboard defective	Exchange operating unit
14	2026	FUP Task inactive		
15	2027	FUP Airsensor CALDATA CRC	Air inline sensor defective	Replace sensor
16	2028	FUP Airsensor PROGDATA CRC	Air inline sensor defective	Replace sensor
17	2029	FUP Airsensor Calibration Error	Air inline sensor defective	Replace sensor
18	2030	No Airtest Kup	Air inline sensor defective	Replace sensor
19	2031	FUP Temperature Sensors difference	Air inline sensor defective	Replace sensor
20	2032	FUP Temperature Raw Values difference	Air inline sensor defective	Replace sensor
21	2033	FUP Airsensor Signature Error	Air inline sensor defective	Replace sensor
22	2034	FUP CAN packet scheduler list failure	Communication error on CAN-interface	Switch device off and on
23	2035	Light barrier or motor defect/turn backwards	Light barrier defective	Exchange processor PCB
24	2036	FUP Language Flash Memory Error	Language file faulty	Update software
25	2037	FUP Language Version Error	Language file faulty	Update software
26	2038	FUP CRC Task inactive	Communication error on CAN-interface	Switch device off and on

Table 2 - 2 Device alarms of the function processor

Device Alarms of the Control Microprocessor

	Error Code	Definition	Possible Cause	Fault Clearance
1	2100	Timebase too fast	Quartz of the processor PCB	Exchange processor PCB
2	2101	Timebase too slow	Quartz of the processor PCB	Exchange processor PCB
3	2102	Timebase fail	Quartz of the processor PCB	Exchange processor PCB
4	2103	Keyboard High	Keyboard defective	Carry out device check
5	2104	EA_KEY defect 25sec	Keyboard defective	Carry out device check
6	2105	No keydecode	Keyboard defective	Carry out device check
7	2106	ROM Romtest defect	Software	Update unit software
8	2107	ROM Program defect		
9	2109	MPU_Test failed		
10	2110	RAM_Test failed		
11	2111	KUP active reset	Voltage supply during operation interrupted	
12	2112 ... 2114	Internal Error		
13	2115	Drive too fast	Motor drive Recognition of direction of rotation	Exchange processor PCB
14	2116	Drive too slow	Motor drive Recognition of direction of rotation	Exchange processor PCB
15	2117 ... 2118	Internal Error		
16	2119	lcd backlight on defect	LC display defective	Exchange operating unit
17	2120	lcd backlight off defect	LC display defective	Exchange operating unit
18	2121	red led on defect	LC display defective	Exchange operating unit
19	2122	red led off defect	LC display defective	Exchange operating unit
20	2123	key pressed too long (without EA-Key) 60sec	Keyboard defective	Carry out device check
21	2124 ... 2127	Internal Error		
22	2128	Drive motion rightless forward	Motor drive Recognition of direction of rotation	Exchange ISP processor PCB
23	2129	Drive motion rightless backward		
24	2130 ... 2200	Internal Error		
25	2201	different version FuP to KuP	Software	Update unit software

Table 2 - 3 Device alarms of the control microprocessor (Sheet 1 of 2)

	Error Code	Definition	Possible Cause	Fault Clearance
26	2202	stepmotor PH1A not 0	Stepper motor defective	Replace pump drive motor or ISP processor PCB
27	2203	stepmotor not middle current		
28	2204	stepmotor K_SM_CLK		
29	2205	stepmotor PH1A not 1		
30	2206	stepmotor not zero current		
31	2207	stepmotor not middle current		
32	2208	stepmotor not high current		
33	2209	stepmotor PH1A, PH1B, PH2A, PH2B not 0		
34	2210	K_PKM_UB not off	Door bolt drive defective	Replace door bolt drive or ISP processor PCB
35	2211	K_PKM_UB not on		
36	2215	no V_MOT	Processor PCB defective	Exchange ISP processor PCB
37	2216	overvoltage test fail		
38	2217	no V_MOT		
39	2218	undervoltage test fail		
40	2220	door poti defect	Door bolt drive (potentiometer) defective	Replace door bolt drive
41	2221	tube change timeout	Software defective or obsolete	Update software, change ISP processor PCB if necessary
42	2222	temperature sensor difference	Air inline sensor defective	Replace air inline sensor
43	2223	airsensor defect		
44	2224	rate compensation difference	Dose calculation error	Update unit software
45	2225	rate compensation max value		
46	2226	rate compensation min value		
47	2227	received Airdata defect	Air inline sensor defective	Replace air inline sensor
48	2228	defect temperature sensor switch		
49	2229	FuP not stopped by KuP alarm	Software defective or obsolete	Update software, change ISP processor PCB if necessary
50	2230	drive totphase is defective	Software defective or obsolete	Update software, change ISP processor PCB if necessary
51	2231	tube data set is defective	Software defective or obsolete	Update software, change ISP processor PCB if necessary
52	2237 ... 2255	Internal Error		

Table 2 - 3 Device alarms of the control microprocessor (Sheet 2 of 2)

The Most Important Error Modes

The following list specifies the most important error modes and their clearance.

Note

The device must be checked after every repair or service (see "Device Check" ➔ p. 2 - 9).

	Error	Possible Cause	Fault Clearance
1	The battery module discharges too fast	The device was not used for a longer time. The battery module was not discharged and charged at regular intervals.	<input type="checkbox"/> Discharge and charge battery module several times <input type="checkbox"/> Replace battery module
2	Pump drive runs continuously	Light barrier defective	<input type="checkbox"/> Exchange processor PCB
3	Noise during opening or closing the operating unit	Toothed wheels in door bolt drive defective	<input type="checkbox"/> Replace door bolt drive
4	Device alarm 2027	Air inline sensor defective	<input type="checkbox"/> Replace air inline sensor (air inline sensor optimized from serial number 3050 on)
5	Device alarms 2021 ... 2022	Upstream pressure sensor defective	<input type="checkbox"/> Replace upstream pressure sensor
6	Device alarms 2023 ... 2024	Downstream sensor defective	<input type="checkbox"/> Replace downstream pressure sensor
7	Device alarm 2119	Manufacturing tolerance of the LC-display too high	<input type="checkbox"/> Exchange ISP processor PCB (optimized from serial number 3050 on)

Table 2 - 4

Device Check

UTS	Activity	Function	If yes	If no
1	The device is inserted in a SpaceStation or connected to a SpaceControl.		UTS 2	UTS 3
2	Remove the device.		UTS 3	
3	Loosen all connections from the device.		UTS 4	
4	Plug service connector Space on connector "P2".		UTS 5	
5	Connect power supply to the device via service connector Space.	All LEDs light up for a short moment.	UTS 6	TS 1
6		The battery charge state and the mains connection are displayed at the top left of the LC display (without lighting).	UTS 7	TS 5
7	Switch on unit.	All LEDs light up (from left: yellow, green, blue).	UTS 8	TS 5
8		A short deep and then a short high beep sound.	UTS 9	TS 7
9		The colour of the middle LED changes from green to red, then the LED goes out. The yellow and the blue LED remain on for a short moment.	UTS 10	TS 8
10		The message "Self-test active" and the current software version are displayed.	UTS 11	TS 8
11		The keyboard and the LC display are lighted.	UTS 12	TS 9
12		"Open door and insert line or press "C" to input parameters" is displayed.	UTS 13	TS 10
13	Press button to open the operating unit and confirm.	The door bolt unlocks the operating unit which then opens.	UTS 14	TS 11
14		The safety clamp is opened and the caution sign at the front of the unit flashes yellow.	UTS 17	UTS 15
15	Open safety clamp.	The operating lever of the safety clamp can be pressed down uniformly against spring tension and engages.	UTS 16	TS 14
16		The caution sign at the front of the unit flashes yellow.	UTS 17	TS 15
17	Insert an air-filled Infusomat® Space line and close operating unit.	The operating unit is tightened by the door bolt and then fixed.	UTS 18	TS 18
18		The line selection menu appears on the LC display.	UTS 19	TS 18

Table 2 - 5 Device check (Sheet 1 of 3)

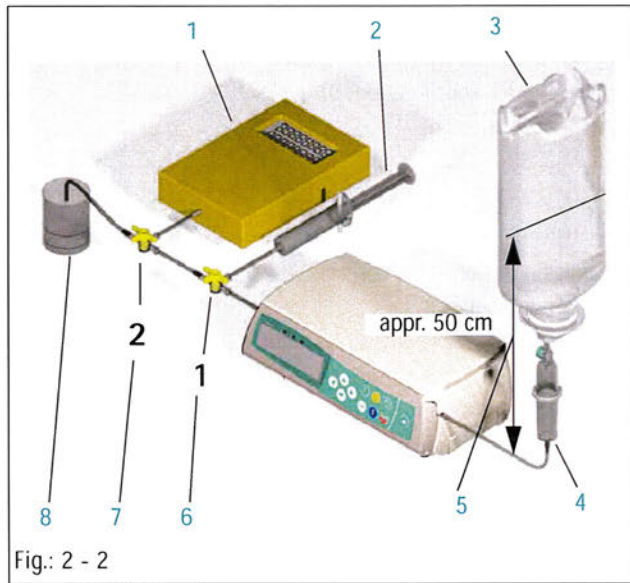
UTS	Activity	Function	If yes	If no
19	Press the ">" key.	The following Service info is displayed, incl.: - air inline sensor: _____ The value displayed (air value) is within the specifications of the TSC. - Temp1: _____ - Temp2: _____ The difference of the values displayed is within the specifications of the TSC.	UTS 20	TS 20
20	Remove the air-filled Infusomat® Space line out of the device.		UTS 21	
21	Prepare test setup (see "Test Setup" ➔ p. 2 - 12) and set three-way valves as shown in Fig.: 2 - 3.		UTS 22	
22	Insert the Infusomat® Space line of the test setup and close operating unit.	The line selection menu appears on the LC display.	UTS 23	
23	Select line type.	"Vent line - 16 ml?" is displayed.	UTS 24	TS 23
24	Confirm venting by pressing "Yes".	You can hear the pump as it is delivering and the line is vented.	UTS 25	TS 25
25	Pull out the service connector Space.		UTS 26	
26	Input a delivery rate for upstream as specified in the TSC and any volume, select the first pressure stage according to the TSC and start infusion.		UTS 27	
27	Close the roller clamp of the Infusomat® Space line or squeeze the Infusomat® Space line between container and pump.	The message "Alarm / Check supply" is displayed.	UTS 28	
28	Acknowledge alarm and open roller clamp.		UTS 29	
29	Input a delivery rate for downstream according to the TSC and start infusion.		UTS 30	
30	Set three-way valves as shown in Fig.: 2 - 4.	When the maximum pressure of this pressure stage is reached, the delivery is stopped, the red LED on the operating unit flashes and the message "Alarm / Pressure too high" is displayed. The maximum value read on the pressure gauge must correspond with the specification of the TSC for the respective pressure stage.	UTS 31	
31	Confirm alarm.		UTS 32	

Table 2 - 5 Device check (Sheet 2 of 3)

UTS	Activity	Function	If yes	If no
32	Select the second pressure stage according to the TSC and start infusion.	When the maximum pressure of this pressure stage is reached, the delivery is stopped, the red LED on the operating unit flashes and the message "Alarm / Pressure too high" is displayed. The maximum value read on the pressure gauge must correspond with the specifications of the TSC for the respective pressure stage.	UTS 33	
33	Confirm alarm.		UTS 34	
34	Select the third pressure stage according to the TSC and start infusion.	When the maximum pressure of this pressure stage is reached, the delivery is stopped, the red LED on the operating unit flashes and the message "Alarm / Pressure too high" is displayed. The maximum value read on the pressure gauge must correspond with the specification of the TSC for the respective pressure stage.	UTS 35	
35	Confirm alarm.		UTS 36	
36	Plug service connector Space on connector "P2".		UTS 37	
37	Open operating unit for a short moment and close it again.		UTS 38	
38	Press the „>“ button on the LC display in the "Line selection" menu.	The following Service info is displayed, incl.: - air inline sensor: _____ The value displayed (water value) is within the specifications of the TSC.	UTS 39	TS 27
39	Dismantle the test setup.		UTS 40	
40	Switch device off.	The message "Pump is switched off in 1 .. 2 .. 3 sec" is displayed.	UTS 41	
41		The device switches off.	UTS 42	
42	Pull off the power supply.	The blue LED lights up for a short moment and the LC-display is getting dark.	UTS 43	
43	Switch on unit.		UTS 44	
44	Remove battery.	A permanent alarm (high beep) sounds.	UTS 45	
45	Insert battery and switch on the device.	The message "Devicealarm / 2111" is displayed.	UTS 46	
46	Switch device off.		This step terminates the device check.	

Table 2 - 5 Device check (Sheet 3 of 3)

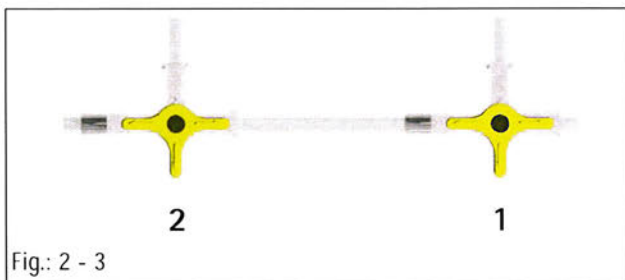
Procedural Instructions for the Device Check



Legend to fig. 2 - 2:

Item Designation

- 1 Electronic pressure gauge
- 2 10 ml syringe (piston fixed)
- 3 Infusion bottle (min. 100 ml)
- 4 Infusomat® Space line, standard type
- 5 Distance between liquid level and middle of the Infusomat® Space line
- 6 Three-way valve 1
- 7 Three-way valve 2
- 8 Graduated cylinder



Test Equipment

Designation

- Infusomat® Space line, standard type (new, unused) (1 piece)
- Infusion bag or -bottle, min. 100 ml (1 piece)
- Three-way valve (2 pieces)
- 10 ml syringe (air buffer for measurement with electronic pressure gauge) (1 piece) (syringe drawn up to 10 ml and piston fastened mechanically)
- Electronic pressure gauge with peak value recognition or barometric cell (1 piece)
- Graduated cylinder 25 ml, $\pm 0,4$ ml (1 piece)

Test Setup

1. Mount test setup as shown in Fig.: 2 - 2.

Note

The liquid level in the container must be appr. 50 cm above the middle of the unit opening for the Infusomat® Space line.

2. Vent.

3. Measure pressure.

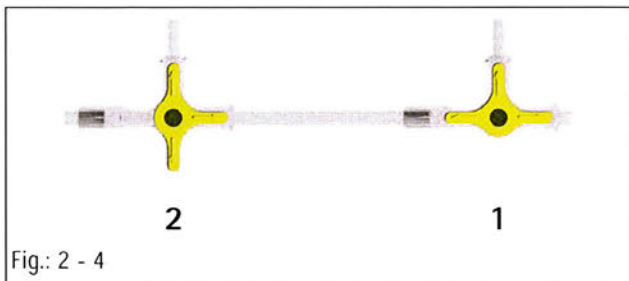


Fig.: 2 - 4

Calibration

CS	Activity	Function	If yes	
1	Connect unit to PC with interface cable.		CS 2	
2	Start Service Program on the PC (see "Starting the Service Program" ➔ p. 1 - 9).	The desired device is found by the Service Program and then displayed.	CS 3	
3	Start calibrating the unit (see "Procedural Instructions for Calibration" ➔ p. 2 - 13).		CS 4	
4	Close the Service Program (see "Quit the Service Program" ➔ p. 1 - 13).			

Table 2 - 6 Calibration

Procedural Instructions for Calibration

Test Equipment

Designation

Slide clamp
(of the Infusomat®Space line)

Procedure

Note
Calibration must be carried out with power supply connected, since the calibration can be interrupted suddenly if the unit is battery-operated and the battery gets discharged so that the device is switched off.

Note
Please note that text and / or functions of the Service Program may change depending on the software version. The following screen illustrations are only examples and represent the state when the manual was printed.

1. Start the Service Program (see "Starting the Service Program" ➔ p. 1 - 9).
2. Select the register tab "Calibration".

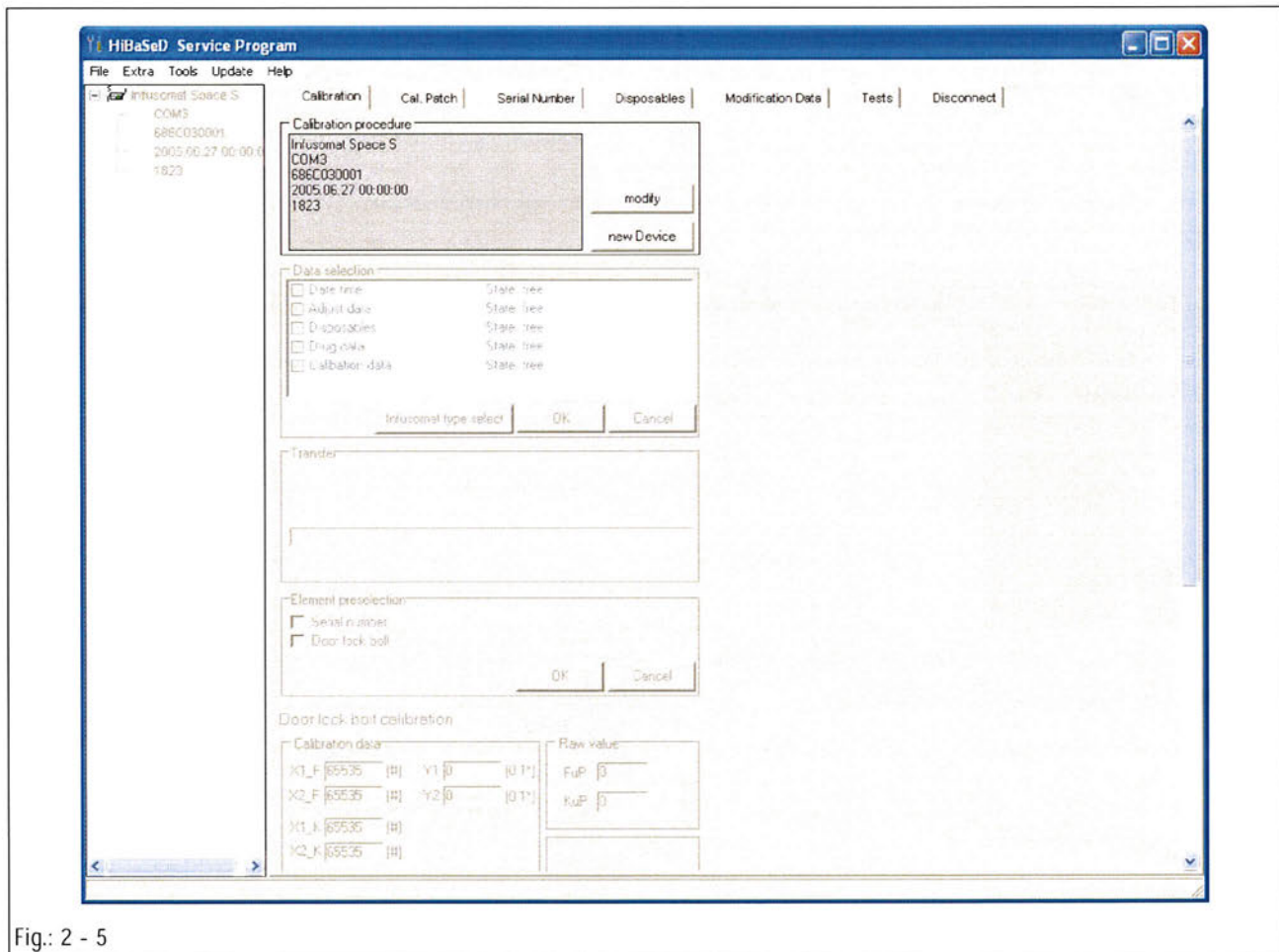


Fig.: 2 - 5

3. Press the "New device" button in the frame "Calibration procedure". The window "User number" is opened.

Note

If you do not have an allocated user number, enter "0001".

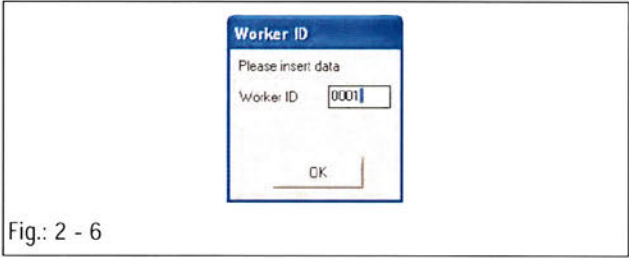


Fig.: 2 - 6

4. Input your user number in the window "User number" as well as the six-digit serial number of the device, if necessary.
5. Confirm the input with "OK". The frame "Data selection" is now activated.

Note
 If HiBaSeD could not clearly read the device serial number, the number must be entered according to the rating plate.

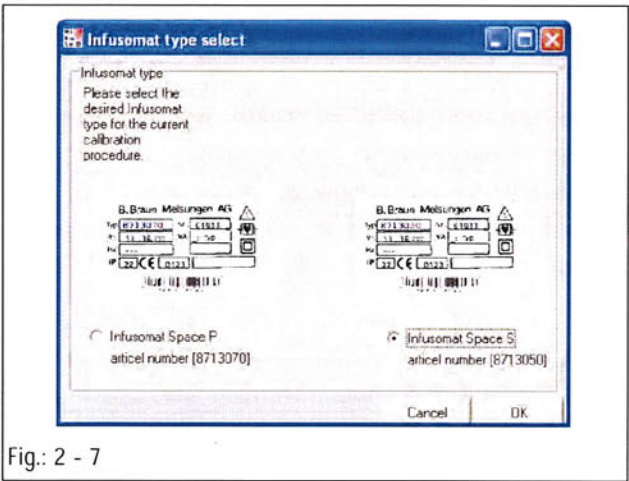


Fig.: 2 - 7

6. If the device type was not clearly recognized, the user is prompted to select a device type. Select the device type by clicking the flag with the mouse.

Note
 The device type can be defined via the article number. This article number is indicated on the rating plate.

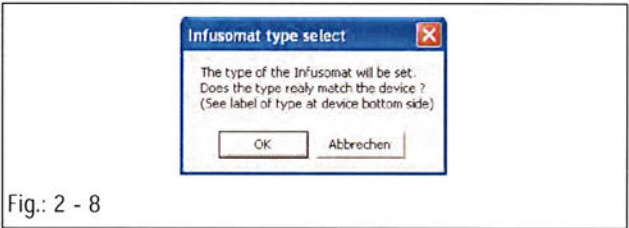


Fig.: 2 - 8

7. Click the "OK" button. You are prompted to confirm the selection again.

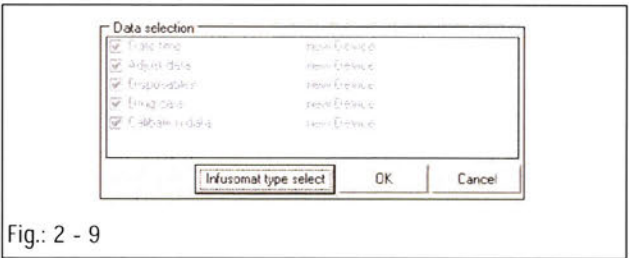


Fig.: 2 - 9

8. Click the "OK" button.
9. Start calibration with the "OK" button. You are prompted to press the blue connection key on the device.



