

Technical Documentation

Oxylog 3000

Emergency and transport ventilator



Revision 4.0
5503.403
9036041

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General

1 Symbols and Definitions

WARNING

A **WARNING** statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

A **CAUTION** statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the equipment or other property.

NOTE

A **NOTE** provides additional information intended to avoid inconvenience during operation.

Definitions according to German standard DIN 31051:

Inspection	= examination of actual condition
Maintenance	= measures to maintain specified condition
Repair	= measures to restore specified condition
Servicing	= inspection, maintenance, and repair

2 Notes

This Technical Documentation conforms to the IEC 60601-1 standard.

Read each step in every procedure thoroughly before beginning any test. Always use the proper tools and specified test equipment. If you deviate from the instructions and/or recommendations in this Technical Documentation, the equipment may operate improperly or unsafely, or the equipment could be damaged.

It is our recommendation to use only Dräger parts and supplies.

The maintenance procedures described in this Technical Documentation may be performed by qualified service personnel only. These maintenance procedures do not replace inspections and servicing by the manufacturer.

The information in this Technical Documentation is confidential and may not be disclosed to third parties without the prior written consent of the manufacturer.

This Technical Documentation is for the purpose of information only. Product descriptions found in this Technical Documentation are in no way a substitute for reading and studying the Instructions for Use/Operating Manual enclosed with the product at the time of delivery.

Know-how contained in this Technical Documentation is subject to ongoing change through research and development and Dräger Medical reserves the right to make changes to this Technical Documentation without notice.

NOTE

Unless otherwise stated, reference is made to laws, regulations or standards (as amended) applicable in the Federal Republic of Germany for equipment used or serviced in Germany. Users or technicians in all other countries must verify compliance with local laws or applicable international standards.

Function Description

- | | | |
|------------|-------------------------------|--|
| 1 | General introduction | Oxylog 3000 is an emergency and transport ventilator for short-time treatment of lung damage of a wide variety of kinds. It provides timed and volume-controlled ventilation, as well as assisting the patient's breathing in pressure-controlled mode. |
| 1.1 | Monitoring | <ul style="list-style-type: none"> – Airway pressure P_{aw} – Expiratory minute volume MV – Apnoea |
| 1.2 | Area of application | <ul style="list-style-type: none"> – Mobile use in emergency medicine or primary care of emergency patients. – In transit in emergency vehicles or helicopters. – During transfers by road and air. – In the emergency room. – During secondary transfers from hospital to hospital. |
| 2 | Principle of operation | <p>Oxylog 3000 primarily comprises the pneumatic components with the connection and metering block and the control and display electronics (Figure 1).</p> <p>The connection block supplies a constant pressure to the metering block, contains the safety functions such as the emergency air and safety valves, control the pressure (PEEP) during expiration and, together with the ventilation accessories, provides the interface to the patient.</p> <p>The metering block passes defined volumes of gas between 40% and 100% oxygen to the connection block.</p> <p>The control and display electronics evaluate the measurement signals, control the valves and provide the interface to the operator.</p> |

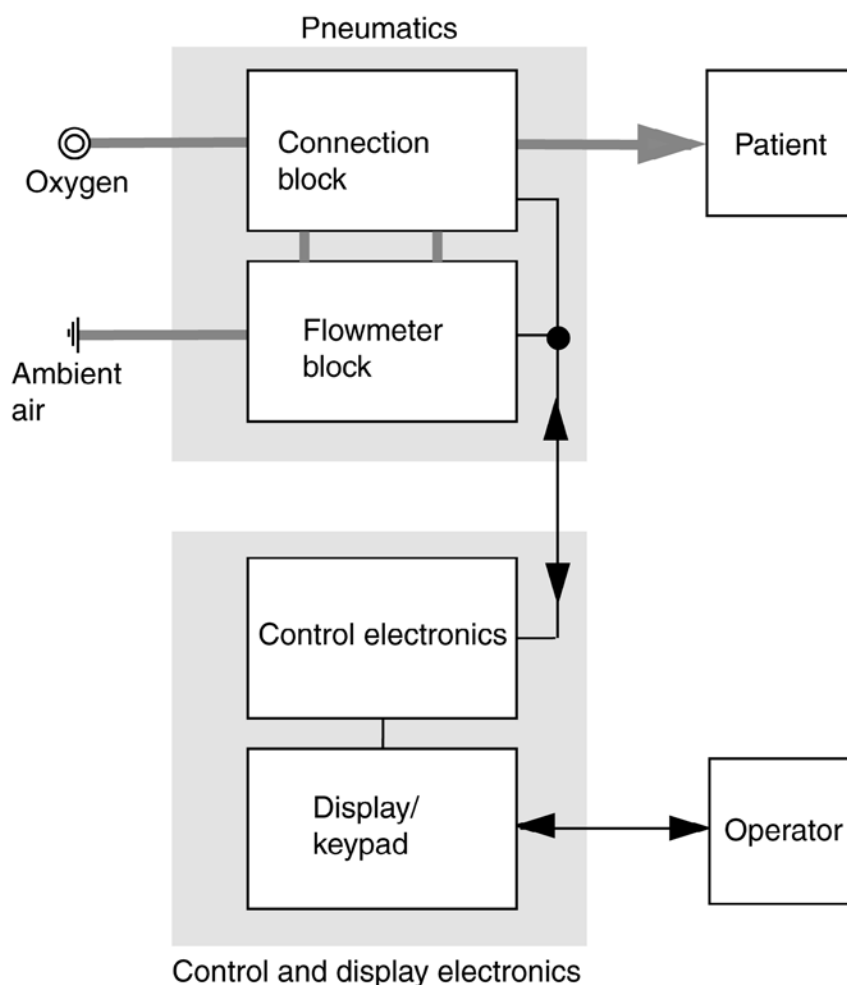


Figure 1 Principle of operation

3 Pneumatic system

The following description relates to the [pneumatic components diagram](#) Oxylog 3000. The evaluation of the measurement signals from the sensors and operation of the valves is handled on the control PCB.

3.1 Inlet

The compressed oxygen passed through the filter F1 and the pressure regulator DR to the valves V1 to V3. The pressure regulator regulates the pressure to 3 bar. This is done to attain a stable flow control. The control PCB monitors this pressure, which is measured with sensor S3.

3.2 Metering

Valves V1 to V3 are proportional valves, each delivering a flow proportional to the overall flow of 0 to 35 L/min. The flow sensor S1 measures the delivered flow and the control PCB corrects the valve operation as necessary.

Valve V3 comprises two parallel configured valves, to produce a total flow greater than 100 L/min.

With the valve V1 and the ejector E1 ambient air can additionally be drawn in. Valve V1 meters a flow through the ejector. The resultant negative pressure draws ambient air through the filter F2, the flow sensor S2 and the non-return valve V9.

Valve V2 adds oxygen to the ambient air depending on the pre-set O2 concentration. The flow sensor S2 measures the intake air flow and the control PCB corrects valves V1 and V2 accordingly.

The proportion of ambient air may be a maximum of 75%. The minimum oxygen concentration may thus be 40%.

At flows less than 9 L/min the volume of intake air is so low that an oxygen concentration of 40% is no longer guaranteed. At flows greater than 35 L/min oxygen is added accordingly. An oxygen concentration of 40% is no longer guaranteed.

In a flow range from 9 to 35 L/min an oxygen concentration of 40% to 100% can be set. The non-return valve V9 prevents oxygen escaping into the ambient air. L1 prevents swirling, and ensures a uniform oxygen concentration.

3.3 Sensors and safety functions

The flow sensor S1 measures the inspiratory flow inside the unit and the control PCB corrects the operation of valves V1 to V3 as necessary based on the measured value.

The safety valve SV opens at a pressure greater than 80 mbar, to prevent the patient from being exposed to high pressure in the event of unit malfunctions.

The emergency breathing valve NV allows the patient to breathe spontaneously in case the unit fails.

The pressure sensor S4 measures the internal patient pressure inside the unit and the PEEP pressure at the ventilation valve V10.

The pressure sensor S6 measures the differential pressure above the flow sensor S8 located close to the patient ([Figure 2](#)). From it, the control PCB calculates the flow.

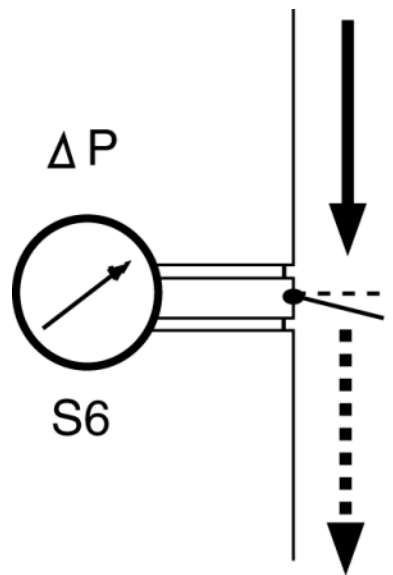


Figure 2 Block diagram of external flow sensor

The pressure sensor S5 measures the pressure at the patient. Based on this pressure value, the control PCB makes calculations including for actuation of the PEEP valve V6.

Valves V7 and V8 switch the connections of S6, S5 against atmosphere at cyclic intervals. The control PCB calibrates the sensors and any offset drift is prevented.

3.4 PEEP valve

The PEEP valve V6 controls the PEEP setting of the ventilation valve V10.

The control PCB actuates a coil which delivers a pressure to a diaphragm. The internal tubing system vents to this pre-set PEEP pressure during expiration.

This PEEP pressure also acts on a valve diaphragm in the ventilation valve V10 (Figure 3/1). On expiration the pre-set PEEP pressure is established at the patient.

During expiration an internal flow of 0.5 L/min flows through the PEEP valve V6 to hold the diaphragm of the PEEP valve still and ensure uniform opening of the PEEP valve.

During inspiration the PEEP valve V6 closes at 100 mbar.

