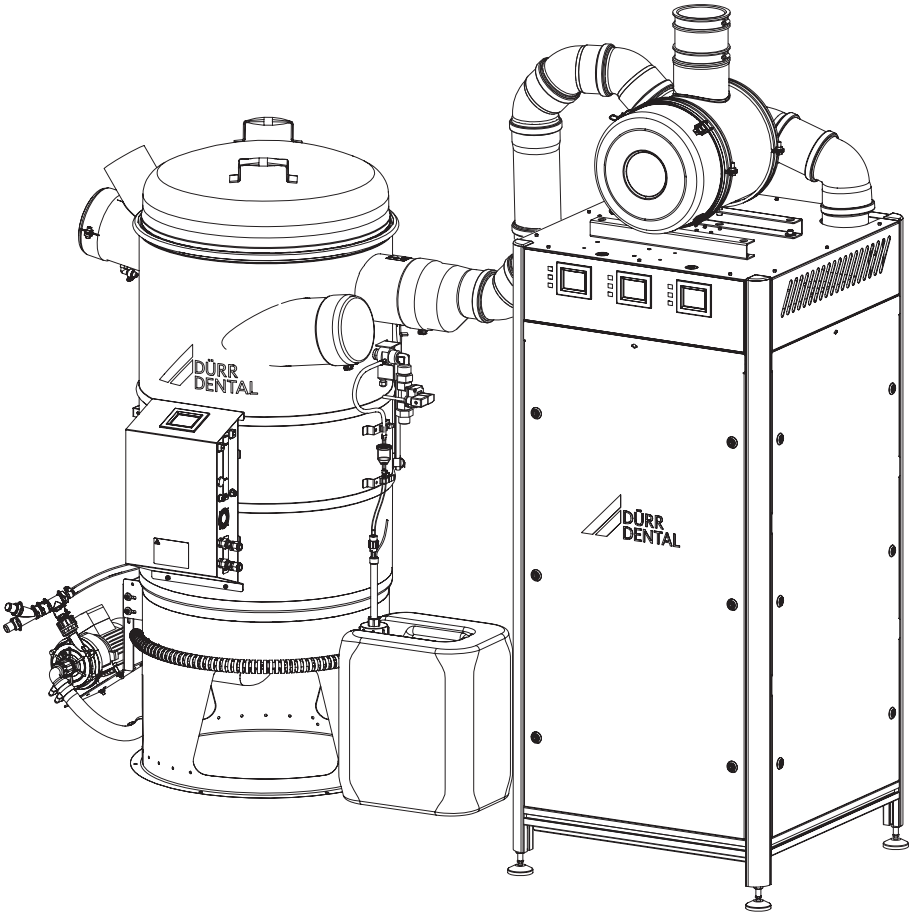
Clinic suction system

Tyscor V 20, V 30



EN Installation and operating instructions

CE 0297

DÜRR DENTAL

1802100018L02 2412V004

The current version of the installation and operating instructions is available in the Download Center:

http://qr.duerrdental.com/1802100018

Contents

Important information

Product description

Assembly

Usage

Troubleshooting

Appendix

Important information

1 About this document

These installation and operating instructions represent part of the unit.

The manufacturer and the distributor will not offer any guarantee or accept any liability for the safe operation and the safe functioning of the unit if the instructions and information in these installation and operating instructions are not complied with.

The German version of the installation and operating instructions is the original manual. All other languages are translations of the original manual.
These installation and operating instructions apply to:
Tyscor V 20
REF: 1802100510
Tyscor V 30
REF: 1803100510

1.1 Warnings and symbols

Warnings

The warnings in this document are intended to draw your attention to possible injury to persons or damage to machinery.
The following warning symbols are used:

General warning symbol

Warning – dangerous high voltage

Warning - automatic start-up of the unit

Biohazard warning

Warning – hot surfaces

The warnings are structured as follows:

SIGNAL WORD
Description of the type and source of danger
Here you will find the possible consequences of ignoring the warning
› Follow these measures to avoid the danger.

The signal word differentiates between four levels of danger:
– **DANGER**
Immediate danger of severe injury or death
– **WARNING**
Possible danger of severe injury or death
– **CAUTION**
Risk of minor injuries
– **NOTICE**
Risk of extensive material/property damage

Other symbols

These symbols are used in the document and on or in the unit:

Note, e.g. specific instructions regarding efficient and cost-effective use of the unit.

Refer to Operating Instructions.