Fig.: 2 - 10

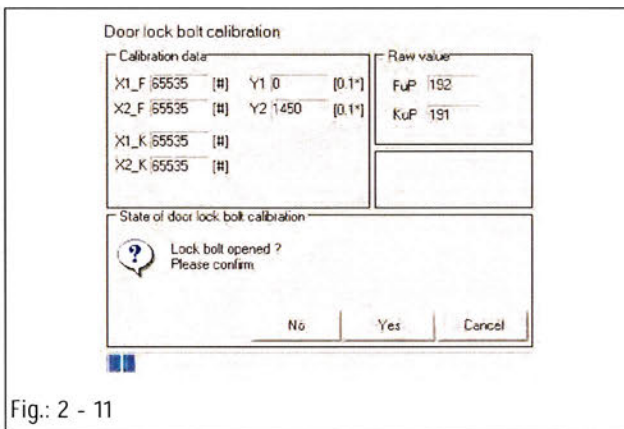


Fig.: 2 - 11

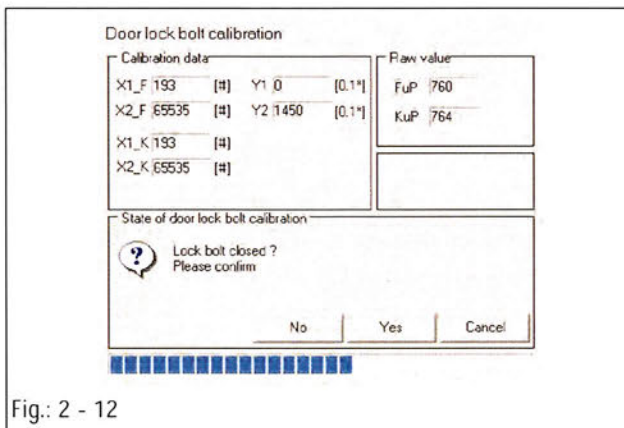


Fig.: 2 - 12

10. Press the blue connection key. All device data is read out and stored in the PC. The frame "Door bolt calibration" is now activated and the door bolt is moved in the open position.

11. Check the position of the door bolt in the device. The door bolt lugs must not be visible in the three openings. It must be possible to tilt the operating unit nearly in the closed position (gap between upper edge of the operating unit and upper edge of the housing top is about 5 mm).

12. Check the gap and confirm the door bolt position by pressing the "Yes" button.

13. Check the position of the door bolt in the device. The door bolt lugs are visible in the three openings. It must not be possible to tilt the operating unit in the closed position (gap between upper edge of the operating unit and upper edge of the housing top is about 10 mm).

14. Check the gap and confirm the door bolt position by pressing the "Yes" button. The door bolt is moved in the open position.

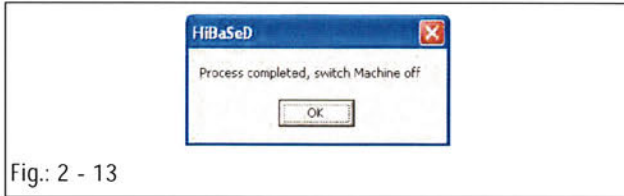


Fig.: 2 - 13

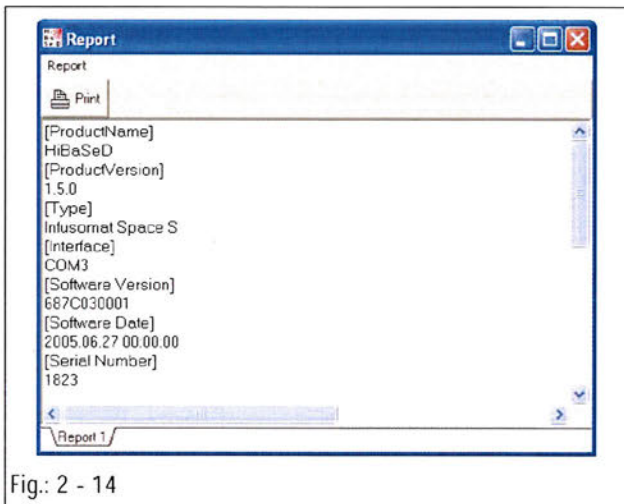


Fig.: 2 - 14

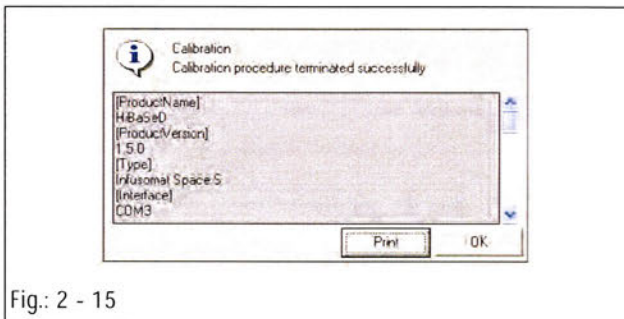


Fig.: 2 - 15

15. After calibration you are prompted to switch the device off. Disconnect all connectors from the device.
16. Switch the device off (without connection to the power supply) and press the "OK" button.
17. At the end of calibration the result with all the values is displayed in the frame "Calibration process terminated successfully" and data is stored in the unit.
This report can be printed out by pressing the "Print" button.

18. With "OK" the calibration process is terminated.

Further Trouble Shooting

Note

The following trouble shooting cannot be carried out independently. It is based on the precise observance of the steps for the device check (see "Device Check" ➔ p. 2 - 9). From there reference is made to the corresponding trouble shooting steps.

TS	Activity	Function	If yes	If no
1	Replace power supply.	All LEDs light up for a short moment.	UTS 6	TS 2
2		At least one LED lights up for a short moment.	TS 3	TS 4
3	Replace the LC display.		UTS 5	
4		A message is displayed on the LC display.	TS 6	TS 5
5	Exchange processor PCB.	All LEDs light up for a short moment and a message is displayed on the LC display.	UTS 6	TS 6
6	Exchange operating unit.		UTS 7	
7	Exchange loudspeaker and switch on unit.	A short deep and then a short high beep sound.	UTS 9	TS 8
8	Exchange processor PCB.		UTS 9	
9	Exchange operating unit.	The keyboard and the LC display are lighted.	UTS 12	TS 10
10	Exchange processor PCB.		UTS 12	
11	Replace door bolt drive.	The door bolt unlocks the operating unit which then opens.	UTS 14	TS 12
12	Exchange processor PCB.	The door bolt unlocks the operating unit which then opens.	UTS 14	TS 13
13	Exchange operating unit.		UTS 14	
14	Replace safety clamp.		UTS 16	
15	Exchange pressure sensor, downstream.	The caution sign at the front of the unit flashes yellow.	UTS 17	TS 16
16	Exchange processor PCB.	The caution sign at the front of the unit flashes yellow.	UTS 17	TS 17
17	Replace safety clamp.		UTS 17	
18	Replace door bolt drive.	The operating unit is tightened by the door bolt and then fixed.	UTS 18	TS 19
19	Exchange processor PCB.		UTS 18	
20	Replace air inline sensor.	The Service info appears on the LC display.	UTS 20	TS 21

Table 2 - 7 Trouble shooting (Sheet 1 of 2))

TS	Activity	Function	If yes	If no
21	Exchange operating unit.	The following Service info is displayed, incl.: - air inline sensor: _____ The value displayed is within the specifications of the TSC. - Temp1: _____ - Temp2: _____ The difference of the values displayed is within the specifications of the TSC.	UTS 20	TS 22
22	Exchange processor PCB.		UTS 20	
23	Exchange operating unit.	"Vent line - 16 ml?" is displayed.	UTS 24	TS 24
24	Exchange processor PCB.		UTS 24	
25	Exchange pump drive.	You can hear the pump as it is delivering and the line is vented.	UTS 25	TS 26
26	Exchange processor PCB.		UTS 25	
27	Replace air inline sensor.	The following Service info is displayed, incl.: - air inline sensor: _____ The value displayed (water value) is within the specifications of the TSC.	UTS 39	TS 28
28	Exchange processor PCB.		UTS 39	
29	Charge battery module for about 16 hours in the device with power supply connected.			
30	Replace battery module.			

Table 2 - 7 Trouble shooting (Sheet 2 of 2)

3.1 General

Remarks on Disassembly / Assembly

Before disassembling the unit, the system must be checked (see "Device Check" ➔ p. 2 - 9) to isolate the part to be exchanged.

The necessary steps to disassemble the complete unit, all its sub-systems and spare parts are detailed in the following description. Steps that are not necessary can be skipped.

Before disassembling the unit make sure that all Infusomat® Space lines are removed from the device and that the operating unit is in the open position.

CAUTION

Remove the battery module before opening the device to avoid damage to the system or the battery module through a short-circuit.

Note

Special screws for plastic housings are used in this unit. Pay attention to the corresponding notes when you fit the screws.

Preparations for Exchanging the Processor PCB

If the processor PCB is to be replaced a back-up of the pump settings is to be carried out, if this is still possible.

Note

Please note that text and / or functions of the Service Program may change depending on the software version. The following screen illustrations are only examples and represent the state when the manual was printed.

1. Start the Service Program (see "Starting the Service Program" ➔ p. 1 - 9).

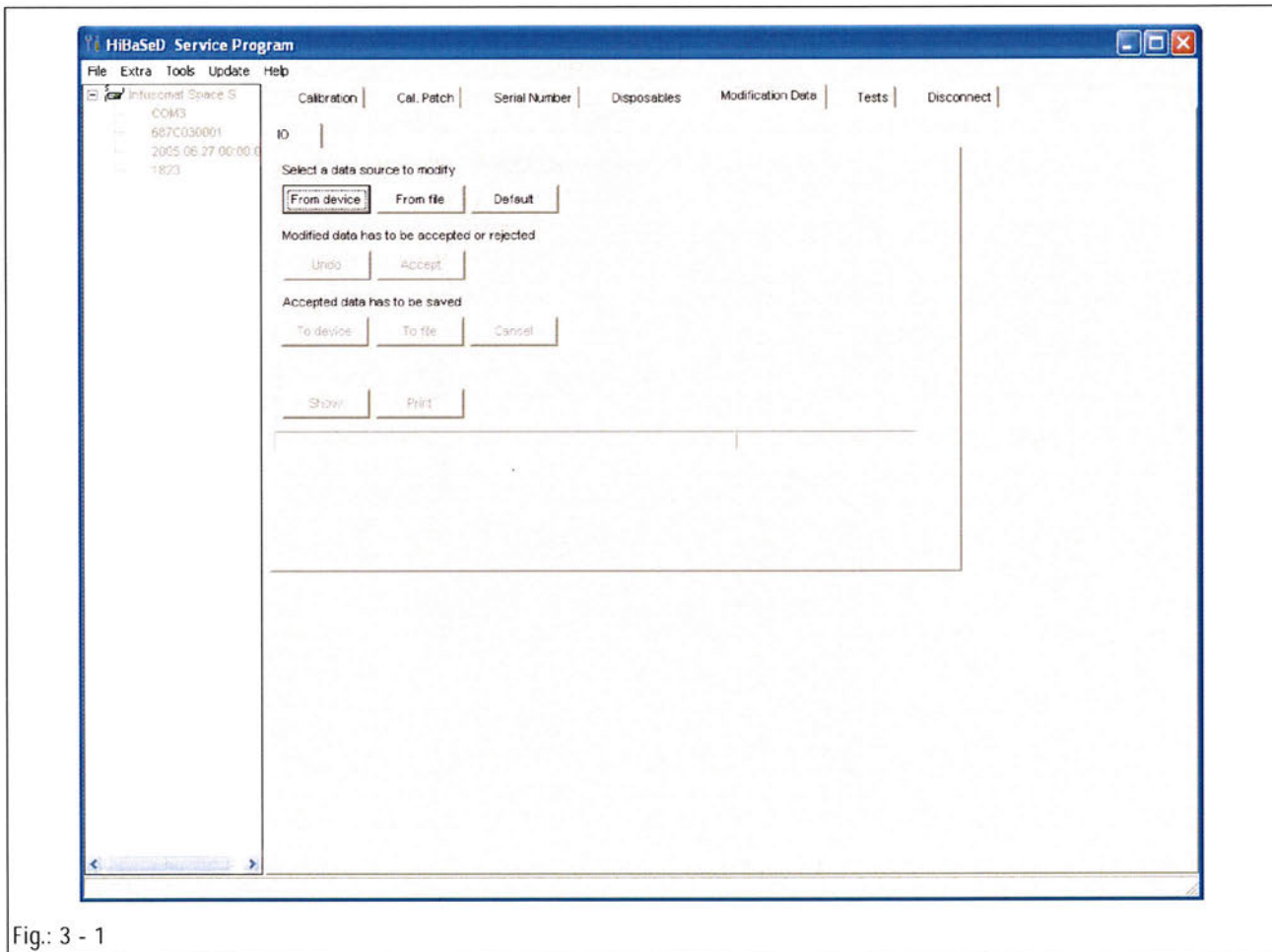


Fig.: 3 - 1

2. Select the register tab "Modification data".

3. Press the "from device" button. The data is read from the device.
4. The query "Update date and time on next transmission?" is displayed.

When the "Yes" button is pressed, date and time of the PC are transmitted together with the data to the device.

Press "No" if date and time of the device are not to be updated.

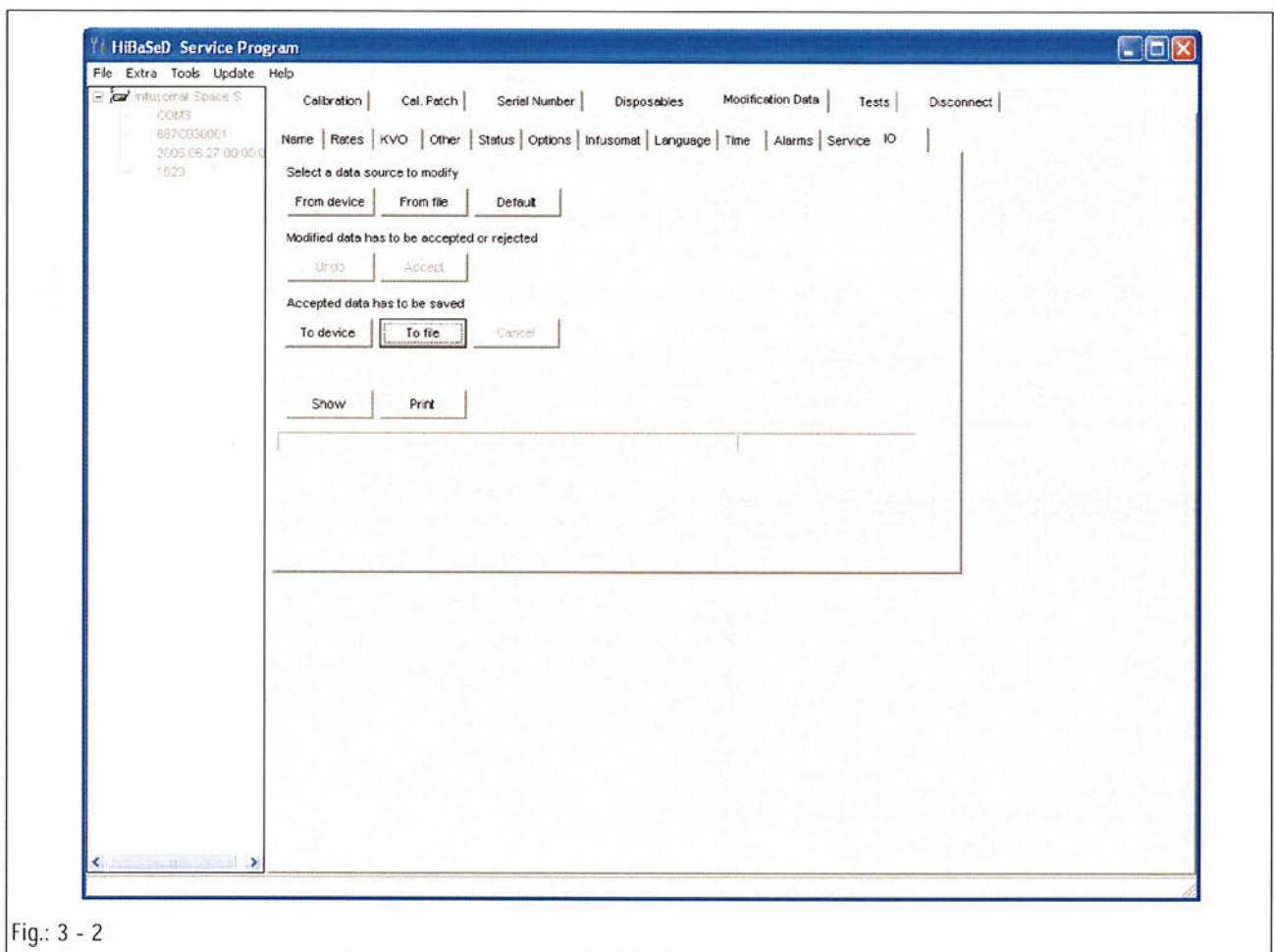


Fig.: 3 - 2

5. Press the "to file" button.
In the window which opens, you are asked for the storage file name and location of the file on the PC hard disk.

Note

The storage position which is proposed should not be changed.

6. Press the "Print" button to transmit the device data to a printer.
7. Actuate the "Display" button to display the device data on screen.

With "Close" the window is closed again.

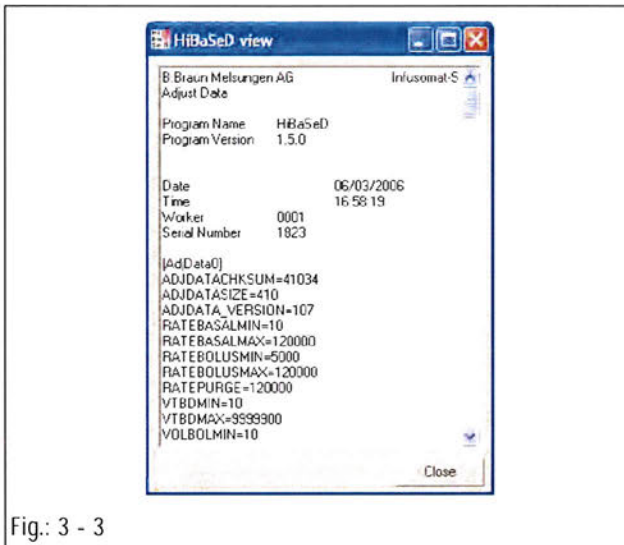


Fig.: 3 - 3

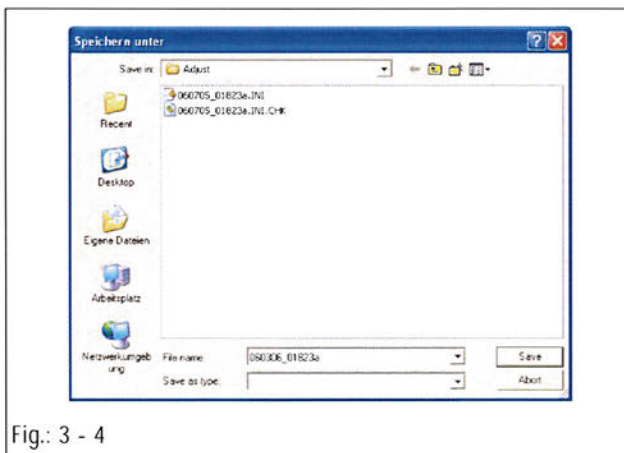


Fig.: 3 - 4

8. Select the storage position in the "Save file as" window and input a unique file name.
9. Press the "Save" button. The data of the pump is saved on the PC hard disk.

10. Select the tab "Disposable article".

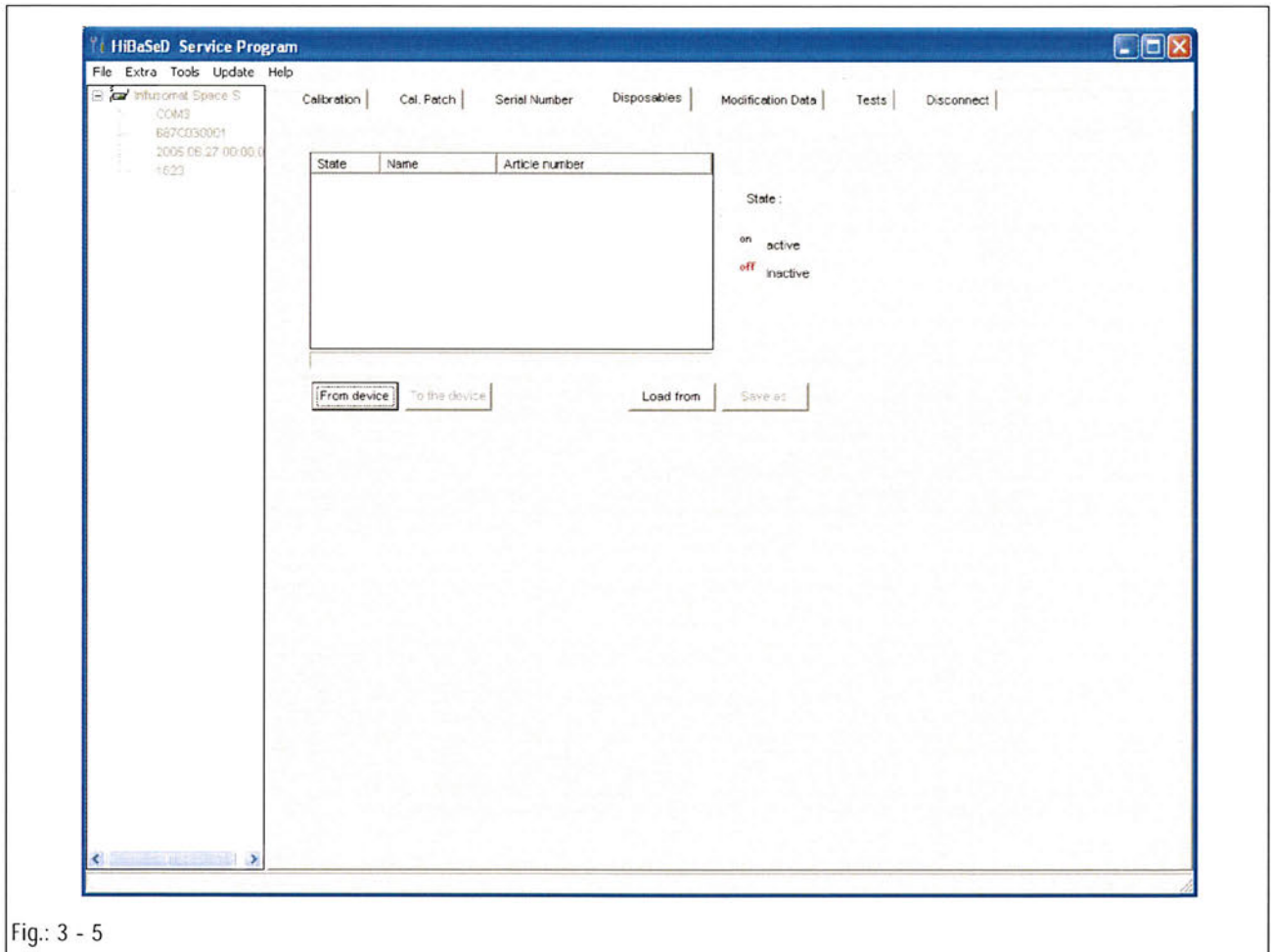


Fig.: 3 - 5

11. Actuate the "from device" button. The data is read from the device.

The data of the disposable articles read out is displayed on screen.

