Service Manual

Technical Description and Service Instructions

for

THERMOFLATOR®
MODEL 26 4320 20
MODEL 26 4320 20-1

Order No. SV3339

Contents

0. General

Thank you for your expression of confidence in the KARL STORZ brand name. Like all of our other products, this product is the result of years of experience and great care in manufacture. You and your organization have decided in favor of a modern, high-quality piece of equipment from KARL STORZ.
KARL STORZ instruments and equipment are for use only by qualified medical personnel who are trained in their use. All electrical installations at the location of use should meet applicable national and local electrical codes.
Refer servicing to duly authorized KARL STORZ service personnel. Always use genuine replacement parts from KARL STORZ. To determine which replacement parts are required please refer to the enclosed replacement parts list. Repair and calibration of this device requires special tools and gauges; certain internal adjustments must not be altered.
For further information, please consult this service manual or contact:

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Fax: +49 (0)7461 708-75500
E-Mail: technicalsupport@karlstorz.com
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Warranty

All KARL STORZ instruments and equipment are warranted to be free from defects in workmanship and materials for **two (2) years** from date of sale, unless otherwise specified; any instruments or equipment with such defects during the applicable warranty period will be promptly repaired or replaced at no charge to the customer.

KARL STORZ shall not be liable, expressly or implicitly, for:

- Any damages which might arise or be caused, whether by the customer or by any of the users of the instrument or equipment, as a result of:
  - misuse, mishandling, and/or improper operation,
  - repairs, modifications and/or alterations performed other than by KARL STORZ or a KARL STORZ authorized repair facility, or
  - use in combination with adaptors and/or equipment, or use in any manner or medical procedure, other than those for which it is designed; and
- Any special, indirect and/or consequential damages of any kind and however caused arising from the sale or use of the instrument and/or equipment.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS, IMPLIED, AND/OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY, FITNESS, AND/OR OF SUITABILITY FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON KARL STORZ'S PART.
KARL STORZ neither assumes nor authorizes any person to assume for it any other liabilities in connection with the sale of said instrument and equipment. To ensure proper use, handling, and care of instruments and equipment, consult the applicable product literature, catalog, brochure, instruction manual, teaching film and other materials which are included with the product and/or otherwise available from KARL STORZ, at no charge, upon request.

Maintenance and Repair

KARL STORZ recommends that all equipment be checked and inspected once a year by KARL STORZ, or by an authorized agent. All services such as modifications, repairs, calibrations, and/or readjustments may only be performed by KARL STORZ or by an authorized agent.

CAUTION: *Repairs may only be performed by qualified technicians trained in electrical or electronic engineering, in compliance with the relevant occupational, safety and accident prevention regulations.*
Always unplug the equipment before performing any repairs.
Safety Testing based on IEC EN62353, IEC / UL 60601-1, whichever may apply, must be performed after servicing has been completed.

By making the enclosed technical information available, KARL STORZ does not authorize any service or repair by unauthorized service personnel. Tampering with the instruments or equipment, or unauthorized service or repair of the device nullifies and voids the warranty.

Reservation of Rights

Section 1.

Instruction Manual

Direction Sign:

Section 2.

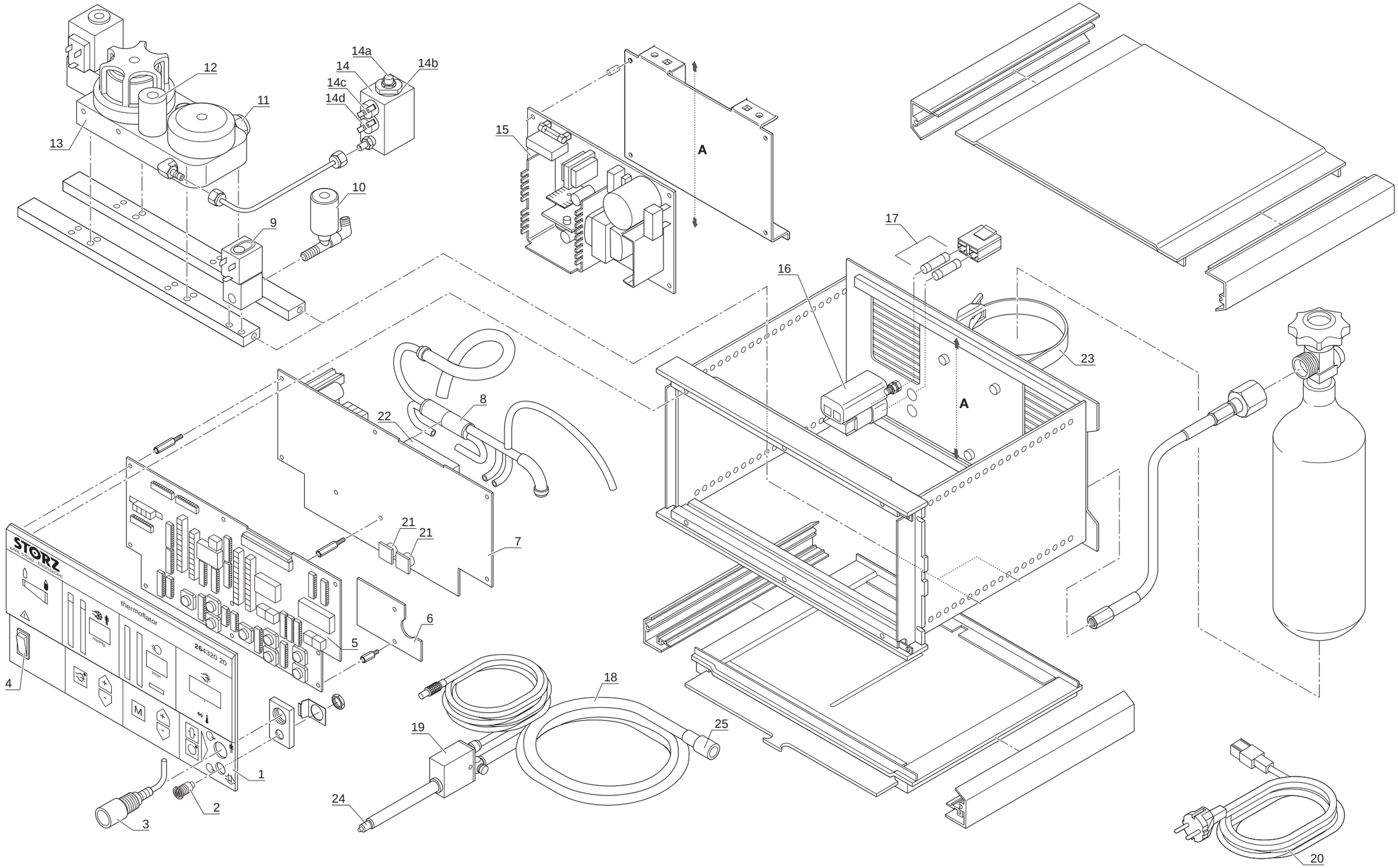
Physical Design

Direction Sign:

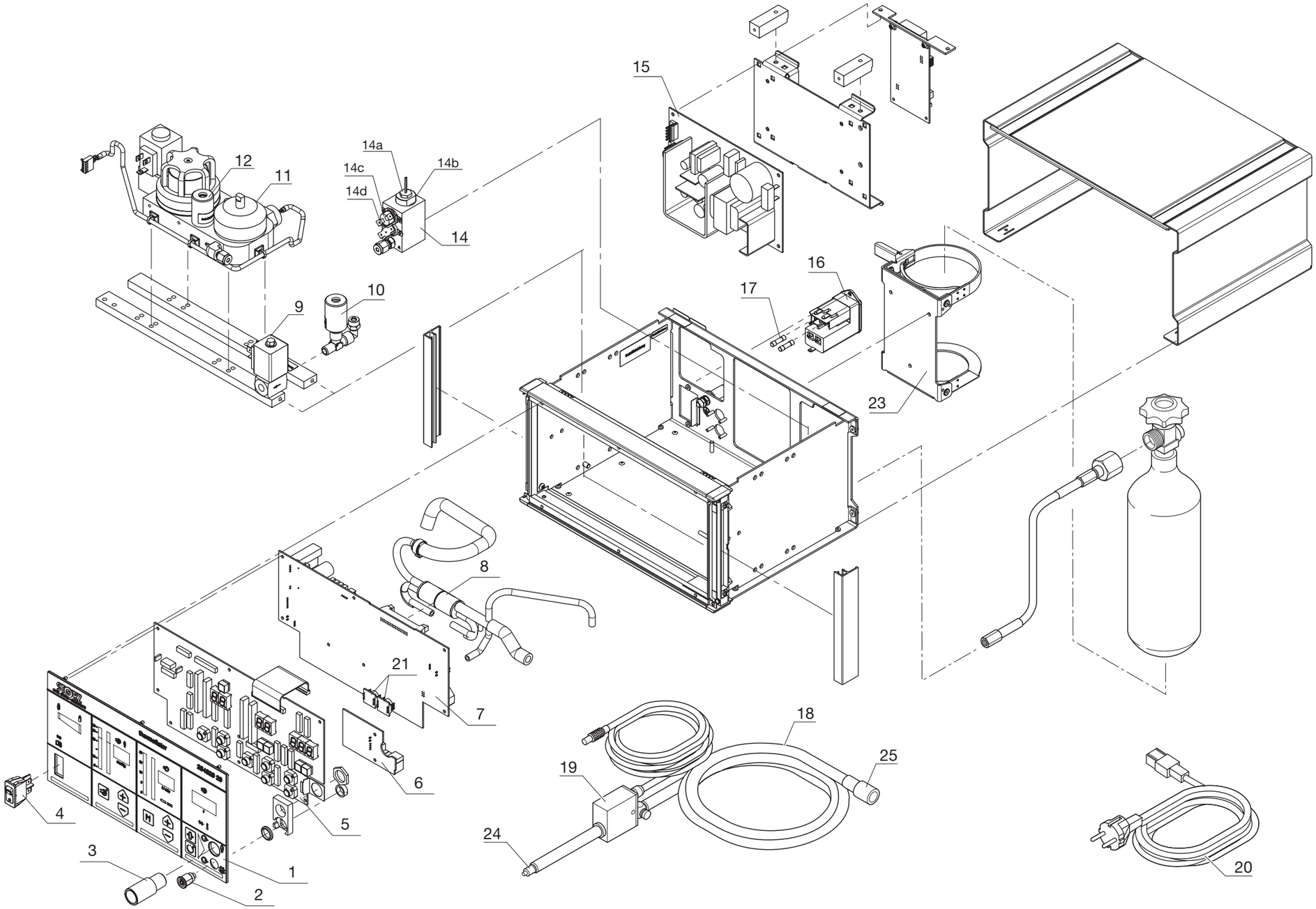
Contents 2. Physical Design

2.1 Exploded views of the THERMOFLATOR®

2.1.1. Exploded view of the THERMOFLATOR® with standard housing



2.1.2. Exploded view of the THERMOFLATOR® with new system housing



2.2 Spare parts of the THERMOFLATOR®

Position	Item description	Order no.
1	Front panel	**26** 4320 85
2	OPTITHERM® heating element socket	**26** 4320 89
3	Insufflation line fitting, line to patient	**26** 4320 88
4	Power switch	**20** 0112 80
5	Display board	**26** 4320 83
5a	Module display board “new system housing” consisting of:	
	Display board and 7-segment-displays	**26** 4320 93
6	Temperature controller board	**26** 4320 86
7	Controller board with supply line	**26** 4320 84
8	Gas flow splitter with hose set connected	**26** 4320 81
9	Pressure relief valve	**20** 0120 80
10	Low pressure blow off valve, blue	**20** 4001 81
11	High pressure transducer with supply line	**20** 0121 80
12	High pressure blow off valve, black	**20** 4005 81
13	Pressure manifold with high pressure sensor and solenoid valve connected	**26** 4320 80
14	Gas preheater, complete	
14a	Heat cartridge including swirl body	**20** 0122 80
14b	Sealing fluid, thermal resistance up to 200 °C (392 °F)	5903550
14c	Temperature limiter	49600000001
14d	Temperature regulator	49600000002
15	Power supply unit, 110 W	**20** 0119 80
16	Line plug with line filter	**20** 0115 80
17	Line fuses 2 x T 2.0 AL / 250 V	**20** 2759 0
18	Silicone tubing set	**20** 4000 43
19	OPTITHERM® heating element with connecting cord, sterilizable	**20** 4320 30
19a	Valve with lever to the heating element	6567591
19b	Spring cover to lever	VO4210
20	Power cord (with ground lead)	400A
	Power cord “hospital grade” (USA)	400B
21	Pressure sensor (patient pressure, …)	**20** 0109 80
21a	Pc board pressure sensor, equipped	45413004L00
22	Flow sensor (control board)	**20** 0108 80
23	Bottle holder	**20** 4000 31
24	LUER-LOCK connector to the device, male	**20** 3001 84
25	Connector, plastic, male, cone 15 mm	**20** 4000 81
–	High pressure inline gas filter	**20** 4000 32
–	Gasket to CO2 bottle with German connector	2903490

Important note:

When ordering replacement parts always provide the following data

Item description **Order no.**

Position	Item description	Order no.
–	Gasket to CO_2 bottle with Pin-Index connector	2903390
–	Software Update Set (includes the latest software version)	**26** 4320 75-V02
–	KARL STORZ-SCB® upgrade kit	**26** 4320 77
–	Utility lines	A012-507 A012-605

Important note:

When ordering replacement parts always provide the following data

Item description **Order no.**

Section 3.

Descriptions of Operation and Circuit Diagrams

Direction Sign:

Contents 3. Descriptions of Operation and Circuit Diagrams

3.1 Description of operation of the THERMOFLATOR®

The THERMOFLATOR® **26** 4320 20 / **26** 4320 20-1 allows microprocessor-controlled CO_2 insufflation into the patient's body. The user now has an option for working with a very high flow rate of up to 30 l/min and with preheating of the insufflation gas.

The device offers various operating modes, providing appropriate support for modern-day operating techniques, like the use of lasers or electrosurgery. The operating modes are as follows:

– **Initializing mode**
This mode is used to set up the pneumoperitoneum with the aid of the Veress needle. The setpoint values for this mode are 15 mmHg and 1 l/min as defaults after the device has been switched on, but can be subsequently altered by the user. This mode works with a continuous gas flow, i.e. the pressure display always shows the static pressure inside the patient (gas flow = 0) or the insufflation pressure. In order to support the user in placing the Veress needle correctly, this mode provides a monitoring function for the speed of pressure rise and an alarm where appropriate.

– **Operation mode with intermittent gas flow**
This is the usual operating mode for electronically controlled insufflators. The gas flow is reduced to zero for measuring the static pressure inside the patient. Depending on the result measured, a new filling cycle is then started or not. The pressure display corresponds to the static pressure inside the patient, and is updated after every filling phase.

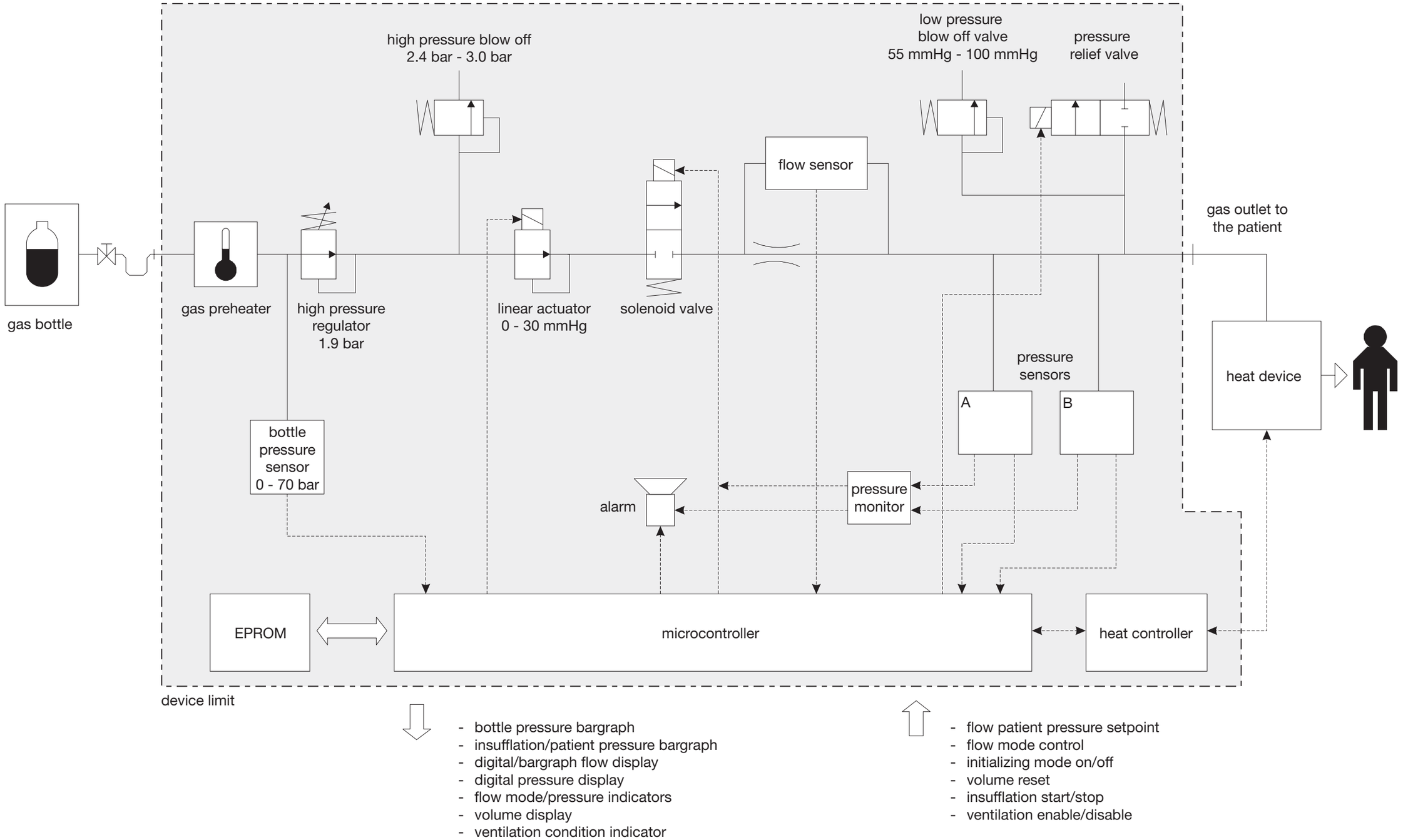
– **Operation mode with semi-continuous gas flow**
This operating mode is primarily used for laser and electrosurgery applications, and ensures extensive freedom from smoke (free visibility). Problems with defocusing, too, are avoided due to the quasi-steady gas flow. In this operating mode, the gas flow is for purposes of pressure measurement reduced not to zero but to approx. 20% of the preset setpoint value. This means that it is not the static pressure inside the patient which is displayed, but the insufflation pressure. In this mode, it is expedient to work with an opening to the outside or with an aspiration feature. The THERMOFLATOR® here monitors the ongoing flow rate and warns the user if the gas flow is interrupted.

The setpoint values for pressure and gas flow in the various operation modes remain stored in memory even after the device has been switched off, but have to be confirmed by the user pressing a button when the device is switched on again.

When the gas heater is connected, and there is a flow rate setpoint value of at least 3 l/min in one of the operation modes, the insufflated gas is automatically warmed up to body temperature. This gas heating feature is implemented by the OPTITHERM® inline heating.

The THERMOFLATOR® offers an option for bleeding off an overpressure by activating a pressure relief valve. This is done automatically after the overpressure has persisted for a defined time period (5 s). This venting function can, however, also be disabled by the user if it is not desired.

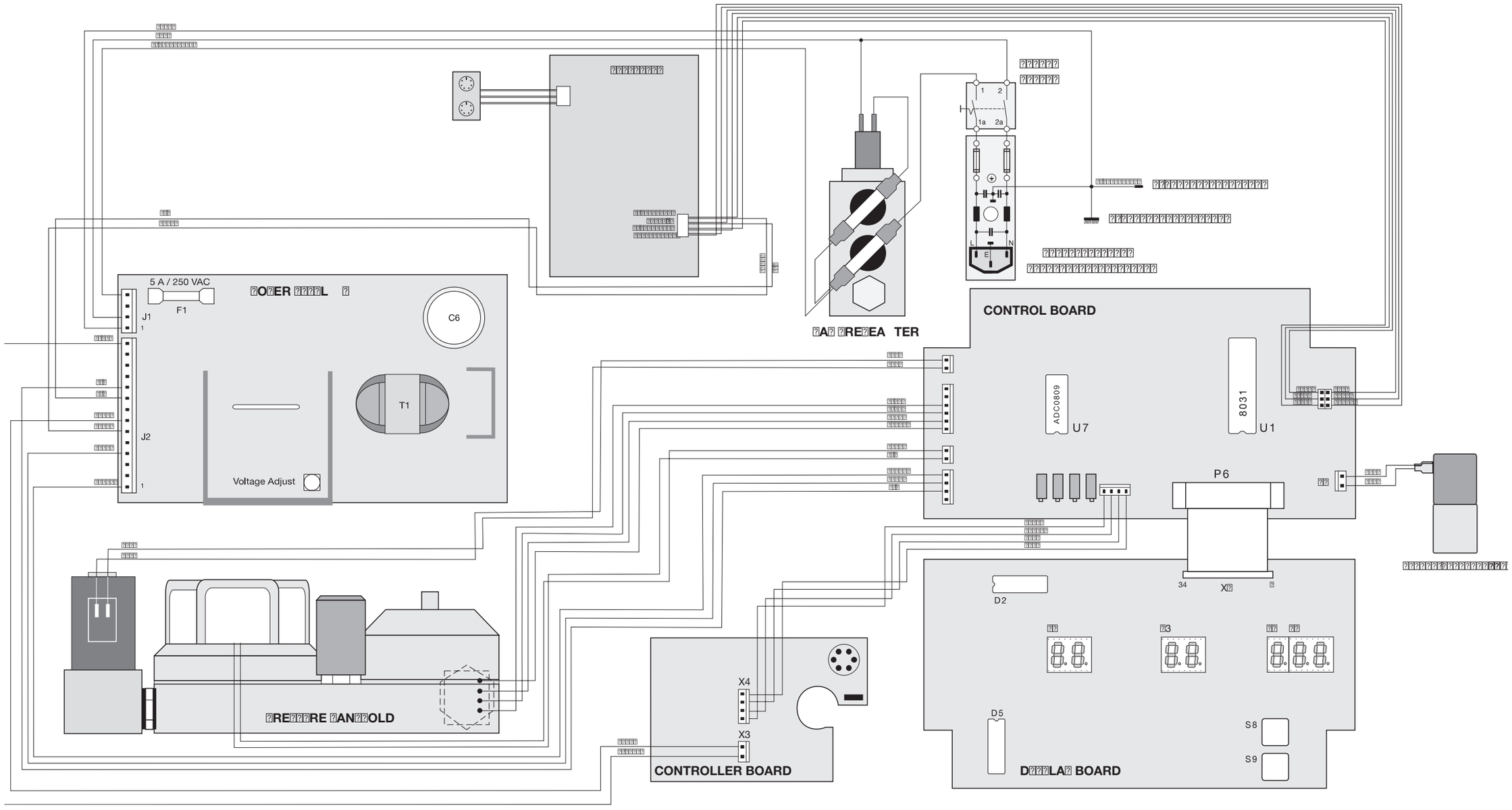
3.2 Block diagram of the THERMOFLATOR®



- bottle pressure bargraph
- insufflation/patient pressure bargraph
- digital/bargraph flow display
- digital pressure display
- flow mode/pressure indicators
- volume display
- ventilation condition indicator