Product for the disinfection and cleaning of suction units

Disconnect all power from the unit.

Wear protective gloves.

Wear ear protectors.

Do not sit on the unit

Do not climb onto the unit

Do not push or slide the unit.

CE xxxx CE labelling with the number of the notified body

UK CA XXXX Conformity mark for the United Kingdom of Great Britain and Northern Ireland, with the number of the designated authority

UA.TR.099 Ukrainian conformity mark with registration number

REF Order number

SN Serial number

MD Medical device

HIBC Health Industry Bar Code (HIBC)

Manufacturer

1.2 Copyright information

2 Safety

The unit has been developed and designed in such a way that dangers are effectively ruled out if used in accordance with the Intended Use.
Despite this, the following residual risks can remain:
– Personal injury due to incorrect use/misuse
– Personal injury due to mechanical effects
– Personal injury due to electrical shock
– Personal injury due to radiation
– Personal injury due to fire
– Personal injury due to thermal effects on skin
– Personal injury due to lack of hygiene, e.g. infection

2.1 Intended purpose

The suction unit provides the dental treatment unit with vacuum and volume flow.

2.2 Intended use

Working in combination with the suction unit with treatment unit, suction handpiece and cannula, the media used in dental treatment (e.g. water, saliva, dentine and amalgam) are removed by suction for disposal.
A semi-dry suction system always requires a central separation tank to ensure separation of the air and fluid/solid particles upstream of the suction unit.
A dry suction system always requires a separation container to ensure separation of the air and fluid/solid particles upstream of the suction unit.
In addition, a condensation separator needs to be installed upstream of the vacuum inlet of the suction unit to collect any condensate that accumulates in the pipe system and direct it outwards.
This unit is technically suitable for the aspiration of nitrous oxide (laughing gas). However, when assembling a system for aspiration of nitrous oxide, it is important to ensure that the other components in the system are also suitable for this purpose. Those responsible for setting up the system must assess this and approve and release the system for the aspiration of nitrous oxide.

Operation with nitrous oxide is only permitted if the exhaust air is transported from the unit to the outside of the building.

2.3 Improper use

Any use of this appliance / these appliances above and beyond that described in the Installation and Operating Instructions is deemed to be incorrect usage. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The operator will be held liable and bears all risks.
– Do not use this device to aspirate flammable or explosive mixtures.
– Do not use the unit as a vacuum cleaner.
– Do not use chemicals containing chlorine or foaming chemicals.
– Operation in operating theatres of explosive areas is not permissible.
– The suction unit must not be set up in the immediate surroundings of the patient (minimum distance: 1.5 m).

2.4 General safety information

– Always comply with the specifications of all guidelines, laws, and other rules and regulations applicable at the site of operation for the operation of this unit.
– Check the function and condition of the unit prior to every use.
– Do not convert or modify the unit.
– Comply with the specifications of the Installation and Operating Instructions.
– The Installation and Operating Instructions must be accessible to all operators of the unit at all times.

2.5 Specialist personnel

Operation

Unit operating personnel must ensure safe and correct handling based on their training and knowledge.
– Instruct or have every operator instructed in handling the unit.

Installation and repairs

– Have the manufacturer or a qualified company authorised by the manufacturer perform mounting, new installations, modifications, expansions and repairs.

2.6 Notification requirement of serious incidents

The operator/patient is required to report any serious incident that occurs in connection with the device to the manufacturer and to the competent authority of the Member State in which the operator and/or patient is established/resident.

2.7 Electrical safety

– Comply with all the relevant electrical safety regulations when working on the unit.
– Never touch the patient and unshielded plug connections on the unit at the same time.
– Replace any damaged cables or plugs immediately.

Observe the EMC rules concerning medical devices

– The unit is intended for use in professional healthcare facilities (in accordance with IEC 60601-1-2). If the appliance is operated in another environment, potential effects on electromagnetic compatibility must be taken into account.
– Maintain a minimum distance of at least 30 cm between the unit and other electronic devices.
– Keep a minimum distance of 30 cm between the unit and mobile radio devices.
– Note that cable lengths and cable extensions have effects on electromagnetic compatibility.

NOTICE

Negative effects on the EMC due to non-authorised accessories

› Use only those accessories named or approved by the manufacturer.
› Using any other accessories may result in increased electromagnetic interference emissions or the unit having reduced electromagnetic immunity, leading to an erroneous operation mode.