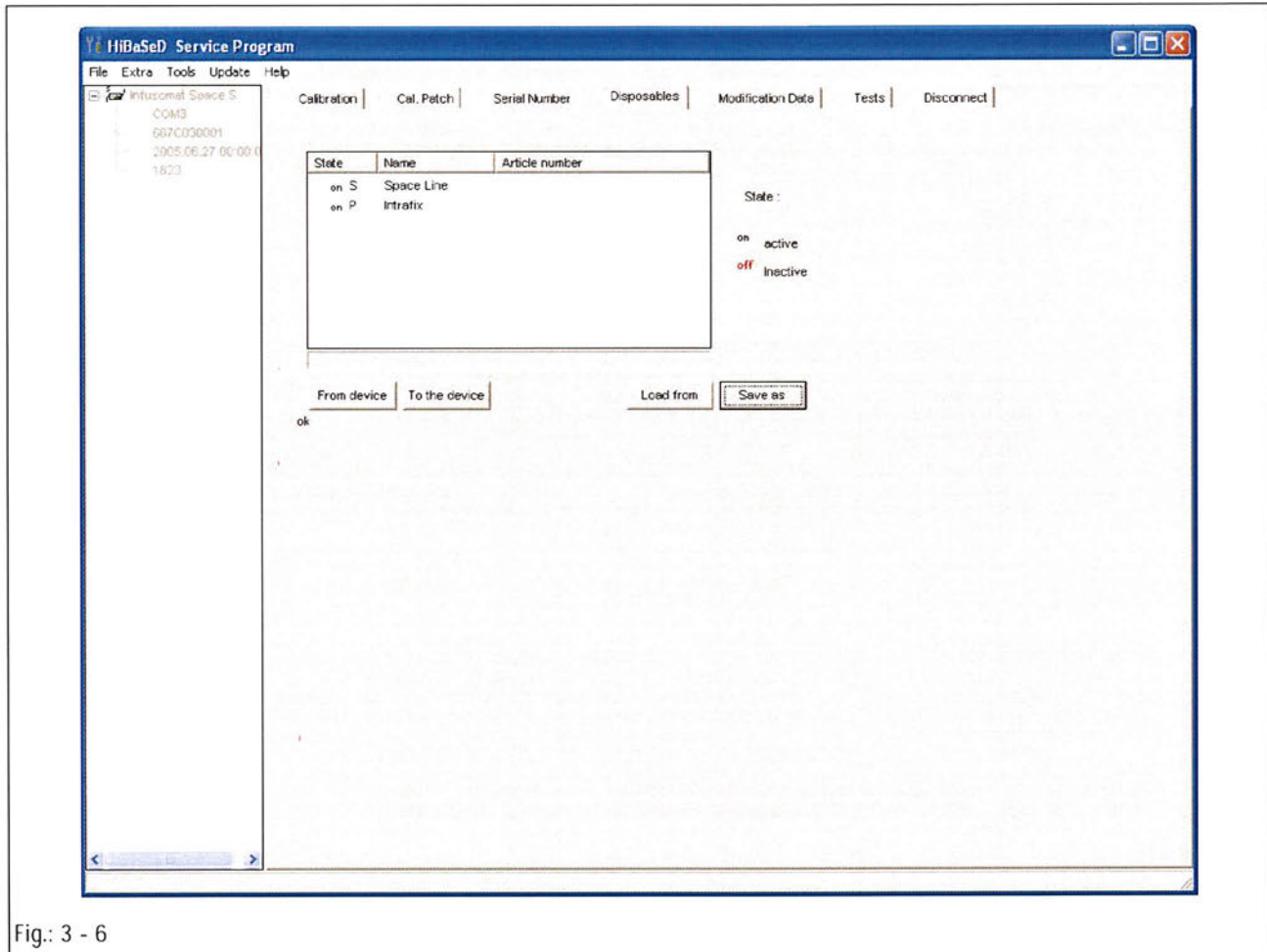


Fig.: 3 - 6

12. Press the "Save as" button.

In the window which opens, you are asked for the storage file name and location of the file on the PC hard disk.

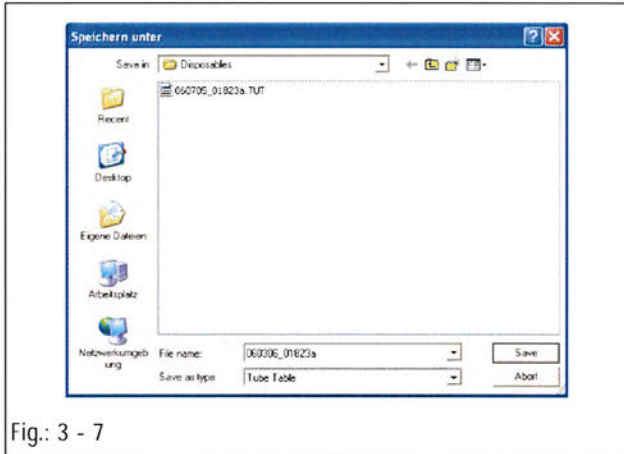


Fig.: 3 - 7

13. Select the storage position in the "Save file as" window and input a unique file name.

Note

The storage position which is proposed should not be changed.

14. Press the "Save" button. The data of the pump is saved on the PC hard disk.
15. Exit the Service Program (see "Quit the Service Program" ➔ p. 1 - 13).

Note

When the new processor PCB has been installed the saved data must be transferred back to the device (see "Processor PCB" ➔ p. 3 - 31).

Service Parts and Screw Kit

All small parts, such as cover caps, are contained in an Infusomat® Space service part kit.

Designation	Ord. No.
Service part kit Infusomat® Space	3452 1593
with:	
housing cover cap (100 pieces)	
housing foot (10 pieces)	
snap-in hook SP (pump lock) with leaf spring (2 pieces)	
emergency release plug ISP incl. O-ring (2 pieces)	
emergency release crank ISP (1 piece)	
bracket locking (10 pieces)	
safety clamp seal, housing bottom part (10 pieces)	
cover cap kit for housing SP (50 pieces)	3477 4386

All screws used in the device are included in an Infusomat® Space screw kit.

Designation	Ord. No.
Screw kit Infusomat® Space	3452 1585
with:	
screw DELTA PT 22x8 WN 5451 TORX plus 6IP (5 pieces)	
screw DELTA PT 25x7 WN 5451 TORX plus 8IP (5 pieces)	
screw DELTA PT 30x8 WN 5452 TORX plus 10IP (10 pieces)	
screw DELTA PT 30x12 WN 5452 A2 TORX plus 10IP (10 pieces)	
countersunk screw DELTA PT 20x9 WN 5454 TORX plus 6IP (5 pieces)	
fillister head screw M3x6 TORX	
fillister head screw M3x10	
countersunk screw M3x5 TORX	
countersunk screw M3x12 A2 TORX	
seal washer PA 2.2x0.3	
hexagon nut M3 A2	
toothed locked washer M3 A2	
distance sleeve	

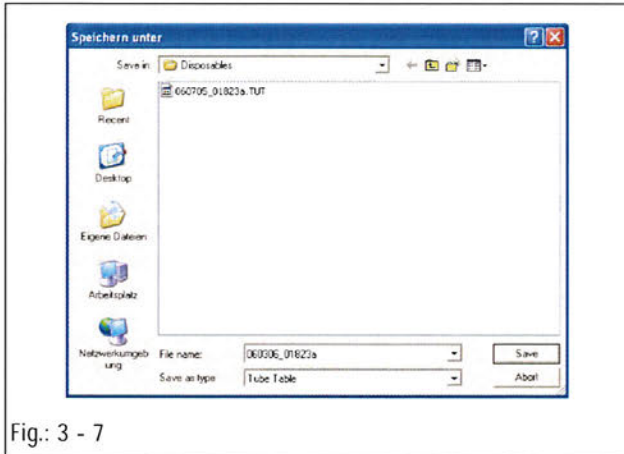


Fig.: 3 - 7

13. Select the storage position in the "Save file as" window and input a unique file name.

Note

The storage position which is proposed should not be changed.

14. Press the "Save" button. The data of the pump is saved on the PC hard disk.
15. Exit the Service Program (see "Quit the Service Program" → p. 1 - 13).

Note

When the new processor PCB has been installed the saved data must be transferred back to the device (see "Processor PCB" → p. 3 - 31).

3.4 Emergency Release Plug

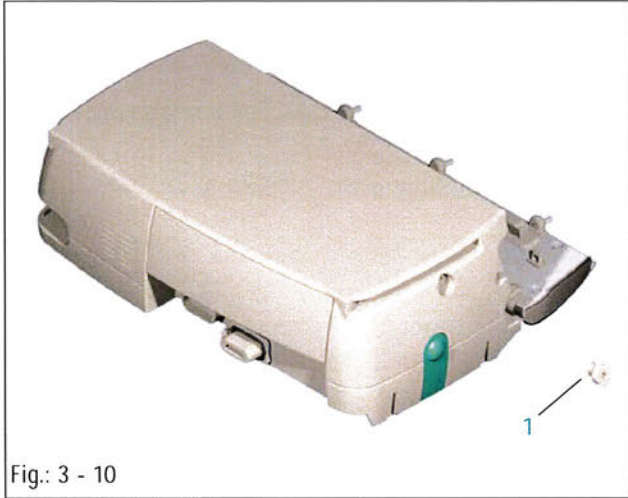


Fig.: 3 - 10

Legend to fig. 3 - 10:

Item Designation

1 Emergency release plug

Designation

Ord. No.

Emergency release plug ISP incl. O-ring
(see "Service Parts and Screw Kit" ➔ p. 3 - 8)

Disassembly

1. Turn the emergency release plug (Fig.: 3 - 10 / Item 1) using a spanner, e.g. the emergency release crank in the battery compartment cover, through 90° to the right and pull the plug out of the housing.

Note

The spanner must be pressed carefully until stop in the opening of the emergency release plug. The hexagon socket of the emergency release plug tapers to the inside to guarantee a certain bond when the plug is removed.

3.5 Unit Foot

Designation

Ord. No.

Unit foot

(see "Service Parts and Screw Kit" ➔ p. 3 - 8)

Disassembly

1. Pull the unit foot (Fig.: 3 - 11 / Item 1) out of the housing.

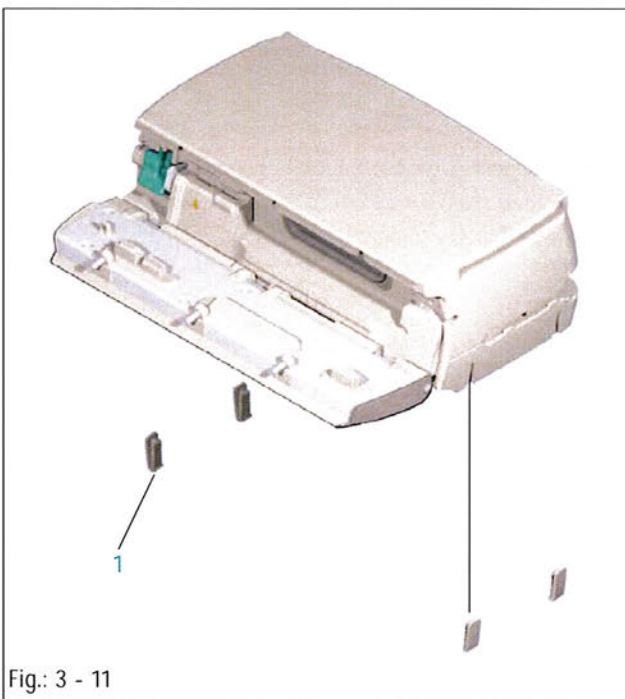


Fig.: 3 - 11

Legend to fig. 3 - 11:

Item Designation

- 1 Unit foot

3.6 Battery Module

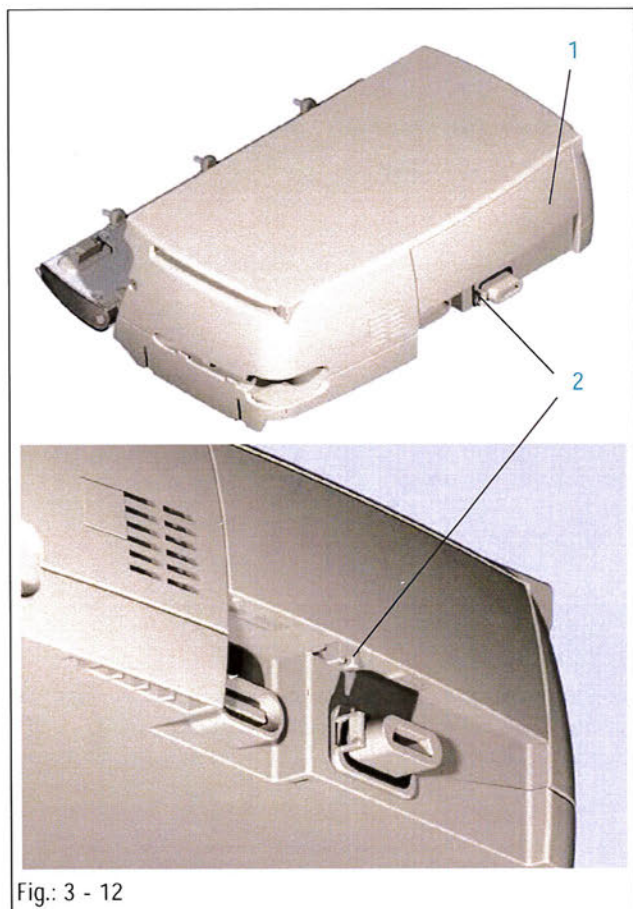


Fig.: 3 - 12

Legend to fig. 3 - 12:

Item Designation

- 1 Battery compartment cover
- 2 Battery compartment cover lock

Designation

Ord. No.

Battery compartment cover ISP, cpl.	3452 1321
(incl. emergency release crank)	
Battery pack SP (NIMH)	0871 3180

Disassembly

1. Press the lock (Fig.: 3 - 12 / Item 2) on the battery compartment cover (Fig.: 3 - 12 / Item 1) with a pointed tool and remove the battery compartment cover.

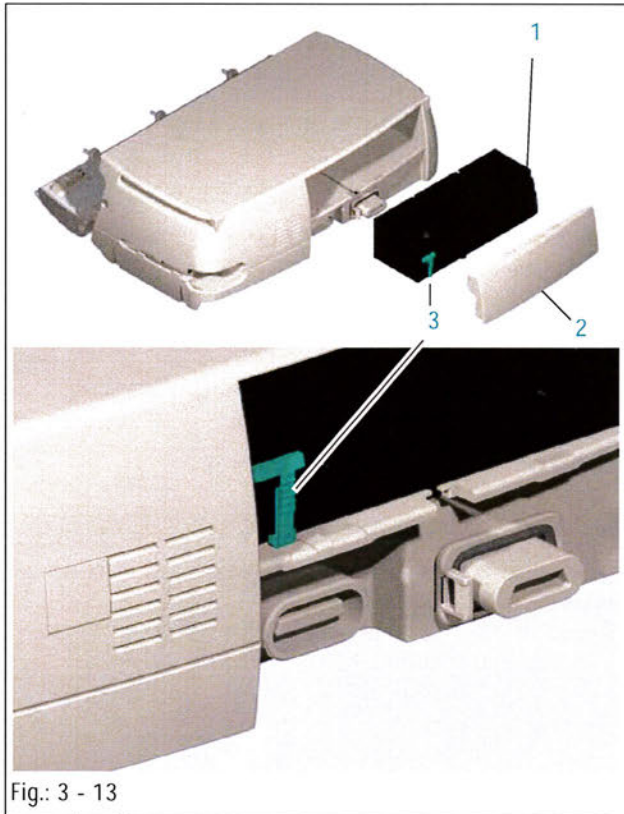


Fig.: 3 - 13

Legend to fig. 3 - 13:

Item Designation

- 1 Battery pack
- 2 Battery compartment cover
- 3 Battery pack lock

2. Lift the lock (Fig.: 3 - 13 / Item 3) on the battery pack (Fig.: 3 - 13 / Item 1) and remove the battery pack out of the device.

3.7 Housing Upper Part

Designation	Ord. No.
Housing, upper part ISP	3452 1313
Screws and cover caps (see "Service Parts and Screw Kit" ➔ p. 3 - 8)	

Note

Please pay attention to the corresponding notes during assembly and installation (see "Housing Upper Part" ➔ p. 3 - 35).

Disassembly

1. Pierce six cover caps (Fig.: 3 - 14 / Item 1) with a small screwdriver and pry the cover caps out.
2. Unscrew six screws (Fig.: 3 - 14 / Item 2).

Note

The other 4 cover caps on the housing bottom side must not be removed during this disassembly state.

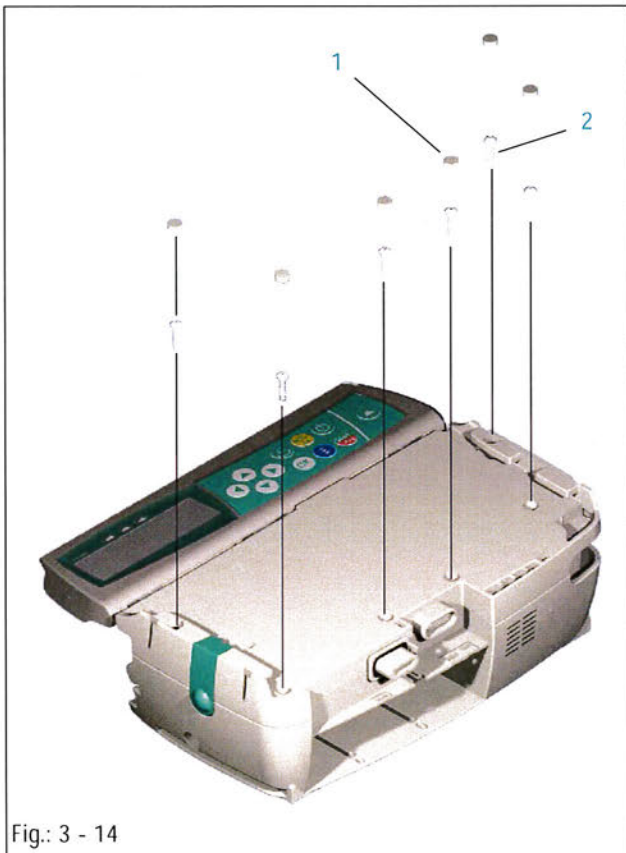


Fig.: 3 - 14

Legend to fig. 3 - 14:

Item Designation

- 1 Cover cap
- 2 Screw DELTA PT 30x12 WN 5452 A2 TORX plus 10IP

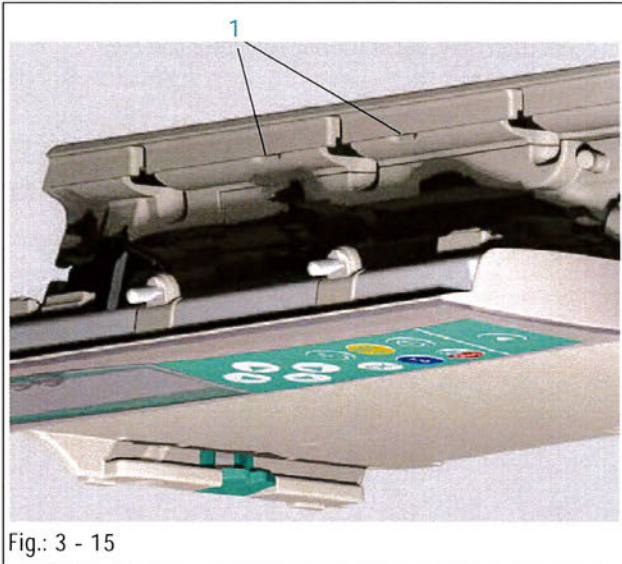


Fig.: 3 - 15

Legend to fig. 3 - 15:

Item Designation

1 Snap-on openings

3. Loosen the snap-on mechanism of the housing upper part (Fig.: 3 - 15 / Item 1) carefully. To do so a screwdriver can be inserted in the two openings between the housing front panel and the housing top.

Note

It is also possible to remove the housing upper part by gripping into the battery compartment and tilting the upper part forward.

4. Remove the housing upper part vertically to the top.

Note

Pay attention to the length of the connection cable to the battery compartment and to the connectors P2 and P3 when dismounting the housing. Do not pull the connectors together with the upper part out of the bottom part. Pay special attention to the loudspeaker and the length of the connection cable to the battery compartment.

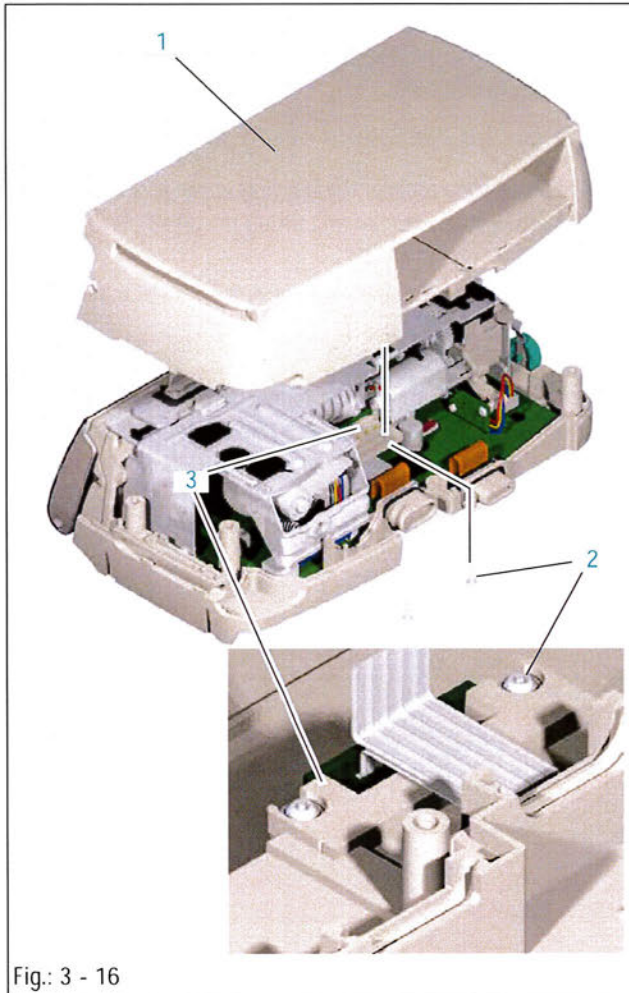


Fig.: 3 - 16

Legend to fig. 3 - 16:

Item Designation

- 1 Housing upper part
- 2 Screw DELTA PT 25x7 WN 5451 TORX plus 8IP
- 3 Contact strip

5. Unscrew two screws and remove the contact strip (Fig.: 3 - 16 / Item 3) to the battery compartment together with the connection cable out of the housing upper part (Fig.: 3 - 16 / Item 1).

Note

If necessary, the spring-mounted contact pins must be carefully pressed in when the contact strip is dismantled.

3.8 Loudspeaker

Designation	Ord. No.
Loudspeaker SP	3452 0937

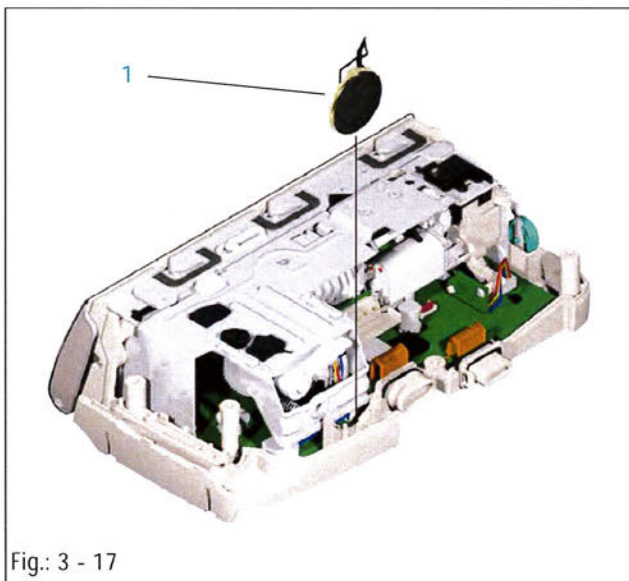


Fig.: 3 - 17

Legend to fig. 3 - 17:

Item Designation

1 Loudspeaker

Disassembly

1. Pull the loudspeaker connector off (Fig.: 3 - 17 / Item 1) the processor PCB and remove the loudspeaker.

3.9 Housing Bottom Part

Designation	Ord. No.
Housing, bottom part ISP	3452 1305
Rating plate ISP	Upon request
Snap-in hook SP with leaf spring (Pump Lock) (see "Service Parts and Screw Kit" ➔ p. 3 - 8)	
Screws and cover caps (see "Service Parts and Screw Kit" ➔ p. 3 - 8)	

Note

Please pay attention to the corresponding notes during assembly and installation (see "Housing Bottom Part" ➔ p. 3 - 35).