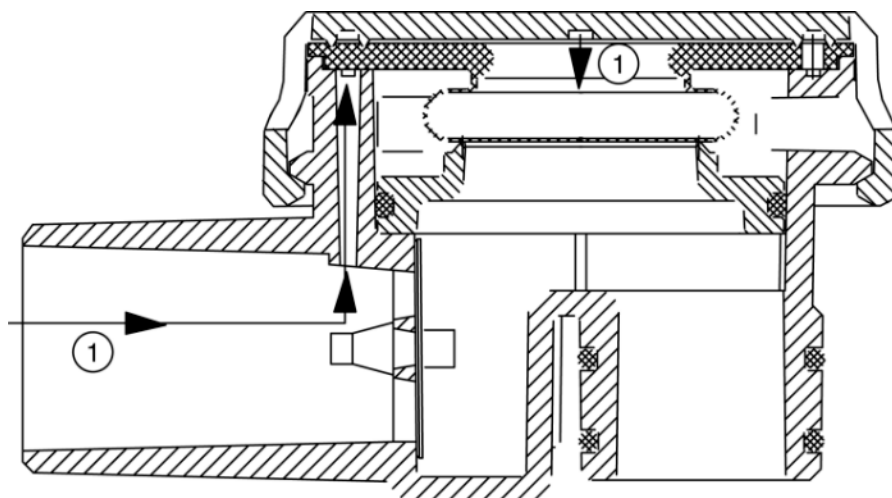


Figure 3 Ventilation valve

3.5 Ambient pressure conditions

Oxylog 3000 meters the tidal volume under BTPS conditions. Sensors S7 and S9 measure the ambient pressure. S5 measures the current pressure level in the lung. In this way the control PCB can balance fluctuating ambient pressure and the BTPS conditions (Body Temperature, Pressure, Saturated. Measurements referred to conditions of the patient's lung, body temperature 37 °C, ambient pressure, water vapour saturated gas).

4 Electronics

The following description relates to the [electronics](#) and represents only the principle of operation. The connections of the individual modules are only indicated indirectly, and are made by cable harnesses, connectors and the conductors on the individual PCBs.

4.1 Charging circuit PCB

The charging circuit PCB controls charging of the internal replaceable battery and selection of the voltage supply (mains, on-board system or internal battery).

The charging circuit PCB accommodates the input for the external voltage supply. The input is isolated from the remaining electronics by a protective circuit.

The charging circuit PCB directly activates the power indicator LEDs. The LEDs are located on the front membrane cover.

The charging circuit PCB has its own processor system, and thus its own software. This software is also located on the control PCB, and is loaded from there onto the charging circuit PCB.

The internal replaceable battery has various dummy resistors, depending on the type used. The charging circuit PCB detects on the basis of the resistor which type is fitted (nickel metal hydride or lithium ion).

The temperature and charge capacity of the internal replaceable battery is determined by the battery itself. These data are transmitted from the charging circuit PCB to the control PCB.

4.2 Sensor PCB

The sensor PCB holds all the pressure sensors of the pneumatic system and the internal temperature gauge. The sensor PCB is the interface for pressure measurement and valve actuation between the pneumatic and electronic systems.

4.3 Front membrane

On the front membrane cover are the keys, the LEDs and the turn knob. Together with the monitor, the turn knob and the potentiometers, the front membrane is the interface between the unit and the operator. The monitor is an EL (Electro Luminescent) display.

4.4 Control PCB

The control PCB holds the electronic On/Off circuit, the generator for the individual internal operating voltages and the microprocessor system to control and monitor ventilation.

The electronic On/Off circuit is operated directly by the unit's On/Off button.

In case of a power failure while the unit is on, an alarm generator delivers an acoustic signal. A Goldcap capacitor delivers the voltage for the signal.

The voltage generator generates the various operating voltages from the supply voltage, such as the +5 Volts for the microprocessor.

The microprocessor system comprises the microcontroller, an EEPROM, a Flash-EPROM, a RAM and a real-time clock (RTC).

The EEPROM holds the calibration data, software options, ID number, unit and service operating hours and the start-up conditions. The Flash-EPROM holds the medical device software and the software for the charging circuit PCB. The real-time clock generates the time and date. The real-time clock's RAM also holds the logs.

The microprocessor system evaluates the measurement signals from the sensors, the settings of the potentiometers and the turn knob and operates the valves and the display accordingly.

On a change of software the unit no longer needs to be opened. The infrared interface transfers the data from the PC/laptop to the microcontroller and vice versa.

Maintenance Procedures

1 Replacing the filter element

1. Switch off the unit.
2. Remove screws [Figure 1](#).

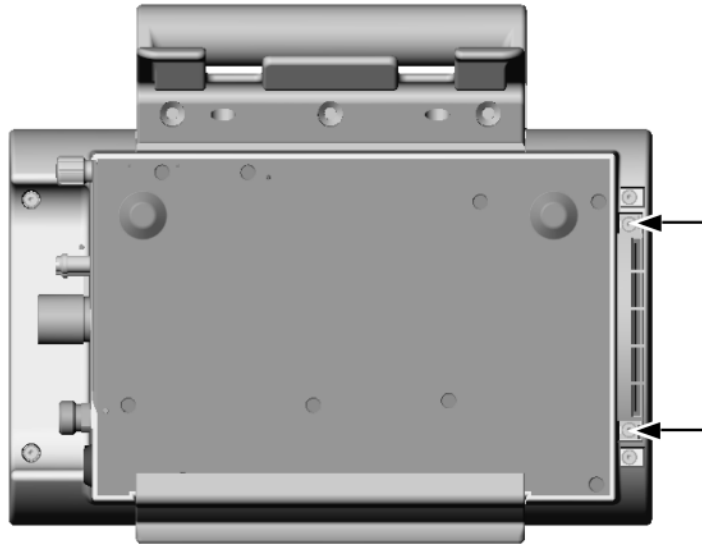


Figure 1 Removing the filter element

NOTE

Note fitting position of filter element.

3. Remove the filter element.
4. Install the new filter element.
5. Carry out a unit test.
6. Place fully functional unit at the user's/owner's disposal.

2 Replacing the internal battery

1. Slacken the screw [Figure 2/1](#) of the battery compartment cover anti-clockwise until the cover can be opened.
2. Fold the cover [Figure 2/2](#) down.
3. Pull the internal battery [Figure 2/3](#) forward by its tab and withdraw it.

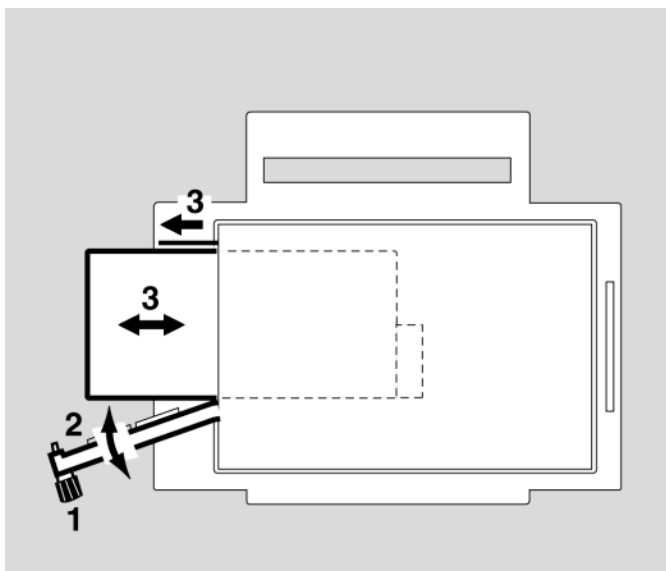


Figure 2 Removing the internal battery

4. Press the button on the new internal battery and check the charge.

The LEDs on the internal battery indicate the charge condition in percent.

5. Charge the internal battery as necessary.

NOTE

The internal battery can be charged by the battery charger station or by the external power supply in the Oxylog 3000.

6. Fit the internal battery.
7. Switch on the Oxylog 3000 and check the battery capacity indicated on the display.

Schematics and Diagrams

1 General introduction

This section presents the diagrams and overviews of the Oxylog 3000, such as the pneumatic components diagram and the block diagram of the electronics. In some cases the diagrams and overviews are also used as references to describe functions.

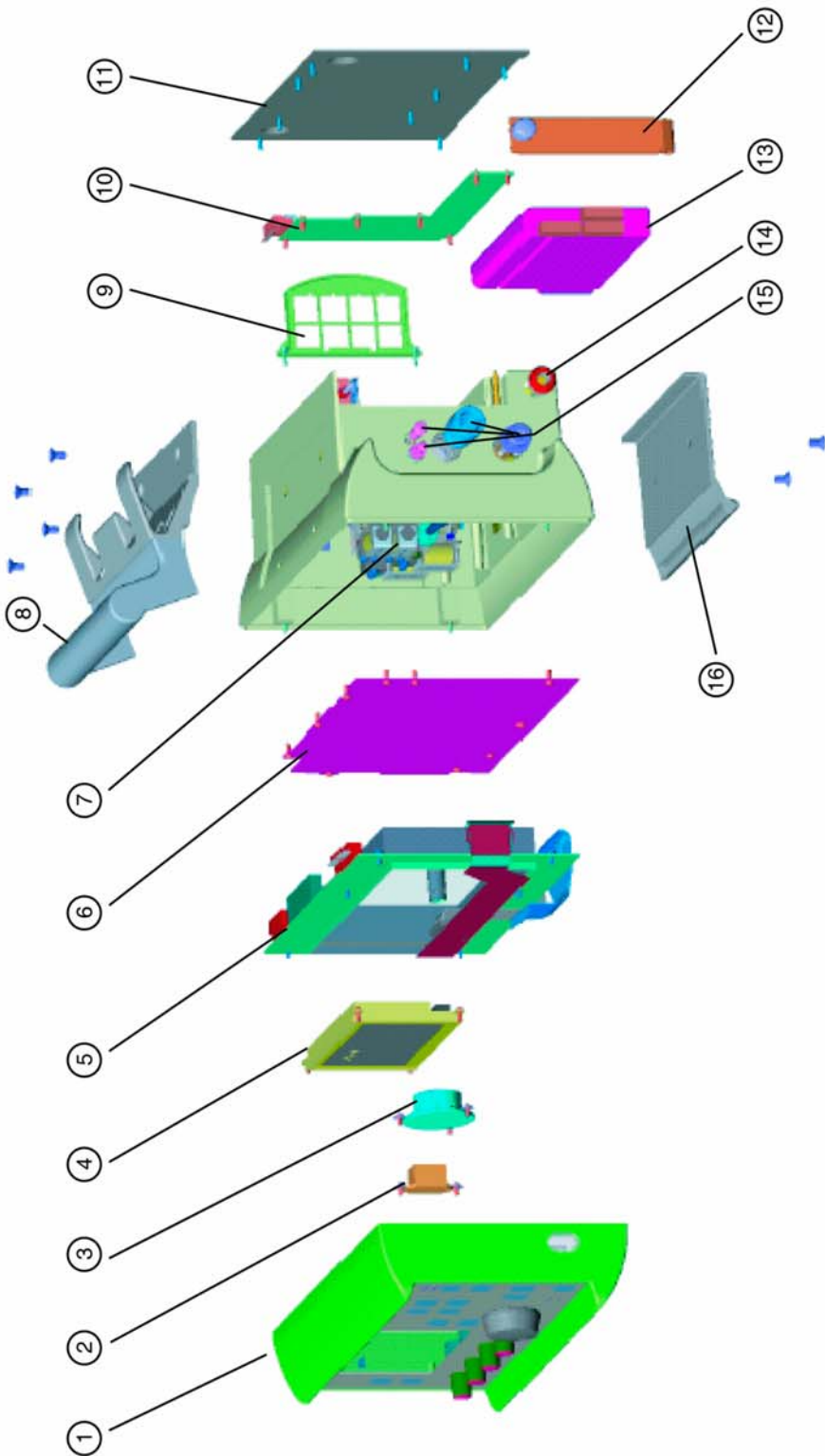


Figure 1 General overview, for legend see [Table 1](#)