- flow patient pressure setpoint
- flow mode control
- initializing mode on/off
- volume reset
- insufflation start/stop
- ventilation enable/disable

3.3 Wiring diagram of the THERMOFLATOR®



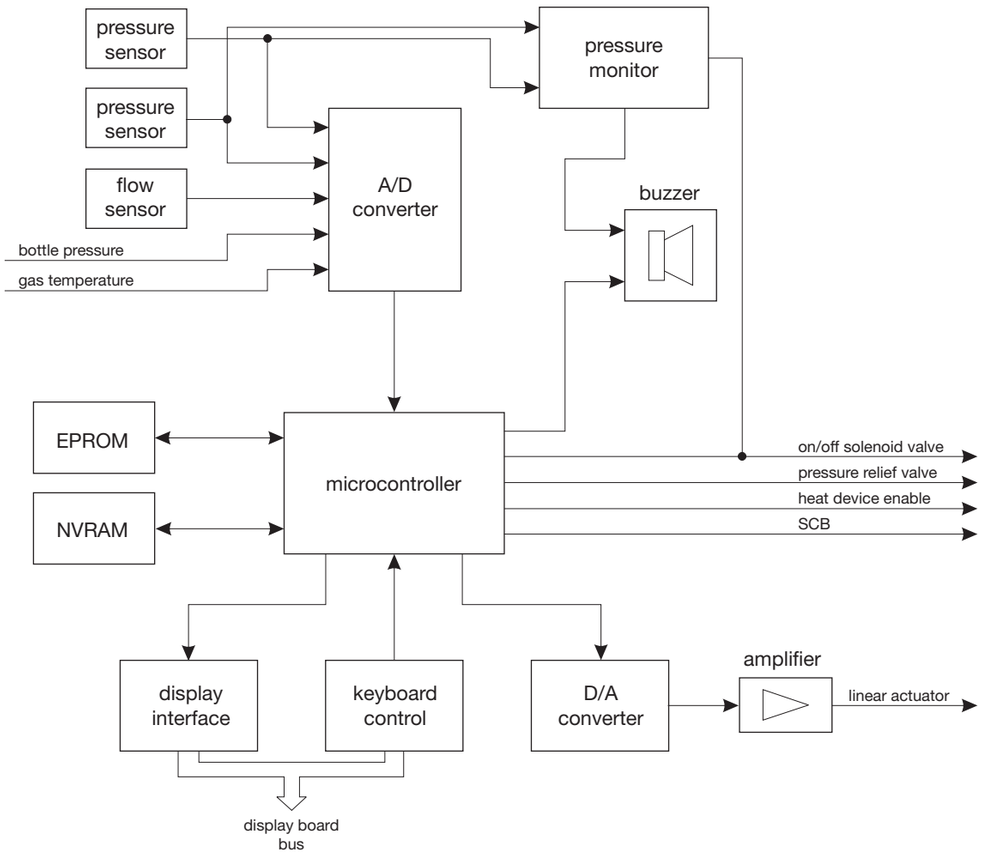
3.4 Electronics of the THERMOFLATOR®

3.4.1. Control board

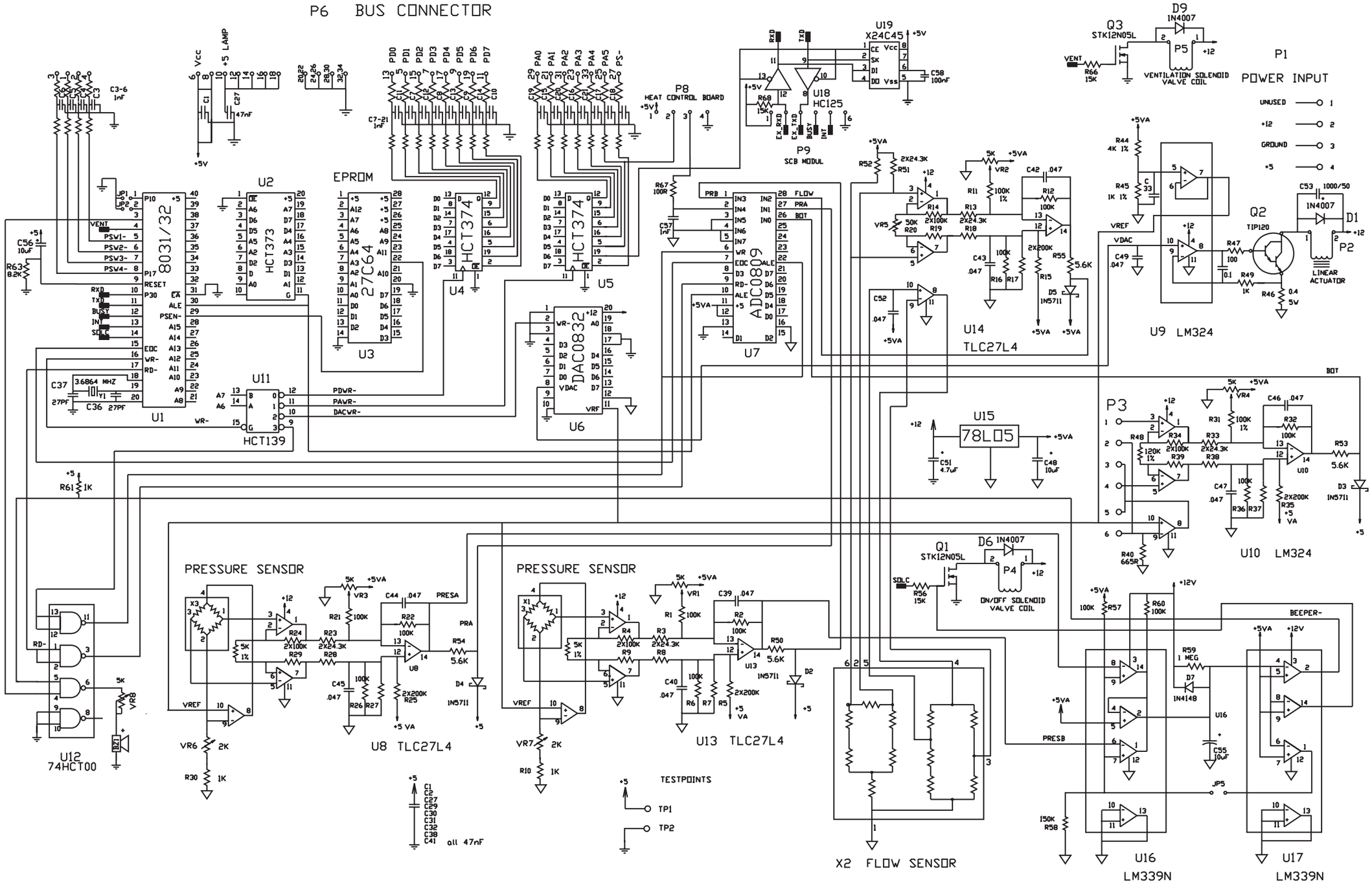
3.4.1.1 Brief description of the control board operation

With the exception of the heater control, the control board accommodates all the analog and digital systems for the acquisition, processing and control of data. The main components are illustrated in *Section 3.4.1.2 Block diagram of the control board*. For more details please refer to *Section 3.4.1.3 Circuit diagram of the control board*.

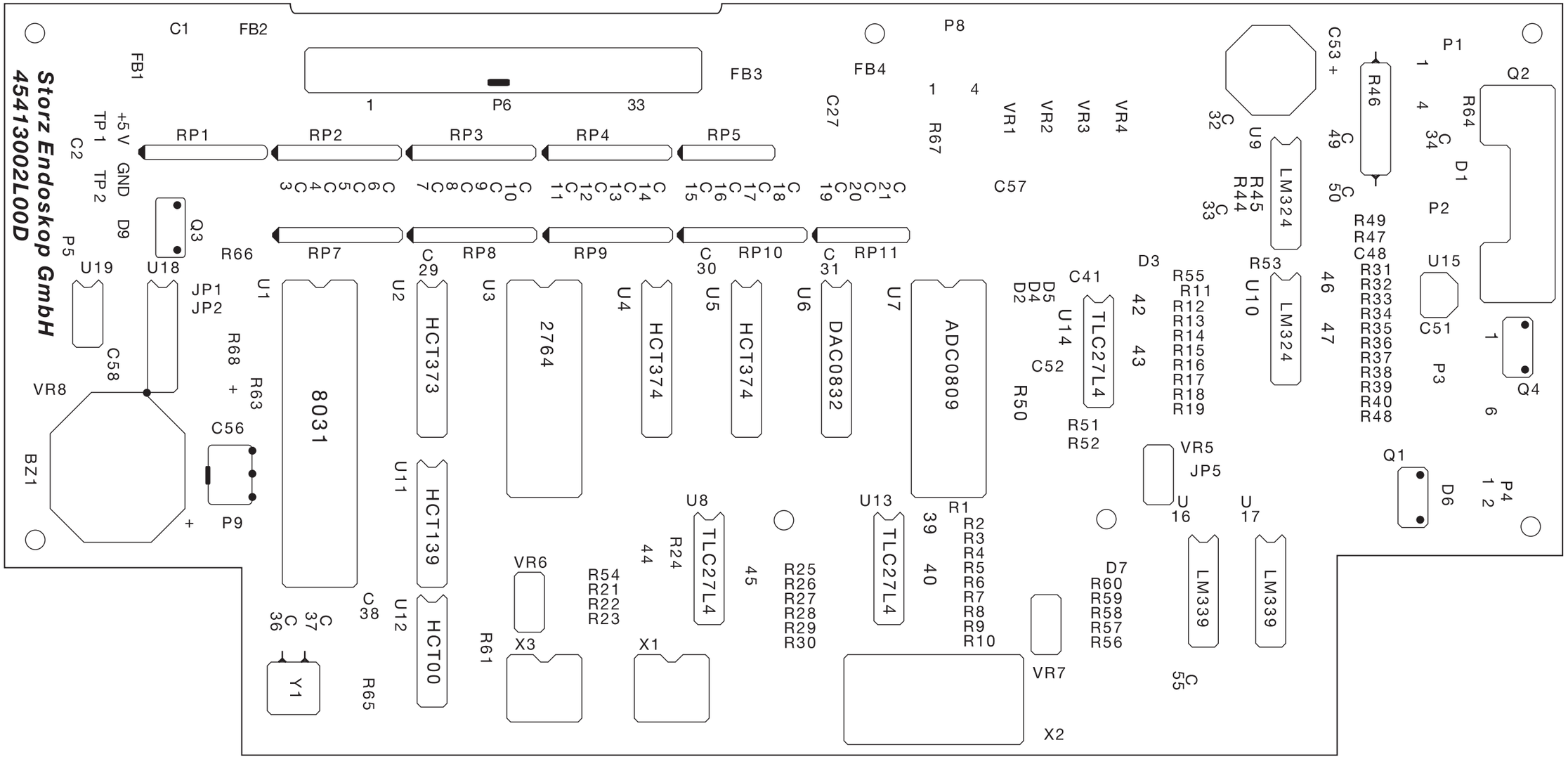
3.4.1.2 Block diagram of the control board



3.4.1.3 Circuit diagram of the control board



3.4.1.4 Component diagram of the control board

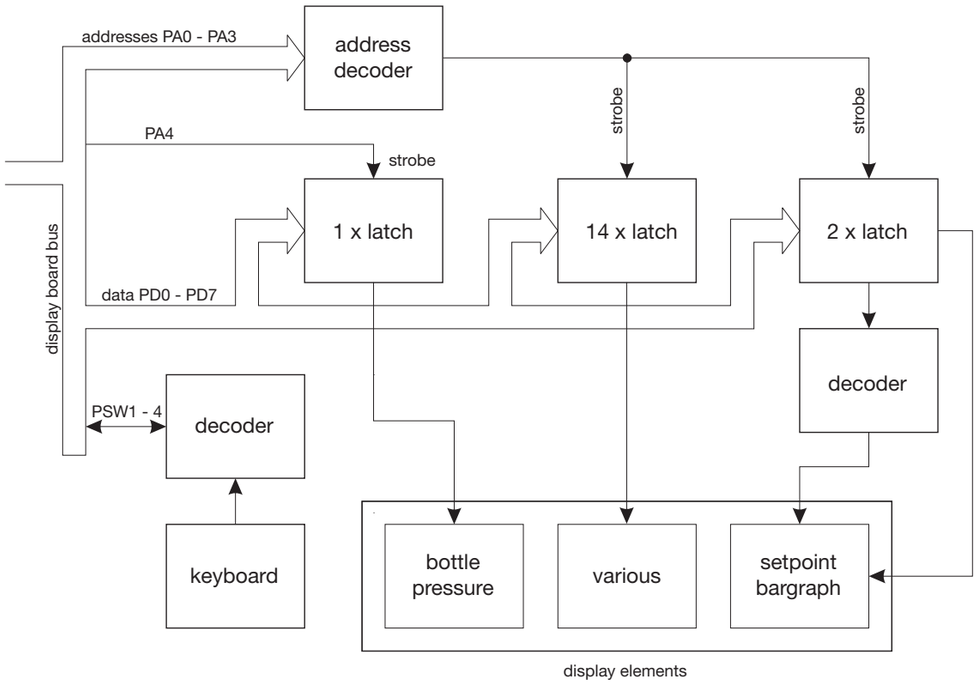


3.4.2. Display board

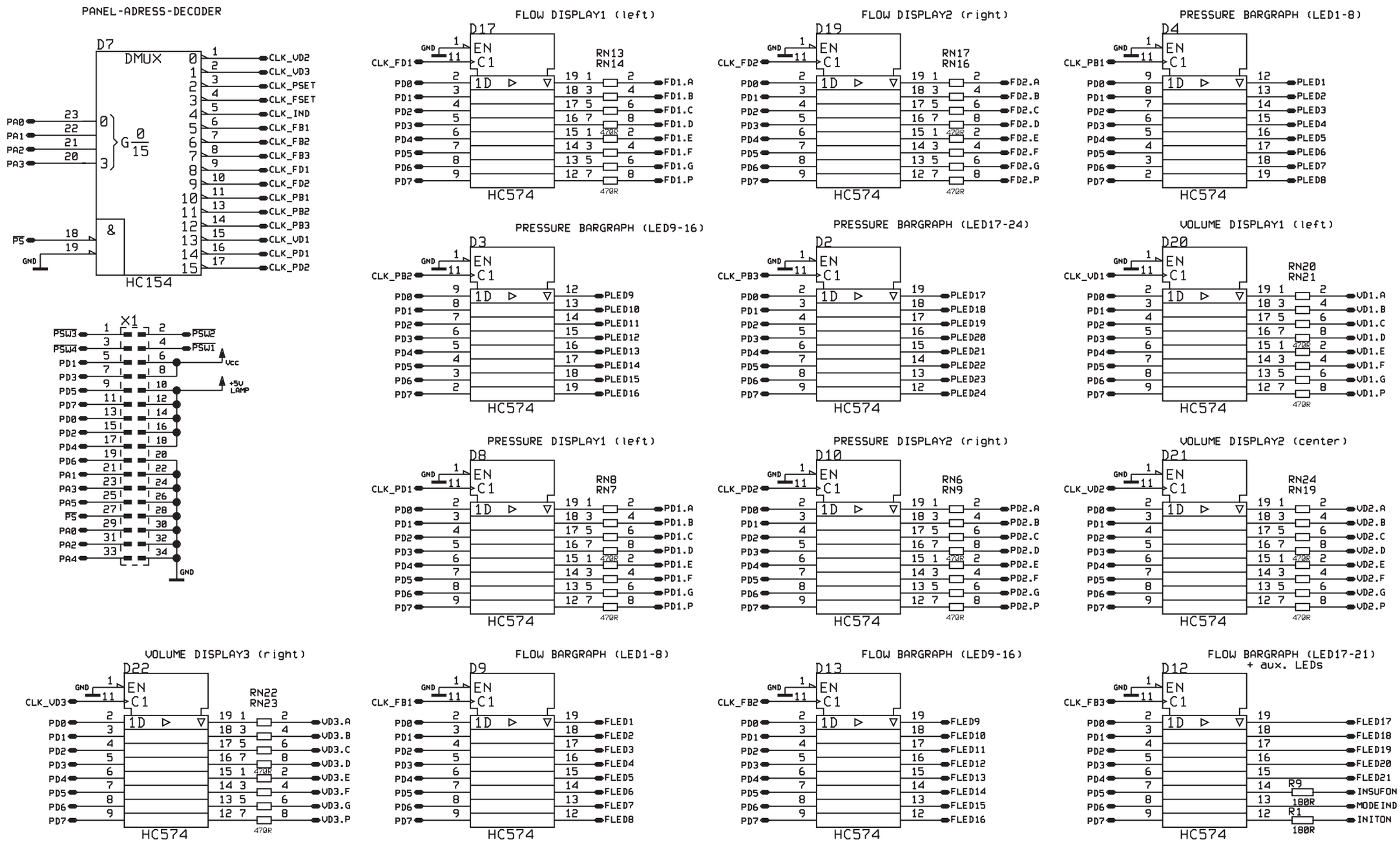
3.4.2.1 Brief description of the display board operation

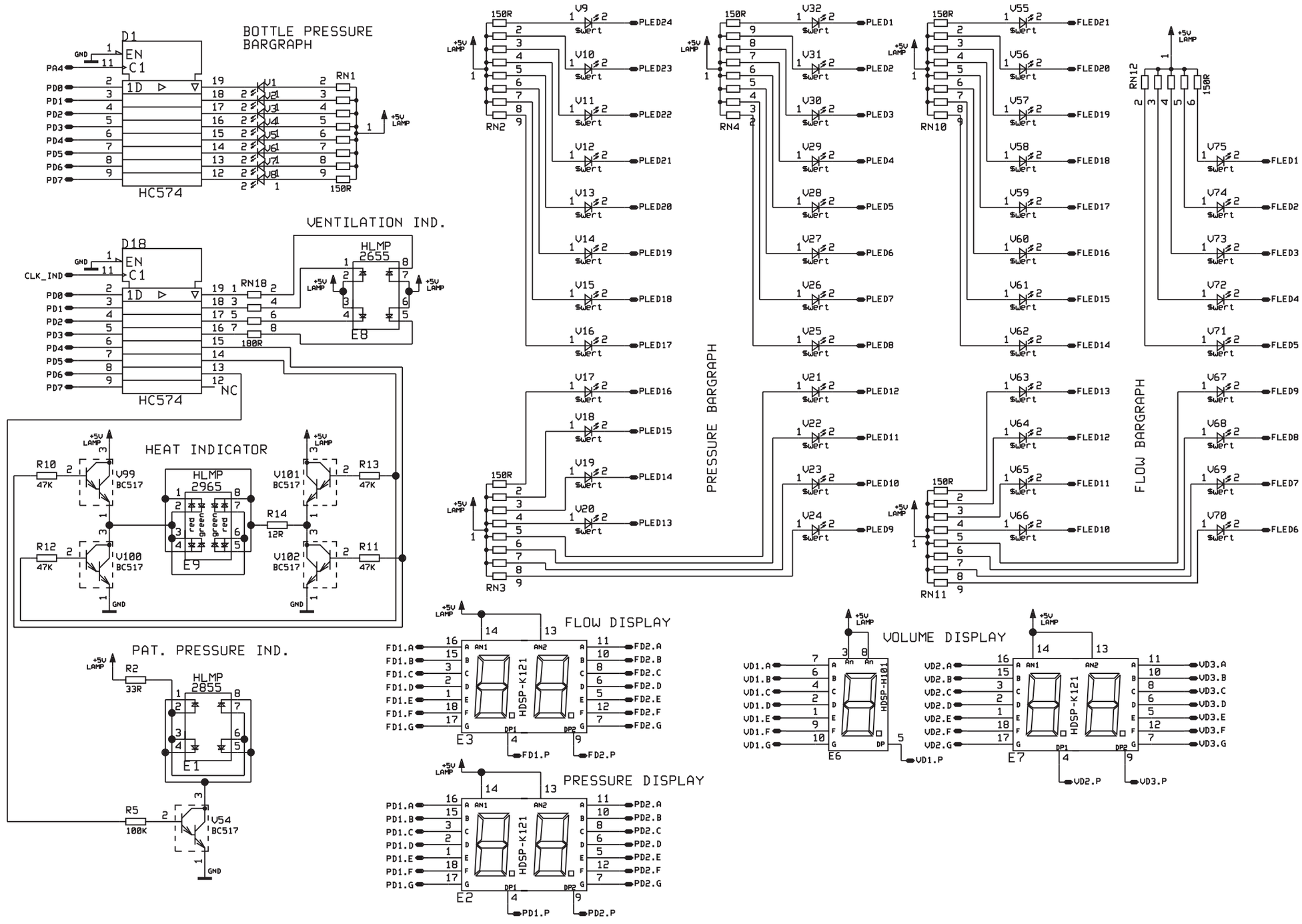
The display board is linked to the control board via the 34-pin front panel bus. The display board accommodates all the input, display and control components for realizing the required user interface. The block diagram referred to in *Section 3.4.2.2 Block diagram of the display board* provides an overview of the function of the display board.