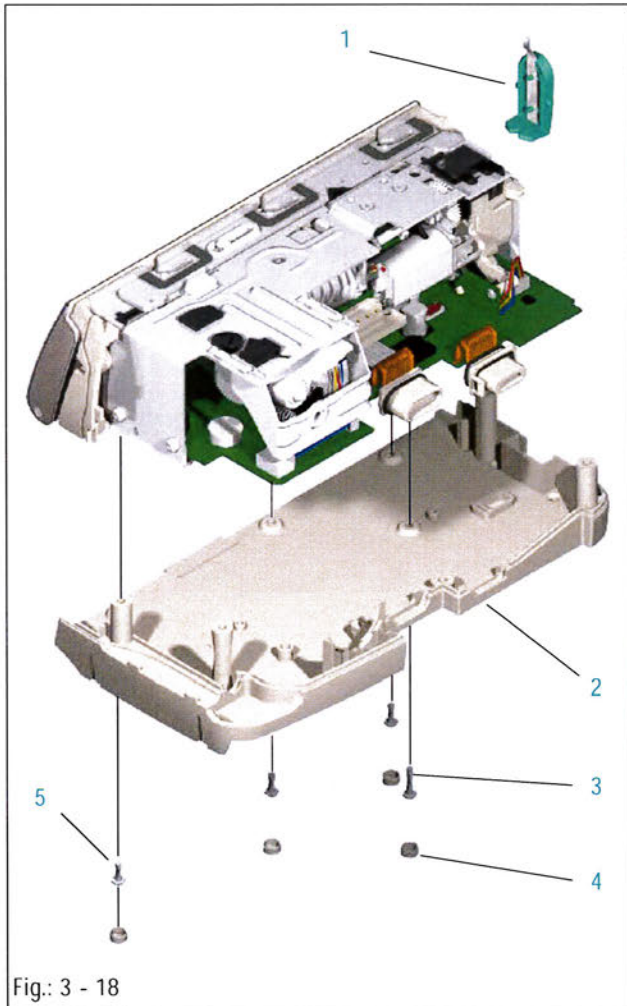


Fig.: 3 - 18

Legend to fig. 3 - 18:

Item Designation

- 1 Snap in hook SP (Pump Lock)
- 2 Housing bottom part
- 3 Screw DELTA PT 30x12 WN 5452 A2 TORX plus 10IP
- 4 Cover cap
- 5 Screw DELTA PT 30x8 WN 5452 A2 TORX plus 10IP

Disassembly

1. Remove the drop sensor connector (not depicted) out of the housing bottom part (Fig.: 3 - 18 / Item 2).

Note

The drop sensor connector is integrated in the processor PCB.

2. Pierce four cover caps (Fig.: 3 - 18 / Item 4) with a small screwdriver and pry the cover caps out.
3. Unscrew three screws (Fig.: 3 - 18 / Item 5) and one screw (Fig.: 3 - 18 / Item 3).
4. Take off the housing bottom part.
5. Pull the snap in hook SP (Fig.: 3 - 18 / Item 1) out of the housing bottom part. (Pump Lock)

3.10 Inner Frame and Housing Front Panel

Designation

Ord. No.

Screws

(see "Service Parts and Screw Kit" ➔ p. 3 - 8)

Note

Please pay attention to the corresponding notes during assembly and installation (see "Inner Frame and Housing Front Panel" ➔ p. 3 - 33).

Disassembly

Note

When dismantling the inner frame and the housing front panel please pay attention to the length of the connection cables to the processor PCB.

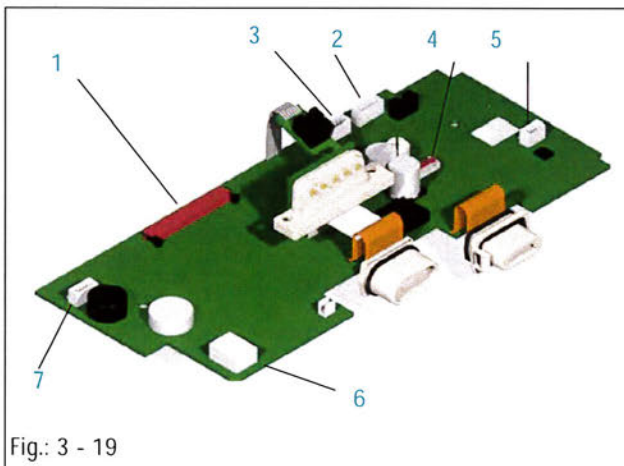


Fig.: 3 - 19

Legend to fig. 3 - 19:

Item Designation

- 1 Connector for ribbon cable, operating unit
- 2 Door bolt drive connector
- 3 Pressure sensor connector, downstream
- 4 Air inline sensor connector
- 5 Safety clamp connector
- 6 Pump drive connector
- 7 Pressure sensor connector, upstream

1. Fold the lock (Fig.: 3 - 19 / Item 1) of the ribbon cable connector to the air sensor up and pull the ribbon cable off the connector.
2. Pull the safety clamp connector (Fig.: 3 - 19 / Item 5) off the processor PCB.
3. Pull the pump drive connector (Fig.: 3 - 19 / Item 6) off the processor PCB.

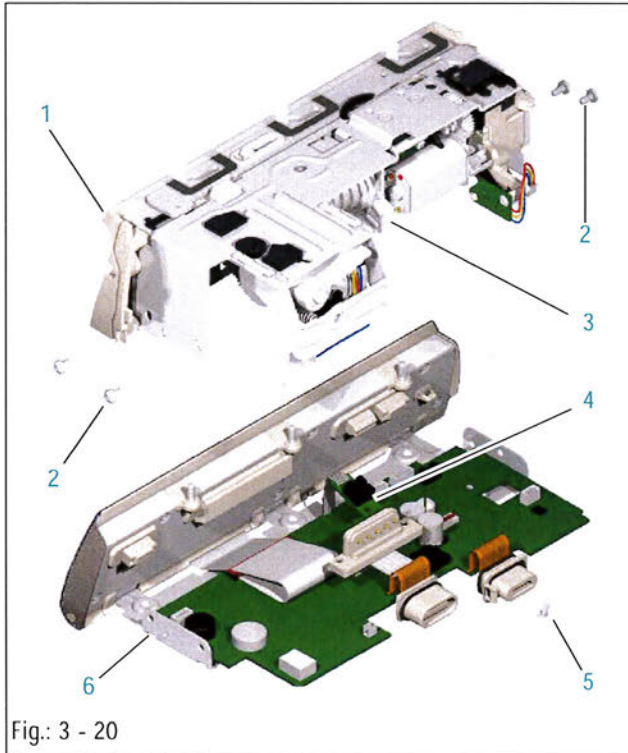


Fig.: 3 - 20

Legend to fig. 3 - 20:

Item Designation

- 1 Housing front panel, cpl.
- 2 Fillister head screw M3x6 TORX
- 3 Inner frame, cpl.
- 4 PCB of direction of rotation sensor
- 5 Screw DELTA PT 25x7 WN 5451 TORX plus 8IP
- 6 Bottom inner frame

4. Loosen four screws (Fig.: 3 - 20 / Item 2) and lift the inner frame together with the housing front panel (Fig.: 3 - 20 / Item 6) from the bottom inner frame.
5. Unscrew one screw (Fig.: 3 - 20 / Item 5) and remove the PCB of the direction of rotation sensor for the pump drive from the pump frame.

Note

The PCB of the direction of rotation sensor is connected to the processor PCB via the ribbon cable.

6. Pull the door bolt drive connector (Fig.: 3 - 19 / Item 2) off the processor PCB.
7. Pull the pressure sensor connector, upstream (Fig.: 3 - 19 / Item 7) off the processor PCB.
8. Pull the pressure sensor connector, downstream (Fig.: 3 - 19 / Item 3) off the processor PCB.

Disassembly

1. Carefully remove the inner frame (Fig.: 3 - 20 / Item 3) from the housing front panel (Fig.: 3 - 20 / Item 1).

Note

The membrane in the housing front panel must not be used again. Always use a new membrane for assembly.

3.11 Inner Frame

Designation	Ord. No.
Door bolt drive ISP	3452 1429
Pressure adjustment unit ISPS	3452 1445
(spring holder, pressure springs, adjusting screw adjusting nut, bracket, bracket locking)	
Pump frame ISP, cpl.	3452 1402
(incl. pump drive motor ISP)	
Pump drive motor ISP	3452 1410
Door bolt ISP	3452 1496
Inner frame ISP	3452 1437
Bracket locking and screws (see "Service Parts and Screw Kit" ➔ p. 3 - 8)	

Note

Please pay attention to the corresponding notes during assembly and installation (see "Inner Frame" ➔ p. 3 - 32).

Disassembly

1. Carefully press two bracket lockings (Fig.: 3 - 21 / Item 4) at the front and rear out of the inner frame (Fig.: 3 - 21 / Item 2).
2. Push the bracket (Fig.: 3 - 21 / Item 5) forward against spring tension, unhook from the inner frame and remove it together with the pressure adjustment unit (Fig.: 3 - 21 / Item 6).
3. Press the pump frame guide (6 mm straight pin) (Fig.: 3 - 21 / Item 7) in longitudinal direction out of the linear bearings of the pump frame and the inner frame holders and remove the pump frame from the inner frame. Do not lift.

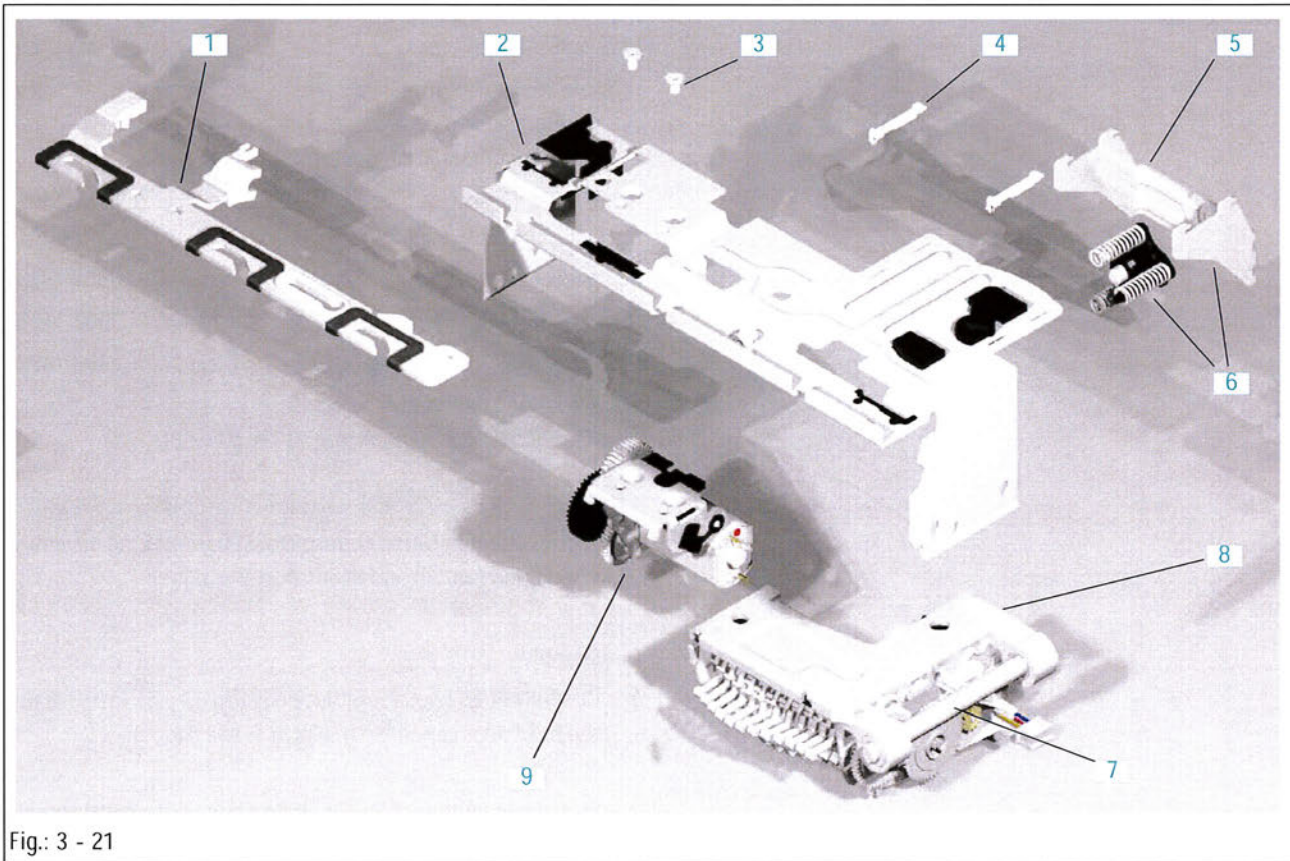


Fig.: 3 - 21

Legend to fig. 3 - 21:

Item Designation

- | | | | |
|---|-----------------------------|---|---------------------------|
| 1 | Door bolt | 6 | Pressure adjustment unit |
| 2 | Inner frame | 7 | Guide (6 mm straight pin) |
| 3 | Countersunk screw M3x5 TORX | 8 | Pump frame |
| 4 | Bracket holder | 9 | Door bolt drive |
| 5 | Bracket | | |

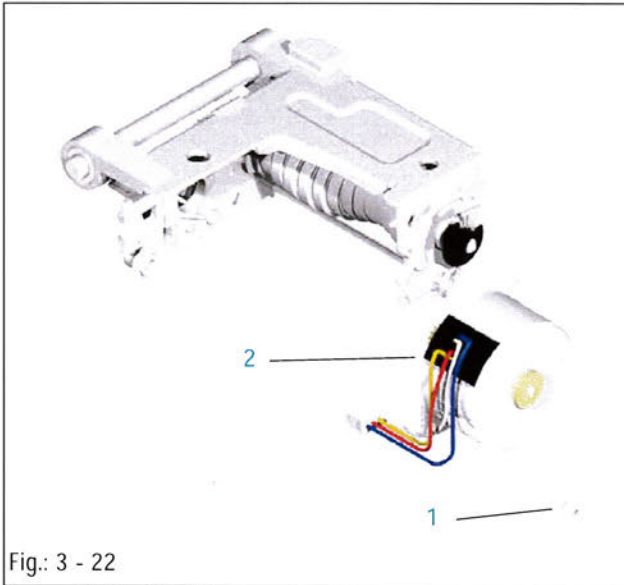


Fig.: 3 - 22

Legend to fig. 3 - 22:

Item Designation

- 1 Screw DELTA PT 30x8 WN 5452 TORX plus 10IP
- 2 Pump drive motor

4. Unscrew one screw (Fig.: 3 - 22 / Item 1), turn the pump drive motor (Fig.: 3 - 22 / Item 2) clockwise out of the holder and remove it from the pump frame.
5. Move the door bolt drive by hand to the middle position.
6. Unscrew two screws (Fig.: 3 - 21 / Item 3) and pull the door bolt drive (Fig.: 3 - 21 / Item 9) off the door bolt tappet (Fig.: 3 - 21 / Item 1).

Note

The door bolt drive is slightly engaged when installed. When dismantling the drive make sure that the toothed wheels do not rub along the metal edges of the inner frame as the toothed wheels can easily be damaged.

7. Lift the door bolt on the right side and push it to the left until the guide rivet is exactly positioned in the mounting hole of the door bolt.
8. Lift the door bolt over the guide rivet of the inner frame.

3.12 Housing Front Panel

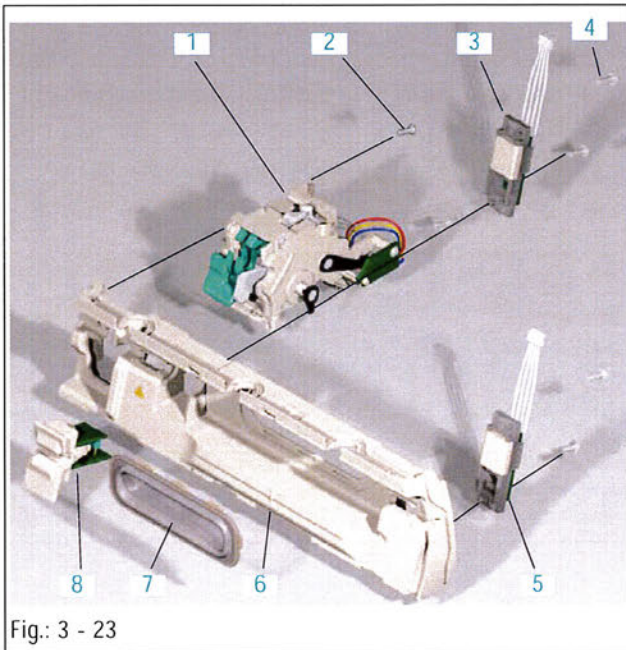


Fig.: 3 - 23

Legend to fig. 3 - 23:

Item Designation

- 1 Safety clamp
- 2 Screw DELTA PT 22x8 WN 5451 TORX plus 6IP
- 3 Pressure sensor, downstream
- 4 Screw DELTA PT 25x7 WN 5451 TORX plus 8IP
- 5 Pressure sensor, upstream
- 6 Front frame
- 7 Membrane
- 8 Air inline sensor

Designation	Ord. No.
Membrane ISP	3452 1356
Pressure sensor ISP	3452 1372
Air inline sensor ISP	3452 1380
Safety clamp ISPS	3452 1399
Front frame ISPS, cpl.	3452 1364
Screws	

(see "Service Parts and Screw Kit" ➔ p. 3 - 8)

Disassembly

1. Press the membrane out of the housing front panel.
2. Unscrew two screws and remove the pressure sensor, upstream from the housing front panel.
3. Unscrew two screws and remove the pressure sensor, downstream from the housing front panel.
4. Unlock two lugs of the air inline sensor carefully and remove the air inline sensor out of the housing front panel.
5. Open the safety clamp with the operating lever and engage.
6. Unscrew two screws and remove the safety clamp out of the housing front panel.

WARNING

THE SAFETY CLAMP MUST NOT BE DISASSEMBLED FURTHER.

Note

Pay attention to the dummy slide ISPS when dismantling the safety clamp. This slide closes one housing opening on the left-hand side of the safety clamp.

3.13 Operating Unit

Designation	Ord. No.
Operating unit ISPS, cpl.	3452 1470
LC display SP.	3452 0988
Metal front sheet ISPS.	3452 1488
Axle ISP.	3452 1461
(incl. hinge covers and hinge spring)	
Screws	
(see "Service Parts and Screw Kit" ➔ p. 3 - 8)	

Note

Please pay attention to the corresponding notes during assembly and installation (see "Operating Unit" ➔ p. 3 - 31).

Assembly / Disassembly

1. Push the right and left connector lock (Fig.: 3 - 24 / Item 2) on the processor PCB carefully rearward.
2. Disconnect the operating unit ribbon cable (Fig.: 3 - 24 / Item 1) from the processor PCB.

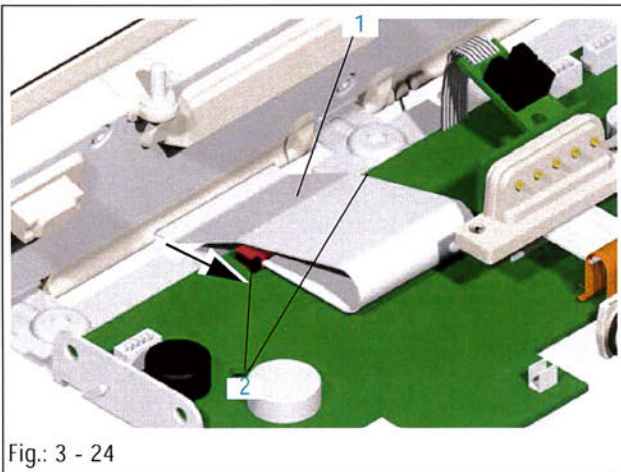


Fig.: 3 - 24

Legend to fig. 3 - 24:

Item Designation

- 1 Operating unit ribbon cable
- 2 Connector lock

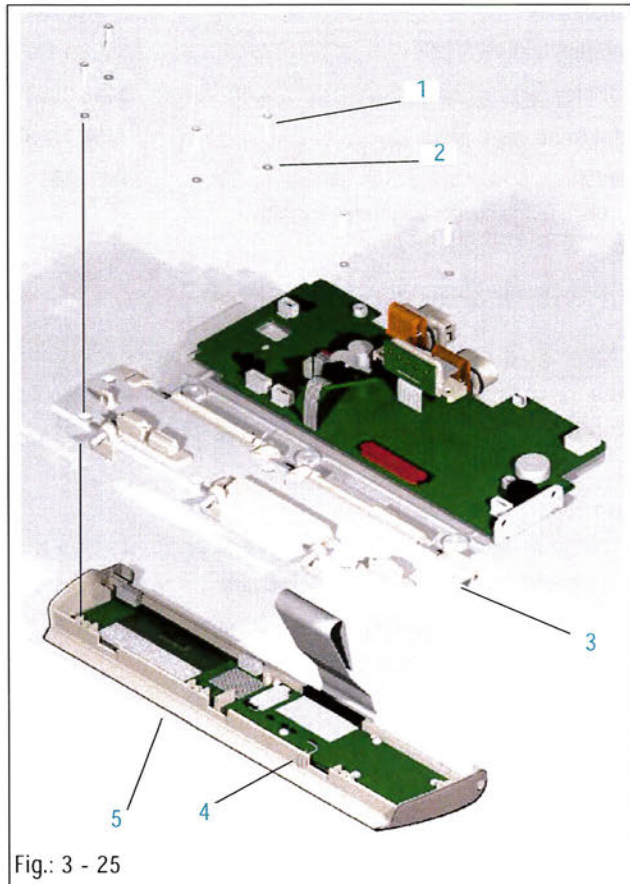


Fig.: 3 - 25

Legend to fig. 3 - 25:

Item Designation

- 1 Countersunk screw EJOT 20x9 WN 5454 TORX plus 6IP
- 2 Seal washer PA 2.2x0.3
- 3 Operating unit rear panel (metal front sheet)
- 4 Bonding
- 5 Operating unit with LC display

3. Unscrew 6 screws (Fig.: 3 - 25 / Item 1) and remove the seal washers (Fig.: 3 - 25 / Item 2) from the operating unit rear panel (metal front sheet) (Fig.: 3 - 25 / Item 3).

Note

The screws of the keyboard must not be loosened. A uniform pressure point of all keys is only guaranteed when a special tool is used for assembly.

4. Remove the operating unit (Fig.: 3 - 25 / Item 5) from the rear panel (metal front sheet).

Note

Please pay attention to the bonding (Fig.: 3 - 25 / Item 4) on the keyboard PCB during disassembly.

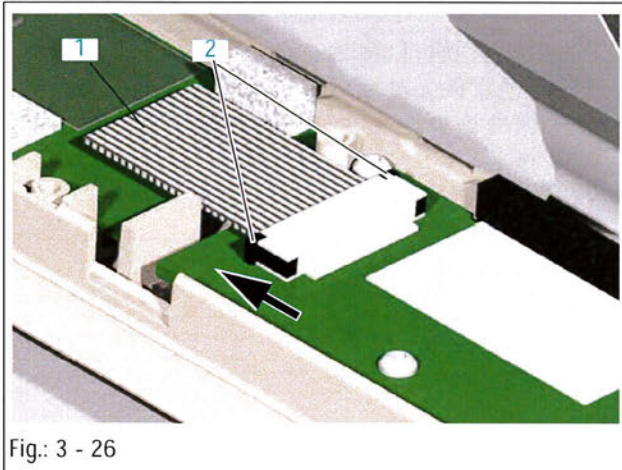


Fig.: 3 - 26

Legend to fig. 3 - 26:

Item Designation

1 Ribbon cable

2 LC display connection cable lock

5. Open the connector lock (Fig.: 3 - 26 / Item 2) on the keyboard PCB.
6. Pull the LC display ribbon cable (Fig.: 3 - 26 / Item 1) out of the connector.

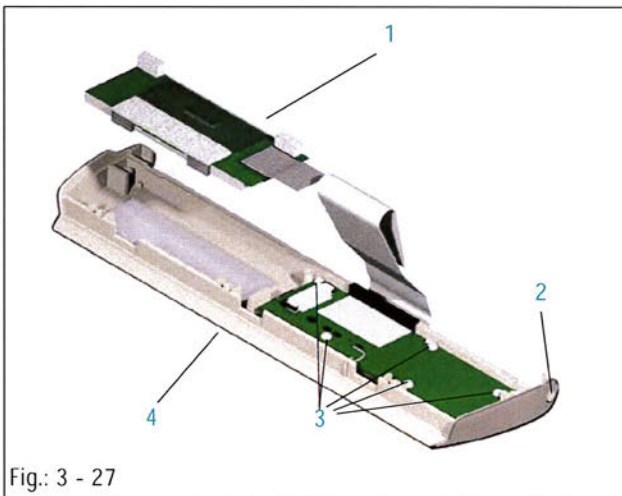


Fig.: 3 - 27

Legend to fig. 3 - 27:

Item Designation

1 LC display

2 Axle mounting plug

3 Keyboard screws

4 Front side, operating unit with keyboard

7. Lift the LC display (Fig.: 3 - 27 / Item 1) out of the operating unit front panel (Fig.: 3 - 27 / Item 4).

Note

The keyboard screws (Fig.: 3 - 27 / Item 3) must not be released. A special procedure is required to install the keyboard, so that a uniform pressure point is guaranteed for all keys.