NOTICE

Erroneous operation mode due to use immediately adjacent to other devices or with other stacked devices

› Do not stack the unit together with other devices.
› If this is unavoidable, the unit and other devices should be monitored in order to ensure that they are working correctly.

2.8 Systems, connection with other devices

Additional devices connected with medical electrical devices must be proven to conform with their corresponding IEC or ISO standards. All configurations must continue to comply with the standard requirements for medical systems (see IEC 60601-1).
Whoever connects additional devices to medical electrical devices automatically becomes the system configurator and is responsible for ensuring that the system corresponds with the standard requirements for systems. Local laws take priority over the requirements outlined above.

2.9 Only use original parts

– Only use accessories and optional articles named or authorised by the manufacturer.
– Only use only original wear parts and replacement parts.

The manufacturer and distributor accept no liability for damages or injury resulting from the use of non-approved accessories, optional accessories, or from the use of non-original wear parts or replacement parts.

The use of non-approved accessories, optional accessories or non-genuine wear parts / replacement parts (e.g. mains cables) can have a negative effect in terms of electrical safety and EMC.

2.10 Transport

The original packaging provides optimum protection for the unit during transportation.

The manufacturer and the distributor do not accept liability, even during the warranty period, for damage during transportation due to improper packaging.

– Only transport the unit secured to the pallet from the original packaging.
– Transport the unit using a forklift truck or pallet truck.
– Keep the packing materials out of the reach of children.

2.11 Disposal

The unit may be contaminated. Instruct the company disposing of the waste to take the relevant safety precautions.

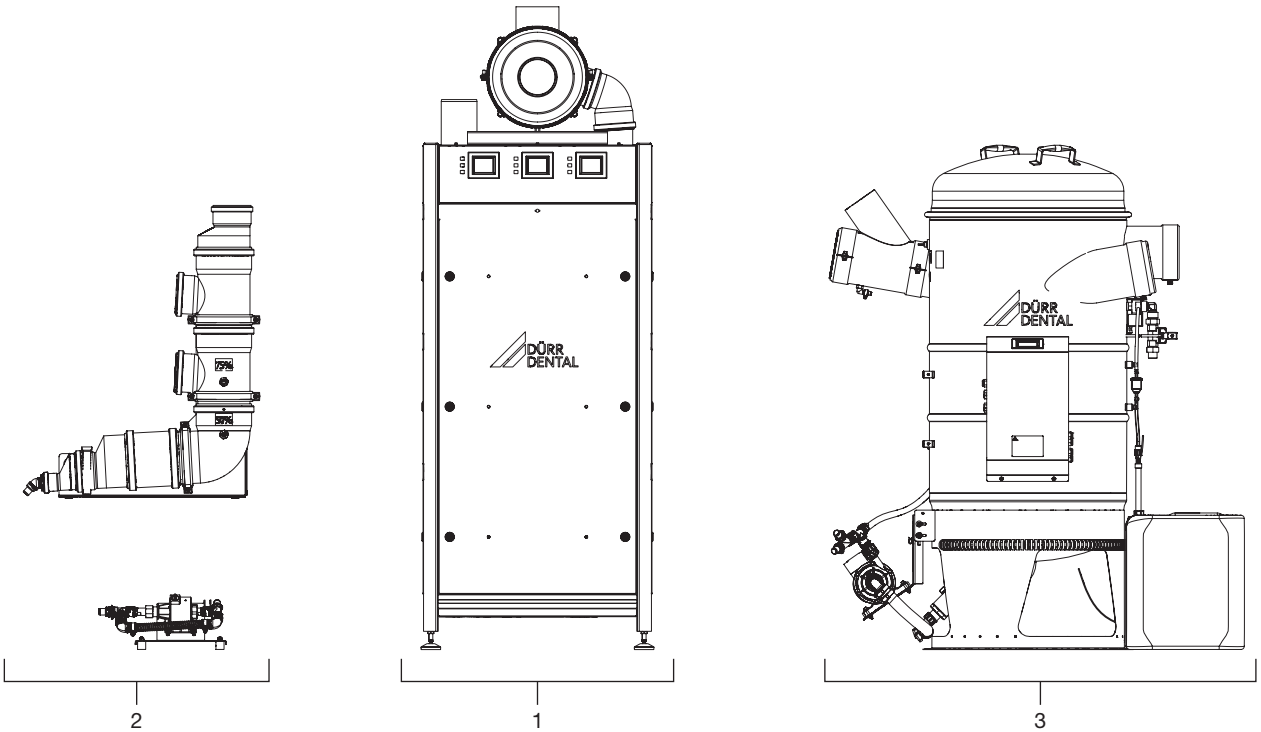
– Decontaminate potentially contaminated parts before disposing of them.
– Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
– If you have any questions about the correct disposal of parts, please contact your dental trade supplier.