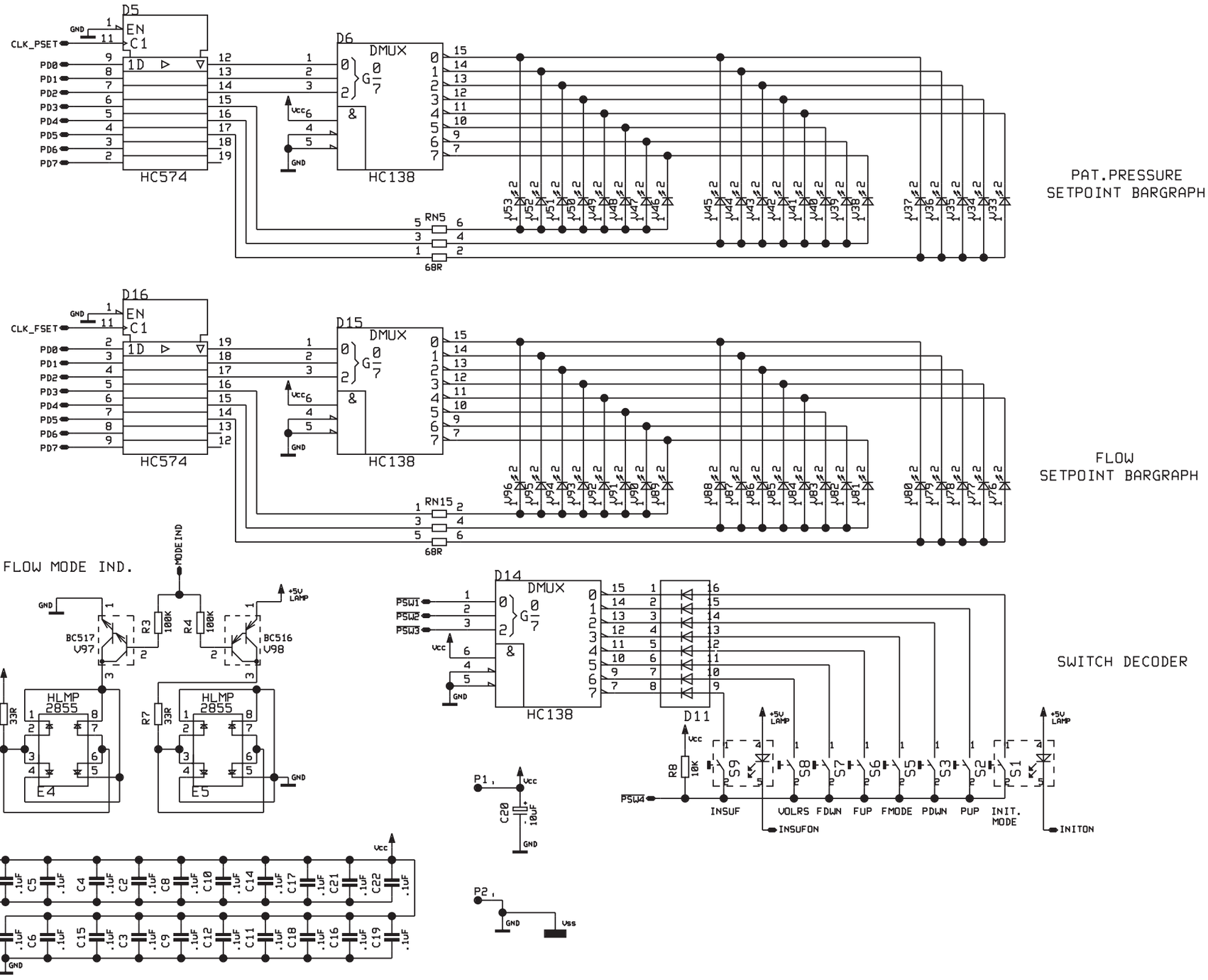
3.4.2.2 Block diagram of the display board



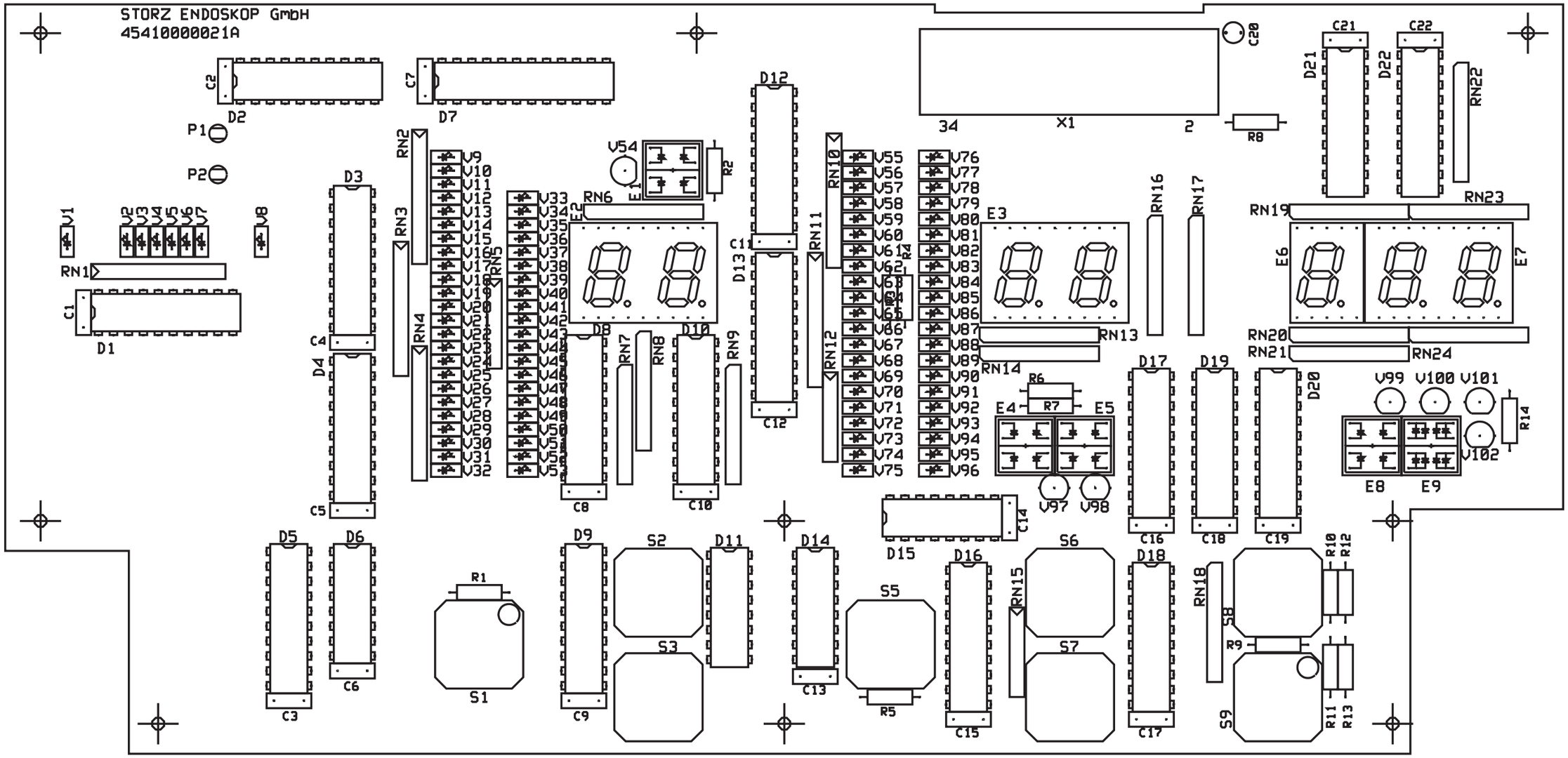
3.4.2.3 Circuit diagram of the display board




BOTTLE PRESSURE BARGRAPH
D1
EN
C1
1D
GND
PA4
PD0
PD1
PD2
PD3
PD4
PD5
PD6
PD7
HC574
RN1
150R
+5V LAMP
V1
V2
V3
V4
V5
V6
V7
V8
VENTILATION IND.
D18
CLK_IND
RN18
180R
HLMP 2655
E8
NC
HEAT INDICATOR
HLMP 2965
E9
R10
47K
V99
BC517
R12
V100
R13
V101
R14
12R
R11
V102
GND
PAT. PRESSURE IND.
R2
33R
HLMP 2855
E1
R5
100K
V54
PRESSURE BARGRAPH
RN2
RN3
RN4
V9
V10
V11
V12
V13
V14
V15
V16
V17
V18
V19
V20
V21
V22
V23
V24
V32
V31
V30
V29
V28
V27
V26
V25
PLED24
PLED23
PLED22
PLED21
PLED20
PLED19
PLED18
PLED17
PLED16
PLED15
PLED14
PLED13
PLED12
PLED11
PLED10
PLED9
PLED1
PLED2
PLED3
PLED4
PLED5
PLED6
PLED7
PLED8
FLOW BARGRAPH
RN10
RN11
RN12
V55
V56
V57
V58
V59
V60
V61
V62
V63
V64
V65
V66
V67
V68
V69
V70
V75
V74
V73
V72
V71
FLED21
FLED20
FLED19
FLED18
FLED17
FLED16
FLED15
FLED14
FLED13
FLED12
FLED11
FLED10
FLED9
FLED8
FLED7
FLED6
FLED1
FLED2
FLED3
FLED4
FLED5
FLOW DISPLAY
E3
HDSP-K121
FD1.A
FD1.B
FD1.C
FD1.D
FD1.E
FD1.F
FD1.G
FD1.P
FD2.A
FD2.B
FD2.C
FD2.D
FD2.E
FD2.F
FD2.G
FD2.P
PRESSURE DISPLAY
E2
PD1.A
PD1.B
PD1.C
PD1.D
PD1.E
PD1.F
PD1.G
PD1.P
PD2.A
PD2.B
PD2.C
PD2.D
PD2.E
PD2.F
PD2.G
PD2.P
VOLUME DISPLAY
E6
HDSP-H101
VD1.A
VD1.B
VD1.C
VD1.D
VD1.E
VD1.F
VD1.G
VD1.P
E7
VD2.A
VD2.B
VD2.C
VD2.D
VD2.E
VD2.F
VD2.G
VD2.P
VD3.A
VD3.B
VD3.C
VD3.D
VD3.E
VD3.F
VD3.G
VD3.P


D5
HC574
D6
DMUX
HC138
RN5
68R
PAT.PRESSURE
SETPOINT BARGRAPH
D16
HC574
D15
DMUX
HC138
RN15
68R
FLOW
SETPOINT BARGRAPH
FLOW MODE IND.
MODEIND
BC517
V97
BC516
V98
HLMP
2855
E4
E5
D14
DMUX
HC138
D11
SWITCH DECODER
INSUF
VOLRS
FDWN
FUP
FMODE
PDWN
PUP
INIT.
MODE
INSUFON
INITON

3.4.2.4 Component diagram of the display board

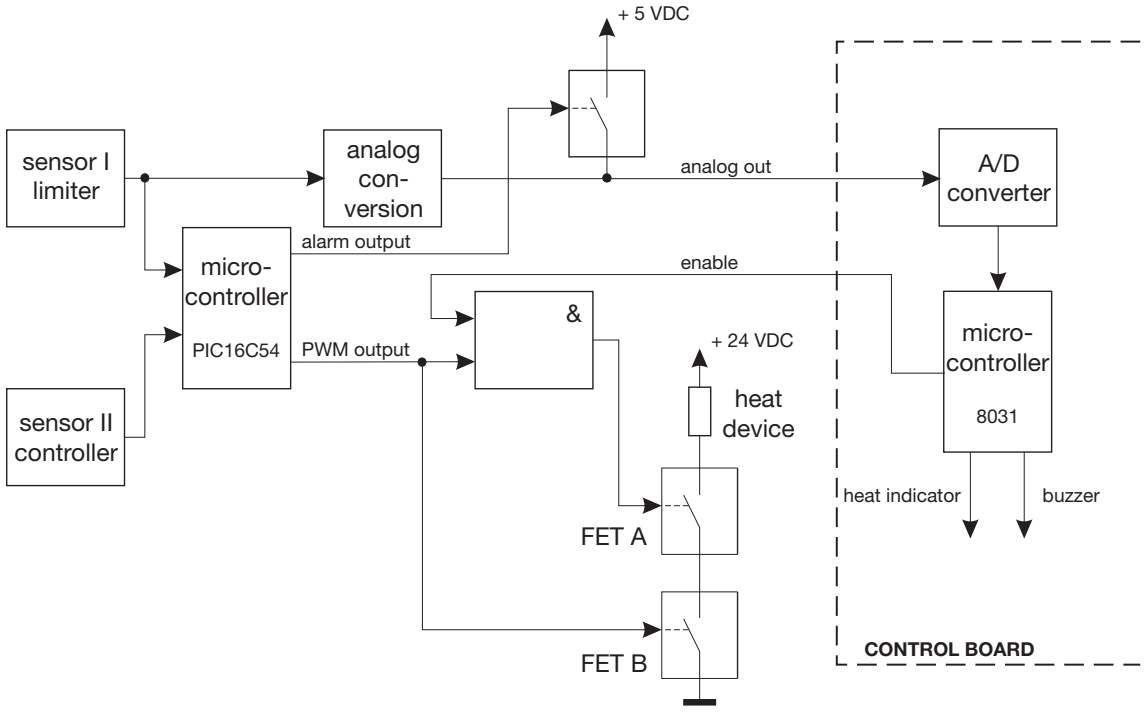


3.4.3. Controller board

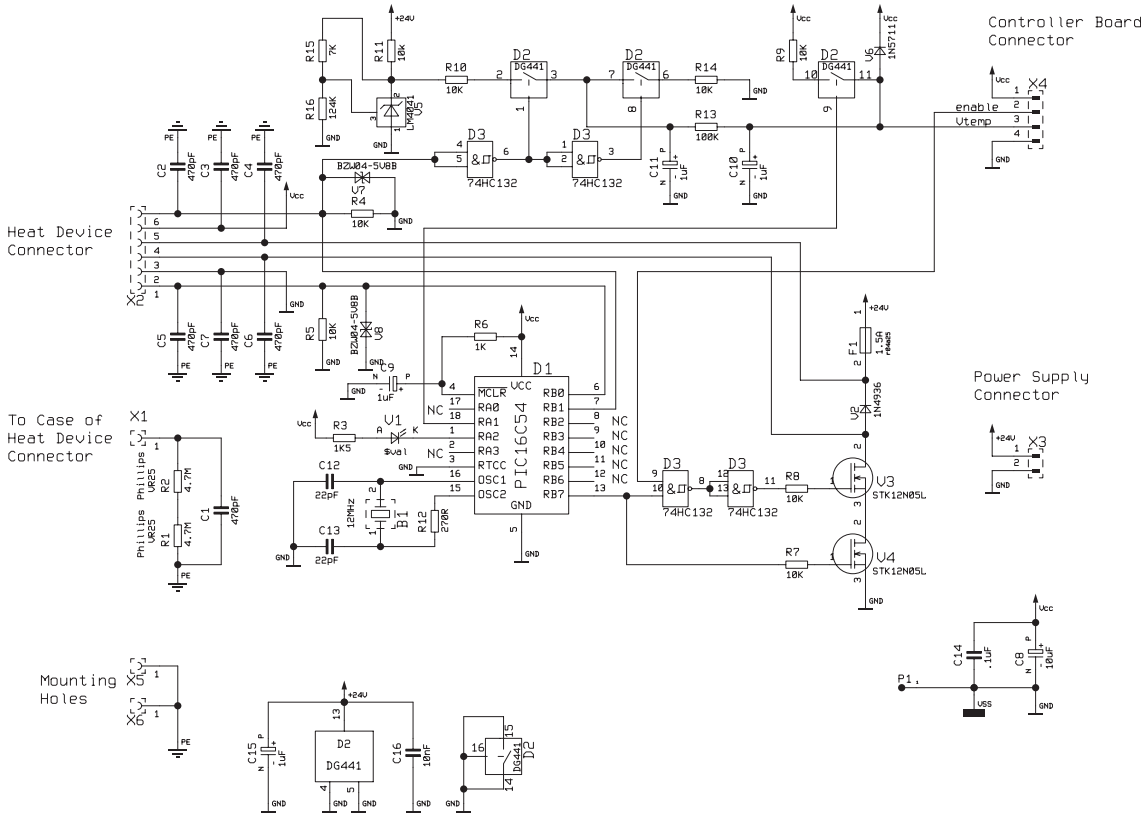
3.4.3.1. Brief description of the controller board operation

This device, located on a separate controller board, uses its own microcontroller to handle gas temperature control autonomously. The main components are illustrated in *Section 3.4.3.2 Block diagram of the controller board*. For more details please refer to *Section 3.4.3.3 Circuit diagram of the controller board*.

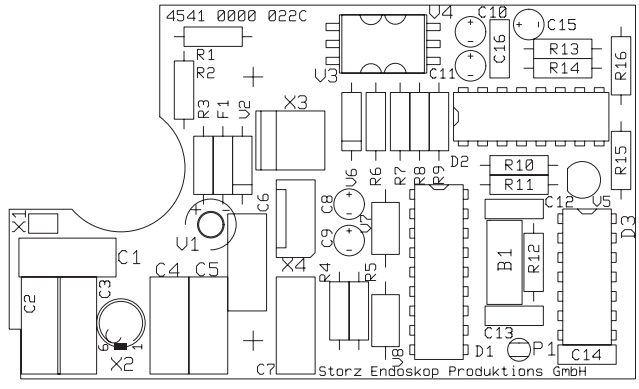
3.4.3.2. Block diagram of the controller board



3.4.3.3. Circuit diagram of the controller board



3.4.3.4. Component diagram of the controller board



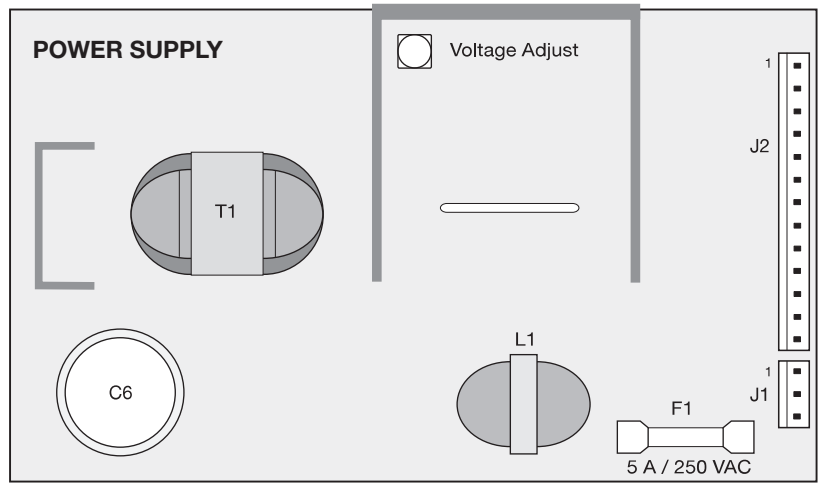
3.4.4. Power supply unit

3.4.4.1. Brief description of the power supply unit operation

A 110 W switching power supply unit (order no. **20** 0119 80), is used for the power supply of the electronic control unit and pumps. The type NFS110-7902P power supply unit is approved for use in medical apparatus. The conformity is documented under following test numbers:

– VDE 0750, EN 60601 – 1, IEC 601, IEC 1010 file no. 10401 – 3336 – 1049 licence no. 2874
– UL 544 file no. E147937
– CSA C22.2 no. 125 file no. LR41062C

PIN ASSIGNMENT	
J1	
PIN 1	AC Ground
PIN 2	AC Neutral
PIN 3	AC Live
J2	
PIN 1	+5.1 VDC
PIN 2	+5.1 VDC
PIN 3	+5.1 VDC
PIN 4	Return
PIN 5	Return
PIN 6	Return
PIN 7	Return
PIN 8	+12 VDC
PIN 9	+12 VDC
PIN 10	PFD
PIN 11	-12 VDC
PIN 12	Removed for key
PIN 13	+24 VDC



3.4.5. Gas preheater

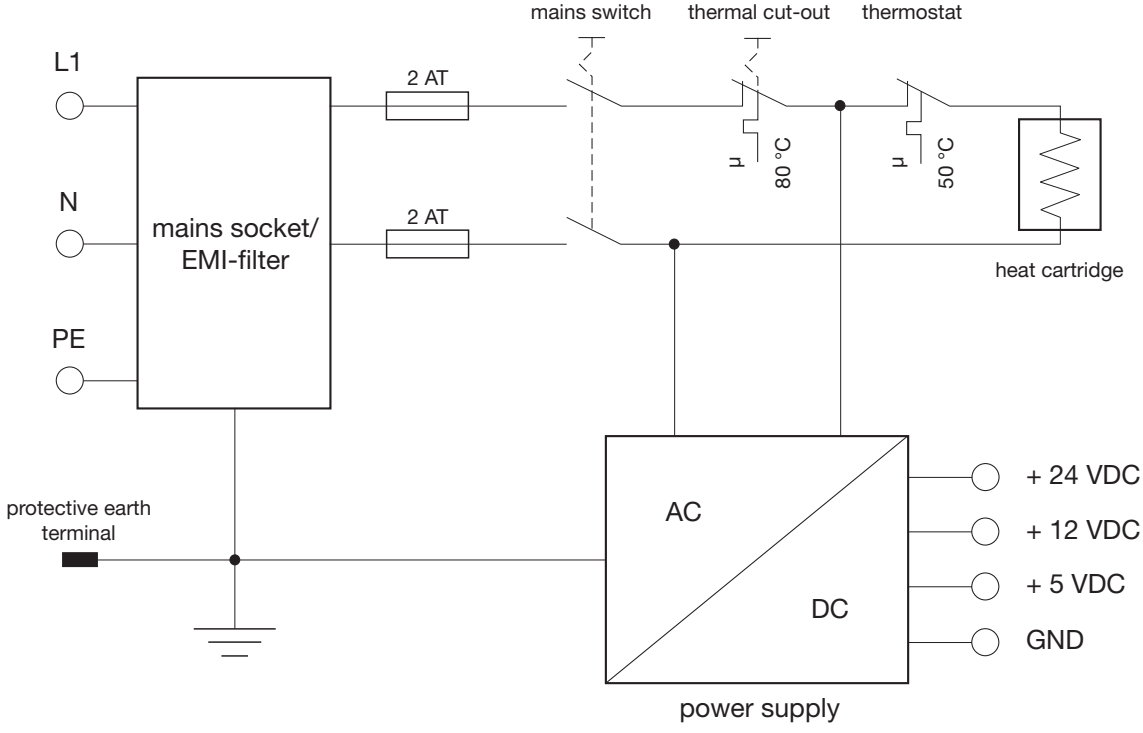
3.4.5.1. Brief description of the gas preheater operation

In order to protect the pressure regulator's passage apertures from icing up even during lengthy periods of high flow rates, the gas has to be preheated before entering the regulator. This gas heater is fitted with a 150 W heat cartridge and a swirl body. It takes its power directly from the mains. When the THERMOFLATOR® is being operated from a 110 VAC mains supply, only 50 W of heating power will be obtained, but this is sufficient for the above purpose. The gas temperature is controlled using the temperature of the swirl body block.

For safety reasons, the control function is monitored by a Microtherm Type R30 limiter. If the control fails, the thermal cut-out will respond, and switch off the heater. At the same time, this causes the mains supply to be disconnected from the switch-mode power supply unit, thus drawing the user's attention to this fault condition.

The temperature limiter does not reset itself automatically. It can be restored to its normal condition by appropriately familiarized personnel using the component's reset pin. The housing has to be opened up for this purpose, please refer to Section 4 Replacement of Individual Assemblies.

3.4.5.2. Block diagram of the gas preheater



3.4.6. KARL STORZ-SCB® flash module

3.4.6.1. Description of KARL STORZ-SCB® flash module operation

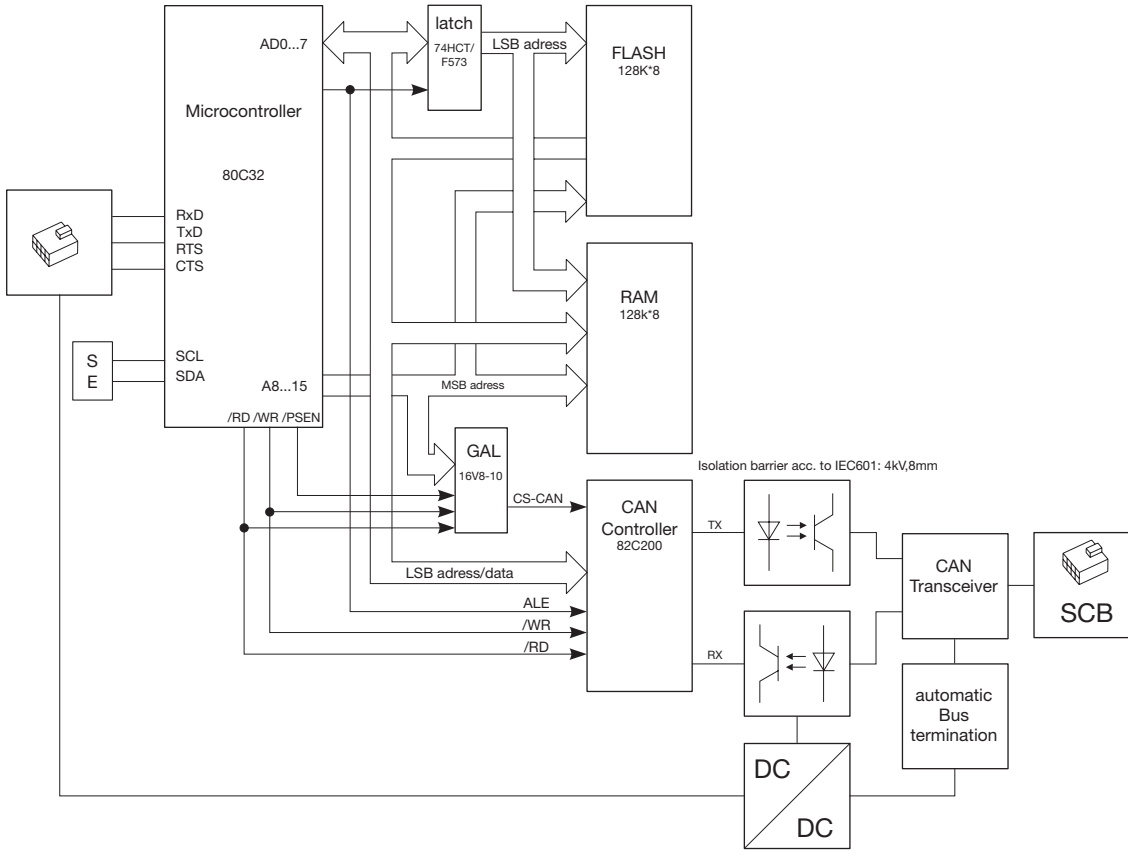
The KARL STORZ-SCB® module is a universal interface, which enables KARL STORZ endoscopical devices to communicate for the purpose of remote display and monitoring.