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Table 1 Legend [Figure 1](#)

Item	Designation
1	Front section with potentiometer, rotary encoder, membrane keypad and label inserts
2	Signal generator
3	Loudspeaker
4	Display
5	Control PCB (see also Figure 6)
6	Cover panel for pneumatic components
7	Pneumatic components and sensor PCB (see also Figure 3)
8	Handle
9	Filter element to filter the ambient air intake
10	Charging circuit PCB
11	Rear panel
12	Battery compartment cover
13	Replaceable battery
14	DC voltage socket
15	Sockets for flowmeter tubes, ventilation tube and compressed gas tube
16	Base plate

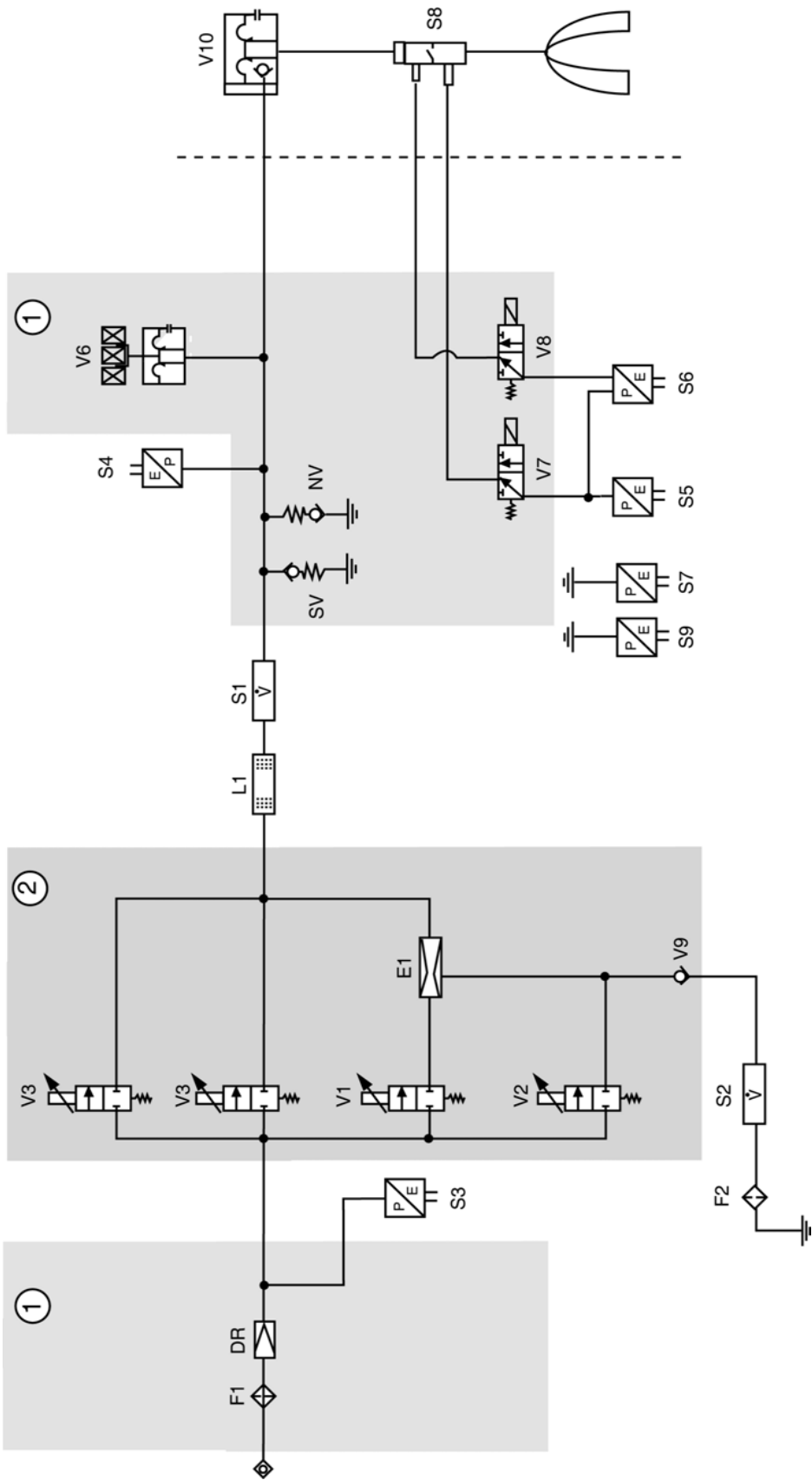


Figure 2 Pneumatic components diagram, for legend see Table 2

Table 2 **Legend Figure 2 and Figure 3**

Item	Designation
1	Connection block
2	Metering block
DR	Pressure regulator
E1	Ejector
F1	Filter in O2 compressed gas connection
F2	Filter for intake air
L1	L1 ensures uniform flow
NV	Emergency air valve
S1	Flow sensor to measure internal inspiratory flow
S2	Flow sensor to measure the ambient air intake
S3	Pressure sensor (Pv) to measure supply pressure for valves V1 to V3
S4	Pressure sensor (Pint) to measure unit-internal patient pressure
S5	Pressure sensor (Paw) to measure pressure close to patient
S6	Pressure sensor (delta P) to measure differential pressure at external flow sensor
S7 and S9	Pressure sensors to measure ambient pressure
S8	External flow sensor
SV	Safety valve
V1 to V3	Metering valves
V10	Ventilation valve
V6	PEEP valve
V7 and V8	Switching valves to calibrate pressure sensors S5 and S6
V9	Non-return valve