An overview of the waste keys for Dürr Dental products can be found in the download area:

http://qr.duerrdental.com/P007100155

Product description

3 Overview



1 Clinic suction system (Tyscor V 20 / V 30)
2 Condensation separator for a dry system
3 Central separation tank (CS 60) for a semi-dry system

3.1 Scope of delivery

The following items are included in the scope of delivery (possible variant-specific deviations due to country-specific requirements and/or import regulations):

Tyscor V 20 1802100510

– Tyscor clinic suction system with two suction units
– Exhaust air filter set
– Connection parts
– HT pipes
– Installation and operating instructions

The corresponding technical data must be taken into account if you are planning an upgrade to V 30.

Tyscor V 30 1803100510

– Tyscor clinic suction system with three suction units
– Exhaust air filter set
– Connection parts
– HT pipes
– Installation and operating instructions

3.2 Optional items

The following items are required for operation of the device, depending on the application:

Dry:

Condensation separator with condensation pump . . 1802400053

Semi-dry:

Central separation tank CS 60 with water rinsing . . A704400068

or

Central separation tank CS 60 with water and Orotol plus rinsing 0704-400-67

Only for Tyscor V 20:

Central separation tank CS 20 with water rinsing . . A704200068

or

Central separation tank CS 20 with water and Orotol plus rinsing A704200067

The following optional items can be used with the device:

General:

Load-break switch 1802100030
Switch (8-fold) with integrated power unit 5922-521-51
Exhaust air noise reducer 1802980051

3.3 Consumables

The following materials are consumed during operation of the device and must be ordered separately:

Cartridge for bacteria filter 0705-991-05

3.4 Wear parts and replacement parts

The following working parts need to be changed at regular intervals (refer to the "Maintenance" section):

Any repairs exceeding routine maintenance may only be carried out by qualified personnel or our service.

Information about replacement parts is available from the portal for authorised specialist dealers at:
www.duerrdental.net

4 Technical data

4.1 Tyscor V 20

Type		1802100510
Workplaces SF* 100% / 60%		20 / 30
Operating pressure (relative pressure)	mbar/hPa	-100 - -160
Flow rate, at operating pressure at 0 mbar	 l/min l/min	 6000 12500

* SF = simultaneity factor

Electrical data		
Rated voltage	V	400, 3~
Mains frequency	Hz	50 / 60
Nominal current	A	14 *
Type of protection		IP 20
Protection class		I

* max. 19 A for expansion to V 30

Network connection		
LAN technology		Ethernet
Standard		IEEE 802.3u
Data rate	Mbit/s	100
Connector		RJ45
Type of connection		Auto MDI-X
Cable type		≥ CAT5

Connections		
Suction connection (outside)	mm	∅ 110
Exhaust air connection (external)	mm	∅ 110
Waste connections (DürrConnect)	mm	∅ 20

General data		
Radial blower speed (n_V) max.	At least^{-1}	14000
Duty cycle	%	100
Dimensions (H x W x D)	cm	165 x 70 x 70
Weight, approx.	kg	180
Noise level * ca.	dB(A)	69

* Noise level in accordance with ISO 3746

Classification	
Medical Device Class (MDR)	IIa

Electromagnetic compatibility (EMC) Interference emission measurements	
High-frequency emissions in accordance with CISPR 11	Group 1 Class A
Interference voltage at the power supply connection CISPR 11:2009+A1:2010	Compliant
Electromagnetic interference radiation CISPR 11:2009+A1:2010	Compliant
Emission of harmonics IEC 61000-3-2:2005+A1:2008+A2:2009	N/A
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3:2013	Compliant