The KARL STORZ-SCB® module is designed as an option for existing and future devices from KARL STORZ. As it is intended for use as a medical device, it has been construed in accordance with the IEC 60601 standard requirements. The module enables the integration of a device in the KARL **S**TORZ **C**ommunication **B**us (KARL STORZ-SCB®) following adaptation of the module software.

It contains the following resources:

– 128 kB program memory
– 128 kB data memory
– microcontroller 80C32
– 22.1184 MHz oscillator frequency
– control trigger / reset during power up
– independent CAN controller
– optically decoupled CAN transceiver
– automatic bus termination
– RS232 interface with hardware handshake
– 1 kB serial EPROM

3.4.6.2. Block diagram of the KARL STORZ-SCB® flash module



3.5 Troubleshooting

Symptom	Possible cause	Remedy
Complete failure of the device.	No power from the power line.	Check power line.
	Line fuses faulty.	Replace fuses as described in the instruction manual, make sure to use the correct type of fuse.
	Power supply plug is not properly connected to the socket on the device.	Push power supply plug firmly into the socket on the device.
	Defective power cord.	Change power cord.
No gas flow.	Bottle empty or not fully open.	Open gas bottle fully (check gas supply on gas reserve indicator).
	Insufflation not switched on.	Switch on insufflation.
	Solenoid valve faulty.	Replace solenoid valve.
	Pressure manifold faulty or dirty.	Replace or clean pressure manifold.
Pressure does not build up.	Leak in tube system.	Check tube system, especially the connections and, if necessary, replace.
	Control circuitry faulty.	Check and, if necessary, repair low-pressure stage. Check and, if necessary, replace control components on the control board.
Read heating element indicator is lit. Acoustic warning signal sounds.	Failure in electronics. Defective gas preheater.	Change controller board. Adjust temperature with reference temperature sensor.
	Failure in heating element.	Change heating element.
Device signs sporadically off or on to SCB.	Utility line faulty.	Replace utility line, see chapter 7.4.

CAUTION: *Always unplug the device from the power supply before carrying out any work on it!*

3.6 Technical data

THERMOFLATOR® **26** 4320 20 / **26** 4320 20-1	
Line voltage	100 VAC … 240 VAC
Line frequency	50 Hz … 60 Hz
Power consumption	250 VA
Line fuses	2 x T 2.0 AL / 250 V
Gas supply:	
– Pressure	Max. 160 bar
– Gas type	CO_2 liquid
Gas flow	0 l/min … 30 l/min (+20% / -10%)
Insufflation pressure (max.)	0 mmHg … 30 mmHg (±1 mmHg)
Heat output max.	25 W
Gas temperature	37 °C, +10% / -15% (98.6 °F, +10% / -15%)
Operating temperature	10 °C … 40 °C (50 °F … 104 °F)
Dimensions (w x h x d)	305 mm x 155 mm x 233 mm
Weight	7.0 kg
Transport and storage conditions:	
Storage temperature	0 °C … 60 °C (32 °F … 140 °F)
Humidity	0% … 95%, rel. humidity, non-condensing
Atmospheric pressure	500 hPa … 1080 hPa

3.6.6.1. Standard compliance

According to IEC 60601-1, UL 2601.1, CAN/CSA C22.2 No. 601.1-M90:

Type of protection against electric shocks: Protection Class I
Degree of protection against electric shocks: Applied part of type BF

Please read the Electromagnetic Compatibility Information in the appendix of the instruction manual.

According to IEC 60601-1-2:2001:

3.6.6.2. Directive compliance

According to Medical Device Directive (MDD):

Medical device in Class II b

This medical device bears the CE mark according to MDD 93/42/EEC. A code number after the CE mark indicates the responsible notified body.

CE

Safety tested · Production monitored · TÜV PRODUCT SERVICE · C NRTL US

Section 4.

Replacement of Individual Assemblies

Direction Sign:

Contents 4. Replacement of Individual Assemblies

4.1 Information about replacements

The device is fully adjusted and tested before it leaves the manufacturers. If the device fails, a test of the assemblies should be carried out by authorized KARL STORZ technical staff.

CAUTION: *Before replacing the control board or the KARL STORZ-SCB® module, first check the compatibility of the following modules:*

- *device software*
- *KARL STORZ-SCB® module software*
- *KARL STORZ-SCB® RUI*

If in doubt, please contact the OR1™ service.

4.2 Tools required for replacing the individual assemblies

– Housing types

Slot head screwdriver, size 4

Torx key 20	**order no.** 5625112
Torx key 10	**order no.** 5610612

– Control board, controller board, display board and front panel

Torx key 10	**order no.** 5610612

5,5 mm hexagonal socket wrench
Side nippers
Conductive work mat, wristband, ground cable

– Pressure manifold, power supply unit, gas preheater

Torx key 25	**order no.** 5625212
Torx key 20	**order no.** 5625112
Torx key 15	**order no.** 5626012

12 mm open-end wrench
17 mm open-end wrench
Conductive work mat, wristband, ground cable

– Line plug with line filter

Torx key 10	**order no.** 5610612

CAUTION: *Repairs may only be performed by qualified technicians trained in electrical or electronic engineering, in compliance with the relevant occupational, safety and accident prevention regulations.*
Always unplug the equipment before performing any repairs.
To prevent damage to the components caused by the build-up of electrostatic charges, we recommend that you connect yourself to ground via the wristband throughout servicing.
Safety Testing based on IEC EN62353, IEC / UL 60601-1, whichever may apply, must be performed after servicing has been completed.

4.3 Opening the various types of housing

Opening the standard housing

Insert screwdriver into the recess at the rear of the side cover and lift the cover out toward the front.

(slot head screwdriver, size 4)

Undo the upper screw located under the side panel on the front of the device.

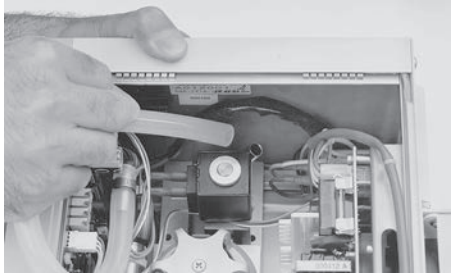
(Torx key 20)

Similarly, undo the corresponding upper screw on the rear of the device.

(Torx key 20)

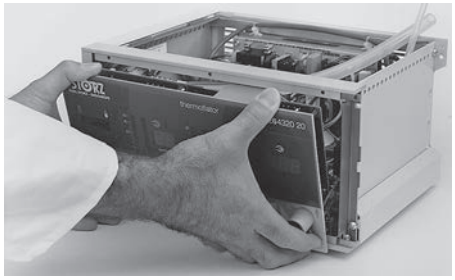
To release the housing cover, grip both ends and pull upward.

The housing cover can now be removed toward the right.



Remove the tube connection gas flow splitter/solenoid valve from the solenoid valve.

Pull out the two sliding bolts of the front panel sideways using a screwdriver or the like.



Remove the front panel and all boards toward the front.

Opening the new system housing

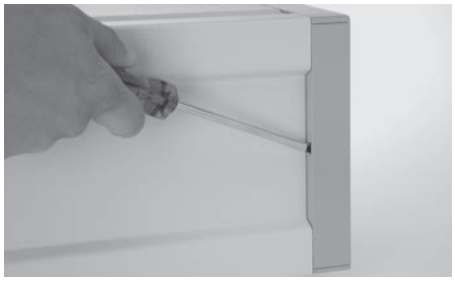
ⓘ ***Note:*** *The new system housing is used in devices with series no. 2520-B and higher.*

Undo the screws on the underneath of the device.

(Torx key 10)

Optionally undo the screws on the rear of the device and remove the bottle stand.

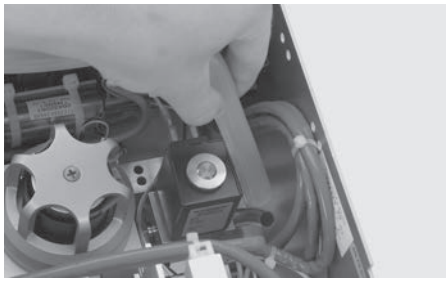
(Torx key 20)



Insert screwdriver into the recess at the rear of the side cover and lift the cover out toward the front.

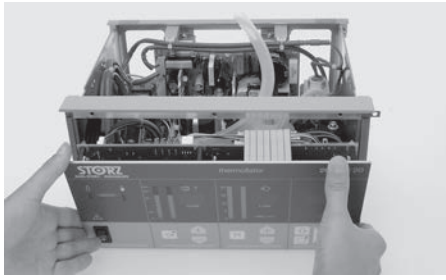
(Slot head screwdriver, size 4)

Pull the housing cover off toward the rear.



Remove the tube connection gas flow splitter/solenoid valve from the solenoid valve.

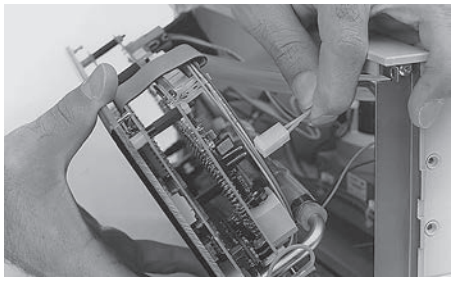
Pull out the two sliding bolts of the front panel sideways using a screwdriver or the like.



Remove the front panel and all boards toward the front.

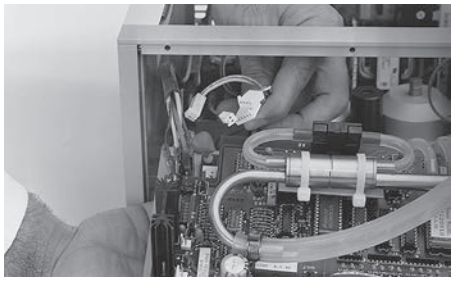
4.4 Replacement of the control board, controller board, display board and front panel

Open the housing as described in Section 4.3 Opening the various types of housing.



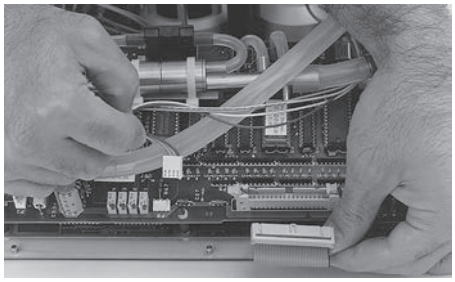
Replacement of the control board

Remove the cable connection of the relief valve from the control board.

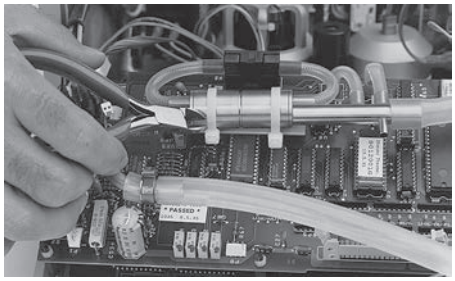


Remove all cable connections on the left-hand side of the control board.

ⓘ ***Note:*** *The cable connections are polarized so it is impossible to incorrectly connect when reassembling.*



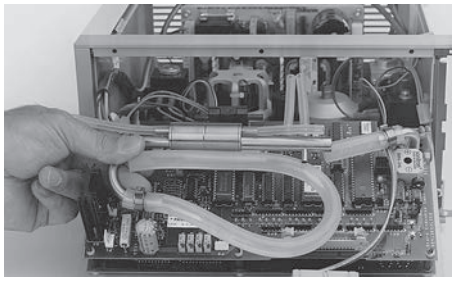
Remove the cable connections of the display board (flat cable) and the controller board from the control board.



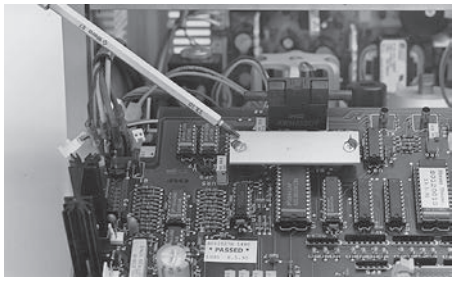
Loosen the cable connector of the gas flow splitter.

(Side nippers)

ⓘ ***Note:*** *For assembly, use the cable tie order no. 77500000013 (width 4.8 mm).*

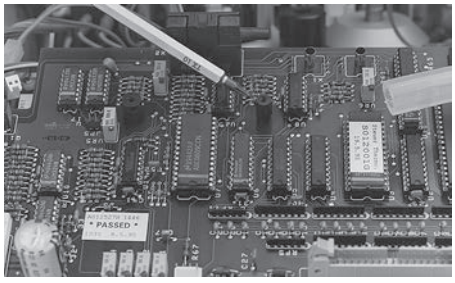


Withdraw the tube connections of the gas flow splitter from the control board and insufflation line fitting, line to patient.

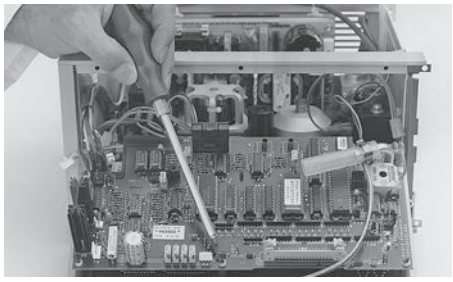


Remove the two screws used to mount the gas flow splitter.

(Torx key 10)

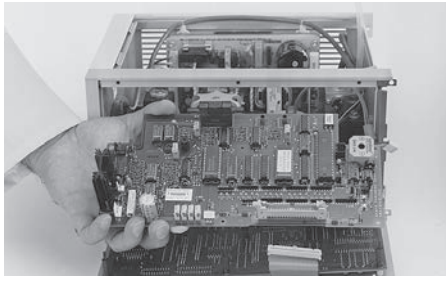


Also loosen the right-hand spacer.

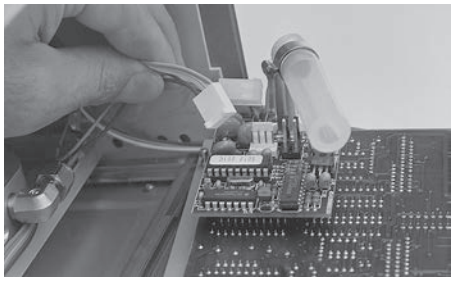


To replace the control board, the 4 transparent nuts must first be removed.

(5,5 mm hexagonal socket wrench)

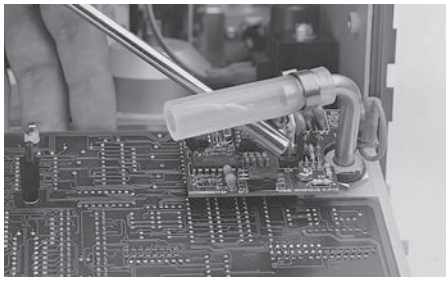


The control board can then be replaced.



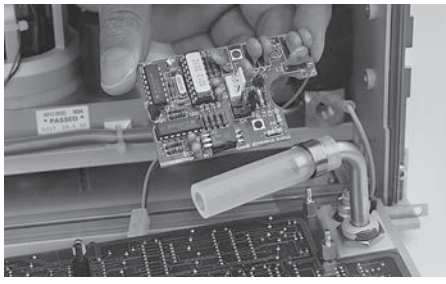
Replacement of the controller board

Remove the cable connection from the board.

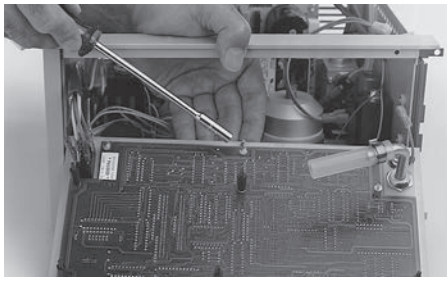


To replace the controller board, remove the 2 fastening nuts.

(5,5 mm hexagonal socket wrench)



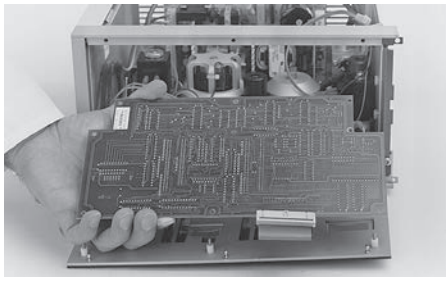
The controller board can now be replaced.



Replacement of the display board

To replace the display board, the 7 spacers (fastening screws) and the 2 transparent nuts must first be removed.

(5,5 mm hexagonal socket wrench)



Remove the display board.

Note: *When fastening the new display board in place the spacers and transparent nuts must be screwed in uniformly and not too tight so that the operability of the buttons is not im-paired.*

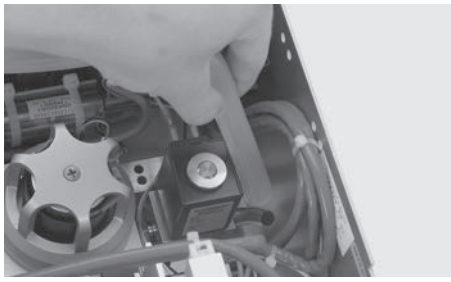
After removing the display board and removing the wire connections from the mains power switch, the front panel quick disconnect will be completely detached.

To assemble, proceed in the reverse order.

Note: *In order to avoid connecting up the assemblies incorrectly when assembling, refer to Section 3.3 Wiring diagram of the THERMOFLATOR®.*

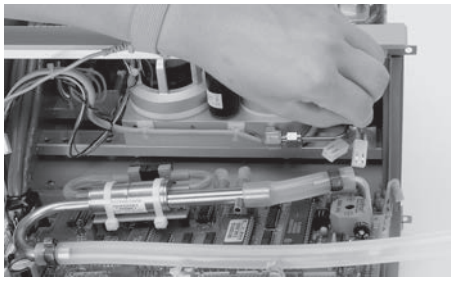
4.5 Replacement of the pressure manifold, power supply unit and gas preheater

Open the housing as described in *Section 4.3 Opening the various types of housing*.



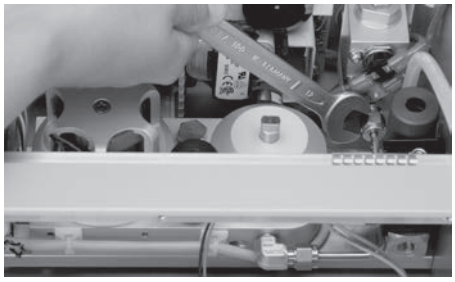
Replacement of the pressure manifold

Remove the tube connection gas flow splitter/solenoid valve from the solenoid valve.



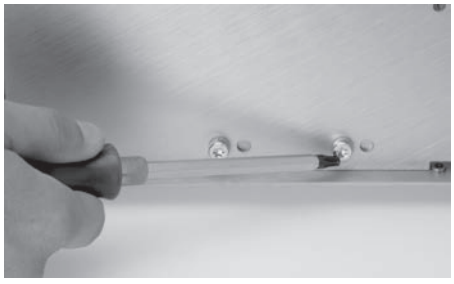
Remove all cable connections from the control/controller boards and front panel.

Note: *The cable connections can become mixed up, attention should therefore be paid to their positioning so that it is possible to reproduce the connections correctly during assembly..*



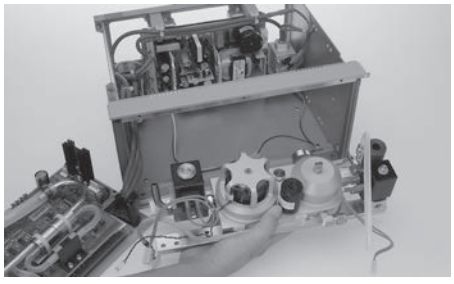
Remove the swivel nut on the pressure line to the gas preheater.

(12 mm open-end wrench)

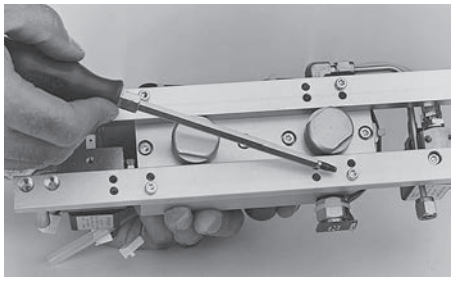


To replace the pressure manifold, unscrew the 4 fastening screws of the module rails and remove them from the side panels.

(Torx key 25)

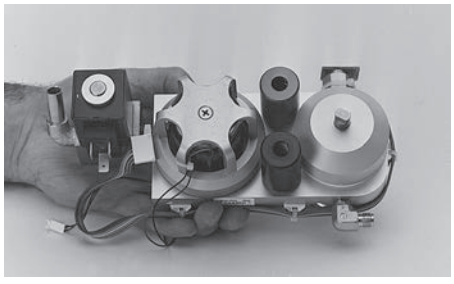


The complete flush-mounting module (pressure manifold) can then be removed from the housing.

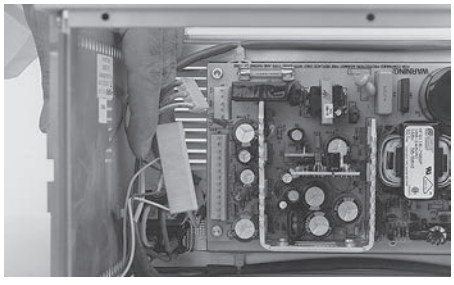


To replace the pressure manifold, unscrew the 4 fastening screws of the module rails.

(Torx key 20)

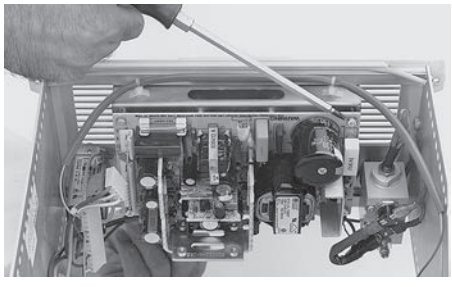


The pressure manifold can then be replaced.



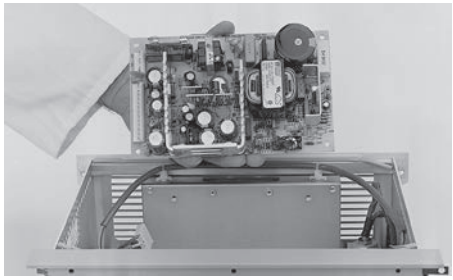
Replacement of the power supply unit in the standard housing

Remove all cable connections from the power supply.