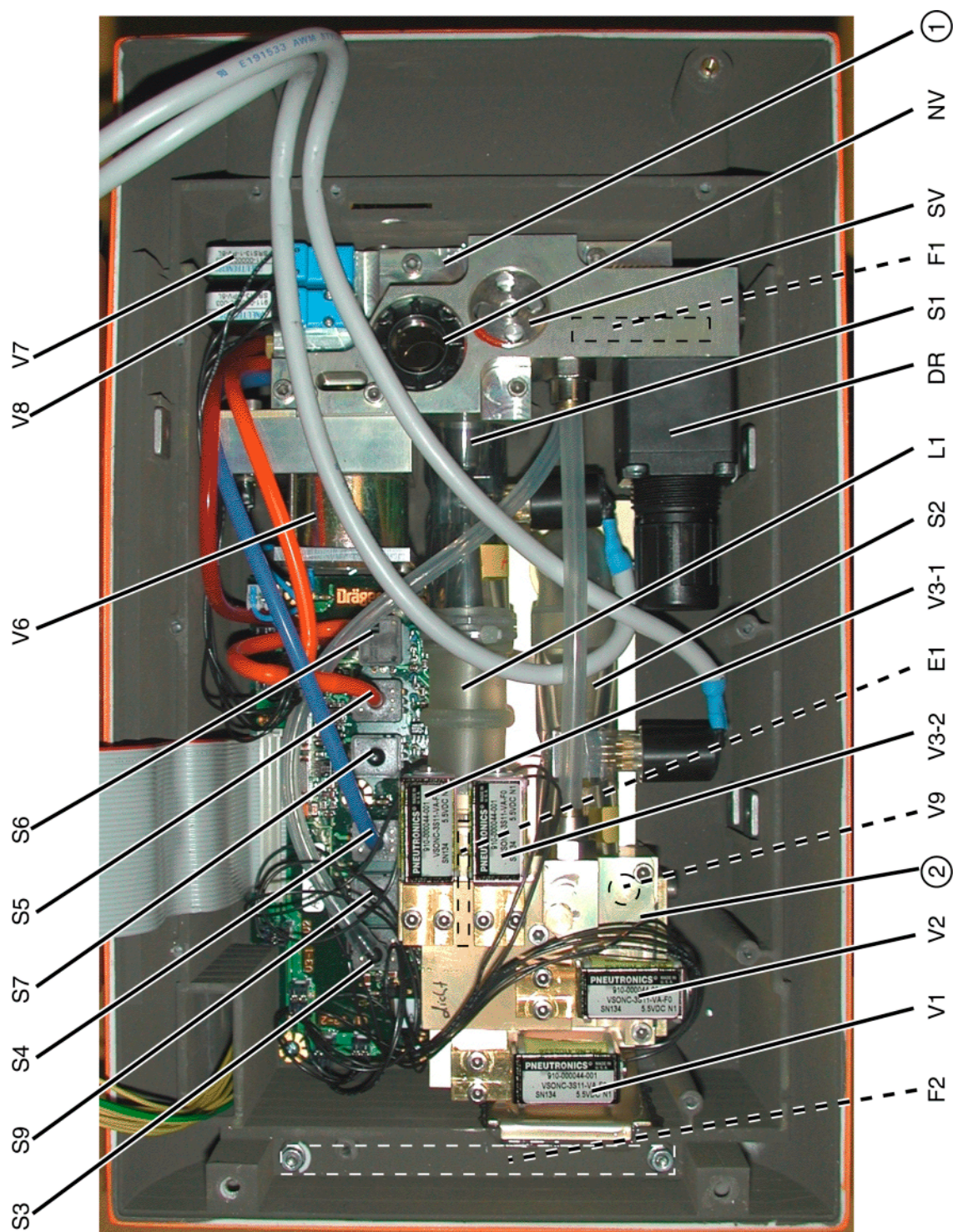


Figure 3 Overview of pneumatic components, for legend see Table 2

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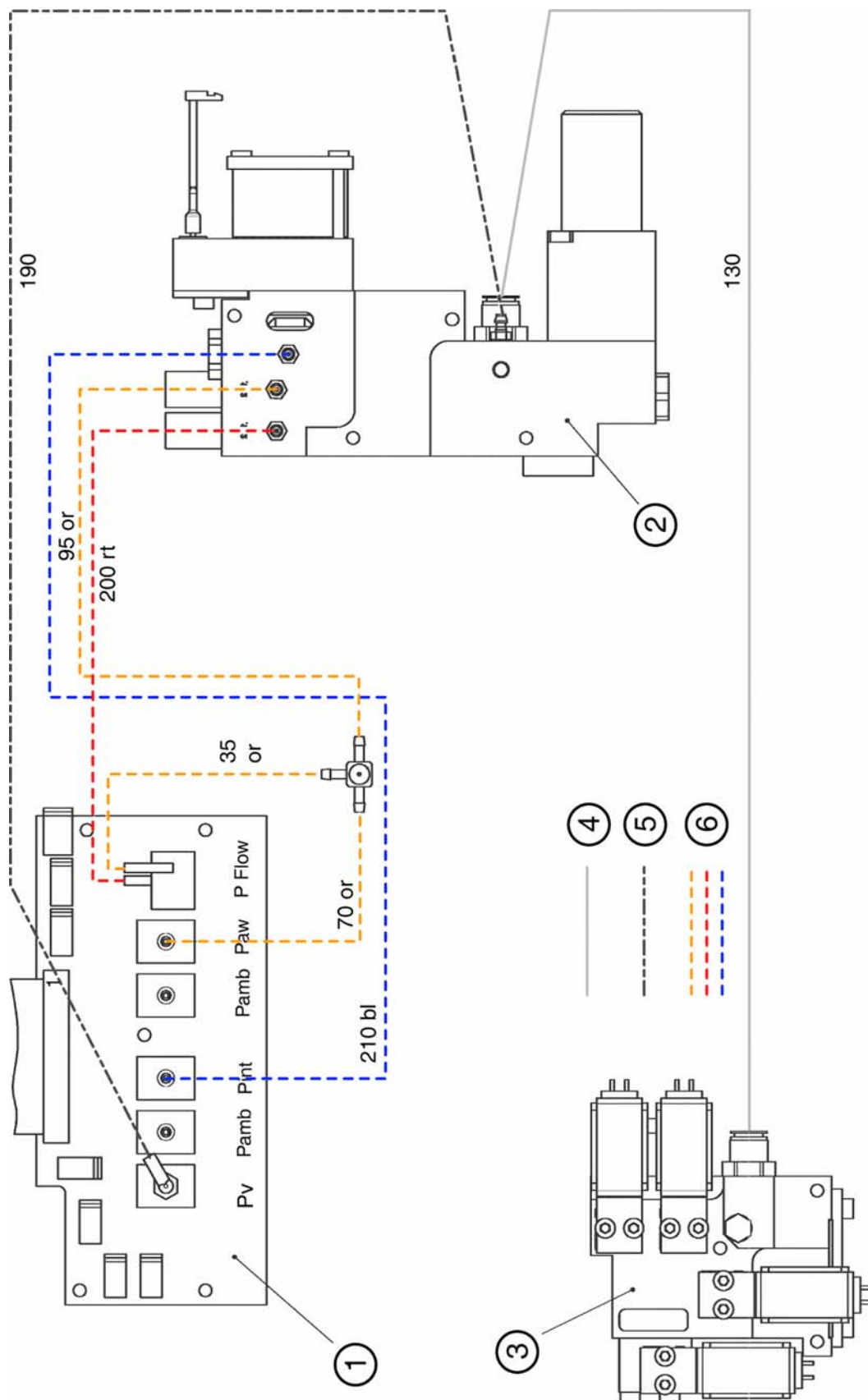


Figure 4 Tubing diagram, for legend see [Table 3](#)

Table 3 Legend Figure 4

Item	Designation
1	Sensor PCB
2	Connection block
3	Metering block
4	Tube 4x1 PAE not coloured (nc)
5	Tube 2x1.5 Si not coloured (nc)
6	Tube 2x1 Si blue (bl), red (rd), orange (or)

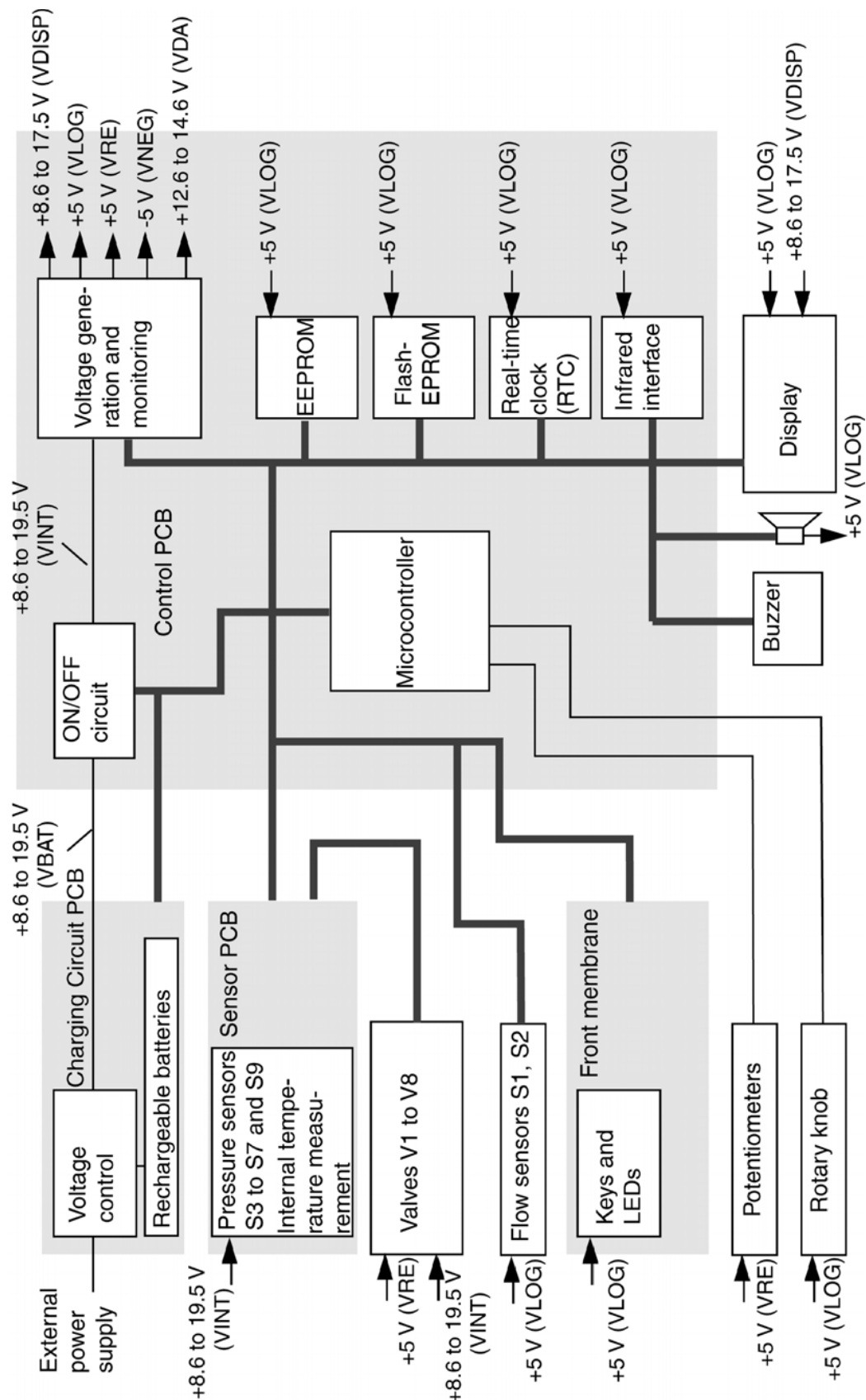


Figure 5 Electronics block diagram

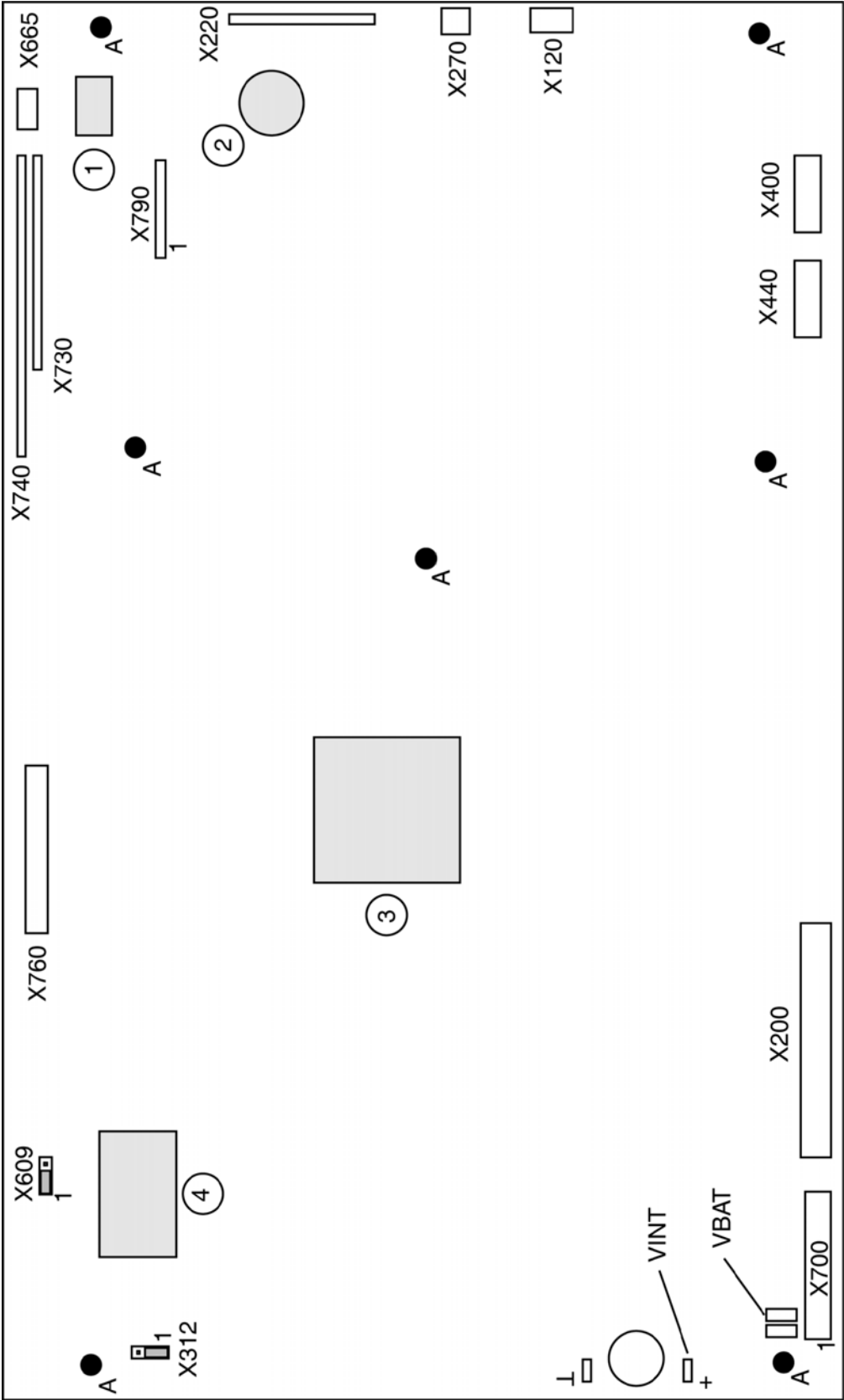


Figure 6 View of control PCB, for legend see Table 4

Table 4 Legend Figure 6

Item	Designation
1	EEPROM
2	Goldcap capacitor
3	Microcontroller
4	Real-time clock with battery
A	Control PCB fixing screws
X120	Connection to signal generator
X200	Connection to sensor PCB
X220	Connection to potentiometers
X270	Connection to loudspeaker
X312	Jumper to trigger a reset
X400	Connection to flow sensor S1
X440	Connection to flow sensor S2
X609	Jumper to perform the bootstrap download
X665	Connection to rotary encoder
X700	Connection to charging circuit PCB
X730	Connection to front membrane (keys)
X740	Connection to front membrane (LEDs)
X760	Connection to display
X790	Pin strip for bootstrap download