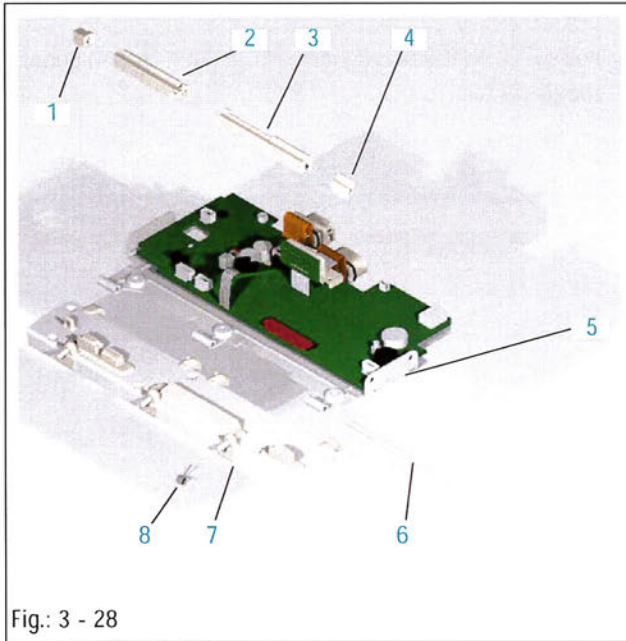


Fig.: 3 - 28

Legend to fig. 3 - 28:

Item Designation

- 1 Hinge cover, left
- 2 Hinge cover, spring
- 3 Hinge cover, cable
- 4 Hinge cover, right
- 5 Bottom inner frame
- 6 Axle
- 7 Operating unit rear panel
- 8 Hinge spring

8. Pull the left (Fig.: 3 - 28 / Item 1) and right hinge cover (Fig.: 3 - 28 / Item 4) off the axle (Fig.: 3 - 28 / Item 6).
9. Press the axle out of the operating unit rear panel (Fig.: 3 - 28 / Item 7), the bottom inner frame (Fig.: 3 - 28 / Item 5), from the hinge cover, spring (Fig.: 3 - 28 / Item 2), the hinge cover, cable (Fig.: 3 - 28 / Item 3) and the hinge spring (Fig.: 3 - 28 / Item 8).

3.14 Processor PCB

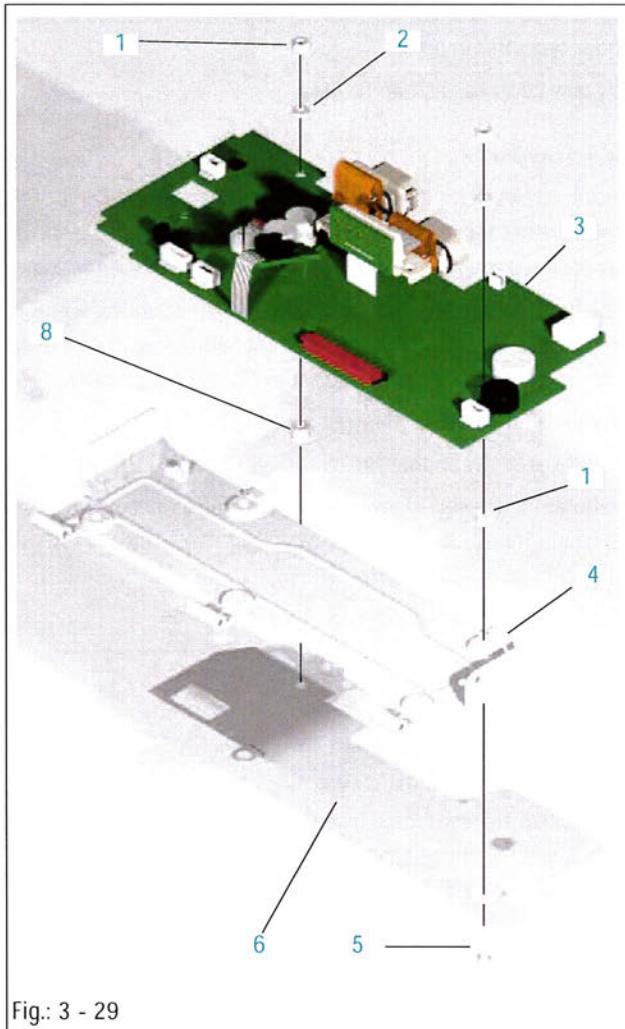


Fig.: 3 - 29

Legend to fig. 3 - 29:

Item Designation

- | | |
|---|--|
| 1 | Hexagon nut M3 |
| 2 | Toothed locked washer M3 |
| 3 | Processor PCB |
| 4 | Bottom inner frame |
| 5 | Fillister head screw M3x10 |
| 6 | EMC shield |
| 7 | Countersunk screw M3x12 A2 TORX (not depicted) |
| 8 | Distance sleeve |

Designation

Ord. No.

Processor PCB ISP	3452 1348
(incl. connectors)	
Bottom inner frame ISP	3452 1453
Screws	
(see "Service Parts and Screw Kit" ➔ p. 3 - 8)	

Note

Please pay attention to the corresponding notes during assembly and installation (see "Processor PCB" ➔ p. 3 - 31).

Disassembly

1. Loosen two hexagon nuts (Fig.: 3 - 29 / Item 1) and remove the nuts with the toothed locked washers (Fig.: 3 - 29 / Item 2), the distance sleeve (Fig.: 3 - 29 / Item 8) and the countersunk screw.
2. Remove the processor PCB (Fig.: 3 - 29 / Item 3) from the bottom inner frame.
3. Loosen one hexagon nut and remove the nut together with the EMC shield (Fig.: 3 - 29 / Item 6) and the screw (Fig.: 3 - 29 / Item 5) from the bottom inner frame (Fig.: 3 - 29 / Item 4).

3.15 Assembly / Installation

Assembly or installation of the modules and subsystems is done in reverse order of disassembly. Special steps to be observed are described hereafter in detail.

Only new cover caps are to be used.

Special Screws

Special screws for plastic housings are used in this unit. The screws are not self-cutting but produce a thread in the plastic of the housing through deformation when fitted in for the first time. If the beginning of the thread is not engaged when the screw is fitted, a new thread is produced and the old thread is destroyed so that the security of the fixing can no longer be guaranteed.

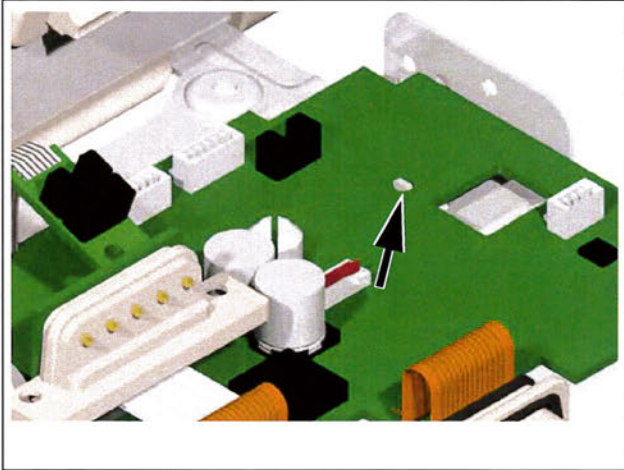
Proceed as follows to fit the special screws:

1. Put the screw on the thread.
2. Rotate screw anti-clockwise (loosen) until a faint click can be heard. This click is produced when the screw thread drops into the existing thread.
3. Screw-in screw and tighten carefully.

Zero Force Insertion Connector

Note

Make sure that the ribbon cable is centered between the plug guides when the zero force insertion connector is locked. Check the lock and the ribbon cable for correct fit before any further installation.



Operating Unit

1. Insert the hinge spring with its long side in the hinge cover opening, spring, and with its angled side in the rear panel bore hole of the operating unit.
2. Please pay attention to the bonding on the keyboard PCB when mounting the rear panel of the operating unit.
3. The grooves of the hinge covers are pointing to the operating unit rear panel.
4. Push the operating unit connection cable into the processor PCB connector.
5. Lock the connector.
6. The ribbon cable cover of the operating unit must be layed between the bottom inner frame and the operating unit and over the connector.
7. Check the seal washers for correct position and completeness once again after assembly.

Processor PCB

1. The adjusting lug of the bottom inner frame must be positioned in the processor PCB boring.

When the processor PCB is replaced all data of the pump except for the calibration data was probably saved on a PC. (see ["Preparations for Exchanging the Processor PCB" ➔ p. 3 - 2](#)) Carry out the following steps to transmit the data back to the device (see ["Rework when Replacing the Processor PCB" ➔ p. 3 - 35](#))

Inner Frame

1. Make sure that the following components are sufficiently lubricated when installing the inner frame. If the grease film is not sufficient (stiff or inconsistent movements) grease these areas slightly with Polylub GLY 501.

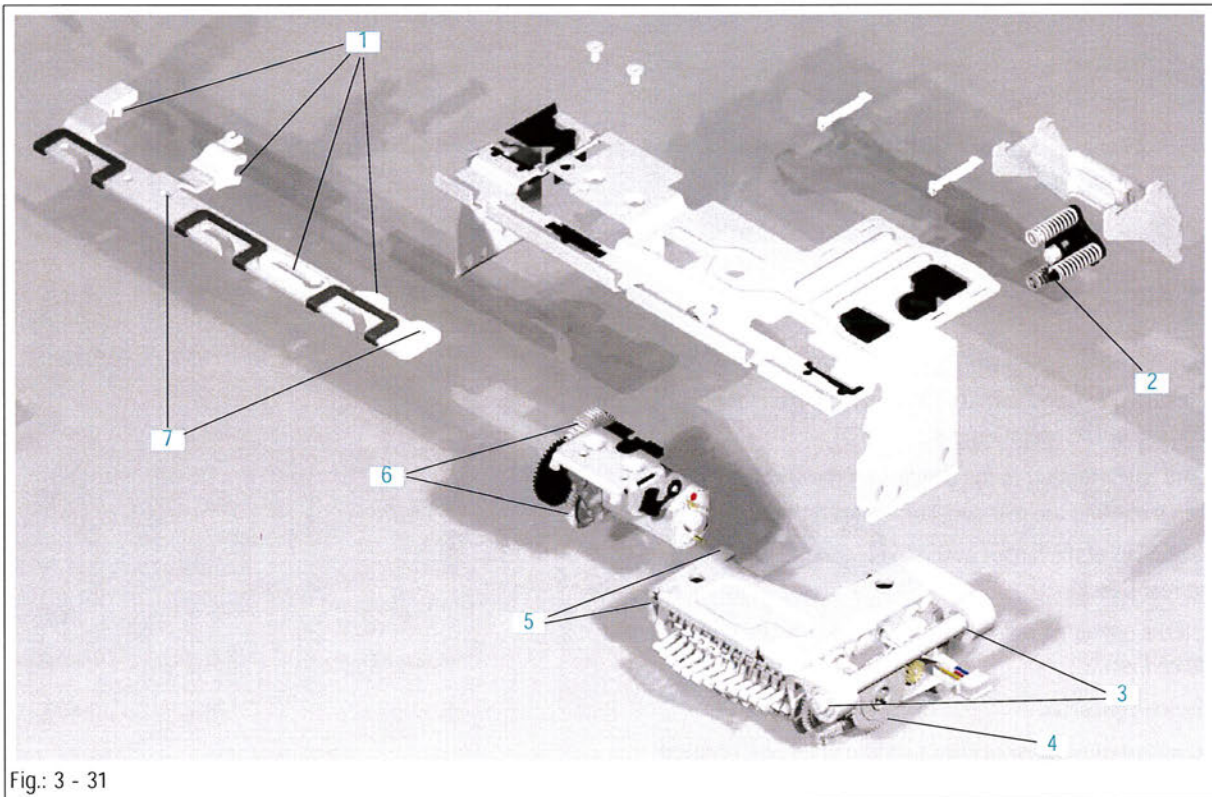


Fig.: 3 - 31

Legend to fig. 3 - 31:

ItemDesignation

- | | |
|--|---|
| 1 Door bolt, plastic guides | 5 Pump drive, movement areas |
| 2 Inner frame, spring holder | 6 Door bolt drive, toothed wheels |
| 3 Pump frame, bearing of the 6 mm straight pin | 7 Door bolt, guides and supporting area |
| 4 Pump drive, toothed wheels | |

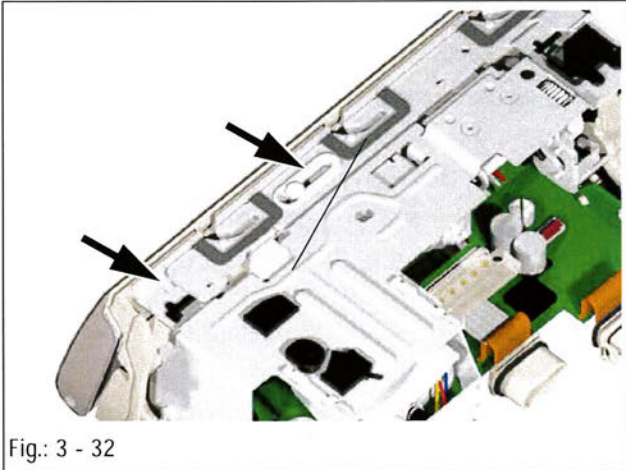
- Plastic guides (Fig.: 3 - 31 / Item 1) of the door bolt
 - Spring bearings and dovetail of the spring holder (Fig.: 3 - 31 / Item 2)
 - Guide (6 mm straight pin) of the pump frame at the bearings (Fig.: 3 - 31 / Item 3)
 - Toothed wheels (Fig.: 3 - 31 / Item 4) of the pump drive
 - Movement areas (Fig.: 3 - 31 / Item 5) of the pump frame
 - Toothed wheels (Fig.: 3 - 31 / Item 6) of the door bolt drive
 - Guides (Fig.: 3 - 31 / Item 7) and supporting area of the door bolt
2. Pay attention to the operating pin of the linear potentiometer when installing the door bolt drive. The pin must engage in the fork for the potentiometer when the spindle tappet is clipped in.
 3. Check all toothed wheels for damage after installation of the door bolt drive.
 4. The spring holder of the pressure adjustment unit must run smoothly with its dovetail guide in the guide of the pump frame. Check smooth running without springs inserted before final assembly.

Inner Frame and Housing Front Panel

1. Move the door bolt by hand to the left until stop (open position) before mounting the housing front panel.
2. Close the safety clamp with a slide clamp after installation.
3. Push the membrane carefully over the pump drive pusher.
4. Route the cable of the door bolt drive in the cable guide on the door bolt drive and between the two cable guide pins of the front frame.

Note

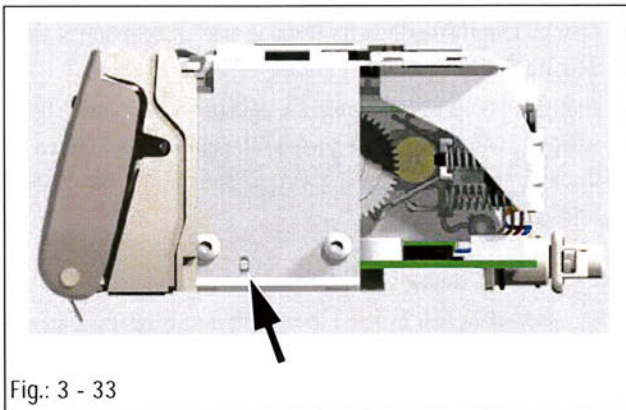
Always use a new membrane for assembly.



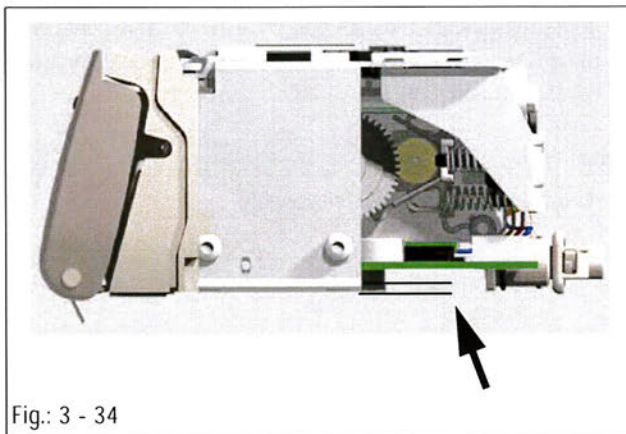
5. Engage the front frame lugs (arrow, [Fig.: 3 - 32](#)) exactly in the inner frame openings.

Note

When mounting the inner frame and the housing front panel, make sure that the operating unit is opened.



6. During installation of the complete housing front panel on the bottom inner frame the positioning hemispheres (arrow, [Fig.: 3 - 33](#)) of the inner frame must be adjusted in the slots of the bottom inner frame.



7. The housing front panel is pushed on to the bottom inner frame until stop and aligned in parallel (arrow, [Fig.: 3 - 34](#)).

Snap-in Hook (Pump Lock)

1. The snap-in hook is to be inserted before mounting the housing bottom part.

Housing Bottom Part

1. Check the correct position of the seal relative to the safety clamp before mounting the housing bottom part.
2. Make sure that the hinge spring with the housing bottom part is pressed in the spring holder of the housing front panel.

CAUTION

Please pay attention to the various screw lengths when you mount the bottom part.

Housing Upper Part

1. If you have carried out any activities on the pressure adjustment unit, or dismantled or replaced the pressure adjustment unit, remove the rectangular cover cap from the housing top and keep it in a safe place until calibration, before mounting the housing upper part.

Note

Take care that no cables are squeezed, and check that the connector seals at the back are correctly placed in the housing, the snap-in hook spring is located outside the housing wall and that the loudspeaker is correctly placed when the housing is fitted. The two wires must point downwards, so that the loudspeaker wires are placed in the insulation to the coil in the cut-out of the housing bottom part.

2. Check beforehand the position of the cable cover at the top and bottom of the housing upper part and the bottom part.
3. Lower the upper part of the housing vertically and carefully on to the lower part.
4. Engage the snap-in hooks between housing top and front frame.

Rework when Replacing the Processor PCB

When the processor PCB is replaced all data of the pump except for the calibration data was probably saved on a PC. (see "Preparations for "Exchanging the Processor PCB" ➔ p. 3 - 2) Carry out the following steps to transmit the data back to the device.

WARNING

WHEN DATA PREVIOUSLY SAVED IS TRANSFERRED BACK TO THE DEVICE, CALIBRATION DATA IS NOT TRANSFERRED. THEREFORE, A COMPLETE NEW CALIBRATION OF THE UNIT IS REQUIRED.

Note

Please note that text and / or functions of the Service Program may change depending on the software version. The following screen illustrations are only examples and represent the state when the manual was printed.

1. Start the Service Program (see "[Starting the Service Program](#)" ➔ p. 1 - 9).
2. Select the register tab "Modification data".