To replace the power supply, the 4 fastening screws must first be removed.

(Torx key 20)



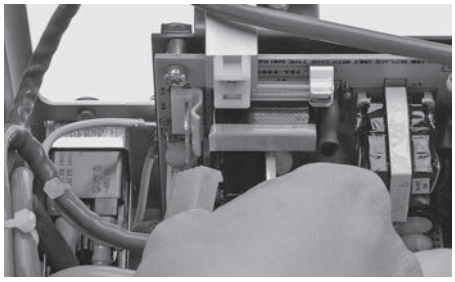
The power supply can then be replaced.

ⓘ ***Note:*** *Do not forget or swap the three polymer insulating spacers, the top left metal spacer between the logic module and the power supply unit mount.*

Replacement of the power supply unit in the new system housing

Remove the two cable ties from the power supply mount.

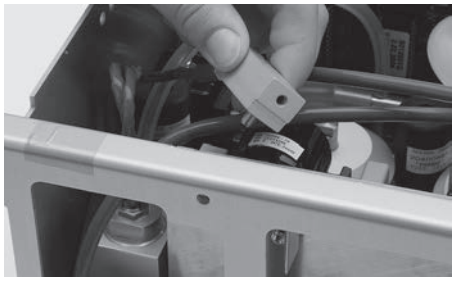
(Side cutters)



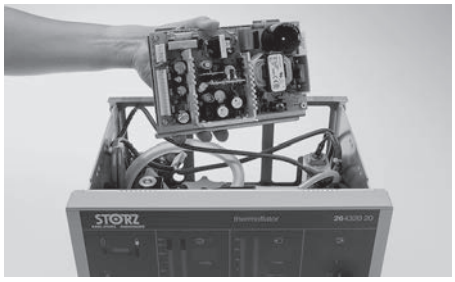
Remove all cable connections from the power supply unit.

Undo the two screws on the power supply mounts.

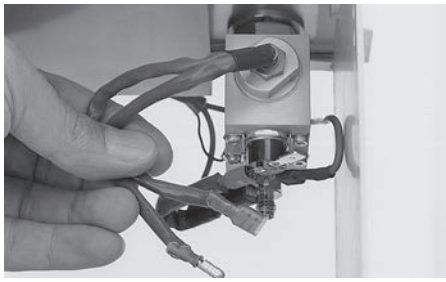
(Torx key 20)



Remove the two power supply mounts.

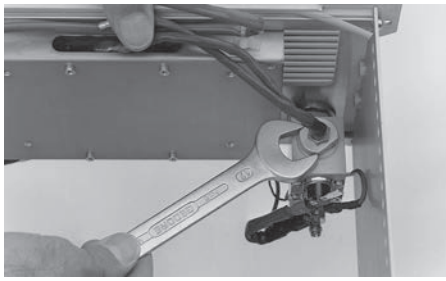


Remove the power supply unit from the device housing.



Replacement of the heat cartridge (gas preheater)

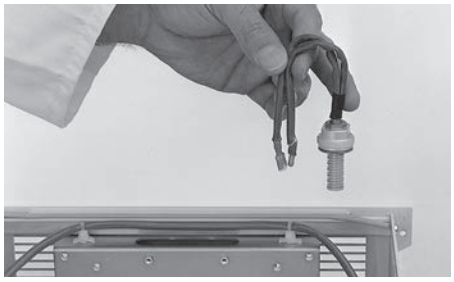
Remove the 2 cable connectors of the heat cartridge.



Undo the heat cartridge.

(Wrench 17 mm)

Note: *In the case of devices produced since January 2002 and also gas preheaters repaired since January 2002, the swirl body is glued in with sealing fluid (order no. 5903550). For this reason the associated O-ring is no longer necessary.*



The heat cartridge can now be replaced.

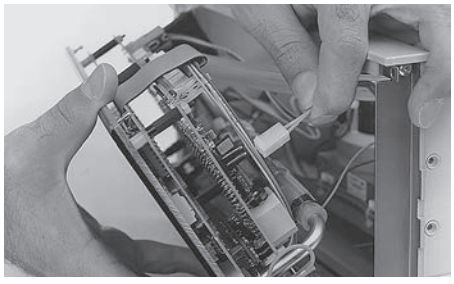
Apply sealing fluid (order no. 5903550) to the new heat cartridge before mounting it.

To assemble, proceed in the reverse order.

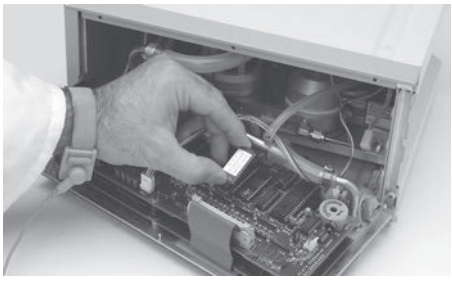
Note: *In order to avoid connecting up the assemblies incorrectly when assembling, refer to Section 3.3 Wiring diagram of the THERMOFLATOR®.*
Visual inspection and an electrical test must be carried out in compliance with IEC 60601-1 or UL-544, whichever may apply, to ensure that the protective grounding cable is properly secured on the back panel of the device.

4.6 Replacement of the EPROM and the microcontroller

Open the housing as described in Section 4.3 Opening the various types of housing.



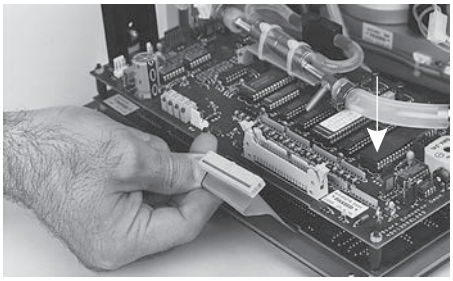
Remove the cable connection of the relief valve from the control board.



Replacement of the EPROM

Replace the EPROM.

CAUTION: *When using the new EPROM, make certain you have the correct mounting position (recess). At the same time, avoid bending or kinking the pins.*



Replacement of the microcontroller

Replace the microcontroller.

CAUTION: *When using the new microcontroller, make certain you have the correct mounting position (recess). At the same time, avoid bending or kinking the pins.*

To reassemble proceed in reverse order.

Note: *After replacing with the new EPROM and the microcontroller, check the equipment functions and, if necessary, perform a readjustment, see Section 5 Testing and Adjustments.*

Section 5.

Testing and Adjustments

Direction Sign:

1 ⇦ Instruction Manual

2 ⇦ Physical Design

3 ⇦ Descriptions of Operation and Circuit Diagrams

4 ⇦ Replacement of Individual Assemblies

Maintenance and Safety Checks ⇨ 6

Modifications and Supplements ⇨ 7

Appendix ⇨ 8

Contents 5. Testing and Adjustments

5.1 Notes to testing and adjustments

The device is fully adjusted and tested by the manufacturer. Readjustments should be performed by qualified personnel only.

To determine the cause of c ertain errors prior to opening the device, the THERMOFLATOR® features the following test routines:

– **Service programs P1, P2, P3 and P4**
If the device is switched on while the volume reset button is pressed, P1 appears briefly on the display. Depending on the default operating mode, the high supply pressure mode (HiSup) or the low supply pressure mode (LoSup) can be set using the “Plus and Minus” buttons in the “flow display field”. These settings permit various different warnings and displays.
If CO_2 bottles (high supply pressure) are used, the bottle pressure is shown in the “gas bottle pressure gauge” field. If the bottle is empty (pressure less than 7 bar), a “bottle empty” alert is sounded, which also appears on the monitor in the KARL STORZ-SCB® system.
If the THERMOFLATOR® is connected to a central gas supply (low supply pressure), only the right green LED lights up to indicate the status.

CAUTION: *This display also appears when no gas is being supplied to the device. A “bottle empty” alert is not sounded. Nothing is displayed in the KARL STORZ-SCB® system.*

Pressing once more the “Plus and Minus” buttons in the “Pressure” field activates the service program P2. This is an LED test program.

Pressing once more the “Plus and Minus” buttons in the “Pressure” field activates the service program P3. This displays the number of operating hours of the device.

Pressing once more the “Plus and Minus” buttons in the “Pressure” field activates the service program P4. If the OPTITHERM® heating element is inserted the current OPTITHERM® heating element temperature is displayed (in °C). The current room temperature is displayed if the heating element has been able to cool sufficiently. In the absence of the OPTITHERM® heating element “- - -” appears.

– **HEX display test**
If you connect the device while pressing the start/stop button, the system branches into the “HEX mode display”. The output voltage of the 4 amplifiers (bottle pressure, patient pressure A, patient pressure B, flow) is displayed as HEX values on the display, see also *Section 5.3 Testing and adjusting the control board*.

5.2 Test instruments required for the individual adjustment procedures

– Variable-voltage isolating transformer (0 VAC … 250 VAC / 0 A … 3 A)
– Multimeter with measuring leads
– Hand-held-pressure gauge, e.g. SV4023
– Pressure gauge transducer 0 bar … 400 mbar, relative, e.g. SV4024
– Flowmeter (up to 45 l/min.), calibrated for CO_2, 20 °C, 1013 mbar
– Hand pump with hoses, and T-connector
– Temperature measuring device (reference thermometer), accuracy of ±0,5 K or ±0,5 °C
– Water bath made of purified water, warmed up to 30 °C … 38 °C (86 °F …100.4 °F)
– Insufflation testing device (artificial volume)
– Adjustment tools

5.3 Testing and adjusting the control board

Adjustment of the control board may only be carried out when the device is fully assembled. For this purpose the device must be switched on at least 10 minutes beforehand.

5.3.1. Adjusting the operating voltage

The 5 VDC operating voltage can be measured between test points TP1 and TP2 on the control board. If necessary, the voltage can be re-adjusted using R26 on the power supply unit. After the 5 VDC operating voltage has been re-adjusted, an offset calibration routine and, if necessary, an amplification calibration routine should be performed.

5.3.2. Offset calibration

A separate offset calibration routine must be performed for each section: patient pressure A, patient pressure B, bottle pressure and flow. The THERMOFLATOR® is switched into “Hex display mode” with a shorting plug on JP1. This mode can also be accessed by pressing the start button at device power-up (it can be exited only by switching off).

Trimmer VR1 is used to calibrate the offset for patient pressure B to the value “21” in the volume display.

Trimmer VR2 is used to calibrate the offset for the flow to the value “10” in the flow display.

Trimmer VR3 is used to calibrate the offset for patient pressure A to the value “21” in the patient pressure display.

Trimmer VR4 is used to calibrate the bottle pressure so that in the bottle pressure display 1 red and 2 green LEDs light up. No supply bottle may be connected at this point, nor may insufflation have been started.

5.3.3. Amplification calibration for patient pressure

For each of the two identically designed pressure amplifiers, a separate calibration routine must be performed with VR6 and VR7. For this purpose, a pressure is first applied to pressure sensor B (pos. X1). The value in the numerical pressure display must agree with the value of a reference instrument connected in parallel. VR7 can be used to set the display. The pressure display must be compared at several different values (5 mmHg, 15 mmHg, 30 mmHg). VR7 and VR1 are dependent on each other. It may prove necessary to repeat the offset and amplification calibration routines several times alternately.

Then a pressure must be applied in parallel to both pressure sensors, and the hex value displayed by the two amplifiers compared with a shorting plug on JP1. VR6 is used to calibrate amplifier “A” so that both displays agree. Here, too, both displays must be compared at the three values listed above. VR6 and VR3 are dependent on each other. It may prove necessary to repeat the offset and amplification calibration routines several times alternately. The deviation between the device display and the reference display must not exceed 1 mmHg.

5.3.4. Amplification calibration for flow rate

For the flow rate function, amplification must be calibrated using VR5. For this purpose, a calibrated flowmeter is connected to the patient outlet. Care must be taken to ensure that feed lines and measuring equipment have a minimized flow resistance, since otherwise the maximum possible flow may not be reached. With a shorting plug on JP2, the THERMOFLATOR® is switched into the “Sustain mode” in order to generate an even gas flow. It is immaterial in this context which of the two operating modes is currently selected. The setpoint values must set to 20 mmHg and 25 l/min. After insufflation has been started, the device’s flow display must be harmonized with that of the flowmeter, using VR5. VR5 and VR2 are dependent on each other. It may prove necessary to repeat the offset and amplification calibration routines several times alternately. Now the flow is checked in normal operation (without a shorting plug), in initializing mode, and in the two operation modes.

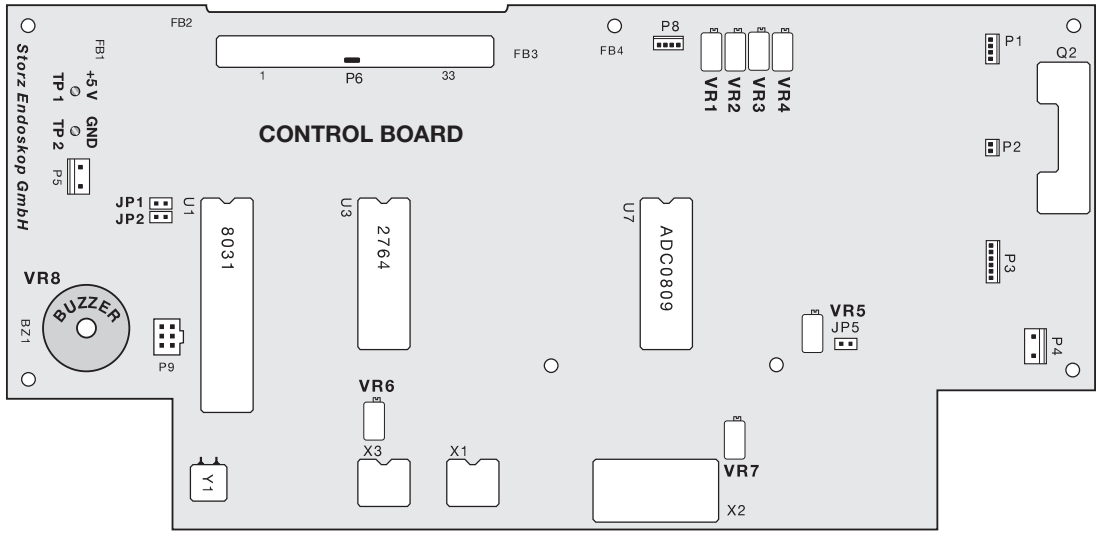
If using a thermal flow measuring instrument the values specified in the tables below must be complied

Flow setpoint (l/min)	Flow display (l/min)	Volume display THERMOFLATOR® (l) after 1 min
Initializing mode (pressure setpoint: 15 mmHg, Veress needle connected)		
1.0	0.0 ... 2.0	0.0 ... 2.0
Intermittend mode (pressure setpoint: 20 mmHg)		
3.0	2.0 ... 4.0	2.0 ... 4.0
10.0	9.0 ... 12.0	9.0 ... 12.0
30.0	27.0 ... 36.0	27.0 ... 36.0
Semi-continuous mode (pressure setpoint: 20 mmHg)		
3.0	2.0 ... 4.0	2.0 ... 4.0
10.0	9.0 ... 12.0	9.0 ... 12.0
30.0	27.0 ... 36.0	27.0 ... 36.0

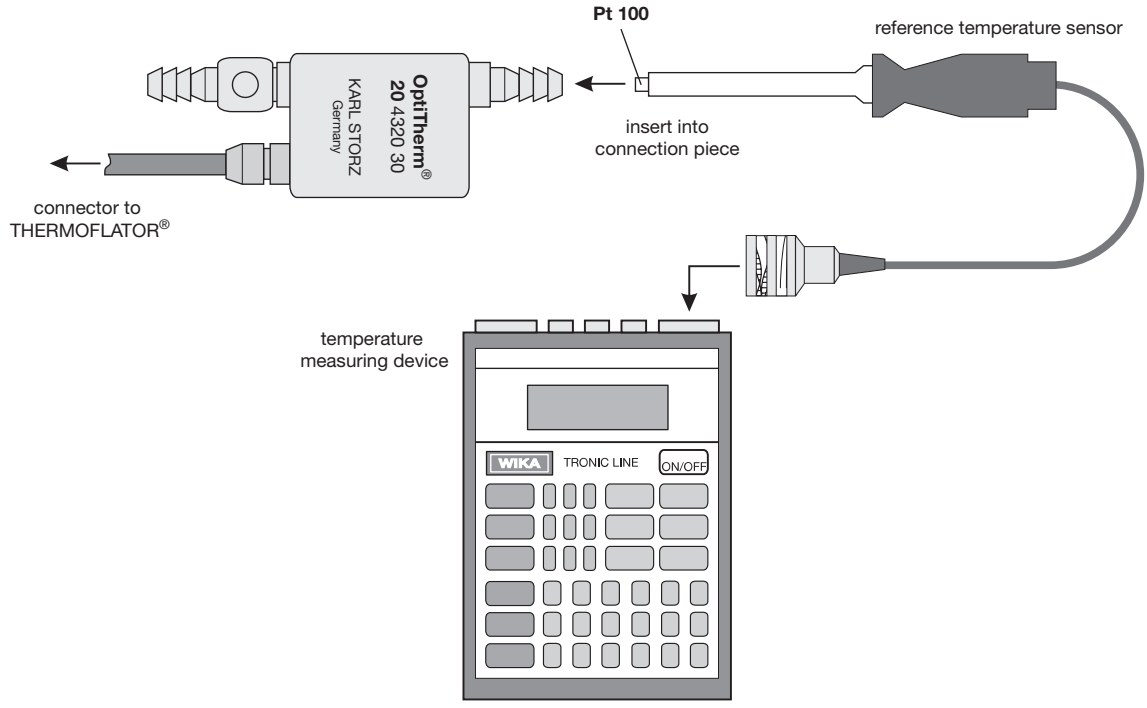
with here:

5.3.5. Adjusting the volume of the acoustic alarm signal

The resistor trimmer VR8 can be used to adjust the volume of the acoustic signalling device. But the acoustic signal cannot be switched off altogether. In the device's as delivered condition, the volume is set to maximum.



5.3.6. Temperature adjustment of the OPTITHERM® heating element



5.3.6.1. Adjustment for devices with software versions up to S012001Q

In order to minimize the influence of component tolerances of the reference elements, a temperature adjustment is required after the processor board or the control board have been exchanged.

Allow the heating element of the OPTITHERM® inline heating element to cool down to room temperature. Connect the heating cable to the jack located on the front panel and activate service program P4. "°C" is displayed as well as the registered temperature. Now place a reference thermometer (with a min. accuracy of 0.5 °C) near the monitoring sensor (insert into the hose connection piece of the OPTITHERM® inline heating element). If the value displayed on the THERMOFLATOR® is not equal to the reference value, correct it using the ± buttons (located next to the "M" button). As the resolution equals approx. 0.6 °C, the temperature steps can equal 0.5 °C or 1.0 °C. The maximum correction range equals ±3 K. You can use the "0" button to reset the correction value to zero. As soon as the device is disconnected, the current value is automatically stored.

5.3.6.2. Adjustment for devices with software versions as from C012001R

In order to minimize the influence of component tolerances of the reference elements, a temperature adjustment of the OPTITHERM® heating element is required after the following components have been replaced:

- control board
- temperature controller board
- EPROM on the control board (changing the device's software from less or equal version S012001Q to equal or greater than version C012001R)
- NVRAM on the control board

Allow the heating element of the OPTITHERM® heating element to cool down to room temperature. Connect the heating cable to the jack located on the front panel of the THERMOFLATOR® and activate the service mode by switching on the device while the volume reset button is pressed; then forward to service program P4 by pressing the + button. "°C" is displayed as well as the registered temperature.

Now place the reference thermometer as well as the OPTITHERM® heating element into the warmed up water bath for at least 5 minutes. If the value displayed on the THERMOFLATOR® is not equal to the reference value, correct it using the + or – button for the flow (temperature steps can equal 0.5 °C or 1 °C).

As soon as the THERMOFLATOR® is switched off the displayed temperature value will be stored.

ⓘ ***Note:*** *For the adjustment the usage of an OPTITHERM® heating element is mandatory; otherwise "°C" and "---" will be displayed in service program P4.*
The temperature display range of the THERMOFLATOR® is 10 °C … 42 °C (50°F … 107.6 °F). Outside of this display range an adjustment is not possible.
Using the volume reset button the value of temperature can be set on center of the temperature display range.

5.4 Functional test of the low-pressure safety valve

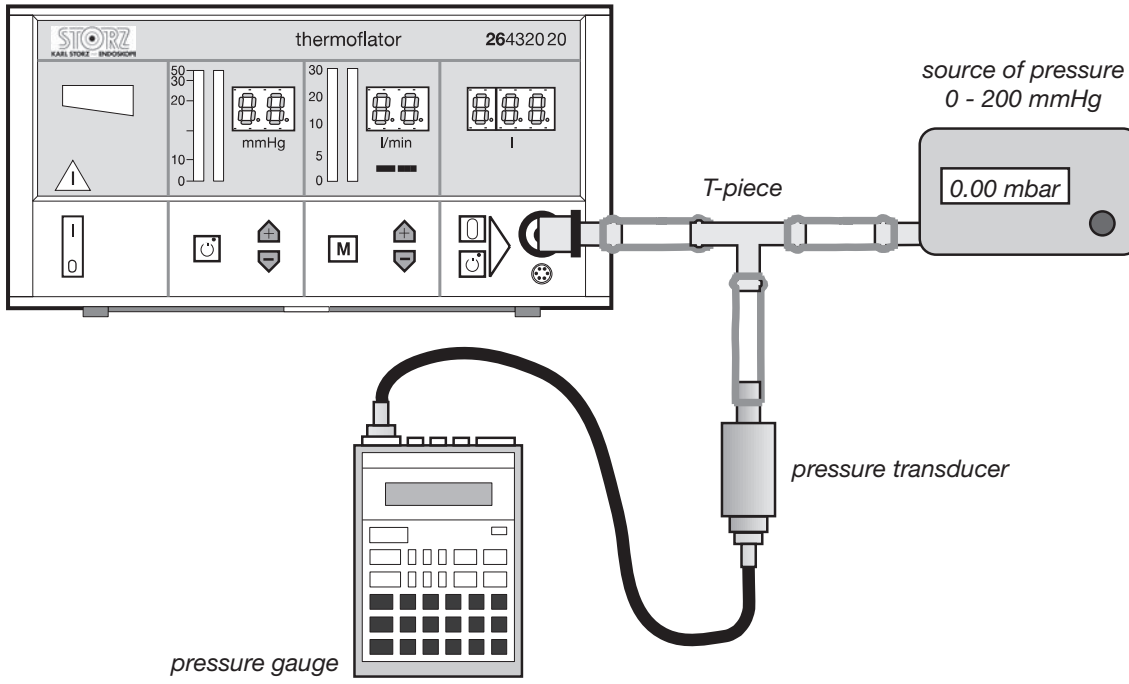
– Disconnect relief valve (press "M" button for min. 2 s).
– Fit a self-made, suitable hose set with a T-piece, as shown in the diagram, to the hose connection piece. Connect a calibrated pressure gauge to the free end of the T-piece. Reference measuring devices as detailed in Section 5.2 Test instruments required for the individual adjustment procedures.
– Connect a controllable source of pressure (e.g. leak testing device 13242 XL) to the hose.

ⓘ ***Note:*** *The pressure to be expected varies between 55 mmHg and 100 mmHg.*

– Slowly increase the pressure to approx. 50 mmHg. Disconnect the pump, and observe the pressure display. Check the system for leaks. Seal possible gas leaks.
– Increase pressure to 55 mmHg or higher, if required.