Annex

Parts catalog

Test List

Technical Information

Parts catalog

Oxylog 3000

Revision: 2006-02

5503.403



Item No.	Part No.	Description	Qty.	Qty. unit	Remark
	2M86955	Oxylog 3000	1.000	St	
	2M86300	Oxylog 3000	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



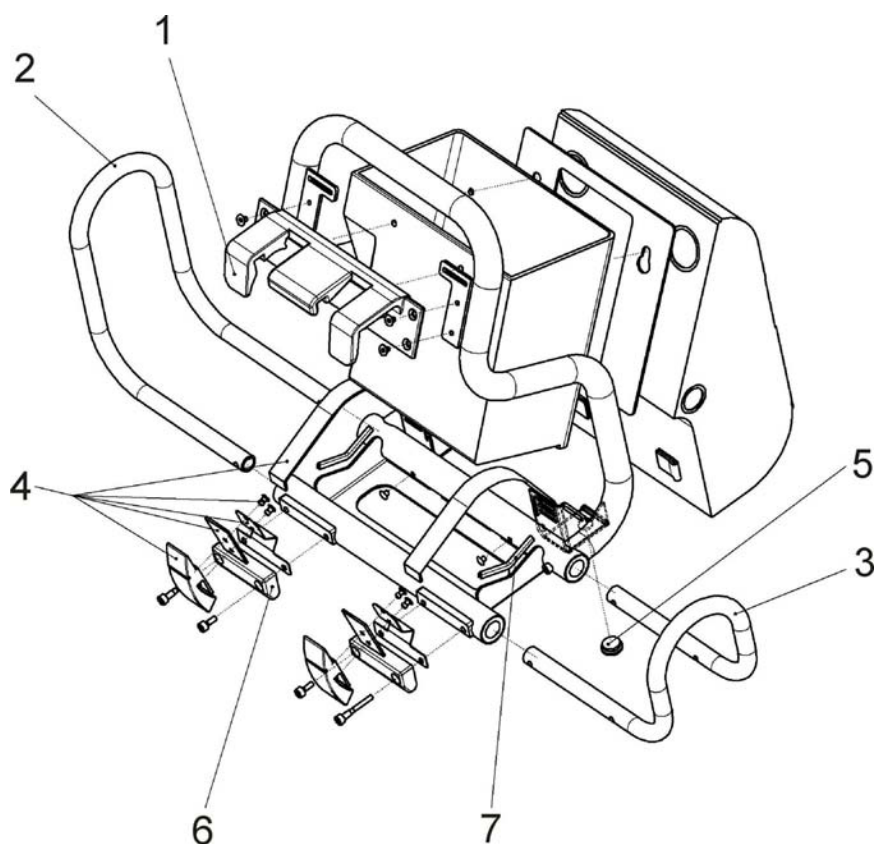
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
	5703300	Caddy	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



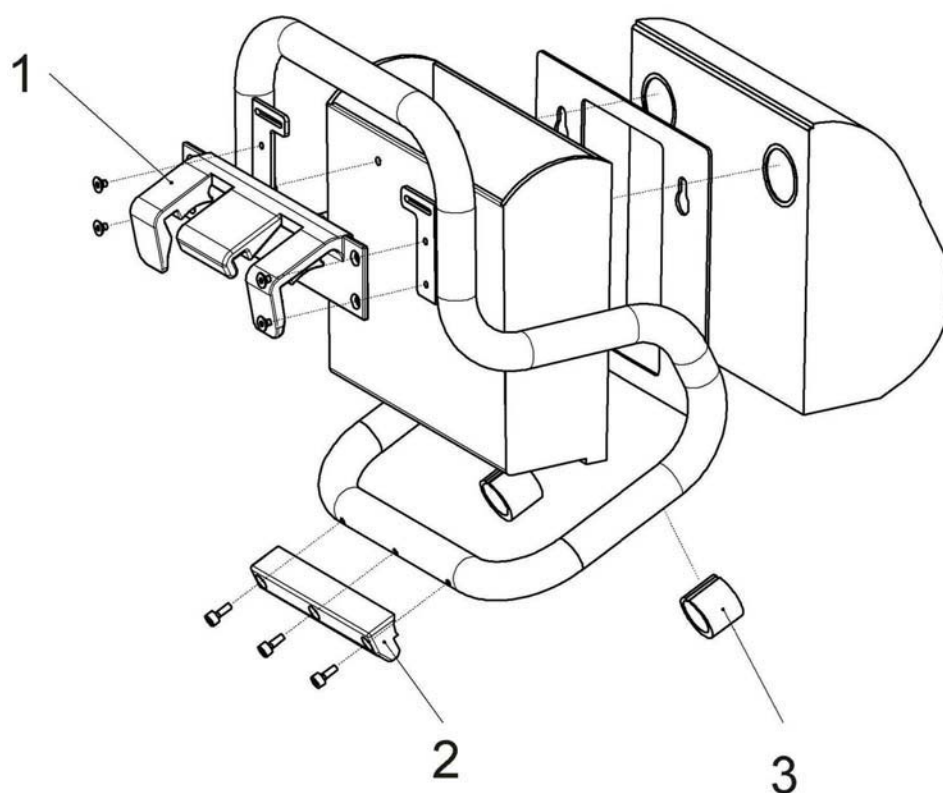
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1	5703303	BAG OXYLOG 1000 FOR CADDY	1.000	St	
2	5703304	BAG OXYLOG 2000 FOR CADDY	1.000	St	
3	5703305	Bag for CompactCaddy	1.000	St	
4	5703306	PROTECTION COVER	1.000	St	
5	5703307	Carrying Belt	1.000	St	
6	5704216	All-round Wall Holder	1.000	St	
7	5704218	Wall Holder Adaptation Plate	1.000	St	
8	5704217	Quick Power Connector	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



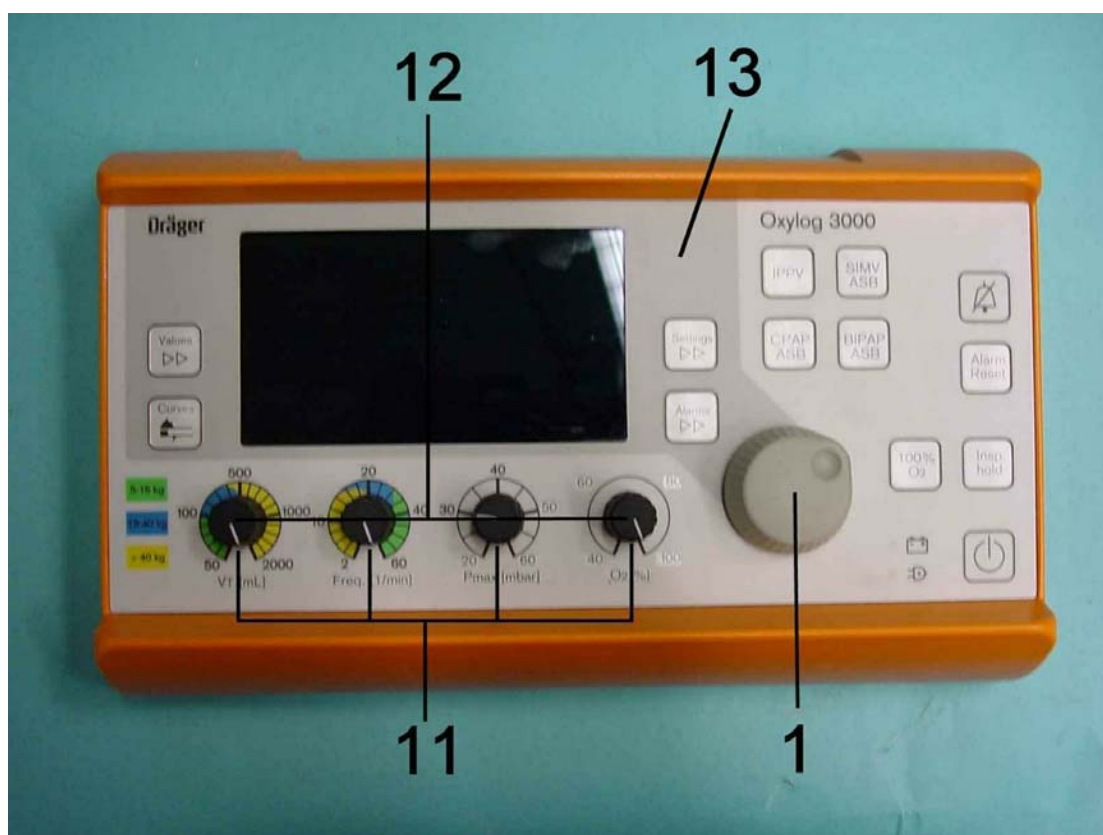
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1	5703310	CLAW_FOR_CADDY	1.000	St	
2	5703329	PROTECTION BAR HIGH FOR CADDY	1.000	St	
3	5703328	PROTECTION BAR LOW FOR CADDY	1.000	St	
4	5703341	CYLINDER FIXATION SET	1.000	St	
5	5703336	PROTECTION FOOT CADDY	1.000	St	
6	5703340	GUIDING RAIL SET FOR CADDY	1.000	St	
7	5703367	PROTECTION STRIP CADDY	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