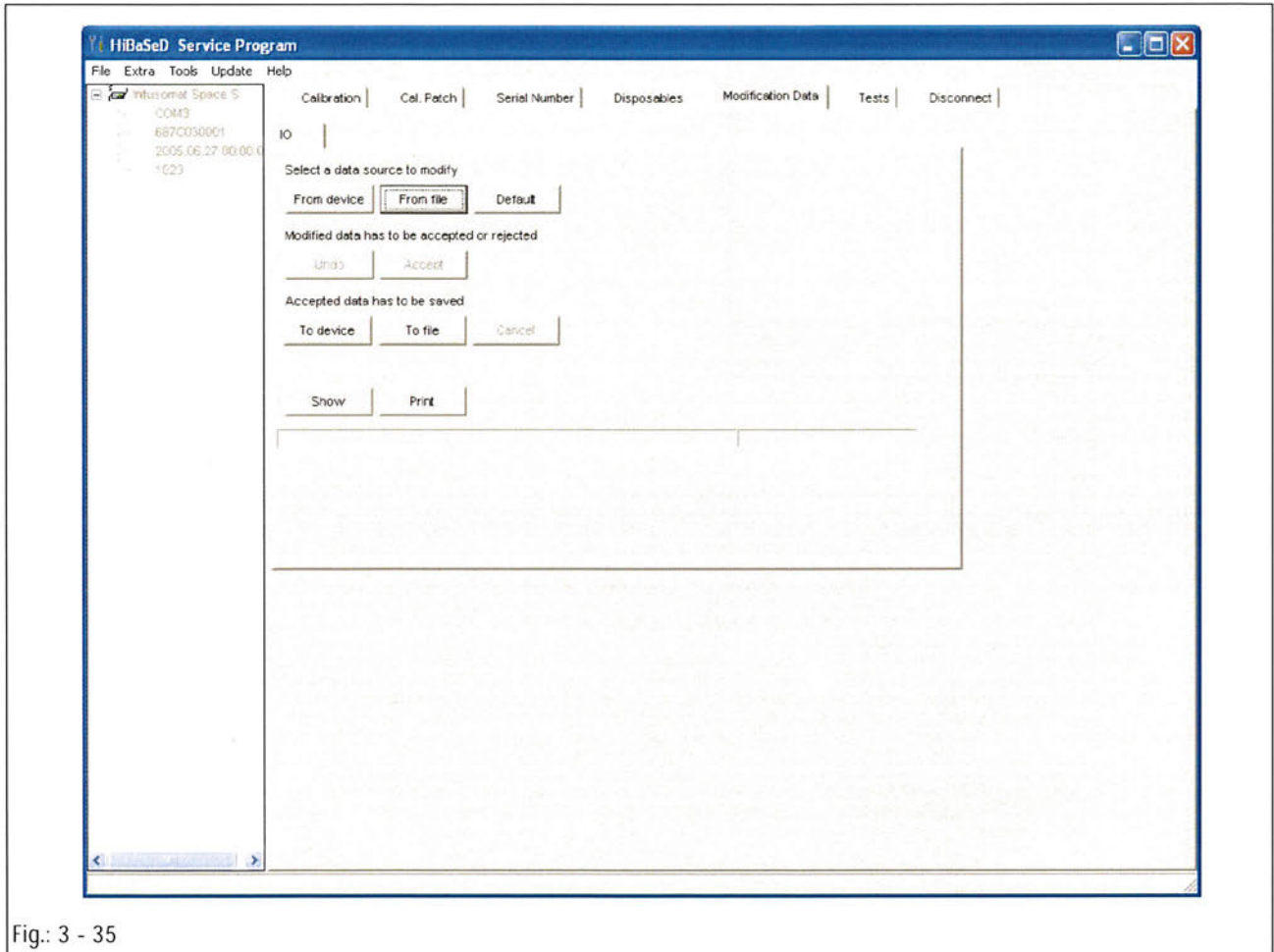


Fig.: 3 - 35

3. Press the "from file" button. The window "Open" is displayed on screen.

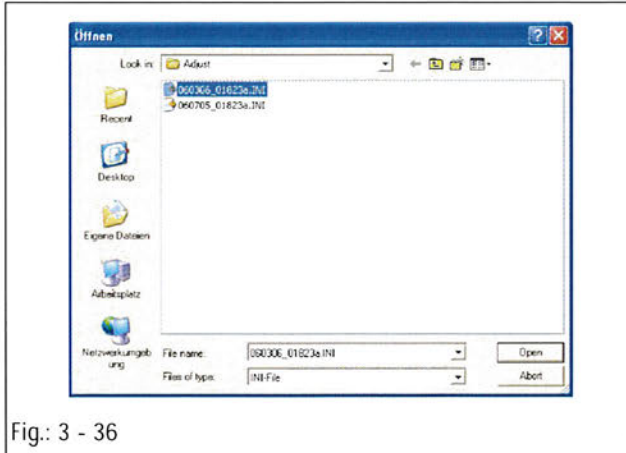


Fig.: 3 - 36

4. Select the desired file with the mouse pointer and press the "Open" button.
5. Press the "to device" button.

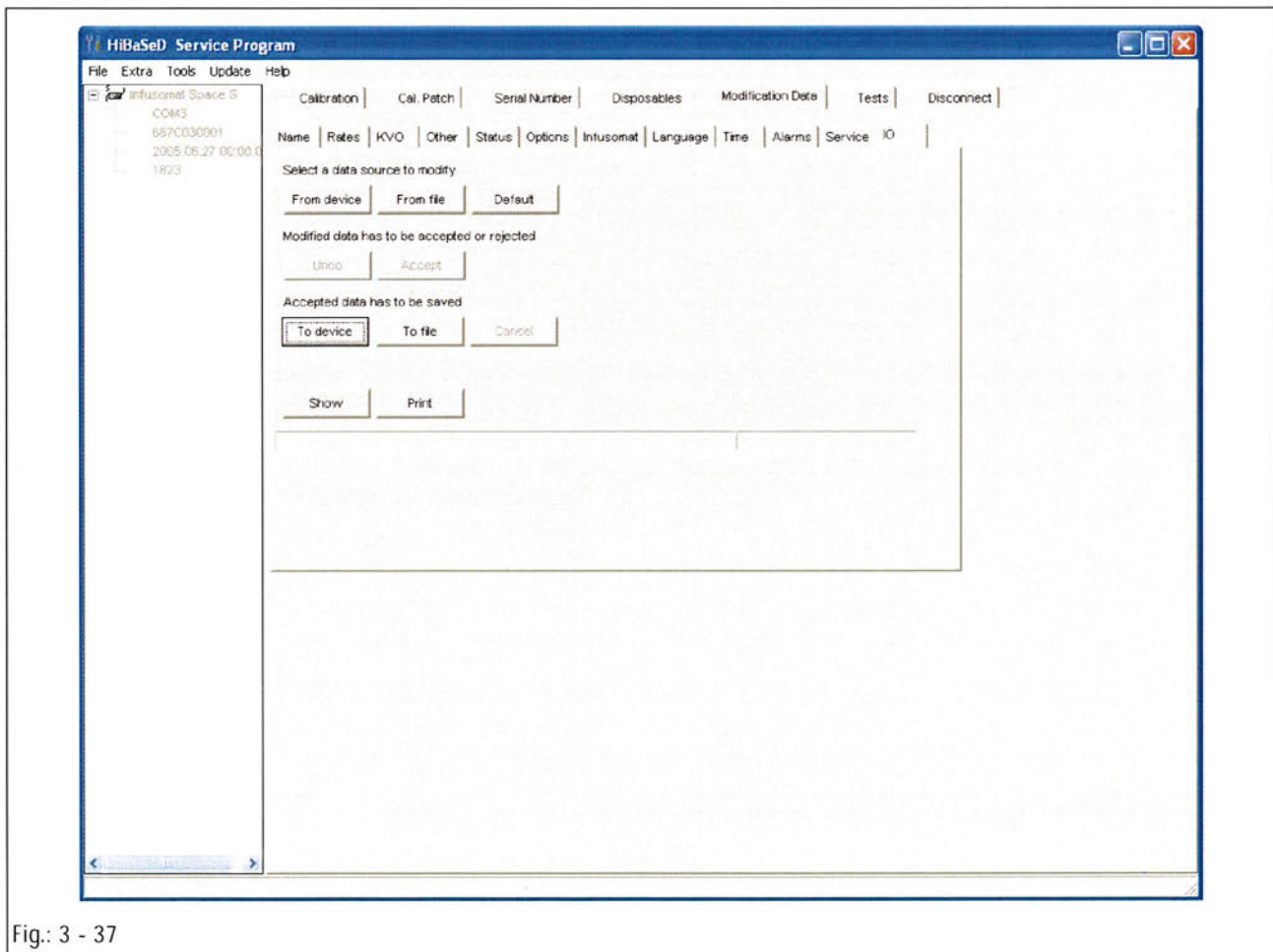


Fig.: 3 - 37

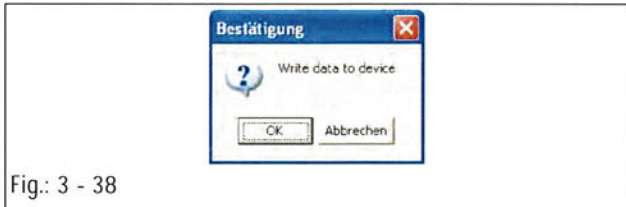


Fig.: 3 - 38

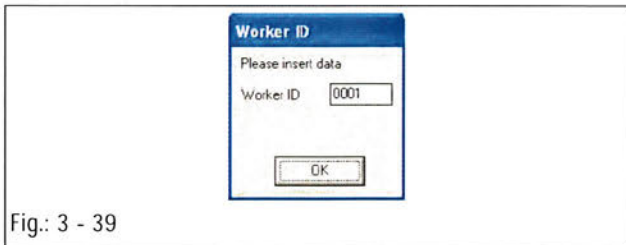


Fig.: 3 - 39

6. Press the "OK" button when the window "Confirmation" is displayed.

7. Input your user number in the window "User number" as well as the six-digit serial number of the device, if necessary.

8. Confirm the input with "OK".

9. The data is transferred to the device.

10. Select the tab "Disposable article".

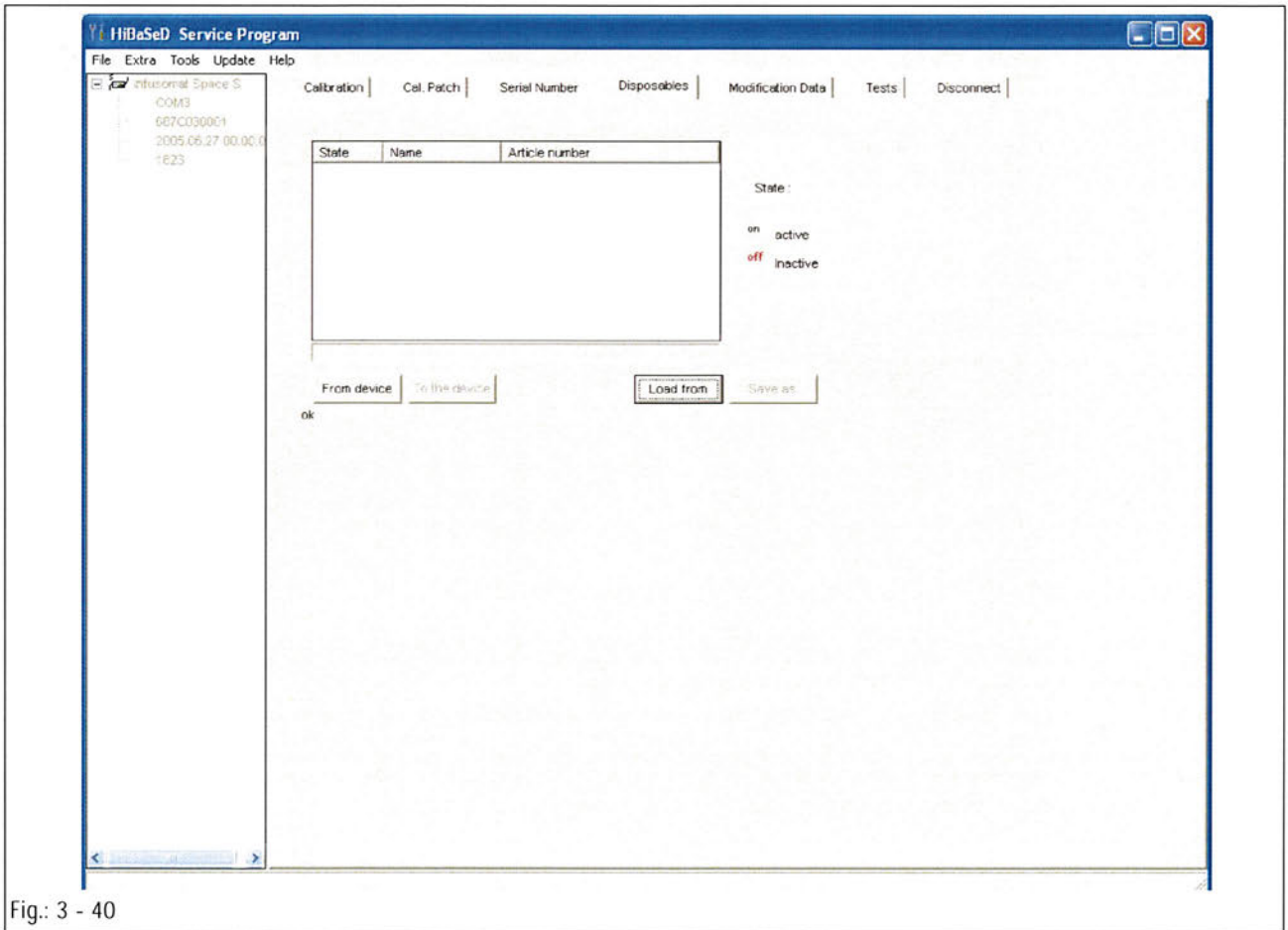


Fig.: 3 - 40

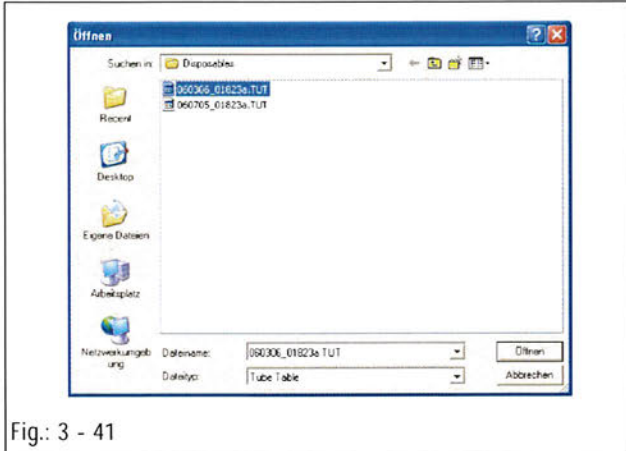


Fig.: 3 - 41

11. Press the "load from" button. The window "Open" is displayed on screen.
12. Select the desired file with the mouse pointer and press the "Open" button. The data loaded is displayed on screen.
13. Actuate the "to device" button. The data is saved in the Infusomat® Space.
14. Exit the Service Program (see "Quit the Service Program" → p. 1 - 13).

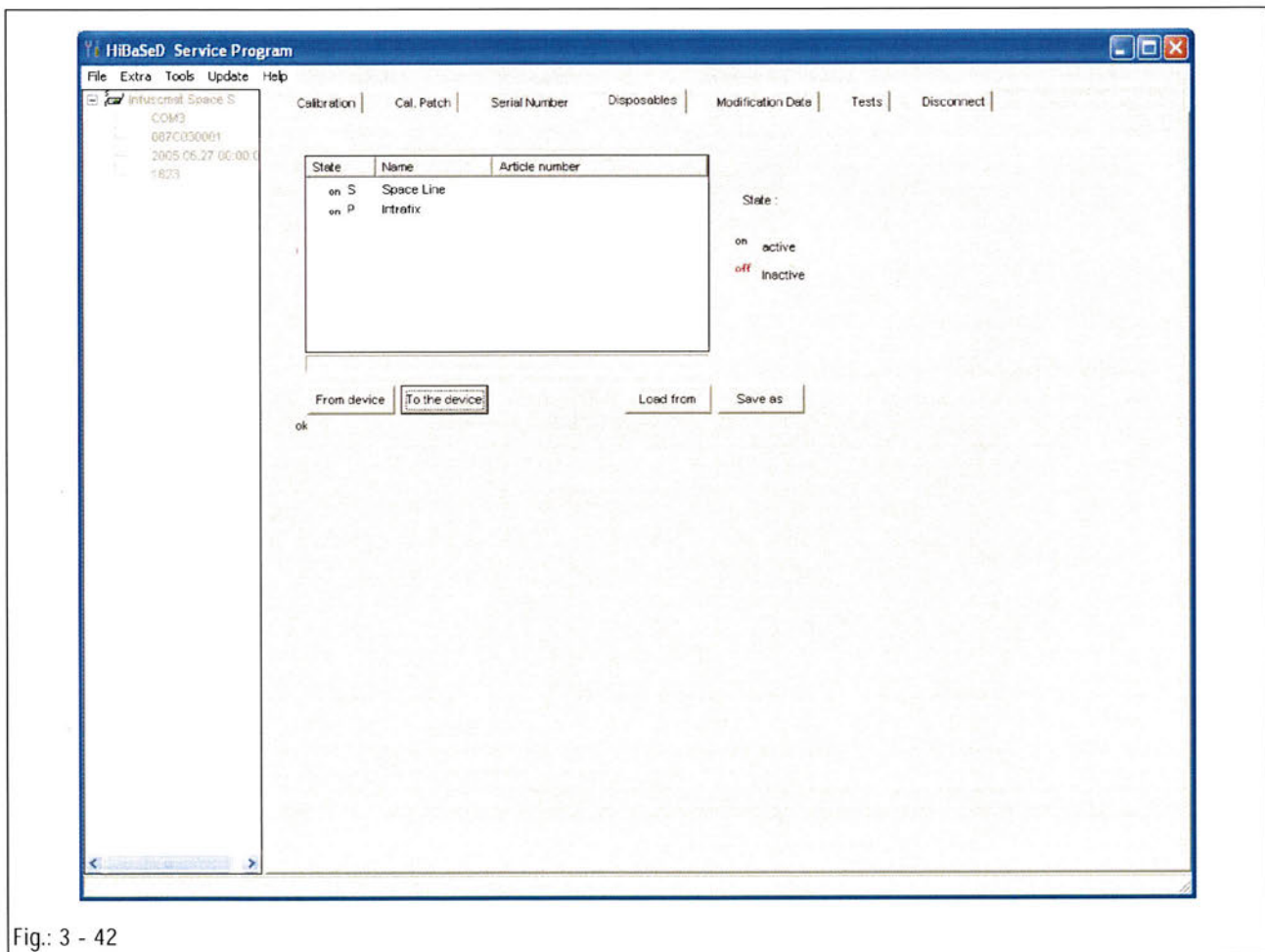


Fig.: 3 - 42

3.16 Checks after Repair

Procedure

1. Remove a slide clamp which may be inserted in the safety clamp and open safety clamp (press and engage operating lever).
2. When activities according to chapter 3.2 to 3.9 were carried out a visual inspection and a self-test are necessary.
3. Check the device (chapter 3.10 to 3.14) to ensure safe functionality of the unit (see "Device Check" ➔ p. 2 - 9).
4. Check the flow accuracy according to the TSC if activities of chapter 3.11 were carried out (see "Technical Safety Check (TSC)" ➔ p. 5 - 1).
5. Depending on the work carried out the specific steps of the TSC must be performed (see "Technical Safety Check (TSC)" ➔ p. 5 - 1).

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Check List for Checks after Repair

Visual Inspection	Electrical Safety according to IEC/EN 60601-1 or VDE 0750 and VDE 0751	Functional Inspection
<ul style="list-style-type: none"> <input type="checkbox"/> Cleanliness <input type="checkbox"/> Completeness <input type="checkbox"/> Damage and faults affecting safety <input type="checkbox"/> Damage to and readability of the label <input type="checkbox"/> Screw covers <input type="checkbox"/> Connectors "P2" and "P3" <input type="checkbox"/> Pressure sensor, downstream (membrane) <input type="checkbox"/> Pressure sensor, upstream (membrane) <input type="checkbox"/> Pump membrane <input type="checkbox"/> Pump slide (all the 12 slides are engaged) <input type="checkbox"/> Coding of pump slide guide <input type="checkbox"/> Pump connecting rod <input type="checkbox"/> Air inline sensor (free from grease or ultrasonic gel, free from cracks) <input type="checkbox"/> Drop sensor (lens) 	<p>The patient and housing leakage current of the Infusomat® Space is caused exclusively by the operating voltage supply (Power Supply SP or SpaceStation).</p> <p>The Technical Safety Checks of the power supply SP (drawing No. M001 32 10 05 F04) or of the SpaceStation (drawing No. M690 00 00 46 F04) serve to check whether both limit values are met.</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Locking with second unit <input type="checkbox"/> Battery compartment cover <p>Switch on unit with power supply</p> <ul style="list-style-type: none"> <input type="checkbox"/> Indicator lamps (LEDs) <input type="checkbox"/> Self-test <input type="checkbox"/> Audible alarm <input type="checkbox"/> Visual alarm <input type="checkbox"/> Status display <input type="checkbox"/> Lighting <p>Operation</p> <ul style="list-style-type: none"> <input type="checkbox"/> Opening and closing mechanism of the operating unit <input type="checkbox"/> Slide clamp releases release lever of the safety clamp. The Infusomat® Space line is squeezed. <input type="checkbox"/> Buttons on the operating unit <input type="checkbox"/> Infusion <input type="checkbox"/> Staff call <input type="checkbox"/> Bolus <input type="checkbox"/> Slide clamp is completely pulled on to the Infusomat® Space line when the operating unit is opened. <input type="checkbox"/> The operating lever of the safety clamp can be pressed down uniformly against spring tension and engages. The yellow caution sign flashes.

(Sheet 1 of 2)

Visual Inspection	Electrical Safety according to IEC/EN 60601-1 or VDE 0750 and VDE 0751	Functional Inspection
		<p>Electronic pressure cut off according to TSC Infusomat® Space line, standard type Delivery rate: 250 ml/h Test without drop sensor</p> <p><input type="checkbox"/> Upstream <input type="checkbox"/> Alarm</p> <p><input type="checkbox"/> Downstream <input type="checkbox"/> Pressure stage 1 <input type="checkbox"/> Pressure stage 5 <input type="checkbox"/> Pressure stage 9</p> <p>Mechanical pressure limitation according to TSC <input type="checkbox"/> P_{max} <input type="checkbox"/> P_{min}</p> <p>Safety clamp <input type="checkbox"/> Occlusion of Infusomat® Space line</p> <p>Drop sensor (optional) Delivery rate: 250 ml/h <input type="checkbox"/> Drop sensor alarm, occlusion <input type="checkbox"/> Drop sensor alarm, flow</p> <p>Air inline sensor according to TSC Infusomat® Space line, standard type <input type="checkbox"/> Water value <input type="checkbox"/> Air alarm <input type="checkbox"/> Difference of temperature sensors <input type="checkbox"/> Air value</p> <p>Switch on unit without power supply <input type="checkbox"/> Self-test <input type="checkbox"/> Magnetic function of the battery compartment cover <input type="checkbox"/> Charge state of the battery module</p> <p>Remove battery module <input type="checkbox"/> Alarm for min. 3 minutes</p>

(Sheet 2 of 2)

Cleaning

Clean and disinfect the Infusomat® Space with a damp cloth at regular intervals. To clean the system we recommend mild soap-suds.

WARNING

WHILE CLEANING AND DISINFECTING THE INFUSOMAT® SPACE, DISCONNECT THE UNIT FROM THE MAINS SUPPLY.

CAUTION

Hold the device horizontally and make sure that no fluids penetrate in the device through the safety clamp or the locking openings. The pushers of the pressure sensors and the air inline sensor in the operating unit must not be pressed during cleaning.

For disinfection refer to your infection control or housekeeping protocol that references how to disinfect equipment of this nature. If you disinfect the device by spraying, make sure not to spray in the system openings (such as interface sockets and connectors, loudspeaker opening).

Servicing the Battery

The instructions for use contain a detailed description on how to service the battery.

If a battery module is not discharged completely for more than 28 days, a servicing program for the battery module can be started on the unit.

Technical Safety Check (TSC)

1.1 Catalog Number:

1.1 Serial Number

Index c
(Master- to be added to the documentation)

Checklist for Technical Safety Check – Every 24 Months

Unit: Infusomat® Space
Manufacturer: B.Braun Melsungen, AG



Observe the Service Manual and the instructions for use. All measured values are to be documented. Accessories used should be included in testing. Use only calibrated measuring equipment.

1.0 Visual Inspection	3.0 Functional Inspection
<p>1.2 Labeling</p> <p>1.2.1 <input type="checkbox"/> Type Plate</p> <p>1.2.2 <input type="checkbox"/> Operating Temperature</p> <p>1.2.3 <input type="checkbox"/> Warning</p> <p>1.2.4 <input type="checkbox"/> Warranty</p> <p>1.2.5 <input type="checkbox"/> CSA/TÜV If applicable</p> <p>1.3 Case Housing</p> <p>1.3.1 <input type="checkbox"/> Upper and lower housings</p> <p>1.3.2 <input type="checkbox"/> Battery Door</p> <p>1.3.3 <input type="checkbox"/> Connectors P2 and P3</p> <p>1.3.4 <input type="checkbox"/> Drop Sensor Plug</p> <p>1.3.5 <input type="checkbox"/> Blind Plug Front Door</p> <p>1.3.6 <input type="checkbox"/> Emergency Crank Plug</p> <p>1.3.7 <input type="checkbox"/> Mechanical Pressure Cap</p> <p>1.3.8 <input type="checkbox"/> Pump Lock</p> <p>1.3.9 <input type="checkbox"/> Unit Feet (x4)</p> <p>1.3.10 <input type="checkbox"/> Screw Caps/Covers</p> <p>1.4 Display and Keypad</p> <p>1.4.1 <input type="checkbox"/> Buttons readable</p> <p><input type="checkbox"/> Display lens clear</p>	<p>3.1 <input type="checkbox"/> Lock Function</p> <p>3.2 <input type="checkbox"/> Install Service Connector and AC plug.</p> <p>3.3 Power on Self Test</p> <p>3.3.1 <input type="checkbox"/> Button Click</p> <p>3.3.2 Power on</p> <p>3.3.2.1 <input type="checkbox"/> Yellow green/red blue LED's illuminate</p> <p>3.3.2.2 <input type="checkbox"/> All display pixels</p> <p>3.3.2.3 <input type="checkbox"/> Self-test pass. Software Version: _____</p> <p>3.3.2.4 <input type="checkbox"/> Air vol. per h: _____ Air bubble: _____</p> <p>3.3.2.5 Audible Tones: <input type="checkbox"/> Low pitch <input type="checkbox"/> High pitch</p> <p>3.3.2.6 <input type="checkbox"/> LCD display backlight illuminates</p> <p>3.3.2.7 <input type="checkbox"/> Front panel backlight illuminates</p> <p>3.4 Front Door and Pump Channel</p> <p>3.4.1 <input type="checkbox"/> Door opens smooth, no binding</p> <p>3.4.2 <input type="checkbox"/> Hinge covers in place and secure</p> <p>3.4.3 <input type="checkbox"/> "Set loading" pictogram secure and legible</p> <p>3.4.4 <input type="checkbox"/> "Safety clamp" pictogram secure and legible</p> <p>3.4.5 <input type="checkbox"/> Door bolts secure (x3)</p> <p>3.4.6 <input type="checkbox"/> Spring loaded pushers: freedom of movement</p> <p>3.4.7 <input type="checkbox"/> Free flow clip catch present, void of cracks.</p> <p>3.4.8 <input type="checkbox"/> Sealing washers not visible (x6)</p>
<p>2.0 Electrical Safety Inspection According to IEC/EN 60601-1 or VDE 7050 and VDE 0751</p> <p>The patient and housing leakage current of the Infusomat Space is caused exclusively by the operating voltage supply (Power Supply SP or SpaceStation). The Technical Safety Checks of the Space Power Supply 8713112A or of the SpaceStation 8713040U serve to check whether both limit values are met</p>	<p>3.5 Pump Channel</p> <p>3.5.1 <input type="checkbox"/> Upstream pressure sensor</p> <p>3.5.2 <input type="checkbox"/> Pumping chamber slides (x12)</p> <p>3.5.3 <input type="checkbox"/> Air-in-line sensor</p> <p>3.5.4 <input type="checkbox"/> Downstream pressure sensor</p> <p>3.5.5 <input type="checkbox"/> Safety clamp warning light</p> <p>3.5.6 <input type="checkbox"/> Safety clamp</p>