! ***CAUTION:*** *The pressure applied may not exceed 150 mmHg.*

– The valving pressure of the valve is displayed on the measuring device. It can be deduced when the output pressure at the source of pressure is increased, but the reading on the measuring device remains nearly constant. It must lie in the range of 55 mmHg to 100 mmHg.
– Remove the hose connection from the insufflation connection piece to the patient.
– Check the safety functions, and perform safety checks as detailed in Section 6 Maintenance and Safety Checks.



5.5 Further tests and functional tests

5.5.1. Pressure and control behavior test

Check the pressure for both operating modes (semi-continuous and intermittent) at various setpoint pressures ranging from 15 mmHg to 30 mmHg. Connect the insufflation output to insufflation testing device, and pressure gauge transformer 0 bar to 0.4 bar with pressure gauge. Set a small leak at the insufflation testing device. Compare the actual values displayed by the pressure gauge, and the digital pressure display. Note the lowest value displayed by the pressure gauge at which the control functions again.

5.5.2. Pressure drop test

– Settings: Intermittent gas flow, pressure 15 mmHg.
– Close leak tap of insufflation testing device completely.
– Create pressure of 15 mmHg in the insufflation testing device.
– Remove plug P2 of the linear actuator from the control board, see *Section 3.3 Wiring diagram of the THERMOFLATOR®*.
  The pressure drop must be equal to or less than 3 mmHg per 15 s (control to pressure gauge).

5.5.3. Functional test of excess pressure alarm messages

– Disconnect relief valve (press “M” button for min. 2 s).
– Testing the software alarm at an excess pressure of > 5 mmHg above setpoint.
– Settings: 15 mmHg, 10 l/min., interm. operating mode, gas flow button ON.
– Close leak tap at insufflation testing device completely.
  The software alarm must react at 18.0 mmHg to 22.0 mmHg with a delay of 3 seconds. Manually set excess pressure at the insufflation testing device balloon, so that a pressure reading of 17.9 mmHg is displayed on the pressure gauge. No alarm may sound after 3 seconds, and the blow-off valve may not open. Now manually set the pressure to 22.0 mmHg. After 3 seconds an alarm sounds intermittently, and the blow-off valve is disconnected.
– Testing the hardware alarm at an actual pressure of > 30 mmHg.
– Settings: 30 mm Hg, 10 l/min., interm. operating mode, gas flow button OFF.

– Close leak tap at insufflation testing device completely.
  The hardware alarm must react at 30.0 mmHg to 33.0 mmHg with a delay of 5 seconds. Manually set excess pressure at the insufflation testing device balloon, so that a pressure reading of 29.9 mmHg is displayed on the pressure gauge. No alarm may sound after 5 s. Now manually set the pressure to 33.0 mmHg. After 5 seconds an alarm must sound continuously.
– Connect relief valve (press “M” button for min. 2 s).

5.5.4. Negative alarm

– Set a small leak at the insufflation testing device, and allow pressure to reduce.
– Settings: 10 mmHg, 10 l/min., intem. operating mode, gas flow button OFF.
– Close leak tap at insufflation testing device completely.
  When the gas flow is disconnected, create a negative pressure by squeezing, and pulling the output hose. An acoustic warning signal sounds.

5.5.5. Dangerous increase of pressure

– Increase of pressure > 5 mmHg every 0.2 s. During operating mode “Insufflation initialization”.
– Settings: operating mode “Insufflation initialization”, gas flow button ON.
– Quickly squeeze the exit hose with your hand to cause an increase of pressure. Three beeps sound, one second apart, and the digital pressure display blinks.

5.5.6. Interrupted flow of gas during semi-continuous operating mode

– Settings: 10 mmHg, 10 l/min., semi-continuous flow of gas.
– While the gas flow is disconnected, stop the flow of gas either by squeezing the output hose with your hand or through a small leak at the insufflation testing device. An acoustic warning sounds, and the digital flow display blinks (flow < 1 l/min.).

5.5.7. Blow-off valve

– Settings: 10 mmHg, 10 l/min., intermittent flow of gas.
– With the gas flow connected, increase the pressure by at least 5 mmHg above the setpoint by squeezing the insufflation testing device balloon. After 3 seconds an acoustic warning sounds, and after 5 seconds the LED “valve symbol” is lit red, and the blow-off valve acts to reduce pressure (valving and measuring every 1.5 seconds).
– You can also deactivate the blow-off valve.
– Press the “M” button for more than 2 seconds until the LED “valve symbol” is lit red. At excess pressures the pressure is not reduced anymore by valving, only the acoustic warning sounds.

Section 6.

Maintenance and Safety Checks

Direction Sign:

Contents 6. Maintenance and Safety Checks

6.1 Safety functions of the THERMOFLATOR®

The safety-relevant variables pressure and temperature are monitored by several different systems:

– **Pressure control**
  ◦ overpressure safety by means of mechanical systems
  ◦ overpressure safety by means of hardware
  ◦ overpressure safety by means of software

– **Heater control**
  ◦ overtemperature safety by means of hardware
  ◦ overtemperature safety by means of software
  ◦ overtemperature safety of preheater by means of an electro-mechanical system

In addition to these monitoring features, the THERMOFLATOR® draws the user's attention to certain operating states by means of visual and acoustic alarms, without initiating further actions on its own. The states involved are:

– **"Supply bottle empty" alarm**[1)]
  Five alarm tones at one-second intervals are outputted when the start button is pressed if the supply bottle is empty (p < approx. 7 bar). At the same time, the red LED in the bottle pressure display will flash.

– **"Dangerous pressure rise" alarm**
  Three alarm tones at one-second intervals are outputted if in initializing mode the speed of pressure rise exceeds a defined value (2.5 mmHg / 0.1 s). This is designed to draw attention to a faulty placement of the Veress needle, e.g. in tissue. At the same time as this acoustic alarm, the numerical pressure display will flash.

– **"Negative pressure" alarm**
  If a negative pressure is measured at the inlet, two short alarm tones will sound at one-second intervals. The alarm will persist until the pressure measured becomes positive once again. This alarm can, however, also be interpreted as positive feedback; for example, if the abdominal wall is raised in conjunction with correct placing of the Veress needle, and a negative pressure is produced inside the abdomen.

– **"Gas flow broken off" alarm**
  If flow = 0 is detected in the operation mode with semi-continuous gas flow, an acoustic alarm will sound at one-second intervals and the numerical gas flow display will flash. Since this operating mode is usually used with a gas leak, this alarm draws the user's attention to a kinked insufflation hose or something similar, and thus indicates an incorrect pressure display.

In order to prevent commissioning of a defective device, the THERMOFLATOR® runs through the following self-testing routines when it is connected:

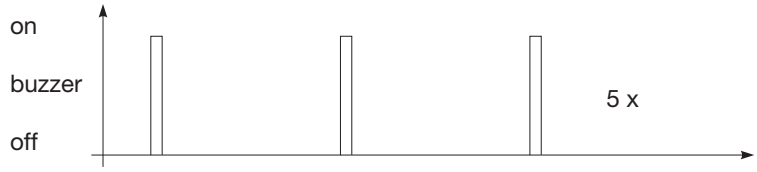
– **Flow amplifier**
  If a flow of more than 0.75 l/min. is measured when the device is connected (offset displacement), the device triggers an acoustic alarm, and the message "Fl Err" is displayed.

– **Pressure amplifier**
  If a pressure offset of more than 1.5 mmHg is registered between the two independent pressure gauge channels (offset displacement), the device triggers an acoustic alarm, and the message "Pr Err" is displayed.
  The device can only be restarted in the hex display mode subsequent to both of the above errors, see Section 5 Testing and Adjustments. You can now debug the device or readjust it.

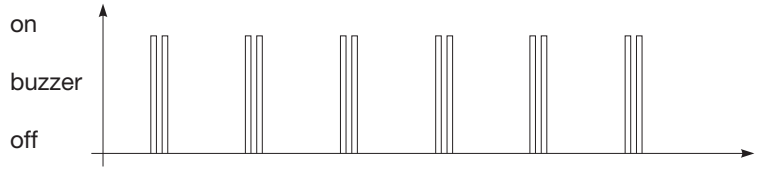
– **Inline heating**
  If a defective temperature feeler or a defective connection is recorded when the device is connected, the device triggers an acoustic alarm, and the thermometer symbol is lit red. The heating element is disconnected. An insufflation of CO_2 is still possible.

1) Valid only in high supply pressure-mode HiSup.

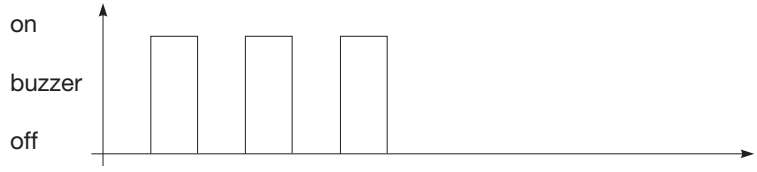
The following illustration provides an overview of the various acoustic alarms involved.



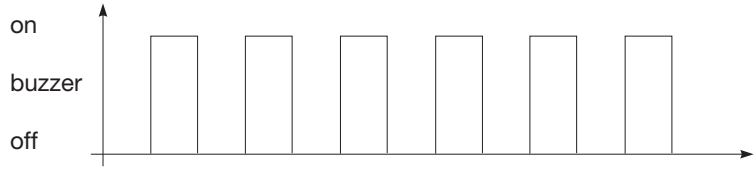
supply bottle empty



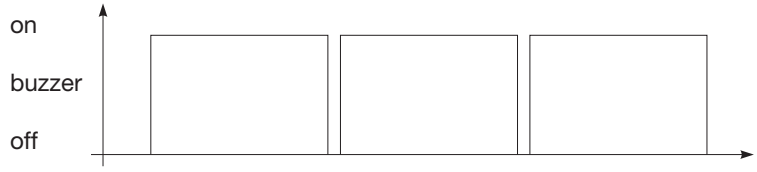
negative pressure



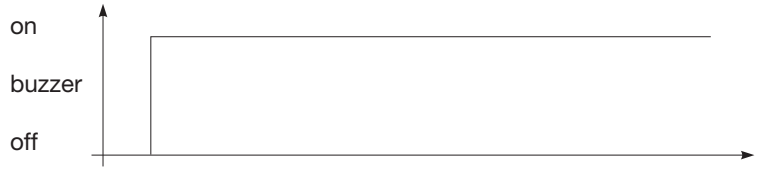
fast pressure rinse
(add. numeric pressure display blinking)



no flow
(add. numeric flow display blinking)



overpressure
$p > p_{set}$ + 5 mmHg more than 3 s



overpressure
p > 30 mmHg more than 5 s or
Excess temperature/defect inline heating unit
add. red illuminated symbol or
Error during self-testing routine
additional "Pr Err" or "Fl Err" display

The volume of the acoustic alarm can be subsequently re-adjusted by the service personnel, but it cannot be switched off completely, see *Section 5 Testing and Adjustments*.

The THERMOFLATOR®'s patient connection has been prepared for accommodating various microfilters to prevent contamination of the device with patient fluid and a concomitant risk to the next patient. Several of these filters are accordingly included in the device's standard accessories.

In order to prevent soiling from the supply side, a filter (50 micron) is used in the input stage of the pressure manifold. In addition, an external high-pressure filter (0.5 micron) is optionally available. This is positioned between the supply bottle or the high-pressure tube and the device.

6.2 Safety checks

We recommend carrying out safety checks at least once a year.

ⓘ ***Note:*** *To document the result of the safety check use a test report, see Section 8. Appendix.*

Work to be carried out	Remark
■ **Visual inspection**	
– Housing and accessories	check for outer damage
– Labelling, Identification plate data	correct, legible, secure, clean, wipable
– CE symbol, Storz test label	attached to the housing
– Instruction manual	present
– Power fuses	correct value, undamaged, securely attached 2 x T 2.0 AL / 250 V
– Fuse label	applied next to the fuse holder, correct fuse ratings
– Bottle holder	present and in perfect condition
■ **Test for proper operation**[2)]	
– Power switch	
– Connection for CO_2 gas supply	in perfect condition
– Pressure relief valve	
– Setpoint bargraph	
– Setpoint digital display	
– Buttons	
– Service mode	P1: gas supply modes, P2: LED self-test, P3: operating hours, P4: OPTITHERM® adjustment
– Gas preheater (1. shutdown at 230 VAC)	45 s (+55 s / -15 s)
– Check bottle pressure (HEX mode)	21 – 10 – 21 (±2 digits)
– Check bottle pressure (operating mode)	
– Check flow rate (semi-continuous; 20 mmHg)	(30 l/min (+6 l/min / -3 l/min)
– Check flow rate (intermittent; 20 mmHg)	30 l/min (+6 l/min / -3 l/min)
– Pressure, and control behavior test (semi-continuous; 10 l/min)	30 mmHg (+3 mmHg / -2 mmHg), 15 mmHg (+3 mmHg / -1 mmHg)
– Pressure, and control behavior test (intermittent; 10 l/min)	30 mmHg (+3 mmHg / -2 mmHg), 15 mmHg (+3 mmHg / -1 mmHg)
– Pressure drop test (≤ 3 mmHg/15 s)	(15 mmHg -20%)
– Software alarm, blow-off valve	
– Hardware alarm	≥ 30 mmHg (+3 mmHg)
– OPTITHERM® heating element	37.0 °C (+3.7 °C / -5.6 °C)
– Negative alarm	
– Bottle empty	≤ 5 bar (±2 bar)
– Drawer for the short instruction manual	

❗ ***CAUTION:*** *Safety Testing based on IEC EN62353, IEC / UL 60601-1, whichever may apply, must be performed after servicing has been completed.*

2) For functional tests see Section 5 Testing and Adjustments.

Work to be carried out	Remark
■ **Electric safety measurements (IEC 62353)** – Protective ground resistance: (with power cord) ≤ 0.3 Ω – Earth leakage current: ≤ 1.0 mA – Touch current: ≤ 0.5 mA – Patient leakage current: ≤ 0.5 mA – Patient leakage current: ≤ 5.0 mA (line voltage on the applied part)	

6.3 Safety devices

For further information about safety devices and instructions please see instruction manual.

6.4 Maintenance operations

Performance of preventive maintenance is not essential. Regular maintenance can, however, contribute to identifying potential problems before they become serious, thus enhancing the instrument's reliability and extending its useful operating life.

Maintenance services can be obtained from your local representative or from the manufacturer.

Regardless of the accident prevention regulations or testing intervals for medical instruments prescribed in different countries, we recommend a safety check of the device at least once a year.

6.5 Servicing and repair

Defective equipment must be serviced and repaired by factory trained technicians and replacement parts must be ordered from KARL STORZ.

Third party substitutions may result in non-compliance of this product with its original specifications.

KARL STORZ maintains a repair and replacement warehouse which is normally adequate to ensure prompt replacement of damaged telescopes and instruments. Under the repair and replacement plan, you receive an identical as-new instrument and are only charged the repair costs for the defective instrument.

For equipment and videoscopes, individual repair is possible.

In Germany you can refer repairs direct to

KARL STORZ GmbH & Co. KG
Repair Service Dept.
Take-off Gewerbepark 83
D-78579 Neuhausen
Phone: +49 (0)7461 708-980
Fax: +49 (0)7461 708-404

In other countries please contact your local KARL STORZ branch or authorized dealer.

6.6 Fuse replacement

For detailed information please see instruction manual.

Section 7.

Modifications and Supplements

Direction Sign:

Contents 7. Modifications and Supplements

7.1 KARL STORZ-SCB® flash module

7.1.1. Description of KARL STORZ-SCB® flash module operation

The KARL STORZ-SCB® module is a universal interface, which enables KARL STORZ endoscopical devices to communicate for the purpose of remote display and monitoring.

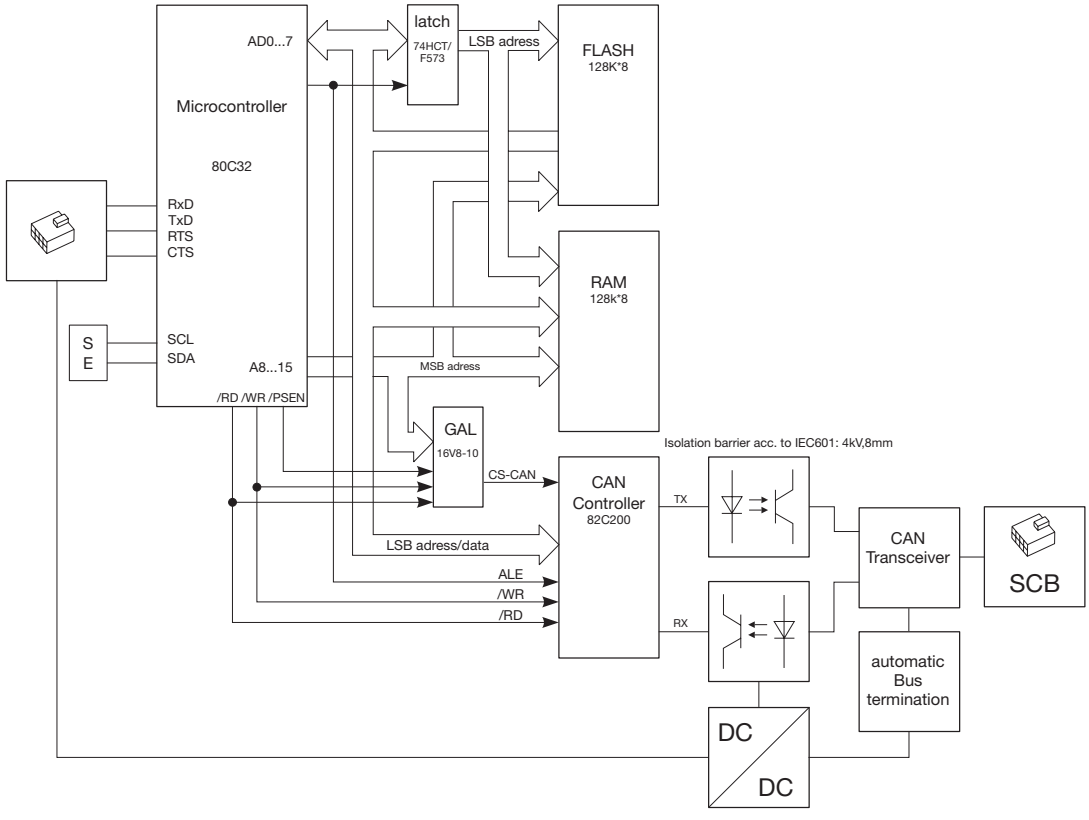
The KARL STORZ-SCB® module is designed as an option for existing and future devices from KARL STORZ. As it is intended for use as a medical device, it has been construed in accordance with the IEC 60601 standard requirements. The module enables the integration of a device in the KARL **S**TORZ **C**ommunication **B**us (KARL STORZ-SCB®) following adaptation of the module software.

It contains the following resources:

– 128 kB program memory
– 128 kB data memory
– microcontroller 80C32
– 22.1184 MHz oscillator frequency
– control trigger / reset during power up
– independent CAN controller
– optically decoupled CAN transceiver
– automatic bus termination
– RS232 interface with hardware handshake
– 1 kB serial EPROM

KARL STORZ-SCB® upgrade kit for THERMOFLATOR® ***order no. 26 4320 77***

7.1.2. Block diagram of the KARL STORZ-SCB® flash module



7.1.3. Notes on the KARL STORZ-SCB® upgrade kit

CAUTION: *Before installing the KARL STORZ-SCB® upgrade kit, first check the compatibility of the following modules:*

- *device software*
- *KARL STORZ-SCB® module software*
- *KARL STORZ-SCB® R-UI*

If in doubt, contact OR1™ service.

Note: *As from serial no. 4105-B the devices have generally installed a KARL STORZ-SCB® module ex factory.*

Installation of the KARL STORZ-SCB® upgrade kit consists of two steps:

– fitting the KARL STORZ-SCB® boards (module board and socket board)
– replacing the EPROM and the microcontroller on the control board

Note: *The microcontroller only needs to be replaced in devices up to serial no. 1929.*

Note: *To ensure functionality of two or more identical devices in the KARL STORZ-SCB®, please observe the settings in Section 7.2 Functionality of two or more identical devices in the KARL STORZ-SCB®.*

7.1.4. Installing the KARL STORZ-SCB® upgrade kit in the standard housing

7.1.4.1. Tools required for installing the KARL STORZ-SCB® upgrade kit in the standard housing

Side cutters

Slot head screwdriver, size 4

Torx key 8 **Order no.** 5610512

Torx key 20 **Order no.** 5625112

Conductive work mat, wristband, ground cable

CAUTION: *Repairs may only be performed by qualified technicians trained in electrical or electronic engineering, in compliance with the relevant occupational, safety and accident prevention regulations.*
Always unplug the equipment before performing any repairs.
To prevent damage to the components caused by the build-up of electrostatic charges, we recommend that you connect yourself to ground via the wristband throughout servicing.
Safety Testing based on IEC EN62353, IEC / UL 60601-1, whichever may apply, must be performed after servicing has been completed.

7.1.4.2. Fitting the KARL STORZ-SCB® boards in the standard housing

Insert a screwdriver into the recess on the rear of the side cover and lift this out towards the front.

(Slot head screwdriver, size 4)

Undo the two screws located underneath the side cover at the front of the device.

(Torx key 20)

Undo the two corresponding screws on the rear of the device.

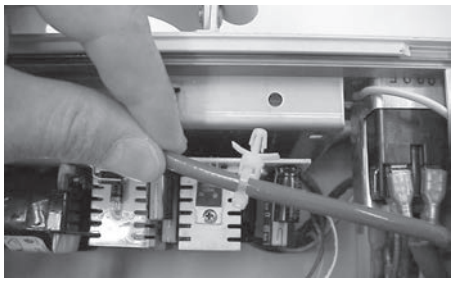
(Torx key 20)

To release the housing cover, press the side rail upwards.

Remove the housing cover by pulling it off towards the right.

Unscrew the base plate in the same way as the housing cover.

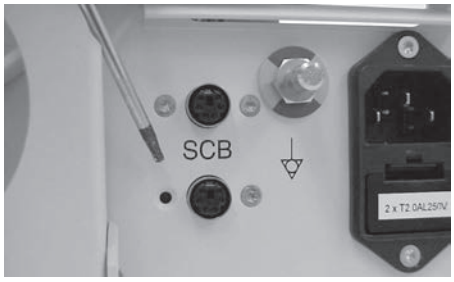
Remove the two coverings from the back panel.



Press out the holder for the cable ties from the power supply mount at the bottom left.

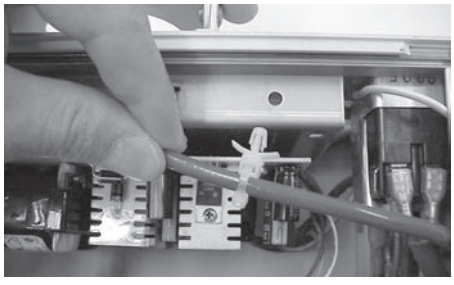
Insert the KARL STORZ-SCB® socket board into the power supply mount sideways from the top.

CAUTION: *If the diameter of the two slots for the KARL STORZ-SCB® socket board on the back panel is too small, it must be increased to 12.5 mm!*



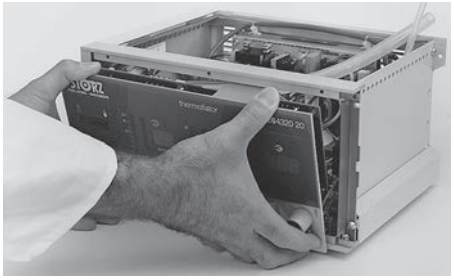
Screw the KARL STORZ-SCB® socket board tightly in place with the four screws supplied.