N/A = not applicable

Electromagnetic compatibility (EMC) Interference immunity measurements	
Immunity to electrostatic discharge IEC 61000-4-2:2008	Compliant
Immunity to high-frequency electromagnetic fields IEC 61000-4-3:2006+A1:2007+A2:2010	Compliant
Immunity to near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010	Compliant
Immunity to fast electrical transients/bursts – AC mains voltage IEC 61000-4-4:2012	Compliant
Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012	Compliant
Immunity to interference, surges IEC 61000-4-5:2005	Compliant
Immunity to conducted disturbances, induced by radio-frequency fields – AC mains voltage IEC 61000-4-6:2013	Compliant
Immunity to conducted disturbances, induced by radio-frequency fields – SIP/SOP ports IEC 61000-4-6:2013	Compliant
Immunity to power frequency magnetic fields IEC 61000-4-8:2009	N/A
Immunity to voltage dips, short interruptions and voltage variations IEC 61000-4-11:2004	Compliant
N/A = not applicable	

Immunity to interference table, near fields of wireless HF communication devices		
Radio service	**Frequency band MHz**	**Test level V/m**
TETRA 400	380 - 390	27
GMRS 460 FRS 460	430 - 470	28
LTE band 13, 17	704 - 787	9
GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE band 5	800 - 960	28
GSM 1800 CDMA 1900 GSM 1900 DECT LTE band 1, 3, 4, 25 UMTS	1700 - 1990	28
Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE band 7	2400 - 2570	28
WLAN 802.11 a/n	5100 - 5800	9

Electromagnetic compatibility (EMC) Interference immunity measurements on the supply input	
Immunity to fast electrical transients/bursts – AC mains voltage IEC 61000-4-4:2012 ± 2 kV 100 kHz repetition rate	Compliant
Immunity to surges, line-to-line IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV	Compliant
Immunity to surges, line-earth IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV, ± 2 kV	Compliant

Electromagnetic compatibility (EMC) Interference immunity measurements on the supply input	
Immunity to conducted disturbances, induced by radio-frequency fields – AC mains voltage IEC 61000-4-6:2013 3 V 0.15–80 MHz 6 V ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz	Compliant
Immunity to voltage dips, short interruptions and voltage variations IEC 61000-4-11:2004	Compliant

Electromagnetic compatibility (EMC) Interference immunity measurements SIP/SOP	
Immunity to electrostatic discharge IEC 61000-4-2:2008 ± 8 kV contact ± 2kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant
Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012 ± 1 kV 100 kHz repetition rate	Compliant
Immunity to impulse voltages, conductor to earth IEC 61000-4-5:2005 ± 2 kV	N/A
Immunity to conducted disturbances, induced by radio-frequency fields – SIP/SOP ports IEC 61000-4-6:2013 3 V 0.15–80 MHz 6 V ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz	Compliant
N/A = not applicable	

4.2 Tyscor V 30

Type		1803100510
Workplaces SF* 100% / 60%		 30 / 50
Operating pressure (relative pressure)	mbar/hPa	-100 - -160
Flow rate, at operating pressure at 0 mbar	 l/min l/min	 9000 15500

* SF = simultaneity factor

Electrical data		
Rated voltage	V	400, 3~
Mains frequency	Hz	50 / 60
Nominal current	A	19
Type of protection		IP 20
Protection class		I

Network connection		
LAN technology		Ethernet
Standard		IEEE 802.3u
Data rate	Mbit/s	100
Connector		RJ45
Type of connection		Auto MDI-X
Cable type		≥ CAT5

Connections		
Suction connection (outside)	mm	∅ 110
Exhaust air connection (external)	mm	∅ 110
Waste connections (DürrConnect)	mm	∅ 20

General data		
Radial blower speed (n_v) max.	At least^{-1}	14000
Duty cycle	%	100
Dimensions (H x W x D)	cm	165 x 70 x 70
Weight, approx.	kg	200
Noise level * ca.	dB(A)	71

* Noise level in accordance with ISO 3746

Classification	
Medical Device Class (MDR)	IIa

Electromagnetic compatibility (EMC) Interference emission measurements	
High-frequency emissions in accordance with CISPR 11	Group 1 Class A
Interference voltage at the power supply connection CISPR 11:2009+A1:2010	Compliant
Electromagnetic interference radiation CISPR 11:2009+A1:2010	Compliant
Emission of harmonics IEC 61000-3-2:2005+A1:2008+A2:2009	N/A
Voltage changes, voltage fluctuations and flicker emissions IEC 61000-3-3:2013	Compliant

N/A = not applicable

Electromagnetic compatibility (EMC) Interference immunity measurements	
Immunity to electrostatic discharge IEC 61000-4-2:2008	Compliant