Technical Safety Check (TSC)

Index c

(Master- to be added to the documentation)

3.0 Functional Inspection	3.0 Functional Inspection																																																																						
<p>3.6 Operation</p> <p>3.6.1 New Infusomat Space line installed.</p> <p>3.6.1.1 <input type="checkbox"/> Safety clamp engages and tubing is squeezed.</p> <p>3.6.1.2 <input type="checkbox"/> Safety clamp warning light extinguishes</p> <p>3.6.1.3 <input type="checkbox"/> Door closing</p> <p>3.6.1.4 <input type="checkbox"/> Space line recognition by unit display.</p> <p>3.6.2 <input type="checkbox"/> Button response</p> <p>3.6.3 <input type="checkbox"/> Infusion begins - green LED illuminates</p> <p>3.6.4 <input type="checkbox"/> Bolus function and indication</p> <p>3.7 <input type="checkbox"/> Staff Call</p> <p>3.8 Delivery Accuracy</p> <p style="text-align: center;">Ambient Temperature = 20 - 25°C</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Time to Infuse 25ml</th> <th>Deviation Percentage</th> <th>Acceptable Range</th> <th>Pass</th> </tr> </thead> <tbody> <tr> <td></td> <td style="text-align: center;">%</td> <td style="text-align: center;">< ±5%</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table> <p>3.9 Electronic Occlusion Pressure Threshold</p> <p><input type="checkbox"/> Upstream Occlusion Alarm</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Pressure Stage</th> <th>Visual "Alarm Pressure High"</th> <th>Reading on Pressure Meter</th> <th>Acceptable Range</th> <th>Pass</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">1</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;">1.5 – 8.7 psi (0.100 - 0.600 vdc)</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">5</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;">5.8 – 14.5 psi (0.400 – 1.000 vdc)</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">9</td> <td style="text-align: center;"><input type="checkbox"/></td> <td></td> <td style="text-align: center;">11.6 – 20.3 psi (0.800 – 1.400 vdc)</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table> <p>3.10 Mechanical Occlusion Pressure Threshold and Safety Clamp Test</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Pressure Stage</th> <th>Reading on Pressure Meter</th> <th>Acceptable Range</th> <th>Pass</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">P_{max}</td> <td></td> <td style="text-align: center;">27.6 – 30.5 psi (1.900 – 2.100 vdc)</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">P_{min}</td> <td></td> <td style="text-align: center;">>21.8 psi (> 1.500 vdc)</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">Safety Clamp >10 sec</td> <td></td> <td style="text-align: center;">>14.5 psi (≥ 1.200 vdc)</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table>	Time to Infuse 25ml	Deviation Percentage	Acceptable Range	Pass		%	< ±5%	<input type="checkbox"/>	Pressure Stage	Visual "Alarm Pressure High"	Reading on Pressure Meter	Acceptable Range	Pass	1	<input type="checkbox"/>		1.5 – 8.7 psi (0.100 - 0.600 vdc)	<input type="checkbox"/>	5	<input type="checkbox"/>		5.8 – 14.5 psi (0.400 – 1.000 vdc)	<input type="checkbox"/>	9	<input type="checkbox"/>		11.6 – 20.3 psi (0.800 – 1.400 vdc)	<input type="checkbox"/>	Pressure Stage	Reading on Pressure Meter	Acceptable Range	Pass	P_{max}		27.6 – 30.5 psi (1.900 – 2.100 vdc)	<input type="checkbox"/>	P_{min}		>21.8 psi (> 1.500 vdc)	<input type="checkbox"/>	Safety Clamp >10 sec		>14.5 psi (≥ 1.200 vdc)	<input type="checkbox"/>	<p>3.11 Drop Sensor Test (Optional)</p> <p><input type="checkbox"/> Flow Alarm <input type="checkbox"/> Upstream Occlusion Alarm</p> <p>3.12 Air Sensor and Temperature Sensors</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Air Sensor</th> <th>Reading on Display</th> <th>Acceptable Range</th> <th>Pass</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Fluid Filled</td> <td></td> <td style="text-align: center;">>600 mV</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Temp Sensors</th> <th>Reading on Display</th> <th>Max Difference</th> <th>Pass</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Temp1</td> <td></td> <td rowspan="2" style="text-align: center;"><3°C</td> <td rowspan="2" style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;">Temp2</td> <td></td> </tr> </tbody> </table> <p><input type="checkbox"/> Set's safety clamp is pulled onto the line.</p> <p><input type="checkbox"/> Air-in-line test – "Air bubble alarm"</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Air Sensor</th> <th>Reading on Display</th> <th>Acceptable Range</th> <th>Pass</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Air Filled</td> <td></td> <td style="text-align: center;"><100 mV</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </tbody> </table> <hr/> <p> Warning: When the service key is installed, the electronic occlusion limits and audible alarms are disables. Remove the key prior to patient use. Failure to remove the Service Key may result in patient injury</p> <hr/> <p><input type="checkbox"/> Remove Service Connector</p> <p>3.13 Battery Verification</p> <p><input type="checkbox"/> Self-test passed on battery power.</p> <p><input type="checkbox"/> Battery compartment alarm.</p> <p>3.14 Measuring Equipment Used</p> <p>Pressure Meter: _____</p> <p>Graduated cylinder _____</p> <p>Collection vessel: _____</p> <p>Stopwatch: _____</p>	Air Sensor	Reading on Display	Acceptable Range	Pass	Fluid Filled		>600 mV	<input type="checkbox"/>	Temp Sensors	Reading on Display	Max Difference	Pass	Temp1		<3°C	<input type="checkbox"/>	Temp2		Air Sensor	Reading on Display	Acceptable Range	Pass	Air Filled		<100 mV	<input type="checkbox"/>
Time to Infuse 25ml	Deviation Percentage	Acceptable Range	Pass																																																																				
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Temp Sensors	Reading on Display	Max Difference	Pass																																																																				
Temp1		<3°C	<input type="checkbox"/>																																																																				
Temp2																																																																							
Air Sensor	Reading on Display	Acceptable Range	Pass																																																																				
Air Filled		<100 mV	<input type="checkbox"/>																																																																				

<p style="text-align: center;">3.13 Test Results:</p> <p>Disposition of unit:</p> <p><input type="checkbox"/> Ready for use</p> <p><input type="checkbox"/> Needs Repair</p> <p>Notes: _____</p>	<p style="text-align: center;">3.13 Inspection performed by:</p> <p>Name _____</p> <p>Signature _____</p> <p>Date: _____</p> <p>Date of Next Service: _____</p>
--	--

Technical Safety Check (TSC)

4.1 Catalog Number:

4.1 Serial Number:

Index c
(Master- to be added to the documentation)

Checklist for Technical Safety Check – Every 24 Months

Unit: Power Supply SP (Space)
Manufacturer: B.Braun Melsungen, AG



Observe the Service Manual and the instructions for use. All measured values are to be documented. Accessories used should be included in testing. Use only calibrated measuring equipment.

4.0 Visual Inspection

- 4.2 Label
- 4.3 Power Supply Housing
- 4.4 Plug Ends
- 4.5 Power Cord

5.0 Electrical Safety Inspection

According to IEC/EN 60601-1 or VDE 7050 and VDE 0751

	Measured Value	Unit of Measure	Acceptable Range	Pass/Fail
Test Voltage		VAC	±5%	
Leakage Current		µA	≤7 µA	<input type="checkbox"/>

Note:

This measurement ensures that the admissible limit values regarding the patient and housing leakage current of the Perfusor® Space or the Infusomat® Space are met.

6.0 Functional Inspection

- 6.1 Connect to AC
- 6.2 Connect to Perfusor or Infusomat Space Unit.
- 6.3 Power up unit self check with AC indication.

Test Results:

Disposition of unit:

- Ready for use
- Needs Repair

Notes: _____

Inspection performed by:

Name _____

Signature _____

Date: _____

Date of Next Service: _____

Procedural Instruction on the TSC

(Technical Safety Check) See the "Instructions for Use" manual (FZ00951095) for additional instructions and descriptions about the Infusomat® Space.

7

1. Visual Inspection

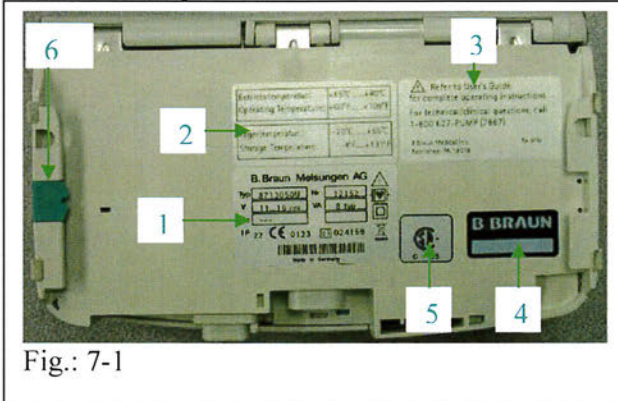


Fig.: 7-1

Legend for fig. 7 - 1

Item Designation

1. Type Plate Label
2. Operating Temperature Label
3. Warning Label
4. Warranty Label
5. CSA or TÜV (not shown) Label - available only on "U" suffix devices
6. Pump Lock

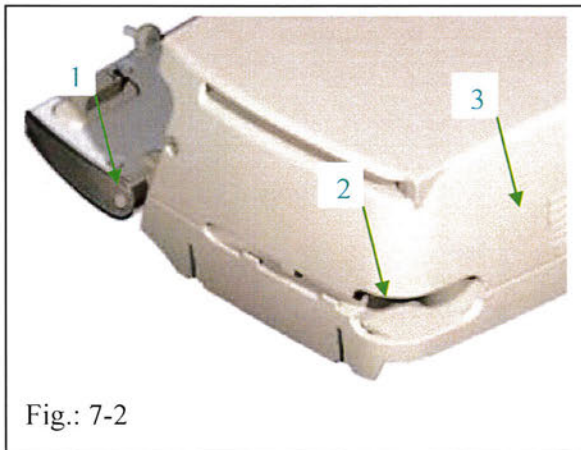


Fig.: 7-2

Legend for fig. 7 - 2

Item Designation

1. Blind Plug in Front Door
 2. Drop Sensor Connector Channel (plug not shown)
 3. Mechanical Pressure Adjustment Cap
- 7-1

- 1.1. Document the unit's Catalog and Serial Number on the TSC. (See Figure 7.1).

Note:

On some devices, the Type Plate, "Typ" = Catalog Number "Nr" = Serial Number.

- 1.2. Labeling, secure and legible: (See Figure 7.1)

- 1.2.1. Type Plate Label
- 1.2.2. Operating Temperature Label
- 1.2.3. Warning Label
- 1.2.4. Warranty (Green or Black)
- 1.2.5. CSA or TÜV Label. Placement may vary. (available "U" suffix catalog numbers only)

- 1.3. Case housing

- 1.3.1. Upper and Lower housings void of cracks and damage that permit fluid intrusion.
- 1.3.2. Battery door secure. (See figure 1-2)
- 1.3.3. Connectors P2 and P3 clean and secure. (See figure 1-2)
- 1.3.4. Drop sensor plug installed (only if sensor is not present) (See Figure 3-9)
- 1.3.5. Blind plug front door installed (See figure 7-2).
- 1.3.6. Emergency crank plug installed (See figure 3-10).
- 1.3.7. Mechanical pressure adjustment cap installed (See figure 7-2).
- 1.3.8. Pump lock secure (See figure 7.1).
- 1.3.9. Unit feet (x4) clean and present (See figure 3-11).
- 1.3.10. Screw Caps/Covers in place, no screws visible.

- 1.4. Display and key panel

- 1.4.1. All buttons are legible. Display lens is clear and void of damage or cloudiness affecting readability of the display.

Procedural Instruction on the TSC (Technical Safety Check)

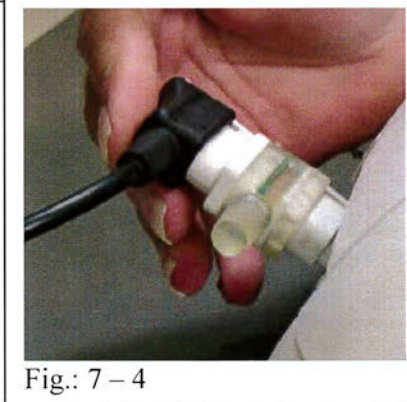
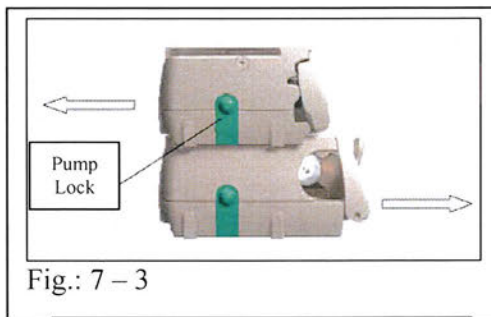
2. Electrical Safety according to IEC/EN 60601-1 or VDE 0750 and VDE 0751.

The patient and housing leakage current of the Infusomat Space is caused exclusively by the operating voltage supply (Power Supply SP or SpaceStation). The Technical Safety Checks of the Space Power Supply 8713112/A or of the SpaceStation 8713040U serve to check whether both limit values are met.

3. Functional Inspection

Hardware required:

- Additional Space Unit
- Service Connector 34521062
- Infusion bag or vented bottle
- Infusomat Space Line, standard
- Two three way stop-cocks
- 10ml syringe, piston drawn back to the 10ml mark and fixed.
- Pressure meter. Display to 0.1 resolution.
- Stop watch
- 1 ml syringe
- Graduated cylinder or collection vessel accurate to ± 0.4 ml.
- Space Power Supply 8713112/A



WARNING :

When the Service Connector is installed, the electronic occlusion limits and audible alarms are disabled. Remove the key prior to patient use. Failure to remove the Service Connector may result in patient injury.

3.1 Lock Function

- 3.1.1 Slide another Space pump to the top of the unit under test. Top unit should lock into place. Press the Pump Lock to disconnect top unit.
- 3.1.2 Slide another Space under the unit under test. Bottom unit should lock into place. Press the Pump Lock of the unit under test to disconnect the bottom unit. See Figure 7 – 3

- 3.2 Install Service Connector 34521062 into connector P2. Plug should lock into place. Connect an AC power supply (8713112/A) line to the Service Connector. LCD display displays

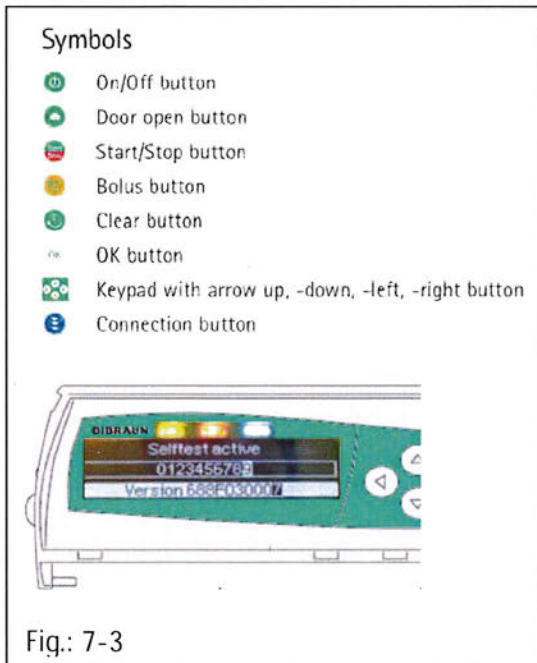
AC connected icon:  See Figure 7 – 4

3.3 Power on self-test

Note:

This test requires the user to pay close attention to the device as it is powering up. If any portion of this test goes unnoticed, repeat the test by powering the unit off, then back on – paying close attention to that which was missed. This step may need to be repeated more than once. To power the device off, hold the power button >3 seconds.

3. Functional Inspection



3.3.1 Press each button one time (power button last). All buttons respond with a mechanical “click.” (See Figure 7.3) If “Battery Maintenance” option appears, select “No.”

3.3.2 Press the On/Off button and allow unit to power-up. Inspect the following:

3.3.2.1 Three LED indicator lamps on front panel illuminate Yellow, Green/Red, Blue.

Note:

Note: The middle LED will illuminate green then switch to red.

3.3.2.2 No blank pixels on display LCD Screen

3.3.2.3 Self Test numbers on the display LCD ascends as the software version is displayed. Document the software version on the Technical Safety Check.

Note:

Only the software prefix is displayed if the Service Connector is not installed. The software version is also displayed in the “Status” option from the main menu of the unit.

3.3.2.4 Observe the Air-in-Line settings displayed during the self test. Document on the TSC.

3.3.2.5 Two Audible tones: Low pitch tone followed by a High pitch tone.

3.3.2.6 LCD display backlight illuminates.

3.3.2.7 Front panel backlight illuminates.

3.4 Front Door

3.4.1 Open the front door by pressing the button. Confirm action by selecting “Yes.” Inspect the following: (See figure 7-4)

Note:

If powering on for the first time, select the default language, followed by a confirmation of that language.

3.4.1.1 Door opens smoothly without binding.

3.4.1.2 Hinge covers installed (x4).

3.4.1.3 Pictogram “set loading” secure and legible.

3.4.1.4 Pictogram “safety clamp” secure and legible.

3.4.1.5 Door bolts (x3) present and secure.

3.4.1.6 Spring-loaded set/tubing pushers present and move freely when pressed.

Procedural Instruction on the TSC (Technical Safety Check)

3. Functional Inspection

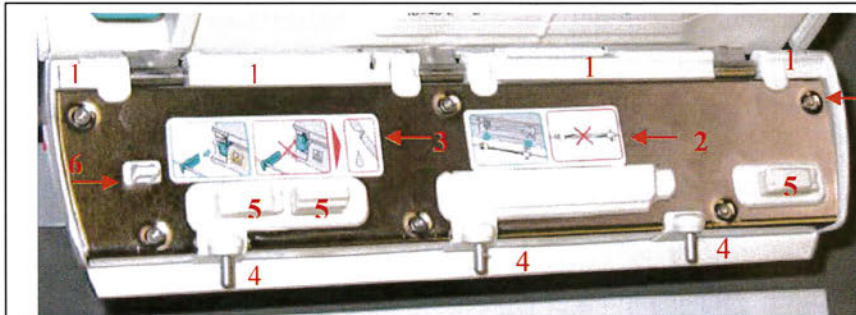


Fig.: 7-4

Legend for fig. 7-.4

Item Designation

1. Hinge Covers (x4)
2. Pictogram "set loading"
3. Pictogram "safety clamp"
4. Door bolts (x3)
5. Tubing Pushers (x3)
6. Free Flow clip catch
7. Sealing washers (x6)

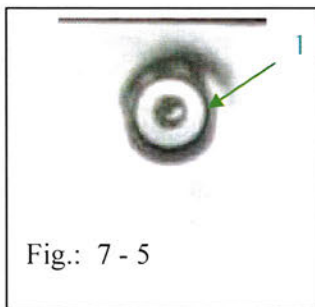


Fig.: 7 - 5

Legend for fig. 7 - 5

Item Designation

1. Sealing washer not visible around screw cap.

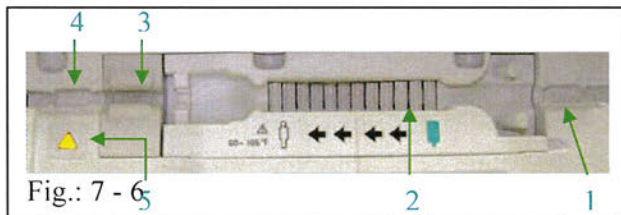
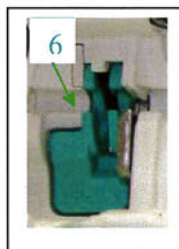


Fig.: 7 - 6

Legend for fig. 7 - 6

Item Designation

1. Upstream pressure sensor
2. 12 slides of pump channel
3. Air-in-line sensor
4. Downstream pressure sensor
5. Safety Clamp Warning LED
6. Safety Clamp



3.4.1.7 Free flow clip catch present, void of cracks.

3.4.1.8 Sealing washers not extruding from under the door screws (x6). (See figure 7-5) Note: The sealing washers are clear and very small. One or more areas of the washer may be slightly visible. If so, ensure the washers are not distorted as to allow fluid into the screw setting.

3.5 Pump Channel (See figure 7-6)

3.5.1 Upstream pressure sensor clean and smooth, void of foreign substance or debris.

3.5.2 All 12 slides of pumping chamber pressed in (not extruding) clean and void of foreign substance or debris.

3.5.3 Air-in-line sensor clean and void of foreign substance or debris.

3.5.4 Downstream pressure sensor clean and smooth, void of foreign substance or debris.

3.5.5 Safety clamp warning light flashes.

Note:

Safety clamp warning light only flashes when the safety clamp is locked open.

3.5.6 Safety clamp locks into open position, clear of foreign substance or debris. No visual indication of cracks or damage.

3. Functional Inspection

3.6 Operation

3.6.1 Install a new fully primed Infusomat Space Line.


Note:

See the Infusomat Space Instruction for Use manual FZ00951095 for information regarding loading an Infusomat Space Line.

The set's anti free-flow clip engages the safety clamp and the pump's tube pincher squeezes the tubing.

3.6.1.1 Safety clamp warning light extinguishes.

3.6.1.2 Close the front door. This is accomplished by applying direct pressure to the top center of the door when it comes in contact with the front of the unit. The door closing sequence begins and the motor engages to fully close the door.

3.6.1.3 Acknowledge the set installed by pressing  to choose "Original Space Line" in the unit display.

Note:

Configuration may prompt for Prime Line, Drug Calculator and/or Use last therapy. Select "No" for these features such as these.

3.6.2 From the main menu, press each of the 11 buttons once. Each button should have a response on the display. If a Yes/No prompt appears during this check, choose "No."

3.6.3 Enter a rate of 100ml/hr and confirm with "OK." Enter a volume to be delivered (VTBI) of 100ml and confirm with "OK." Press start. Infusion begins and the green LED illuminates on the front door.

3.6.4 Perform a Manual Bolus of 2ml: While the pump is running, Press the "BOL" key then press and hold the "OK" key. The rate increases and the word "Bolus" appears in the display. Release "OK" when 2ml is achieved. The rate display reverts back to 100ml/hr.

3.7 Staff Call.

3.7.1 With the device running, clamp the tubing upstream to generate an upstream occlusion alarm. The red LED on the Service Connector illuminates. Confirm the alarm and unclamp the tubing upstream.

7

Procedural Instruction on the TSC (Technical Safety Check)

3. Functional Inspection

Note: Image not to scale. With the exception of specific requirements listed, exact distances between items are not required.