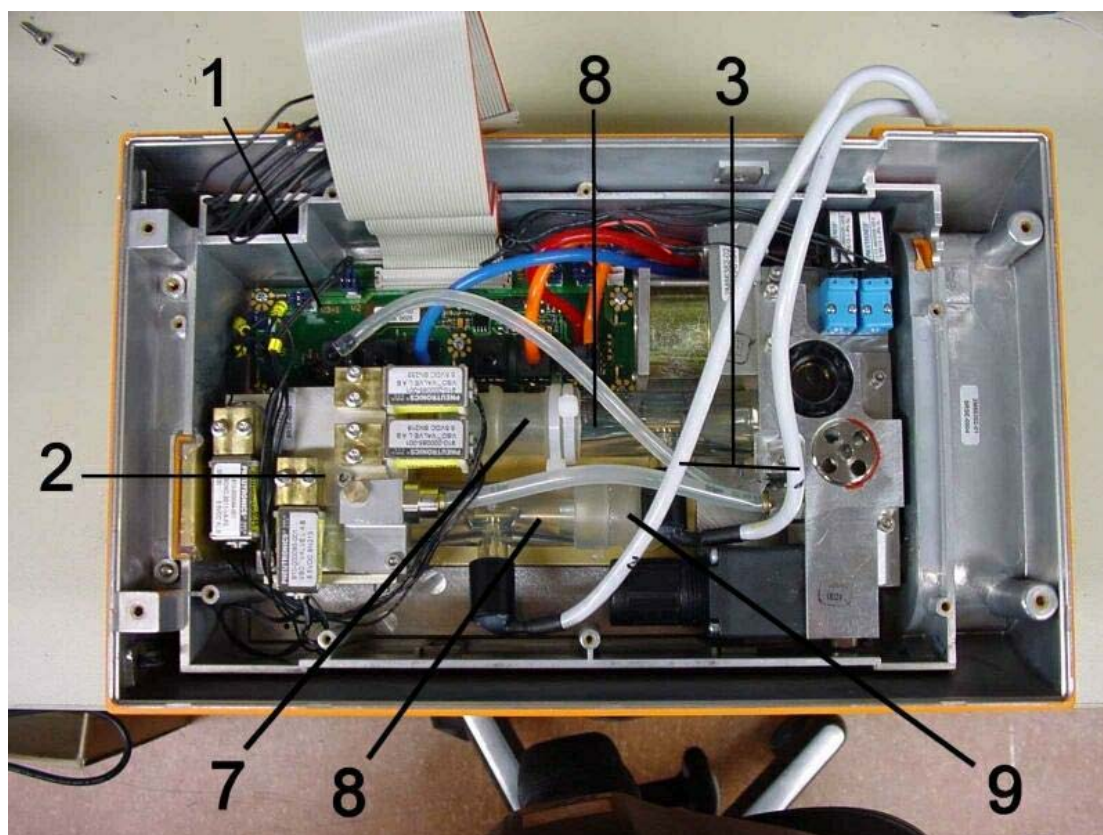
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1	5703310	CLAW_FOR_CADDY	1.000	St	
2	5703333	GUIDING RAIL FOR COMPACTCADDY	1.000	St	
3	5703335	PROTECTION FOOT Compact CADDY	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



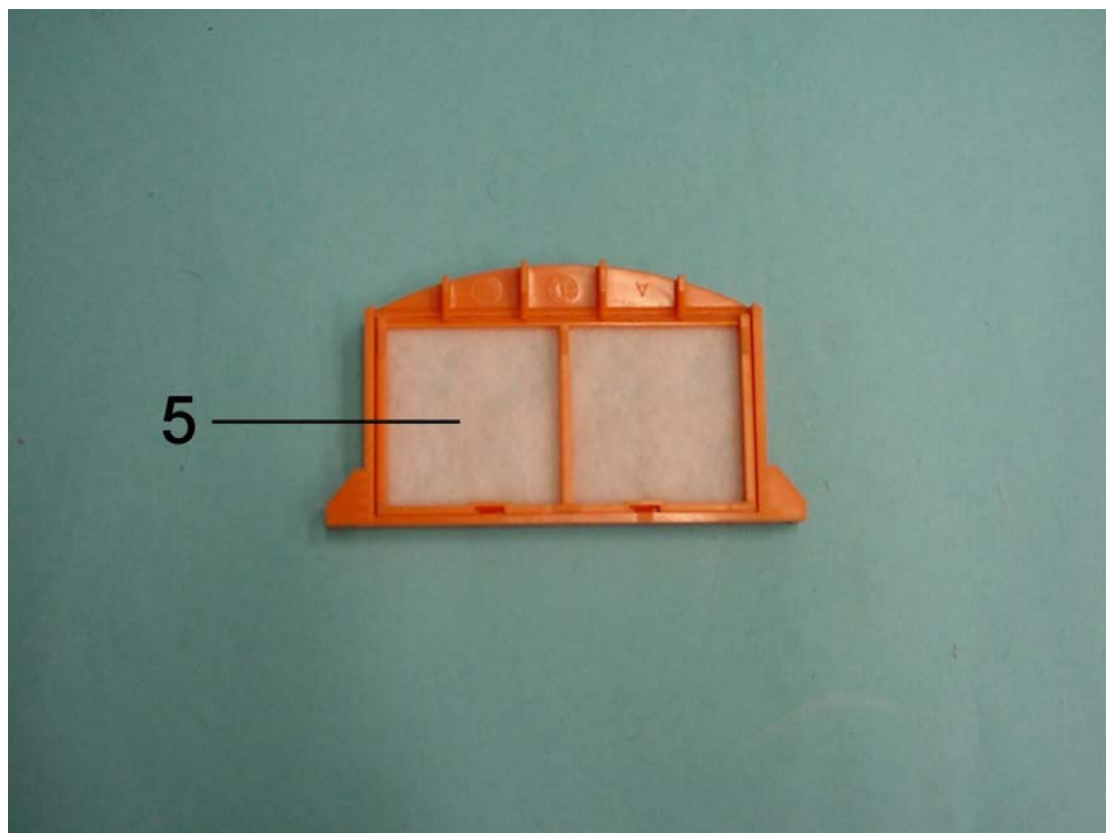
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1	M29655	CONTROL KNOB	1.000	St	
1	1830015	COVER	1.000	St	
12	2M86697	Cover	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



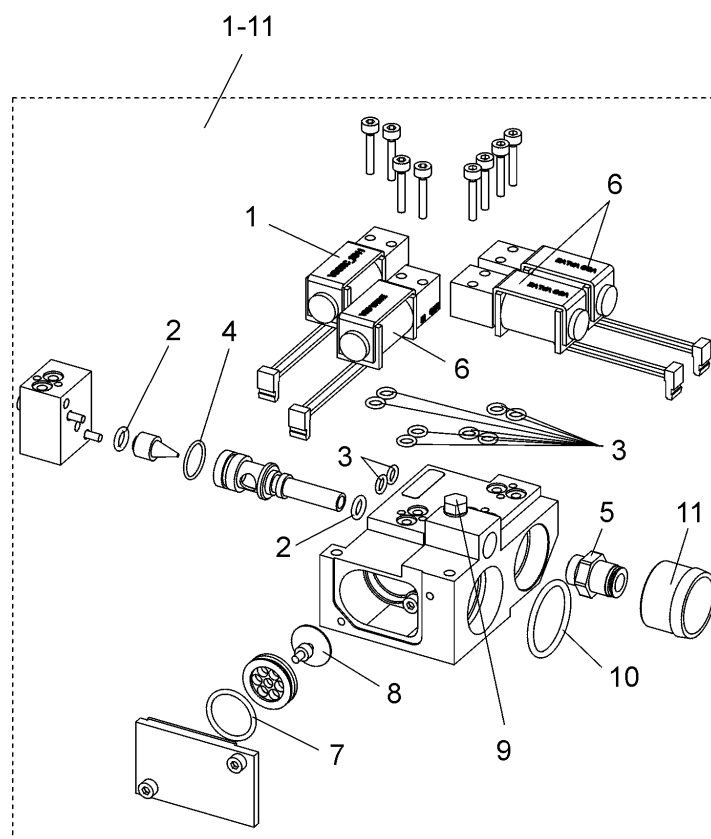
Item No.	Part No.	Description	Qty.	Qty. unit	Remark
8	8403735	Set of 5 Spirolog sensors	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



Item No.	Part No.	Description	Qty.	Qty. unit	Remark
5	2M86341	Filter Mat	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



Item No.	Part No.	Description	Qty.	Qty. unit	Remark
1-11	ME05170	Spare part dosage block	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts



Item No.	Part No.	Description	Qty.	Qty. unit	Remark
	2M86737	Carrying System	1.000	St	
	2M86631	Alduk I O2-DM G3/4	1.000	St	
	2M86632	Alduk II O2-DM G3/4	1.000	St	
	2M86678	Alduk II O2-DM Pin Index	1.000	St	
	B10205	O2 Bottle 2L-200bar-G3/4-GFK	1.000	St	
	B10208	O2 Bottle 2L-200bar-PIN-GFK	1.000	St	
	2M86734	Automatic Oxygen Selector	1.000	St	
	8412716	O2-Connector Tube 0,5m	1.000	St	
	8602728	Adapter O2 DIN/DIN-coupling	1.000	St	
	2M86940	Wall Holder	1.000	St	
	M36005	O2 ZV-Sch. 3m NIST Neutral DIN	1.000	St	
	M36004	O2 ZV-Sch. 1,5m NIST Neutra DIN	1.000	St	

Items that are shown in the illustration but are not listed below the illustration are not available as spare parts