Electromagnetic compatibility (EMC) Interference immunity measurements	
Immunity to high-frequency electromagnetic fields IEC 61000-4-3:2006+A1:2007+A2:2010	Compliant
Immunity to near fields of wireless HF communication devices IEC 61000-4-3:2006+A1:2007+A2:2010	Compliant
Immunity to fast electrical transients/bursts – AC mains voltage IEC 61000-4-4:2012	Compliant
Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012	Compliant
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N/A = not applicable	

Immunity to interference table, near fields of wireless HF communication devices		
Radio service	**Frequency band MHz**	**Test level V/m**
TETRA 400	380 - 390	27
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Immunity to surges, line-to-line IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV	Compliant
Immunity to surges, line-earth IEC 61000-4-5:2005 ± 0.5 kV, ± 1 kV, ± 2 kV	Compliant

Electromagnetic compatibility (EMC) Interference immunity measurements on the supply input	
Immunity to conducted disturbances, induced by radio-frequency fields – AC mains voltage IEC 61000-4-6:2013 3 V 0.15–80 MHz 6 V ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz	Compliant
Immunity to voltage dips, short interruptions and voltage variations IEC 61000-4-11:2004	Compliant

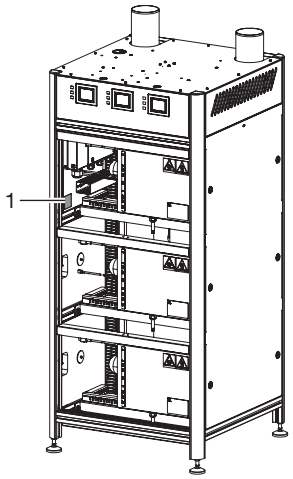
Electromagnetic compatibility (EMC) Interference immunity measurements SIP/SOP	
Immunity to electrostatic discharge IEC 61000-4-2:2008 ± 8 kV contact ± 2kV, ± 4 kV, ± 8 kV, ± 15 kV air	Compliant
Immunity to electrical fast transients/bursts – I/O, SIP/SOP ports IEC 61000-4-4:2012 ± 1 kV 100 kHz repetition rate	Compliant
Immunity to impulse voltages, conductor to earth IEC 61000-4-5:2005 ± 2 kV	N/A
Immunity to conducted disturbances, induced by radio-frequency fields – SIP/SOP ports IEC 61000-4-6:2013 3 V 0.15–80 MHz 6 V ISM frequency bands 0.15–80 MHz 80% AM at 1 kHz	Compliant
N/A = not applicable	

4.3 Ambient conditions

Ambient conditions during storage and transport		
Temperature	°C	-10 - +60
Relative humidity	%	< 95

Ambient conditions during operation		
Temperature	°C	+10 - +40
Relative humidity	%	< 70
Air pressure	hPa	690 - 1030