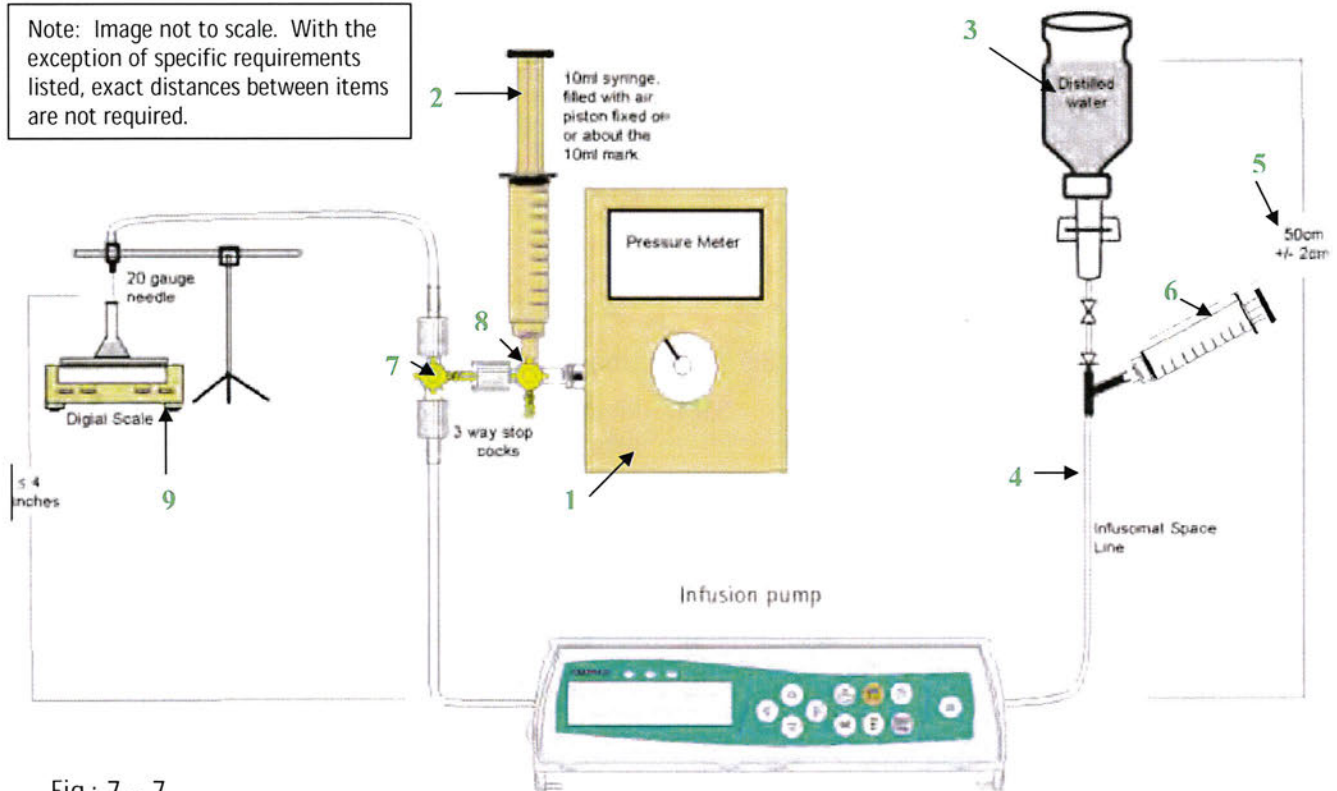


Fig.: 7 – 7

3.8 Delivery Accuracy

Legend for fig. 7-7

Item Designation

1. Electronic pressure gauge
2. 10ml syringe with piston fixed at 10ml mark
3. IV fluid source container, bag or vented bottle.
4. Standard Infusomat Space Line fully primed, drip chamber 2/3 full with a 20 gauge needle installed downstream.
5. Fluid head height approximately 50cm
6. 10ml syringe, or greater, for upstream pressure relief during Mechanical Occlusion Pressure Threshold Test.
7. Three way stop-cock #1: off position right.
8. Three way stop-cock #2: off position down.
9. Graduated cylinder or collection vessel.

- 3.8.1 Set up the test according to figure 7-7. Adjust three way stop-cocks as shown in Fig 7-7. Use a new, unused Infusomat Space Line for each delivery accuracy test. Set must be fully primed.

Note:

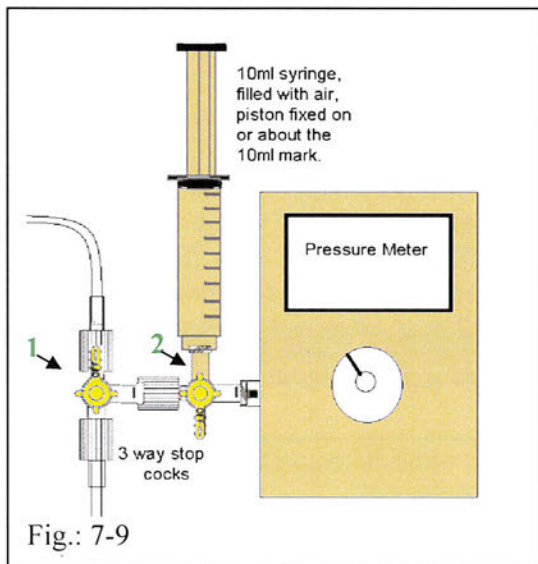
1 ml = 1 cc = 1 g of sterile water at room temperature (70°F/21.1°C)

- 3.8.2 Ensure the ambient temperature is within the range specified on the TSC.
- 3.8.3 Three way stop-cock #1 Shut off flow to the syringe and pressure gauge. See figure 7-9
- 3.8.4 Suspend the 20 gauge needle over the graduated cylinder or collection vessel no more than 4 inches above or below the center of the pump. If using a scale for a collection vessel, zero/tare it now.

3. Functional Inspection

Measuring Time		Deviation %
6 min	40.0 sec	-10
6 min	18.9 sec	-5
6 min	15.0 sec	-4
6 min	11.1 sec	-3
6 min	7.3 sec	-2
6 min	3.6 sec	-1
6 min	0.0 sec	0
5 min	56.4 sec	1
5 min	52.9 sec	2
5 min	49.5 sec	3
5 min	46.2 sec	4
5 min	42.9 sec	5
5 min	27.3 sec	10

Fig.: 7-8



Legend for fig. 7-9

Item Designation

1. Stop-cock #1: off position up
2. Stop-cock #2: off position down.

7-7

3.8.5 Deviation evaluation.

3.8.5.1 Set the delivery rate to 250ml/hr.

3.8.5.2 Set the delivery volume to 30ml.

3.8.5.3 Simultaneously press Start on the pump and Start on the stopwatch. Infusion begins.

3.8.5.4 Stop the stopwatch immediately when the 25ml mark is reached in the graduated cylinder or collection vessel. Document the time on the TSC.

3.8.5.5 Observe the deviation percentage according to figure 7-8. Document the percentage value on the TSC.

3.9 Electronic Occlusion Pressure Threshold

3.9.1 Remove the Service Connector from connector P2. Attach AC power plug directly to connector P2.

3.9.2 If attached, remove the drop sensor.

3.9.3 Verify position of three way stop-cocks match that of figure 7-7.

3.9.4 Set the delivery rate to 250ml/hr.

3.9.5 Set the delivery volume to 250ml.

3.9.6 Press Start. Infusion begins.

3.9.7 Upstream Occlusion Alarm

3.9.7.1 Clamp the tubing between the IV source container and the pump, upstream from the pump approximately 30cm.

3.9.7.2 Confirm with "OK" and unclamp the tubing upstream.

3.9.8 Downstream Occlusion Alarm

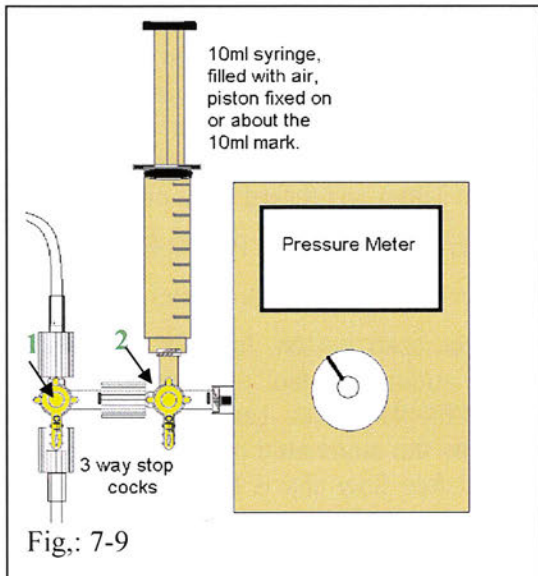
3.9.8.1 Ensure stop-cock #2 has flow to the 10ml syringe. See figure 7-9.

3.9.8.2 Adjust three way stop-cock #1 to turn on flow to the pressure meter and turn off flow to the graduated cylinder. See figure 7-9.

7

Procedural Instruction on the TSC (Technical Safety Check)

3. Functional Inspection



Legend for fig. 7-10

Item Designation

1. Stop-cock #1: off position down, pressure relief.
2. Stop-cock #2: off position down.

3.9.8.3 Set pressure stage 1.

Note:

Note: To set the pressure stage, select "Options" from the main menu. Cursor left to select the desired pressure value. Once selected, confirm with "OK." Press "C" to return to the main menu.

3.9.8.4 Press Start. Infusion begins and pressure builds.

3.9.8.5 Unit displays alarm as *"Alarm Pressure High."* Immediately observe the highest value displayed on the pressure meter, prior to post occlusion bolus reduction. Record the value on the TSC.

3.9.8.6 Press "OK" to confirm the alarm. Select pressure stage 5. Press Start.

3.9.8.7 Unit displays alarm as *"Alarm Pressure High."* Immediately observe the highest value displayed on the pressure meter, prior to post occlusion bolus reduction. Record the value on the TSC.

3.9.8.8 Press "OK" to confirm the alarm. Select pressure stage 9. Press Start.

3.9.8.9 Unit displays alarm as *"Alarm Pressure High."* Immediately observe the highest value displayed on the pressure meter, prior to post occlusion bolus reduction. Record the value on the TSC. Press "OK" to confirm the alarm.

3.9.8.10 Relieve system pressure. See Figure 7-10.

3.10 Mechanical Occlusion Pressure Threshold and Safety Clamp Test.

Note:

Presence of an upstream back-check-valve on the set may affect the Mechanical Occlusion Pressure Threshold test. Measures, such as adding a syringe to the upstream "Y" site, may need to be taken to allow upstream pressure relief. (See Fig.: 7 - 7 Item #6)

3.10.1 Connect the Service Connector into connector P2. Connect AC power to the Service Connector.

3.10.2 Adjust the three way stop-cocks as shown in figure 7-7.





3.10.3 Press Start. Infusion begins. Allow the infusion to first infuse into the graduated cylinder or collection vessel.

3.10.4 As the pump is running, position stop-cock #1 to allow flow into the pressure meter and cut flow to the collection vessel. See figure 7-9.

3. Functional Inspection

- 3.10.5 The pressure will build like a wave, with a crest and a trough. As the pressure peaks at its highest value, spring tension in the mechanism releases the pressure reducing it to its trough. Once the trough pressure is achieved, spring tension mounts and pressure begins to build again. No visual alarm will occur. Monitor the pressure meter for the crest pressure (P_{max}) and the trough pressure (P_{min}). Observe these values and record them on the TSC.
- 3.10.6 Press stop. LEAVE THE SYSTEM PRESSURIZED.
- 3.10.7 Observe the value on the pressure meter.
- 3.10.8 Press the door open button, followed by "Yes," to initialize the automated door opening process. DO NOT FULLY OPEN THE DOOR. Leave the door partially open as left by the automated process. This ensures the set's anti free flow clip is NOT pulled onto the set. Pressure is maintained solely by the pump's free flow safety clamp.
- 3.10.9 Observe the value on the pressure meter for 10 seconds. Document the value on the TSC after 10 seconds
- 3.10.10 Close the door and confirm "Original Space Line." Relieve system pressure by adjusting three-way stop-cocks as shown in Figure 7-10. When pressure is relieved, move valves to positions indicated in figure 7-7.
- 3.11 **Drop Sensor Test** (Optional, available only on units that accompany a drop sensor)
 - 3.11.1 Connect the Drop sensor to the unit. Install onto the drip chamber of the Infusomat Space Line. Ensure the drip chamber's fluid line is below the level of optics. Drop sensor must be clean and free of debris.
 - 3.11.2 Enter the main menu and program a rate of 250ml/hr and a VTBI of 100ml. Press Start.
 - 3.11.3 While the unit is pumping, squeeze the drip chamber of the set to create a stream. An alarm is immediately generated.
 - 3.11.4 Cancel the alarm and press start.
 - 3.11.5 Disconnect the Infusomat Space line from the container. An alarm is generated within 5 seconds.

3. Functional Inspection**3.12 Air Sensor and Temperature Sensors (Service Connector Installed)**

- 3.12.1 Press the Door open button.
- 3.12.2 When the unit display prompts you to confirm opening the door, press the  cursor button to display the value read by the Air Sensor. Observe the displayed value for 120 seconds. Document the lowest value within the 120 seconds on the TSC.
- 3.12.3 Observe the values of Temp1 and Temp2 as displayed below the Air Sensor value. Record values on the TSC. Compare each sensor, they must be within $<3^{\circ}\text{C}$ of each other.
- 3.12.4 Press the  cursor button to return to the "Open door?" prompt. Select "No."
- 3.12.5 Program a rate of 100ml/hr and a VTBI of 200ml. Press Start.
- 3.12.6 Inject a 0.4ml air bubble upstream of the unit. Allow the air to infuse until an "Air bubble alarm" is generated. Confirm the alarm.
- 3.12.7 Open door, ensure the set's safety clamp is pulled completely onto the line. Remove the Infusomat Space line. Install an Infusomat Space line full of dry air, void of any liquid.
- 3.12.8 Close the door.
- 3.12.9 When the unit display prompts you to confirm opening the Original Space Line, press the  cursor button to display the value read by the Air Sensor. Observe the displayed value for 10 seconds. Document the highest value within the 10 seconds on the TSC.
- 3.12.10 Press  to return to the Line change menu. Open the door and remove the set.

W A R N I N G :

When the Service Connector is installed, the electronic occlusion limits are disabled. Remove the key prior to patient use. Failure to remove the Service Connector may result in patient injury.

- 3.12.11 Remove AC power and the Service Connector.

3. Functional Inspection

3.13 Battery verification

Note:

Battery charge time approximately 6 hours. Please see the Infusomat Space Instructions for Use manual FZ00951095 section titled Battery Operation and Maintenance.

3.13.1 Power Off Device (Press and hold the On/off button for >3 seconds) and disconnect AC power.

3.13.2 Power on device to initiate a successful self test.

3.13.3 Open battery compartment to generate a "Battery cover removed" alarm. Confirm the alarm. Replace cover and verify cover snaps into place and is secure.

3.14 Document Measuring Equipment Used

3.14.1 Provide information as to the Serial Number or Identification for the following items used to complete the TSC.

- Pressure Meter
- Stopwatch
- Graduated cylinder or Collection vessel

3.15 Test Results And Final Signature

3.15.1 Indicate the disposition of the unit as either Ready for Use or Needs Repair. Use the Notes section to document any applicable information such as reason for Needs Repair, configuration information, accessories attached, ward ID, etc.

3.15.2 The name of the person performing the TSC is to print, sign and date their name. Indicate the next date a TSC is to be performed.

4 Power Supply Visual Inspection

4.1 Document the catalog and serial number of the Power Supply SP on the TSC.

4.2 Inspect label for readability

4.3 Inspect the power supply housing for cracks and damage.

4.4 Inspect the plug ends for security and cleanliness. The pump plug must be free from corrosion.

4.5 Inspect cord for cuts, scraps or tears in the insulation.

7

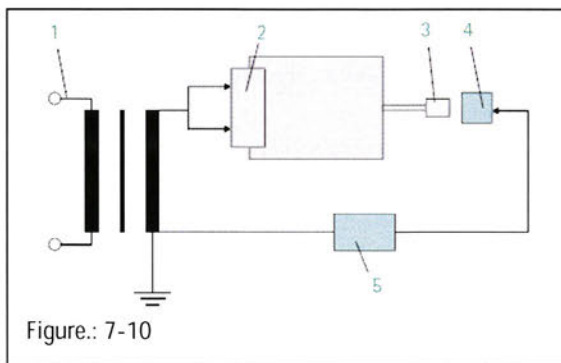
Procedural Instruction on the TSC (Technical Safety Check)

5 Power Supply Electrical Safety Inspection According to IEC/EN 60601-1 or VDE 0750 and VDE 0751.

Hardware Required:
Service Adapter SP (7705174)
Medical Device Tester

- 5.1 Attached the Service Adapter SP to the Pump Plug end of the Power Supply SP.
- 5.2 Configure the Medical Device Tester voltage to the current IEC-60601-1 standard for testing devices of this nature. As of today, the standard calls for an applied test voltage of 110% of the highest rated mains voltage indicated on the power supply. Attach the Power Supply SP to the Medical Device Tester.
- 5.3 Apply test voltage and measure the leakage current at the test point in the Service Adapter SP. Document the value on the TSC. See Figure 7-10.

6 Power Supply SP Function Check



Legend for fig. 7-10

Item Designation:

1. AC Mains Connection
2. AC plug of power supply
3. Pump plug connector
4. Service Adapter with test point
5. Medical Device Tester

- 6.1 Connect the Power Supply to AC power.
- 6.2 Plug the pump plug end into a Perfusor or Infusomat Space unit. Ensure the plug snaps into place and remains secure.
- 6.3 Power the connected space unit on and ensure a successful self check is achieved. Ensure the status display LCD indicates the unit is connected to AC power, not Battery.
- 6.4 Test Results And Final Signature
 - 6.4.1 Indicate the disposition of the unit as either Ready for Use or Needs Repair. Use the Notes section to document any applicable information such as reason for Needs Repair, configuration information, accessories attached, ward ID, etc.
 - 6.4.2 The name of the person performing the TSC is to print, sign and date their name. Indicate the next date a TSC is to be performed.

Test Equipment and Special Tools

8

Test Equipment	Designation	Ord. No.
	For Device Check	
	Service connector Space	3452 1062
	HiBaSeD Service & Update CD.....	FZ8912



Slide clamp (of the Infusomat® Space line)	
For Repairs	
HiBaSeD Service & Update CD.....	FZ8912
For the TSC	
Measuring instrument for electrical safety	
Service adapter SP	0770 5174
for measuring the electrical safety	

Special Tools**Designation**

TORX screwdriver kit

5 - 10, 25

TORX plus screwdriver kit

5 - 10, 25

Screwdriver 6IPx60 TORX plus

Screwdriver 8IPx60 TORX plus

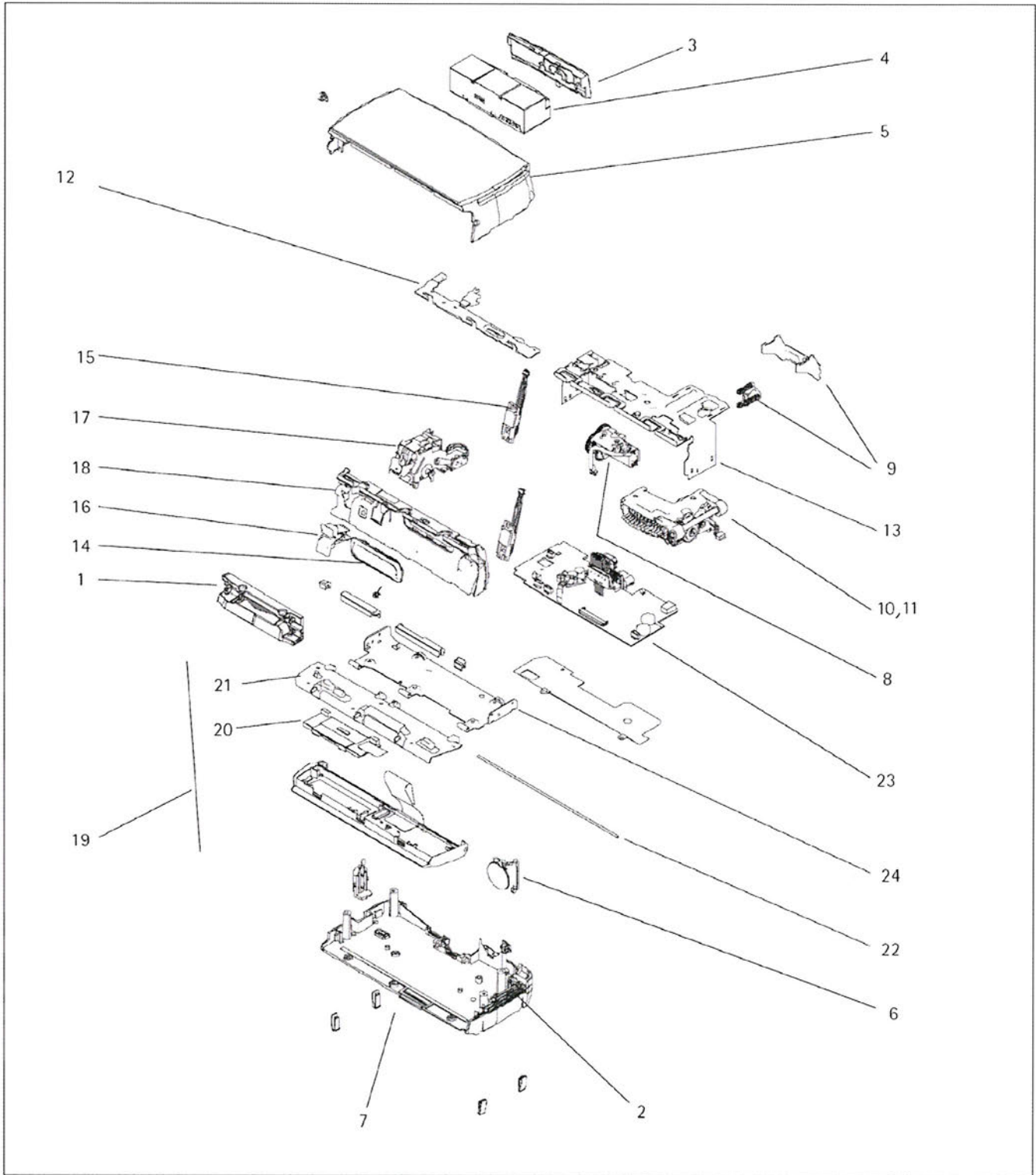
Screwdriver 10IPx60 TORX plus

Screwdriver 25IPx60 TORX plus .

Spare Parts List

9

	Item Designation	Ord. No.
Infusomat® Space	Service part kit Infusomat® Space 3452 1593 with: housing cover cap (100 pieces) housing foot (10 pieces) snap-in hook SP with leaf spring (2 pieces) emergency release plug ISP incl. O-ring (2 pieces) emergency release crank ISP (1 piece) bracket locking (10 pieces) safety clamp seal, housing bottom part (10 pieces) cover cap kit for housing SP (50 pieces) 3477 4386 Screw kit Infusomat® Space 3452 1585 with: screw DELTA PT 22x8 WN 5451 TORX plus 6IP (5 pieces) screw DELTA PT 25x7 WN 5451 TORX plus 8IP (5 pieces) screw DELTA PT 30x8 WN 5452 TORX plus 10IP (10 pieces) screw DELTA PT 30x12 WN 5452 A2 TORX plus 10IP (10 pieces) countersunk screw DELTA PT 20x9 WN 5454 TORX plus 6IP (5 pieces) fillister head screw M3x6 TORX fillister head screw M3x10 countersunk screw M3x5 TORX countersunk screw M3x12 A2 TORX seal washer PA 2.2x0.3 hexagon nut M3 A2 toothed locked washer M3 A2 distance sleeve	



IV SETS
 CALL: 800-854-6851
 CLINICAL
 TECHNICAL
 TO PLACE
 IV SET ORDER - 800-227-2862

1	Slide guide, compl., ISPS	3452 1330
2	Cover, drop sensor connector	3452 1577
3	Battery compartment cover ISP, cpl. (incl. emergency release crank)	3452 1321
4	Battery pack SP (NIMH)	0871 3180
5	Housing, upper part ISP	3452 1313
6	Loudspeaker SP	3452 0937
7	Housing, bottom part ISP	3452 1305
	Rating plate ISP	Upon request
8	Door bolt drive ISP	3452 1429
9	Pressure adjustment unit ISPS	3452 1445
	(spring holder, pressure springs, adjusting screw adjusting nut, bracket, bracket locking)	
10	Pump frame ISP, cpl. (incl. pump drive motor ISP)	3452 1402
11	Pump drive motor ISP	3452 1410
12	Door bolt ISP	3452 1496
13	Inner frame ISP	3452 1437
14	Membrane ISP	3452 1356
15	Pressure sensor ISP	3452 1372
16	Air inline sensor ISP	3452 1380
17	Safety clamp ISPS	3452 1399
18	Front frame ISPS, cpl.	3452 1364
19	Operating unit ISPS, cpl.	3452 1470
20	LC display SP	3452 0988
21	Metal front sheet ISPS	3452 1488
22	Axle ISP	3452 1461
	(incl. hinge covers and hinge spring)	
23	Processor PCB ISP	3452 1348
	(incl. connectors)	
24	Bottom inner frame ISP	3452 1453

Revision Documentation

11

Description of Version

Version B

- Initial release

Version C

- Update part numbers and nomenclature
 - Update software version numbers
-

Servicing the battery	4 - 1	TSC	0 - 5, 5 - 1
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