Description	Part No.	Description	Part No.
90° angled connector	8412235	O2-AIR-CONNECT.HOSE 1,5(BLACK)	M29285
AC/DC power pack	2M86730	O2-Connector Tube 0,5m	8412716
Adapter O2 DIN/DIN-coupling	8602728	O2/AIR-HOSE NIST 1,5MDIN PROBE	M34410
Alduk I O2-DM G3/4	2M86631	O2/AIR-HOSE NIST 3M DIN PROBE	M34411
Alduk I O2-DM G3/4	2M86631	O2/AIR-HOSE NIST 5M DIN PROBE	M34412
Alduk I O2-DM Pin Index	2M86677	Option 100% O2	ME05053
Alduk II O2-DM G3/4	2M86632	Option ASB/PS	ME05055
Alduk II O2-DM G3/4	2M86632	Option BIPAP/PCV+	ME05056
Alduk II O2-DM Pin Index	2M86678	Option O2-Blender	ME05054
Alduk II O2-DM Pin Index	2M86678	Option O2-Inhalation	ME05052
All-round Wall Holder	5704216	Oxylog 3000	2M86300
Automatic Oxygen Selector	2M86734	Oxylog 3000	2M86955
Bag for CompactCaddy	5703305	Power cable 10A, 3m, grey, USA/J	1841793
BAG OXYLOG 1000 FOR CADDY	5703303	Power cable Australia 3m,10A,C13L	1844350
BAG OXYLOG 2000 FOR CADDY	5703304	Power cable DK, 3 m, 10 A	1844342
Breathing valve Oxylog 2000	8412001	Power cable Great Britian 3m black	1844369
Caddy	5703300	POWERCORD CH 3M	1844377
Carrying Belt	5703307	PROTECTION BAR HIGH FOR CADDY	5703329
Carrying System	2M86737	PROTECTION BAR LOW FOR CADDY	5703328
CLAW_FOR_CADDY	5703310	PROTECTION COVER	5703306
CLAW_FOR_CADDY	5703310	PROTECTION FOOT CADDY	5703336
CONTROL KNOB	M29655	PROTECTION FOOT Compact CADDY	5703335
CORRUGATED HOSE	8402041	PROTECTION STRIP CADDY	5703367
COVER	1830015	Quick Power Connector	5704217
Cover	2M86697	Resp.hose w.flow meas.cable	8412068
CYLINDER FIXATION SET	5703341	Respiration hose 3 m	8412913
DC/DC Converter	2M86731	SET 12 STAND. CONE A PLASTIC	8403685
Equipment Holder	2M86900	Set of 5 Spirolog sensors	8403735
External charge station	2M86729	SOCKET	M20101
Filter Mat	2M86341	Spare part dosage block	ME05170
Flowsensor	8412034	SUPPLY MAIN, 3M	1824481
GUIDING RAIL FOR COMPACTCADDY	5703333	TEST LUNG	8403201
GUIDING RAIL SET FOR CADDY	5703340	Vent hose disp Oxylog 3000 set	2M86841
IfU Caddy und CompactCaddy me	9038011	Wall Holder	2M86940
IfU Carrying System 3000 me	9037752	Wall Holder Adaptation Plate	5704218
IfU Equipment Holder 3000 me	9037753		
IfU Oxylog 3000 de	9037170		
O2 Bottle 2L-200bar-G3/4-GFK	B10205		
O2 Bottle 2L-200bar-PIN-GFK	B10208		
O2 ZV-Sch. 3m NIST Neutral DIN	M36005		
O2 ZV-Sch.1,5m NIST Neutra DIN	M36004		
O2-AIR CONNECT.HOSE 3M(BLACK)	M29245		
O2-AIR CONNECT.HOSE 5M (BLACK)	M29265		

Test List (TL)

Oxylog 3000

Notes on field of application:

This test list can be processed with standard commercially available test aids and tools, but does not replace the inspections and maintenance work carried out by the manufacturer.

Tests marked with the symbol '(✓)' are listed in the 'Test list report' and can be documented there.



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1 Device configuration

1.1 Serial number (SN)

- (✓) 1.1.1 **Oxylog 3000** [_____]
The serial number is located on the rating plate.

1.2 Software

- (✓) 1.2.1 **Software version** [_____]
The software version is displayed on-screen immediately after power-up.

2 Electrical safety

2.1 Oxylog 3000 - not applicable -

2.2 AC/DC power pack

The AC/DC power pack is categorized as protection class I (safety insulated). Measure to VDE 0751 or IEC 601.

2.2.1 Equivalent device leakage current test

1. Connect output of AC/DC power pack to Oxylog 3000.

(✓) **2.2.1.1 Initial measured value** [_____ μA]

Import the initial measured value from the old report into the new one. The initial measured value may be maximum 500 μA .

(✓) **2.2.1.2 Current value** [_____ μA]

The current value may exceed the initial measured value by max. 50 % and at the same time must be $\leq 500 \mu\text{A}$.

3 Function and condition test

(✓) 3.1 Accompanying documentation

Instructions for Use are available.

[OK]

(✓) 3.2 Visual check

The condition of the Oxylog 3000 is assessed by a visual check.

3.2.1 Housing

The housing is not contaminated by dirt or damaged. The labels are clearly legible.

[OK]

3.2.2 Compressed gas connection

The compressed gas connection is not damaged.

[OK]

3.2.3 Ventilation tube and ventilation valve

The ventilation tube and ventilation valve are not hardened or damaged.

[OK]

3.2.4 Electrical power supply

The connecting cables are not porous, severely kinked or damaged.

[OK]

3.2.5 Carrier system and accessories

The carrier system and accessories are not damaged.

[OK]

(✓) 3.3 Safety valve

1. Connect unit to power and to O₂ compressed gas supply.
2. Seal off socket for ventilation tube with pressure gauge.
3. Make the following settings:
 - Ventilation mode = CPAP
 - Frequency = 10 1/min

- Alarm limit Pmax = 60 mbar
- PEEP = 20 mbar

The pressure does not rise above 90 mbar.

[OK]

(✓) 3.4 Unit test

1. Connect unit to power and to O2 compressed gas supply.
2. Connect ventilation tube and ventilation valve to flow sensor and flowmeter tubes.
3. Connect test specimens (breathing bag and catheter socket) to flow sensor with elbow adapter.
4. Switch on the unit and immediately press and hold down the knob until the menu for selection of the unit test appears.
5. Select and activate the unit test.
6. Follow the on-screen instructions.

The unit test runs without error.

[OK]

(✓) 3.5 Buttons and potentiometer

1. Set the unit to Customer Service mode (see also "Annex").
2. Activate "Test buttons and potentiometer" test step.
3. Test all buttons on the unit.

When a button is pressed a corresponding "X" appears on-screen. If the button has an integral LED, the LED lights up while the button is being pressed. If there is no LED, the yellow warning LED is lit.

[OK]

4. Set the potentiometer to various settings and compare them against the values displayed on-screen.

The pre-set and displayed values are identical.

[OK]

(✓) 3.6 Loudspeaker, buzzer, LEDs and display

1. Set the unit to Customer Service mode (see also "Annex").
2. Activate "Test loudspeaker, buzzer, LEDs and display" test step.
3. Run the complete test.

The tests of the loudspeaker, the buzzer, the LEDs and the display were successful.

[OK]

3.7 Voltage supply

1. Connect unit to power and to O2 compressed gas supply.
2. Connect ventilation tube and ventilation valve to flow sensor and flowmeter tubes.
3. Connect test thorax, elbow adapter and flow sensor.

(✓) 3.7.1 External power supply

The external power LED lights up green.

[OK]

The charge indicator LED of the internal replaceable battery lights up in the following colours:

- Yellow: when the replaceable battery is charging
- Green: when the battery is fully charged
- Red: when no functional battery is inserted or the battery cannot be charged, such as because the unit is being used outside the temperature range of 0 to 35 °C.

[OK]

(✓) 3.7.2 Internal replaceable battery

1. Switch on unit.
2. Set ventilation mode IPPV.
3. Remove internal replaceable battery.
 - The unit continues ventilating.
 - The display shows the message "No battery".
 - The charge indicator LED is lit red.
 - An acoustic alarm sounds.

[OK]

4. Refit the internal replaceable battery.
 - The charge indicator LED is lit green.
 - The acoustic alarm is deactivated.
5. Press the "Alarm Reset" button.

The "No battery" message is no longer displayed.

[OK]

6. Remove external power supply.

The unit continues ventilating.

 - The external power LED is unlit.
 - The internal replaceable battery charge indicator LED is unlit.

- An acoustic alarm sounds.
- The display shows the message "Battery operating".

[OK]

7. Press the "Alarm Reset" button.

The "Battery operating" message is no longer displayed.

[OK]

8. Remove internal replaceable battery.

- Ventilation stops.
- An acoustic alarm sounds for at least 7 seconds.

[OK]

9. Refit the internal replaceable battery.

10. Connect the external power supply.

Ventilation is resumed with the previous settings.

[OK]

(v) 3.8 Supply pressure/emergency air valve

1. Connect unit to power and to O2 compressed gas supply.
2. Connect ventilation tube and ventilation valve to flow sensor and flowmeter tubes.
3. Connect test thorax, elbow adapter and flow sensor.
4. Set ventilation mode IPPV.
5. Remove compressed gas supply.
 - An acoustic alarm sounds.
 - The display shows the message "!!!Supply pressure low".
 - The red alarm LED lights up.
 - Ventilation stops.

[OK]

6. Simulate spontaneous breathing with the test thorax.

Ventilation through the emergency air valve is possible.

[OK]

7. Connect the compressed gas supply.

- The acoustic alarm stops.
- The red alarm LED is no longer lit.
- Ventilation is resumed with the previous settings.

[OK]

8. Press the "Alarm Reset" button.

The "!!!Supply pressure low" message is no longer displayed.

[OK]

3.9 Ventilation

(✓) 3.9.1 Volume-controlled ventilation

1. Connect unit to power and to O₂ compressed gas supply.
2. Connect ventilation tube and ventilation valve to flow sensor and flowmeter tubes.
3. Connect test specimens (breathing bag and catheter socket) to flow sensor with elbow adapter.
4. Make the following settings:
 - Ventilation mode = IPPV
 - Frequency = 10 1/min
 - Alarm limit P_{max} = 60 mbar
 - PEEP = 5 mbar
 - O₂ = 60 Vol. %
 - I/E = 1:1
 - T_{Plat} = 50%
 - Trigger = off
 - VT = 200 mL
5. Press the "Values" button to select the measured values MV and VTE.
The displayed MV is in the range 1.3 L/min to 2.3 L/min.

[OK]

6. Set VT to 500 mL.
The displayed MV is in the range 3,7 L/min to 5,3 L/min.

[OK]

7. Set VT to 1000 mL.
The displayed MV is in the range 8 L/min to 10 L/min.

[OK]

(✓) 3.9.2 Pressure-controlled ventilation

1. Remove test specimens and connect test thorax in their place.
2. Make the following settings:
 - Ventilation mode = BIPAP
 - Frequency = 6 1/min
 - Alarm limit P_{max} = 60 mbar

- PEEP = 5 mbar
- P_{insp} = 25 mbar
- T_{insp} = 5 s
- O₂ = 60 Vol. %
- NIV = off
- Trigger = 15 L/min
- Ramp = standard (middle curve)

Wait a few breaths for the values to stabilize.

The displayed PEEP value is in the range 3 mbar to 7 mbar.

[OK]

P_{peak} is in the range 23 mbar to 27 mbar.

[OK]

(✓) 3.9.3 Trigger function

1. Make the following settings:

- Ventilation mode = SIMV
- Frequency = 5 1/min
- PEEP = 10 mbar
- T_{insp} = 1 s
- VT = 500 mL
- Alarm limit P_{max} = 60 mbar
- O₂ = 60 Vol. %
- Flow trigger = 3 L/min
- Flow ramp = not applicable, or standard

The test thorax inflates to a PEEP pressure of 10 mbar.