(Torx key 8)

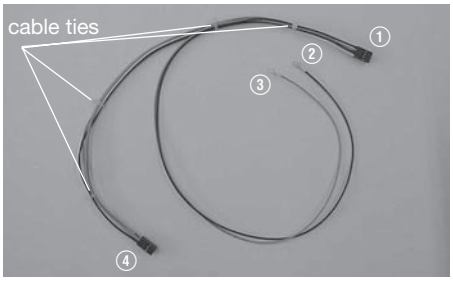


Remount the holder for the cable ties on the power supply mount below on the left.

Remove the two front panel bayonet mounts (sliding bolts) with a screwdriver or similar tool by pulling them out sideways.



Remove the front panel by pulling it out towards the front.



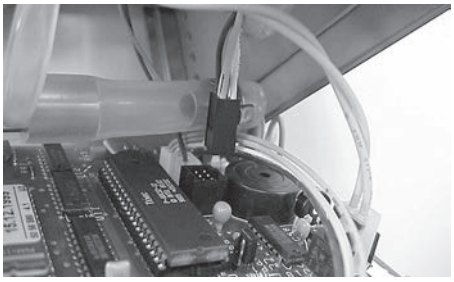
Assemble the connecting cord with four cable ties (distribute ties evenly, see arrows).

① Connection to the KARL STORZ-SCB® module board, X100

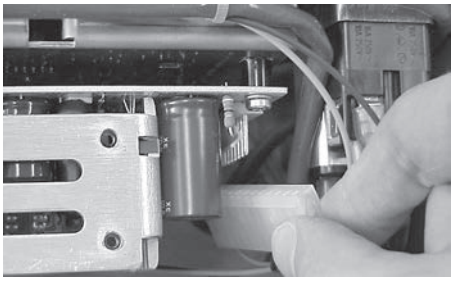
② Connection to the power supply unit, J2 PIN 6 (black cable)

③ Connection to the power supply unit, J2 PIN 8 (red cable)

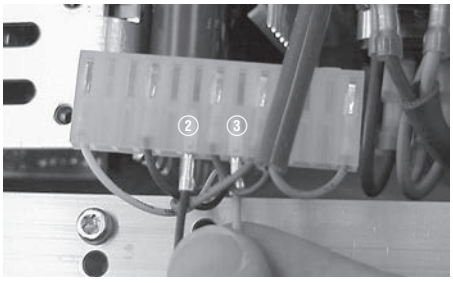
④ Connection to the control board, P9



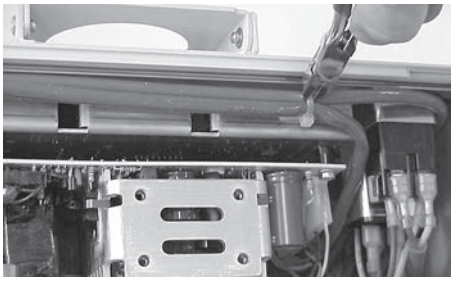
Plug the 6-pole plug ④ of the connector cable into the socket (P9) on the control board.



Unplug the 13-pole connector J2 on the power supply unit.

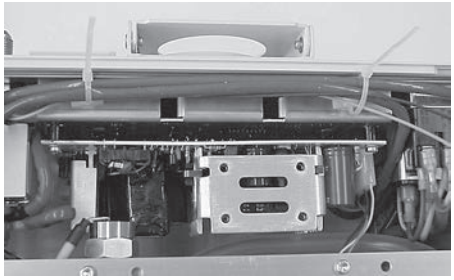


Put the crimp contact ② of the black cable into the plug J2, PIN 6. Put the crimp contact ③ of the red cable into the plug J2, PIN 8.
Plug the connector J2 in again.

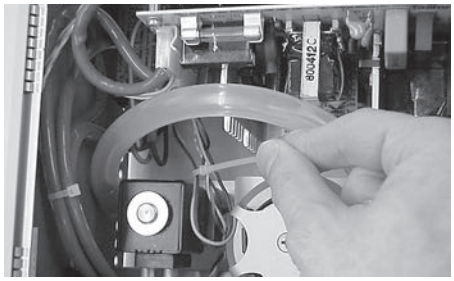


Remove the two cable ties from the bottom of the power supply mount.

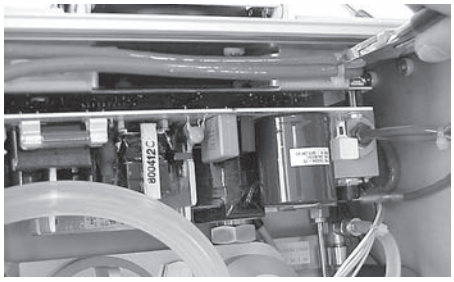
(Side cutters)



Attach the black and red cable to the power supply line with a cable tie.

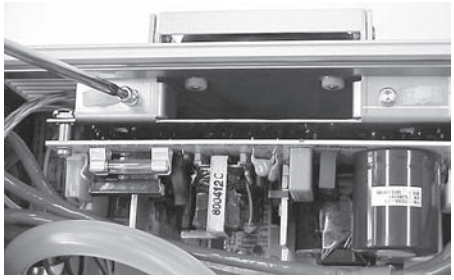


Attach the black and red cable with a cable tie behind the 13-pole plug on the power supply line.



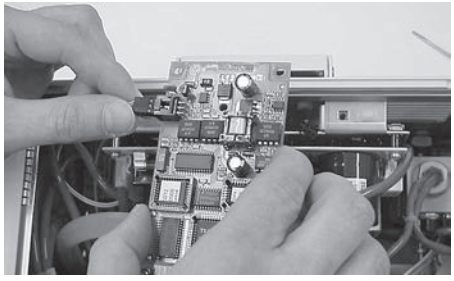
Remove the two cable ties at the top of the power supply mount.

(Side cutters)

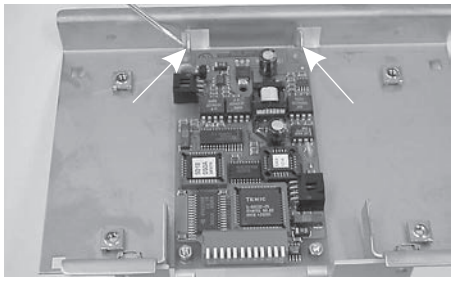


Undo the two fastening screws of the power supply mount.

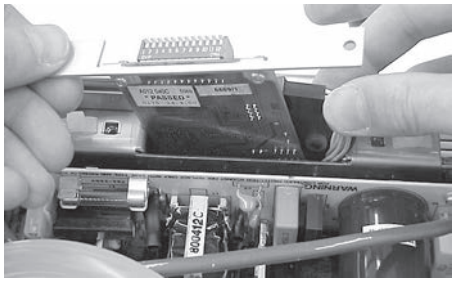
(Torx key 20)



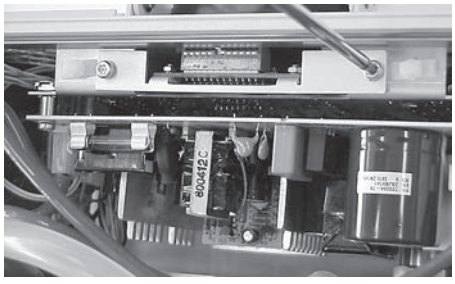
Plug the KARL STORZ-SCB® socket board plug into the KARL STORZ-SCB® module board.



CAUTION: *The KARL STORZ-SCB® module board must be correctly engaged in the recess of the power supply mount.*



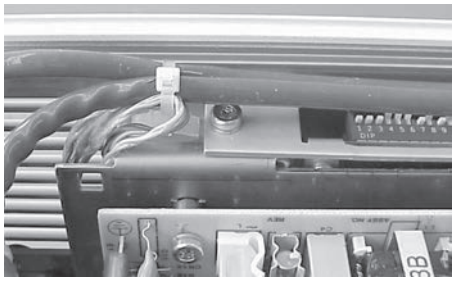
Push the KARL STORZ-SCB® board up to half way into the recess provided in the power supply mount.
Plug the plug of the connector cable (1) into the KARL STORZ-SCB® module board and push the KARL STORZ-SCB® module board in completely.



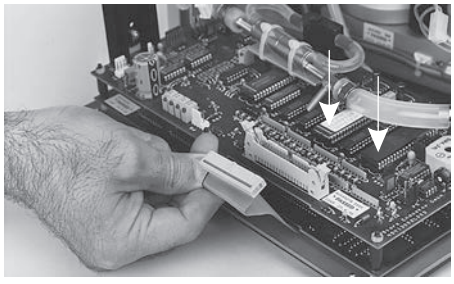
Screw the KARL STORZ-SCB® board firmly to the power supply mount.

(Torx key 20)

CAUTION: *The KARL STORZ-SCB® cables and power supply line must not be trapped between the KARL STORZ-SCB® module board and the power supply mount.*



Connect the cables of the KARL STORZ-SCB® socket board to the power supply line.



7.1.4.3. Replacing the EPROM and the microcontroller

Note: *The microcontroller only needs to be replaced in devices with serial no. 1929 or lower.*

Replace the EPROM U3 (left) and the microcontroller U1 (right) if required.

CAUTION: *When inserting the new EPROM and microcontroller ensure that they are installed in the correct position (recess). Avoid angling or bending the pins while doing so.*

Note: *After replacing the EPROM and the microcontroller, check the device functions and, if necessary, carry out a readjustment, see Section 5 Testing and Adjustments.*

To assemble, proceed in the reverse order.

Note: *It must be checked that the protective grounding on the rear panel is properly secured in accordance with IEC 60601-1 by carrying out a visual inspection and electrical test.*

Stick the KARL STORZ-SCB® label on the front panel.

KARL STORZ — ENDOSKOPE
Mittelstrasse 8
D-78532 Tuttlingen
Germany

Model : 264320 20 -1
Voltage : 100 - 240 V~
Frequency : 50 / 60 Hz
Power : 250 VA

Classification IEC:
Class I
Gas: CO 2

Complete the model number on the manufacturer's identification plate on the underneath of the device by entering '-1' (**26** 4320 20-1).

Note: *To guarantee the functionality of two or more identical devices in the KARL STORZ-SCB®, please see the settings in Section 7.2 Functionality of two or more identical devices in the KARL STORZ-SCB®.*

7.1.5. Installing the KARL STORZ-SCB® upgrade kit in the new system housing

7.1.5.1. Tools required for installing the KARL STORZ-SCB® upgrade kit in the new system housing

Hexagonal socket wrench, size 5.5
Open-end wrench, size 5.5
Side cutters
Slot-head screwdriver, size 4
Torx key 10 **Order no.** 5610612
Torx key 20 **Order no.** 5625112
Conductive work mat, wristband, ground cable

CAUTION: *Repairs may only be performed by qualified technicians trained in electrical or electronic engineering, in compliance with the relevant occupational, safety and accident prevention regulations.*
Always unplug the equipment before performing any repairs.
To prevent damage to the components caused by the build-up of electrostatic charges, we recommend that you connect yourself to ground via the wristband throughout servicing.
Safety Testing based on IEC EN62353, IEC / UL 60601-1, whichever may apply, must be performed after servicing has been completed.

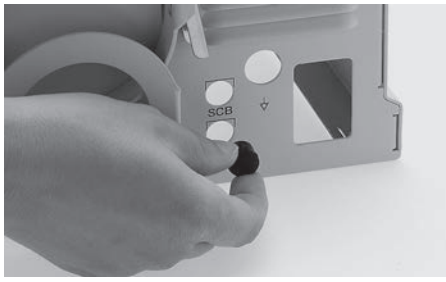
7.1.5.2. Installing the KARL STORZ-SCB® boards in the new system housing

Note: *The new system housing is used in devices with serial no. 2520-B and higher.*

Loosen the screws on the underneath of the device.

(Torx key 10)

Remove the housing cover by pulling it off towards the back.



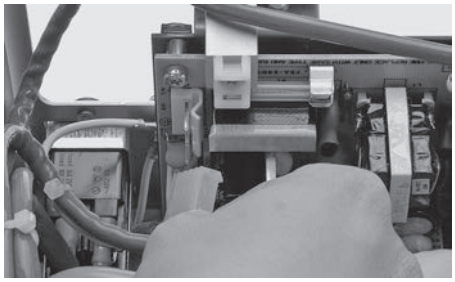
Remove the two coverings from the back panel.

Insert a screwdriver in the recess on the rear of the right side cover, as seen from the front, and lift this out towards the front.

(Slot head screwdriver, size 4)

Remove the two cable ties from the power supply mount.

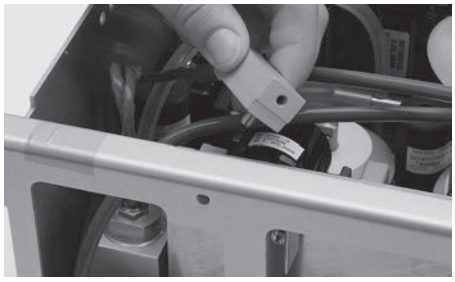
(Side cutters)



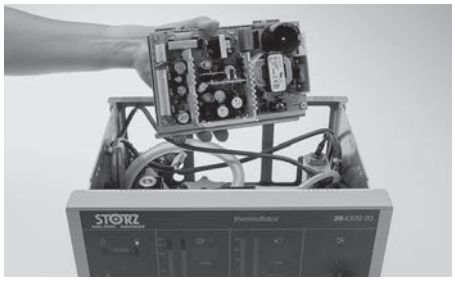
Remove all cable connections from the power supply unit.

Undo the two screws on the power supply mounts.

(Torx key 20)



Remove the two power supply mounts.



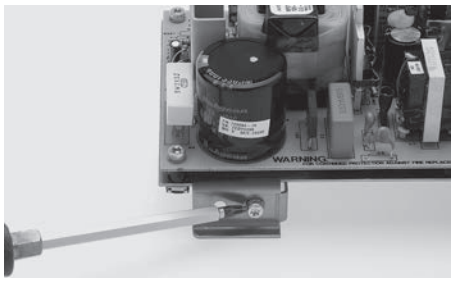
Remove the power supply unit from the device housing.

Place the four spacer sleeves for the new system housing on the retaining bolts of the KARL STORZ-SCB® socket board.

Place the KARL STORZ-SCB® socket board on the retaining bolts.

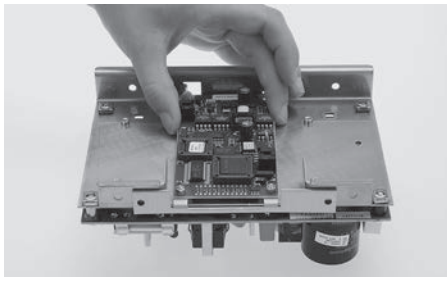
Secure the KARL STORZ-SCB® socket board with the four nuts supplied.

(Hexagonal socket wrench, size 5.5 or open end wrench, size 5.5)



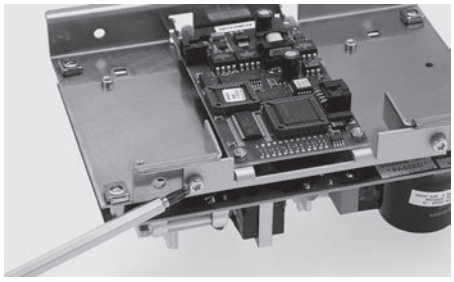
Undo the two fastening screws on the power supply mount.

(Torx key 20)



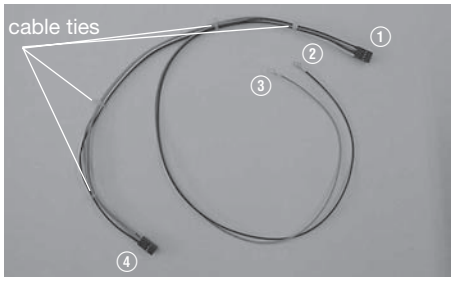
Insert the KARL STORZ-SCB® module board.

CAUTION: *The KARL STORZ-SCB® module board must be correctly engaged in the recess of the power supply mount.*



Screw the KARL STORZ-SCB® board firmly to the power supply mount.

(Torx key 20)



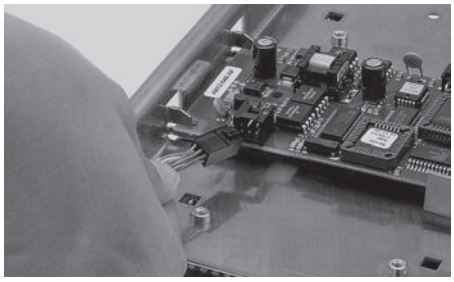
Assemble the connecting cord with four cable ties (distribute ties evenly, see arrows).

① Connection to the KARL STORZ-SCB® module board, X100

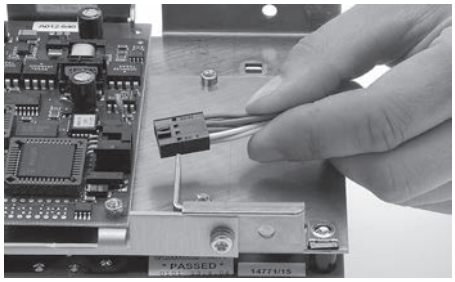
② Connection to the power supply unit, J2 PIN 6 (black cable)

③ Connection to the power supply unit, J2 PIN 8 (red cable)

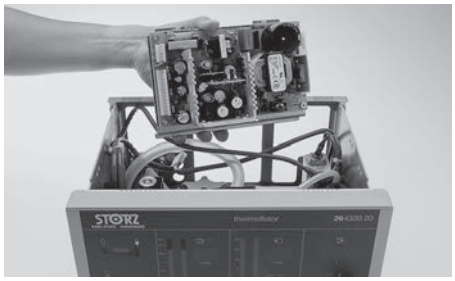
④ Connection to the control board, P9



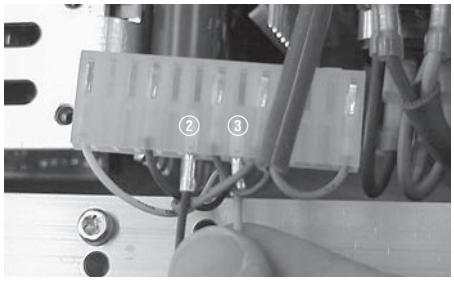
Plug the plug of the KARL STORZ-SCB® socket board into the KARL STORZ-SCB® module board.



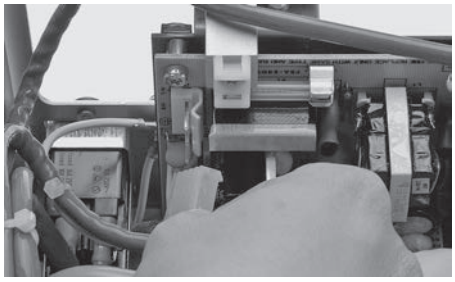
Plug the plug of the connecting cord ① into the KARL STORZ-SCB® module board.



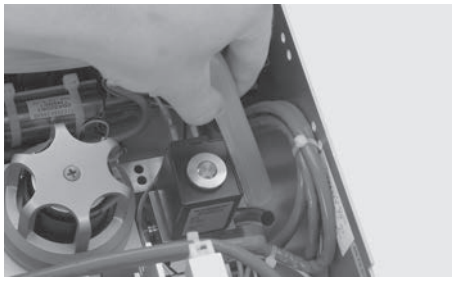
Place the power supply unit back in the device housing.



Put the crimp contact ② of the black cable into the plug J2, PIN 6. Put the crimp contact ③ of the red cable into the plug J2, PIN 8.

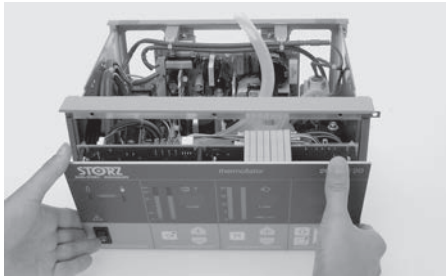


Restore alle the cable connections to the power supply unit and attach alle the cables to the power supply mount with a cable tie.

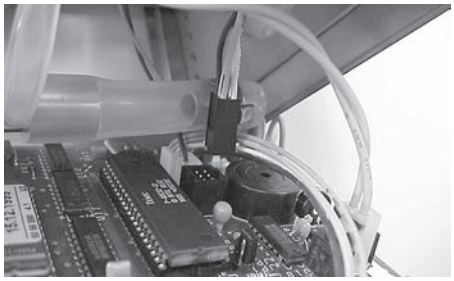


Remove the tube connection from the gas flow divider to the solenoid valve from the solenoid valve.

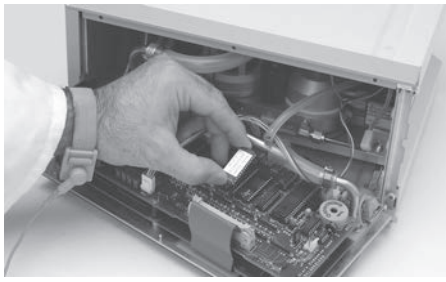
Remove the two front panel bayonet mounts (sliding bolts) with a screwdriver or similar tool by pulling them out sideways.



Remove the front panel by pulling it out towards the front.



Plug the 6-pole plug ④ of the connector cable into the socket (P9) on the control board.



7.1.5.3. Replacing the EPROM

ⓘ ***Note:*** *The EPROM must always be changed in order to guarantee compatibility of the device software and the KARL STORZ-SCB® module software.*

Replace the EPROM U3.

! ***CAUTION:*** *When inserting the new EPROM ensure that it is installed in the correct position (recess). Avoid angling or bending the pins while doing so.*

ⓘ ***Note:*** *After replacing the EPROM and the microcontroller, check the device functions and, if necessary, carry out a readjustment, see Section 5 Testing and Adjustments.*

To assemble, proceed in the reverse order.

ⓘ ***Note:*** *It must be checked that the protective grounding on the rear panel is properly secured in accordance with IEC 60601-1 by carrying out a visual inspection and electrical test.*

Stick the KARL STORZ-SCB® label on the front panel.

Complete the model number on the manufacturer's identification plate on the underneath of the device by entering '-1' (**26** 4320 20-1).

Note: *To guarantee the functionality of two or more identical devices in the KARL STORZ-SCB®, please see the settings in Section 7.2 Functionality of two or more identical devices in the KARL STORZ-SCB®.*

7.2 Functionality of two or more identical devices in the KARL STORZ-SCB®

As from the R-UI version 20090001S243 the KARL STORZ-SCB® R-UI system allows two or more identical devices of the same type to be operated in the KARL STORZ-SCB® network and centrally controlled from the R-UI. Up to three devices can be operated from the R-UI. The precondition is that these devices have different serial numbers.

You will find detailed information on the functionality of two or more identical devices in the KARL STORZ-SCB® system instruction manual (Section “Identical Devices on the SCB”).