4.4 Type plate

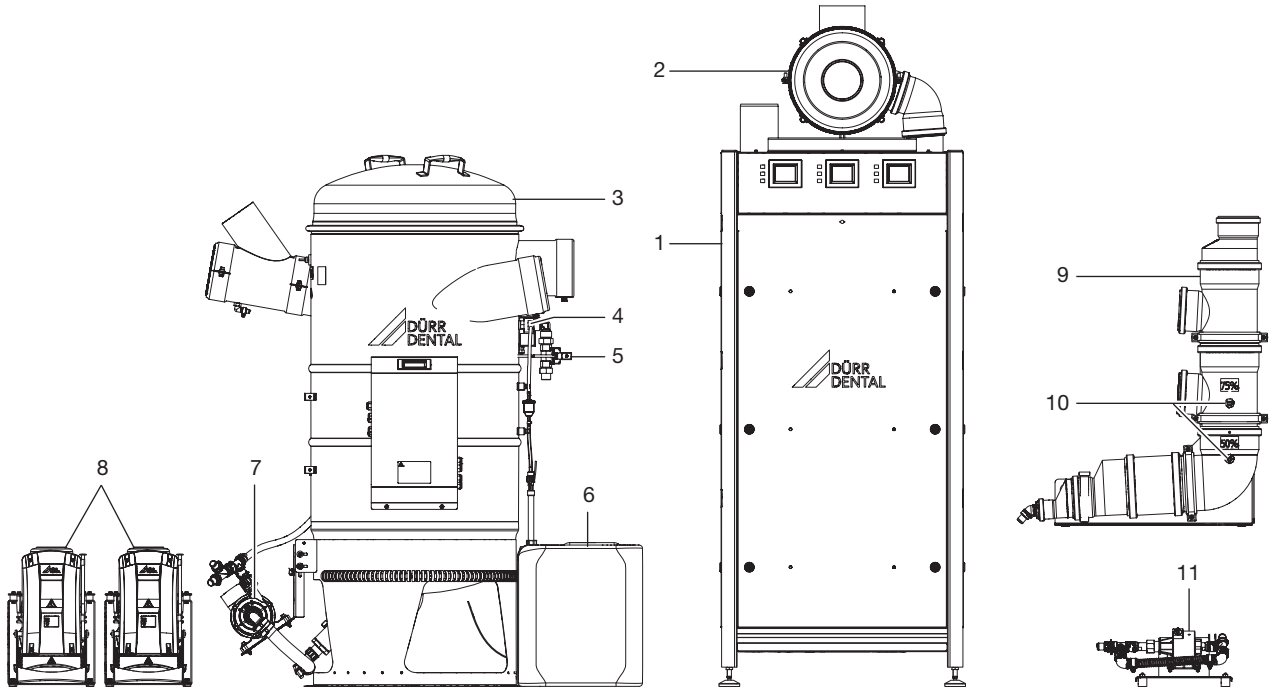


1 Type plate

4.5 Evaluation of conformity

This device has been subjected to conformity acceptance testing in accordance with the current relevant European Union guidelines. This equipment conforms to all relevant requirements.

5 Function



1 Clinic suction system
2 Exhaust air filter
3 Central separation tank CS 60
4 Orotolvalve
5 Container rinsing
6 Orotolcontainer
7 Waste water pump
8 Amalgam separator
9 Condensation separator
10 Float switch
11 Condensation pump

5.1 Clinic suction system

The air that has been separated from the fluids is sucked into the radial blowers. The motors in the radial blowers are regulated on a demand-driven basis by the unit electronics. Afterwards, the aspirated air is passed through the exhaust air connections and out of the device.

5.2 Condensate separator

The condensate separator collects any condensate that occurs in the pipe system and directs it to the outside.

5.3 Central separation tank CS 60

A central separation tank is used in semi-dry suction systems. The purpose of the central separation tank is to separate the fluid/air mixture accumulated from the treatment units – i.e.the air is separated from the fluid and transported to the suction unit. The fluid is fed to the central waste water network.
The central separation tank can be equipped with up to 2 suction inlets and has a connection to the suction unit. The tangential suction inlets allow a flow rate of up to 18000 l/min. Each of the suction inlets has a coarse filter, which needs to be cleaned regularly.
On the central separation tank there is a fresh water connection with a solenoid valve. The connection can be made as required depending on the rinsing and disinfection requirements. (The amount of water and disinfectant depends on the installation and the number of treatment units.)
The central separation tank has a total volume of approx. 300 l. When the fill level reaches approx. 50%, a float switch activates the waste water pump . The waste water pump sucks the fluid out of the central separation tank against the vacuum of the suction system and pumps it into the central waste water network. A safety shut-off is triggered at a level of approx. 75% via a second float switch, i.e. the suction unit is switched off until the fill level has been lowered.

5.4 Operating modes

Three different operating modes are available for Tyscor suction units. These can be set up on the touch screen. If you are using monitoring software then you can also change the settings there.
The operating modes are "Balanced", "Boost" and "Eco". The different operating modes can be used to adjust the available power to the suction system (routeing of lines, line lengths, layout of treatment unit etc.).

5.5 Lag time

The device will continue to run for a few seconds after the suction hose has been hung back in the manifold. The lag time ensures that the remaining fluid in the suction system can be processed. Depending on the installation, the lag time can be adjusted accordingly.

5.6 Combining suction units

Up to three suction units can be operated together in combination in the Tyscor clinic suction system. In this case, one suction unit takes control (main unit); additional suction units (auxiliary unit) are controlled. By combining multiple devices together in this way, the available flow rate can be increased – which in turn means that more therapists can use the system.

When grouped together, mutual controlling and exchange of information takes place via the CAN bus. Only one suction unit may be configured as the main unit; additional suction units must be configured as auxiliary units.