[OK]

No self-triggering occurs.

[OK]

The message "O₂ setting not possible" may appear. The message can be ignored.

2. Trigger using the test thorax.

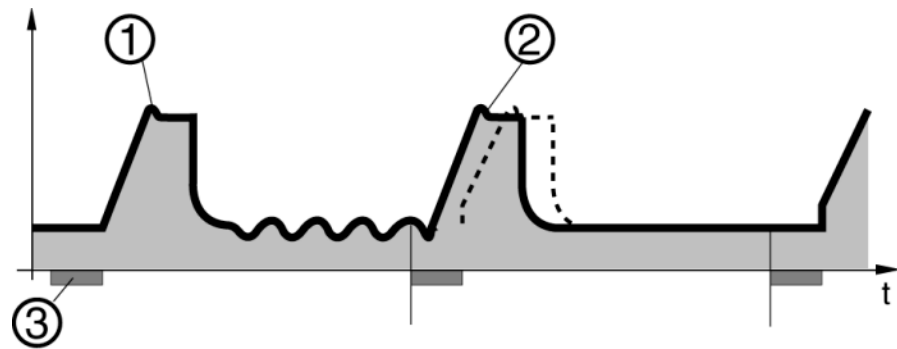


Fig.1 Trigger window

Table 1: Legend to Fig.1

Number	Designation
1	Unsynchronized mandatory ventilation stroke
2	Synchronized mandatory ventilation stroke
3	Trigger window

The unit triggers and activates a ventilation stroke. At the same moment a "star" appears on the top line of the display.

[OK]

(v) 3.10 Unit handover

Place fully functional unit at the user's/owner's disposal.

[OK]

4 Test Equipment

4.1 List of test aids

Designation	Features/Note
Pressure gauge	Measuring range to 1000 mbar
Test lung (test thorax)	-
Test lung, comprising the following components:	
Breathing bag	2 litre breathing bag to simulate lung compliance.
Catheter socket diameter 7 mm	To simulate the airway impedance.

5 Annex

5.1 Access to Customer Service mode (CSM)

To access Customer Service Mode:

1. Turn the adjuster 1 fully clockwise.
2. Switch on the unit by the button 3 and at the same time press and hold down the buttons 2 until Customer Service mode appears.

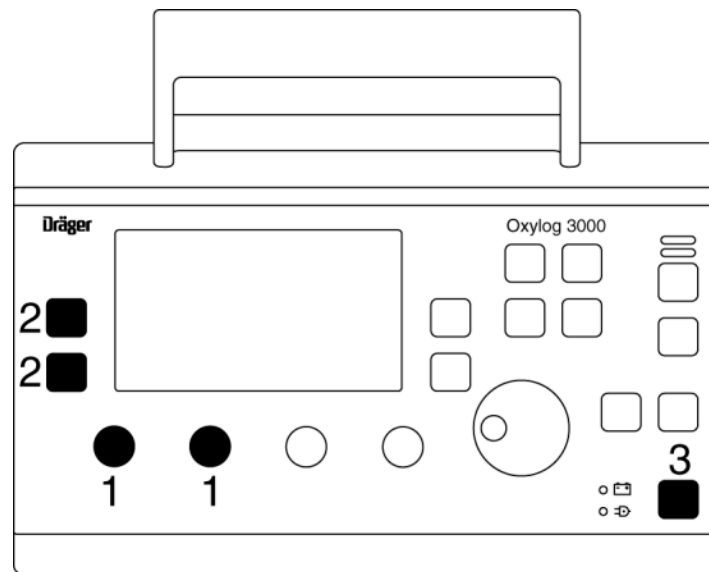


Fig.2 Selecting service mode

Now the appropriate test can be selected and activated. To quit Service mode switch off the unit. The values set in Customer Service mode are retained and reactivated every time ventilation is started following power-up.

Test List Report	Oxylog 3000
Test List Edition:	2002-03-07
Installation site:	

OK	Result	OK	Result
1	Device configuration		
1.1	Serial number (SN)		
() 1.1.1	Oxylog 3000 [_____]		
1.2	Software		
() 1.2.1	Software version [_____]		
2	Electrical safety		
2.2	AC/DC power pack		
2.2.1	Equivalent device leakage current test		
() 2.2.1.1	Initial measured value [_____ μA]		
() 2.2.1.2	Current value [_____ μA]		
3	Function and condition test		
() 3.1	Accompanying documentation		
() 3.2	Visual check		
() 3.3	Safety valve		
() 3.4	Unit test		
() 3.5	Buttons and potentiometer		
() 3.6	Loudspeaker, buzzer, LEDs and display		
3.7	Voltage supply		
() 3.7.1	External power supply		
() 3.7.2	Internal replaceable battery		
() 3.8	Supply pressure/emergency air valve		
3.9	Ventilation		
() 3.9.1	Volume-controlled ventilation		
() 3.9.2	Pressure-controlled ventilation		
() 3.9.3	Trigger function		
() 3.10	Unit handover		

Supply tested and fully functional device to owner/user.
Date: _____ Name/Signature: _____

2005-11-16

Technical Documentation for Oxylog 3000 according to EMC standard IEC/EN 60601-1-2: 2001

General Information

The EMC conformity of the Oxylog3000 includes the use of following external cables, transducers and accessories:

Description	Order-No.
AC/DC converter	2M86730
DC/DC converter	2M86731
Wall Holder	2M86940
Carrying System3000	2M86975

The Oxylog 3000 should not be used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the Oxylog 3000 should be observed to verify normal operation in the configuration in which it will be used.

Electromagnetic Emissions


Electromagnetic Emissions		
The Oxylog 3000 is intended for use in the electromagnetic environment specified below. The user of the Oxylog 3000 should assure that is used in such an environment.		
Emissions	Compliance according to	Electromagnetic environment
RF emissions (CISPR 11)	Group 1	The Oxylog 3000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class B	The Oxylog 3000 is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Class A	N/A
Voltage fluctuations / flicker (IEC 61000-3-3)	Complies	N/A

Information re electromagnetic emissions (IEC 60101-1-2: 2001, table 201)

Electromagnetic Immunity

Electromagnetic Immunity			
This Oxylog 3000 is intended for use in the electromagnetic environment specified below. The user of the Oxylog 3000 should assure that is used in such an environment.			
Immunity against	IEC 60601-1-2 test level	Compliance level (of the Oxylog 3000)	Electromagnetic environment
electrostatic discharge, ESD (IEC 61000-4-2)	contact discharge: 6 kV air discharge: 8 kV	6 kV 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
electrical fast transients / bursts (IEC 61000-4-4)	power supply lines: 2 kV longer input / output lines: 1 kV	2 kV 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
surges on AC mains lines (IEC 61000-4-5)	common mode: 2 kV differential mode: 1 kV	2 kV 1 kV	Mains power quality should be that of a typical commercial or hospital environment.
power frequency magnetic field 50/60 Hz (IEC 61000-4-8)	3 A/m	3 A/m	In close vicinity to the Oxylog 3000, no equipment with extraordinary power frequency magnetic fields (power transformers, etc.) should be operated.
voltage dips and short interruptions on AC mains input lines (IEC 61000-4-11)	dip >95%, 0.5 periods dip 60%, 5 periods dip 30%, 25 periods dip >95%, 5 seconds	>95%, 0.5 per. 60%, 5 per. 30%, 25 per. >95%, 5 sec.	Mains power should be that of a typical commercial or hospital environment. If user requires continued operation during power mains interruptions, it is recommended to power the Oxylog 3000 from an uninterruptible supply or a battery.
radiated rf (IEC 61000-4-3)	80 MHz – 2.5 GHz: 10 (3) V/m	10 V/m	Recommended separation distance from portable and mobile rf transmitters with transmission power P_{EIRP} to the Oxylog 3000 including its lines: $1.84 \text{ m} * P_{EIRP}^{X1}$
rf coupled into lines (IEC 61000-4-6)	150 kHz – 80 MHz: 10 (3) V within ISM bands, 3 V outside ISM bands ^{X2}	10 V 3 V	Recommended separation distance from portable and mobile rf transmitters with transmission power P_{EIRP} to the Oxylog 3000 including its lines: $1.84 \text{ m} * P_{EIRP}^{X1}$

Information re electromagnetic immunity (IEC 60601-1-2: 2001, tables 202, 203, 204)

^{X1}: For P_{EIRP} the highest possible "equivalent isotropic radiated power" of the adjacent rf transmitter has to be inserted (value in Watt). Also in the vicinity of equipment marked with the symbol  interference may occur. Field strengths from fixed, portable or mobile rf transmitters at the location of the Oxylog 3000 should be less than 3 V/m in the frequency range from 150 kHz to 2.5 GHz and less than 1 V/m above 2.5 GHz.

^{X2}: ISM bands in this frequency range are: 6.765 MHz - 6.795 MHz, 13.553 MHz - 13.567 MHz, 26.957 MHz - 27.283 MHz, 40.66 MHz - 40.70 MHz.

Recommended separation distances

Recommended separation distances between portable and mobile RF-Telecommunication devices and the Oxylog 3000			
max. P _{EIRP} (W)	3 V/m distance* (m)	1 V/m distance* (m)	Hint
0.001	0.06	0.17	
0.003	0.10	0.30	
0.010	0.18	0.55	
0.030	0.32	0.95	e.g. WLAN 5250 / 5775 (Europe)
0.100	0.58	1.73	e.g. WLAN 2440 (Europe), Bluetooth
0.200	0.82	2.46	e.g. WLAN 5250 (not in Europe)
0.250	0.91	2.75	e.g. DECT devices
1.000	1.83	5.48	e.g. GSM 1800- / GSM 1900- / UMTS- mobiles, WLAN 5600 (not in Europe)
2.000	2.60	7.78	e.g. GSM 900 mobiles
3.000	3.16	9.49	

Information re separation distances (IEC 60601-1-2: 2001, tables 205 and 206)

* 3 V/m distance to transmitters with frequencies from 150 kHz to 2.5 GHz, otherwise 1 V/m distance.

Manufacturer:

Dräger Medical b.v.
Kanaaldijk 29
NL-5683 CR BEST
The Netherlands

Phone: (+31) 499 331 - 331

Fax: (+31) 499 331 - 335



Directive 93/42/EEC
concerning Medical Devices

Support:

Dräger Medical AG & Co. KG
Moislinger Allee 53 – 55
D-23542 Lübeck
Germany

Phone: (+49) (0) 1805-3723437

Fax: (+49) 451/882 - 3779

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