To guarantee the functionality of two or more identical devices in the KARL STORZ-SCB®, the following settings must be made after installing the KARL STORZ SCB® upgrade kit:

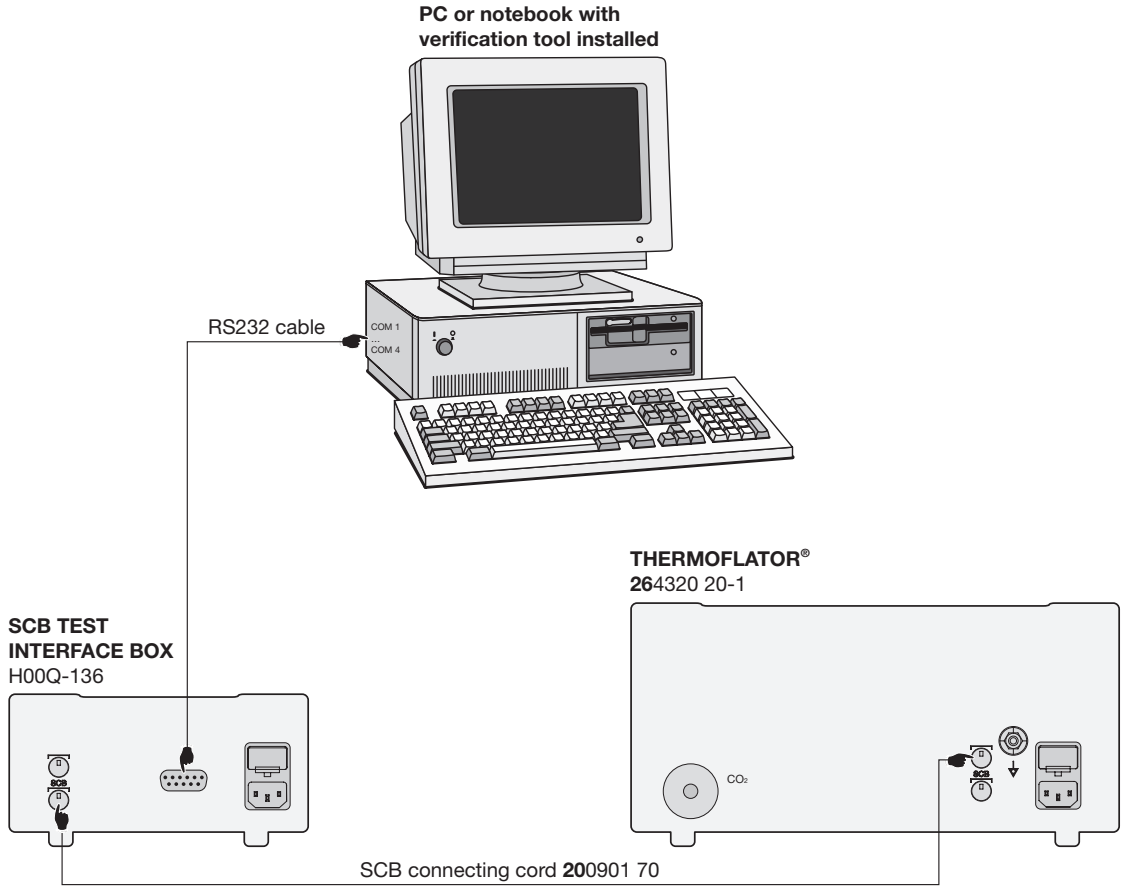
– adjustment of the serial no.
– sticking the corresponding number sticker to the front panel

7.2.1. Tools required to readjust the serial number

The serial no. can be adjusted with the aid of the KARL STORZ-SCB® test interface box (H00Q-136), the SCB Service Tool contained in this package and a conventional PC or notebook.

7.2.2. System design for adjustment of the serial number

Connect the devices to each other as shown in the illustration.



7.2.3. Installation of the SCB Service Tool

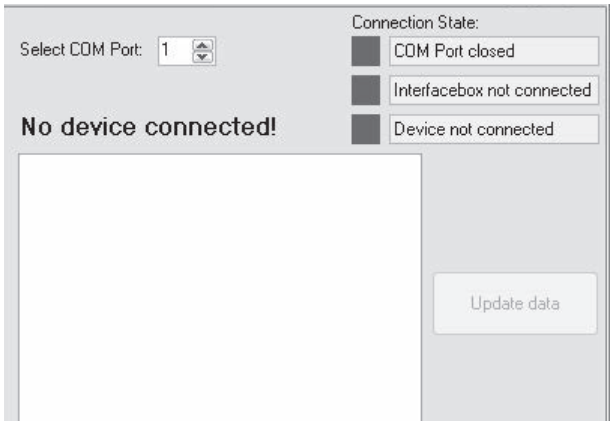
Note: *The SCB Service Tool can be used in conjunction with the operating systems Windows® 2000 (min. Service Pack 3) or Windows® XP (min. Service Pack 2).*

Note: *Before copying the files, we recommend that you create a directory for this purpose on your hard drive.*

Copy the folder **STORZ SCB Service Tool** onto your hard drive.

Remove the write protection from the files you have copied onto your hard drive.

Create a shortcut to the file **SCB_Service_Tool.exe** and rename it **SCB Service Tool**. Copy the shortcut into the program directory of the Start menu on your PC or notebook.

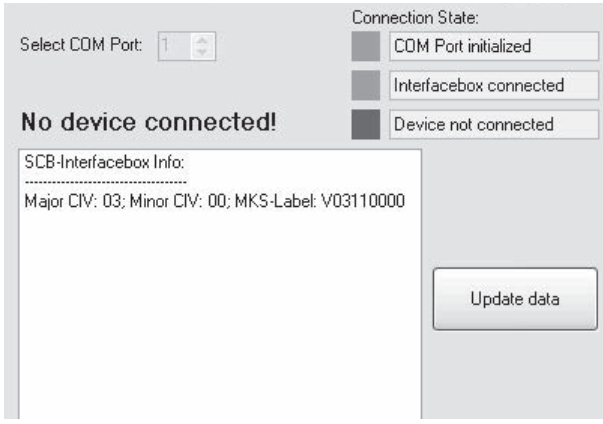


7.2.4. Adjustment of the serial number

Ensure that the system was connected as shown in *Section 7.2.2 System design for adjusting the serial number*.

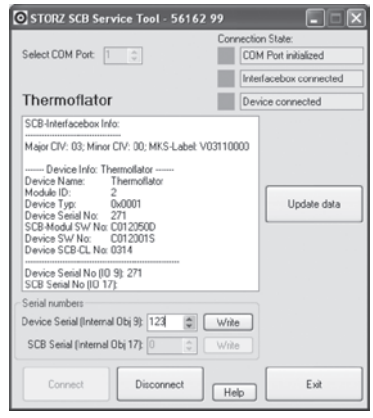
Open the SCB tool by clicking on
Start – Programs – SCB Service Tool.

The window **SCB Service Tool - 5616299** opens.

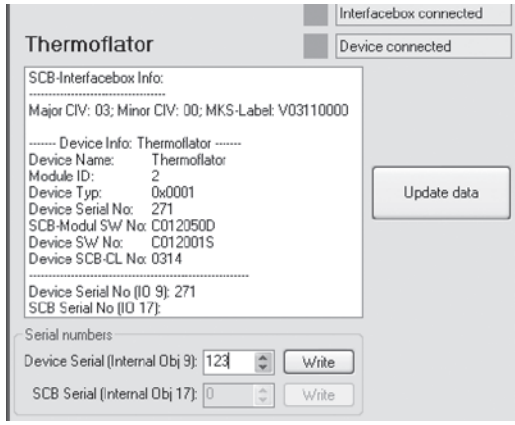


Switch on the KARL STORZ-SCB® test interface box (H00Q-136).

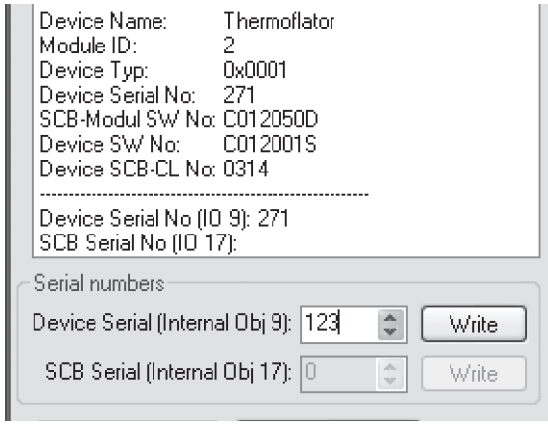
The KARL STORZ-SCB® test interface box reports to the SCB Service Tool.



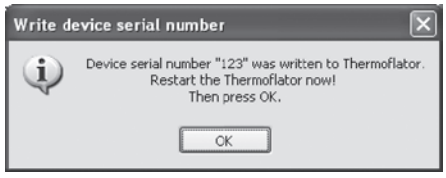
Switch on the THERMOFLATOR® **26** 4320 20-1.
The THERMOFLATOR® reports to the SCB Service Tool.
The device-specific data are read out and displayed.



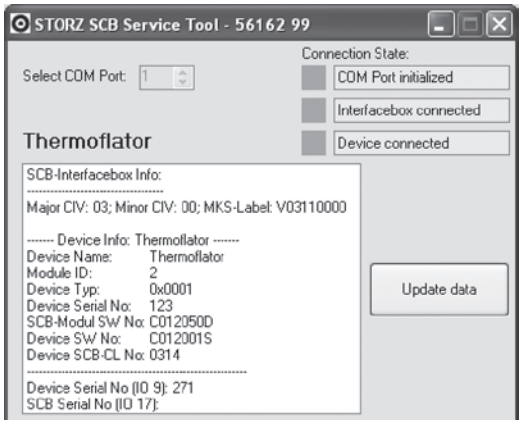
In the area **Serial numbers** the currently programmed serial number is displayed as **Device Serial**.



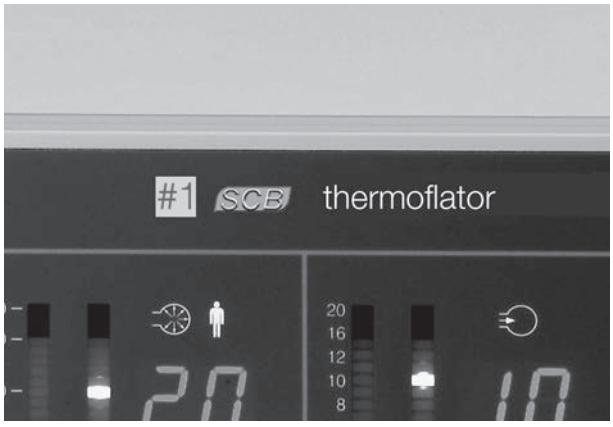
Enter the desired serial number as **Device Serial** and click on the **Write** button.



The window **Write device serial number** opens to confirm the adjustment of the serial number.



Close the SCB Service Tool and switch off the THERMOFLATOR® and the KARL STORZ-SCB® test interface box.



7.2.5. Sticking on the ID number sticker

Attach the corresponding sticker ('#1', '#2' or '#3') beside the KARL STORZ-SCB® symbol on the front panel after you have allocated the ID numbers in the KARL STORZ-SCB®.

ⓘ ***Note:*** *Please see the KARL STORZ-SCB® system instruction manual (Section "Identical devices on the SCB") for detailed information on the functionality of two or more identical devices in the KARL STORZ-SCB®.*

7.3 Software versions

7.3.1. Software version S012001M

7.3.1.1. Note to software version S012001M

The software version S012001M concerns the following items:

At the same time as support of the KARL STORZ-SCB® (KARL STORZ Communication Bus) this software version for the THERMOFLATOR® **26** 4320 20 also introduces or modifies other equipment functions which are not associated with the KARL STORZ-SCB®. The KARL STORZ-SCB® functions will be described separately when they are introduced.

ⓘ ***Note:*** *This software version is included ex factory as from serial no. 960.*

Confirmation of setpoints

Once switched on, the device awaits confirmation or a change of the last set values used. This is signaled by blinking of the corresponding LEDs in the bar displays. The LED in the START/STOP button also blinks.

To confirm all four set values (two set values each for two operating modes), one-time activation of any ± buttons or the START/STOP button is now enough, instead of four individual actions.

Then the LED in the START/STOP button goes out and the LEDs in the bargraph displays are continuously illuminated. Subsequent activation of the START/STOP button then starts insufflation.

ⓘ ***Note:*** *Automatic change of the operating mode is no longer necessary, since only one button must be pressed to confirm the set value.*
The intermittent flow mode is selected as the initial setting since the device is usually operated in this mode. As before, the "M" button must be pressed to switch over into the semi-continuous mode.

Control of OPTITHERM® inline gas heating

The inline gas heating system is now operated independently of the set flow setpoint. A minimum value of 3 l/min was previously required. The gas is now heated up over the entire flow range from 0 l/min to 30 l/min.

Overtemperature alarm

When the gas temperature exceeds 41 °C at the outlet nozzle of the OPTITHERM® heating element, a continuous acoustic alarm is sounded and the red thermometer symbol lights up on the front panel. This alarm is now triggered after a time delay of 5 seconds (previously 1 second). This prevents the occurrence of false alarms when the maximum gas temperature of 41 °C is exceeded for brief periods.

The temperature alarm is then reset automatically when the gas temperature falls under 41 °C. It can also be disabled by removing the connector for the inline gas heating system.

For safety reasons the alarm for detection of a defective inline gas heating system cannot be reset. In this case the device has to be switched off as before and switched back on either with an operational heating system or without heating.

However proper insufflation of (cold) gas is ensured in all cases.

Operation of device using Veress needle with high flow rates

To prevent the user from irritations due to fluctuating pressure indications occurring on creating the pneumoperitoneum with a Veress needle and a high set flow rate, the THERMOFLATOR® is equipped with a slightly modified measuring routine. This ensures a normal stable pressure display as for flow rates < 2 l/min.

KARL STORZ-SCB® support

The device may be supplemented by optional fitting with the KARL STORZ-SCB® auxiliary module (order no. **26** 4320 77) to set up the KARL STORZ-SCB® interface. The functionality of this interface is described in a separate instruction manual.

7.3.2. Software version S012001O

7.3.2.1. Note to software version S012001O

ⓘ ***Note:*** *This software version includes all the changes and improvements of the software versions before.*

The software version S012001O concerns the following items:

ⓘ ***Note:*** *This software version is included ex factory as from serial no. 1930.*

Introduction of two different gas supply modes

The THERMOFLATOR® is frequently used on a central gas supply with pressures below 7 bar. This used to trigger a device warning because the pressure measuring system of the device interpreted it as an "empty" high-pressure bottle.
With this software version the THERMOFLATOR® now distinguishes between two different supply modes:

– high pressure and
– low pressure

Within service program P1 the desired mode can be selected. The programmed mode is saved even when the device is switched off. THERMOFLATOR® is shipped in the high pressure supply mode as the default.

High pressure mode

In this mode the device acts like it used to. When connected to an empty supply bottle or a central low pressure supply the leftmost red LED of the supply pressure bargraph ② blinks. When the insufflation is started a warning sounds.
When the device is connected to the KARL STORZ-SCB® system there is a permanent warning message on the PC or video monitor. Despite these warnings the device is fully functional when connected to a central low pressure supply.

Low pressure mode

In this mode the rightmost green LED of the supply pressure bargraph ② is always lit. There is no "bottle empty" warning.

ⓘ ***Note:*** *If the device is programmed for this mode but is connected to a high pressure supply it automatically switches over to the high pressure mode. However, this switchover only applies until the power is switched off. Powering up the device will always recall the supply pressure mode which was programmed.*

Service programs P1, P2

– Selecting the service programs
To select the service programs the “Volume Reset” button ⑮ has to be pushed during power-up. For about one second P1 (Program 1) is displayed. Then, with Hi SuP (High Supply Pressure) or Lo SuP (Low Supply Pressure) the current mode of gas supply is displayed.

– Changing mode
This mode can be changed with the ± buttons for gas flow ⑱.

– Changing program
Pushing the + button for the pressure ㉑ selects the next service program P2 (LED test program). For about one second P2 (Program 2) is displayed. This is the LED test program which runs in an endless loop. The – button for pressure ㉑ selects the previous program P1.

– Saving mode or leaving service programs
To do this, switch off the device. The user’s inputs will be permanently stored.

Miscellaneous

– Alarm when supply pressure is low
In high-pressure mode, when the supply pressure is less than approx. 5 bar, a warning tone sounds when the insufflation is started or already on. This warning tone is repeated every minute until the supply pressure is increased (replacement of the empty bottle) or the insufflation stopped.

– Set value confirmation
When the user confirms the setpoints a confirmation beep sounds. The beep will be heard whenever a confirmation via a front panel button or the KARL STORZ-SCB® system took place.

7.3.3. Software version S012001P

7.3.3.1. Note to software version S012001P

Note: *This software version includes all the changes and improvements of the software versions before.*

The software version S012001P concerns the following items:

Filling algorithm

In order to maintain a realistic indication of pressure when operating with Veress needle and high set-points, the filling algorithm for the intermittent and semi-continuous operating mode has been changed. From the beginning of ramp-down to the point of measurement, there are now approx. 0.7 seconds until pressure measurement starts. Consequently, even in unfavorable circumstances, the insufflation tube can empty via a small needle opening. The result is a significantly steadier pressure indication when operating with Veress needle.

Alert indicating low supply pressure

The alert given in the high supply pressure mode at a supply pressure of approx. < 5 bar has been changed. Three brief sounds are now given in 0.7 second intervals. This rules out the danger of mixing up this alert and an alert from another device.

Over-pressure alert

The alert given if the specified patient pressure is exceeded by more than 5 mmHg for more than 3 seconds has been changed. A twice-interrupted continuous sound is given. This rules out the danger of mixing up this alert and an alert from another device.

KARL STORZ-SCB® warning indicating faulty temperature sensor

The error bits for the statuses “Gas temperature too high” and “Temperature sensor faulty” are now clearly differentiated. Only one error cause is ever indicated.

Flow regulation in semi-continuous mode

In this mode the average flow at small setpoints was slightly above the tolerance limit. This has been changed.

SECUVENT® blow-off valve

If the SECUVENT® blow-off valve is enabled or disabled via the RUI (press “M” button for longer than 2 seconds), the same acoustic feedback is given as when operating via the front panel button.

7.3.4. Software version S012001Q

7.3.4.1. Note to software version S012001Q

Note: *This software version includes all the changes and improvements of the software versions before.*

The software version S012001Q concerns the following items:

Note: *This software version is included ex factory as from serial no. 2520-B.*

Due to a software version, the sequences of sounds of the acoustic alarm have changed for

– insufficient supply pressure and
– patient overpressure

Insufficient supply pressure (high pressure mode)

If the connected CO_2 gas cylinder is empty, a continuous acoustic warning signal (3 warning sounds in quick succession) is given as soon as insufflation is started.

Note: *This does not apply to low pressure gas supply mode.*

Patient overpressure

As soon as the intra-abdominal pressure exceeds the current setpoint by more than 5 mmHg for longer than 3 seconds, a continuous acoustic warning signal is given (alternating long and short sound) and the gas supply is stopped. After a further 1.5 seconds the overpressure is actively released by a blow-off valve.

7.3.5. Software version C012001R

7.3.5.1. Note to software version C012001R

Note: *This software version includes all the changes and improvements of the software versions before.*

The software version C012001R has been implemented to optimize the device's functions, especially in connection with KARL STORZ-SCB®.
For proper KARL STORZ-SCB® communication the firmware on the KARL STORZ-SCB® hardware module must be updated as well.

Note: *This software version is included ex factory as from serial no. 4165-B.*

CAUTION: *When implementing this software version the OPTITHERM® heating element has to be readjusted, therefore please see Section 5.3.6 Temperature adjustment of the OPTITHERM® heating element.*

7.3.6. Software version C012001S

7.3.6.1. Note to software version C012001S

ⓘ ***Note:*** *This software version includes all the changes and improvements of the software versions before.*

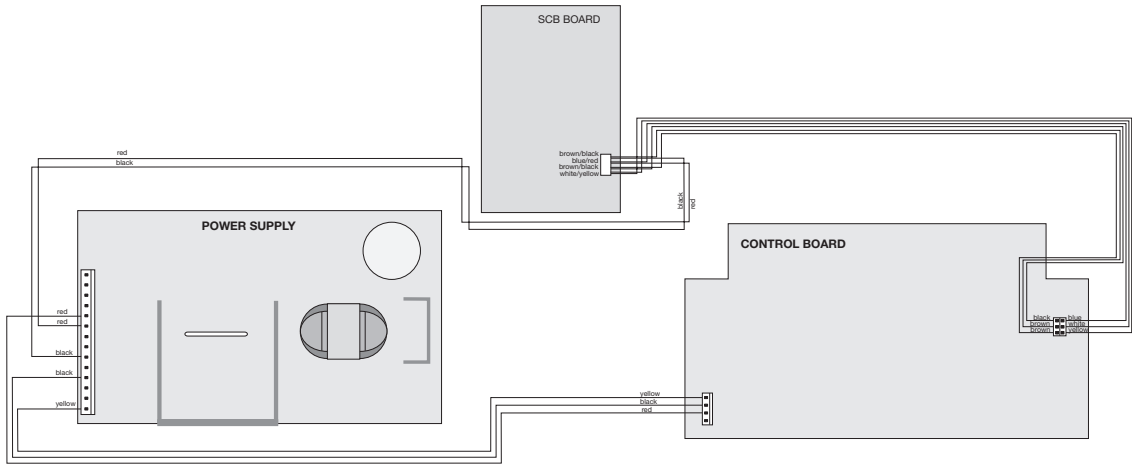
The software version C012001S[4)] has been implemented to optimize the device's functions, especially in connection with the storage of the setpoints.

ⓘ ***Note:*** *This software version is included ex factory as from serial no. 5976-B.*

4) The current control board software version at the time of service manual printing has been "C012001S".

7.4 Replacing the utility lines up to serial number CBxxxxx

To eliminate the in rare cases occurring issue of devices signing off or on to SCB sporadically, devices as from serial number CBxxxx were equipped with new utility lines (Order-Nos A012-507 and A012-605). Devices up to serial number CBxxxx the utility lines can be exchanged.



Section 8.

Appendix

Direction Sign:

1 ⇦ Instruction Manual

2 ⇦ Physical Design

3 ⇦ Descriptions of Operation and Circuit Diagrams

4 ⇦ Replacement of Individual Assemblies

5 ⇦ Testing and Adjustments

6 ⇦ Maintenance and Safety Checks

7 ⇦ Modifications and Supplements

8.1 Test report - Safety Check

Article number			
Serial number			
Visual inspection			
Housing and accessories			
Labeling			
Identification plate data			
Power fuses	T 2 x 2.0 AL / 250 V		
Fuse label			
Bottle holder			
Electrical safety			
Protective ground resistance (with power cord)		≤ 0.30 Ω	
Earth leakage current	N.C.:	≤ 0.50 mA	
	S.F.C.:	≤ 1.00 mA	
Touch current	N.C.:	≤ 0.10 mA	
	S.F.C.:	≤ 0.50 mA	
Patient leakage current	N.C.:	≤ 0.10 mA	
	S.F.C.:	≤ 0.50 mA	
Patient leakage current (line voltage at applied part)	S.F.C.:	≤ 5.00 mA	
Proper operation			
Power switch			
Connection for CO_2 gas supply			
Pressure relief valve			
Setpoint bargraph			
Setpoint digital display			
Buttons			
Service mode	P1		
	P2		
	P3		
	P4		
Bottle pressure	operating mode		
Flow rate	semi-continuous		
	30 l/min (+6 l/min / -3 l/min)		
	intermittent		
	30 l/min (+6 l/min / -3 l/min)		
Pressure, control behaviour	semi-continuous		
	30 mmHg (+3 mmHg / -2 mmHg)		
	15 mmHg (+3 mmHg / -1 mmHg)		
	intermittent		
	30 mmHg (+3 mmHg / -2 mmHg)		
	15 mmHg (+3 mmHg / -1 mmHg)		
Pressure drop	15 mmHg (-20%)		
Software alarm	blow-off valve		
Hardware alarm	> 30 mmHg (+3 mmHg)		
Negative alarm			
Dangerous increase pressure	5 mmHg per 0.2 s		
Date			
Checked by			
Signature			

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