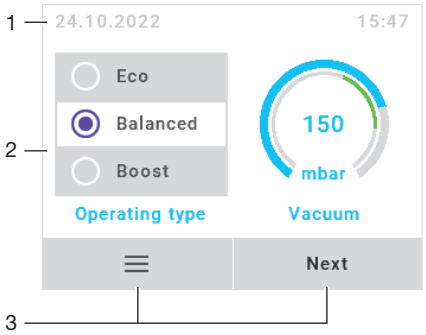
5.7 Combining clinic suction systems

Two clinic suction systems (towers) can be operated together in combination. In this case, one suction unit takes control (main unit); additional suction units (auxiliary unit) are controlled. By combining multiple devices together in this way, the available flow rate can be increased – which in turn means that more therapists can use the system.

When grouped together, mutual controlling and exchange of information takes place via the CAN bus. The number of connected towers must not be identical. Only one suction unit may be configured as the main unit; additional suction units must be configured as auxiliary units.

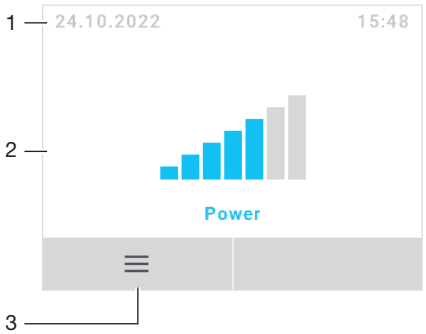
5.8 Overview of the touch screen user interface

Main unit standard display



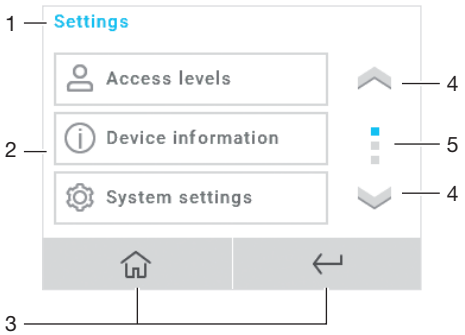
1 Context area (e. g. messages)
2 Content area
3 Navigation buttons

Auxiliary unit standard display



1 Context area
2 Content area
3 Navigation buttons

Settings



1 Title bar / submenus
2 Content area
3 Navigation buttons
4 Scroll button
5 Page indicator

Assembly

6 Requirements

The installation options will vary according to model type and/or the particular building restrictions. On systems with a central separation tank, this must be positioned at the lowest point in the system.

6.1 Installation/setup room

The room chosen for set up must fulfil the following requirements:
- Closed, dry, well-ventilated room
- Should not be a room made for another purpose (e. g. boiler room or wet cell)

6.2 Pipe materials

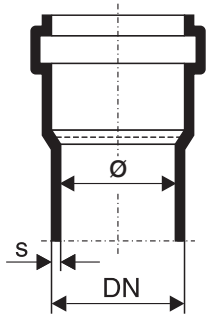
Only use vacuum-sealed HT-waste pipes manufactured from the following materials:
- Polypropylene (PP),
- Chlorinated polyvinyl chloride (PVC-C),
- Plasticizer-free polyvinyl chloride (PVC-U),
- Polyethylene (PE).

The following materials must not be used:
- Acrylonitrile-butadiene-styrene (ABS),
- Styrene copolymer blends (e.g. SAN + PVC).

6.3 Pipe dimensions

Diameters

The diameters of the pipes are designated with **DN**. If no pipes with the corresponding DN sizes are available then pipes with similar internal diameters can be used. The following is a table with the relevant **mm** values:



DN	s [mm]	ø [mm] *
40	1.8	36
50	1.8	46
75	1.9	71
90	2.2	86
110	2.7	105
125	3.1	119
160	3.9	154

* Values rounded

Waste water pipe
- **DN 50**, gradient of at least 2% in accordance with DIN EN 12056, parts 1 and 2
- or choose a pipe diameter in line with national and local regulations.

Suction and exhaust pipes

Pipes of varying diameters are chosen corresponding to the suction power of the suction units. The diameters are given in the planning examples.

6.4 Hose materials

For waste connections and suction lines only use the following hose types:
- Flexible spiral hoses made of PVC with integrated spiral or equivalent hoses
- Hoses that are resistant to dental disinfectants and chemicals

Plastic hoses will display signs of ageing over time. Therefore, they should be inspected regularly and replaced as necessary.

The following types of hoses must not be used:
- Rubber hoses
- Hoses made completely of PVC
- Hoses that are not sufficiently flexible

6.5 Information about electrical connections

- Ensure that the electrical connections to the mains power supply are established in accordance with current valid national and local regulations and standards governing the installation of low voltage units in medical facilities.
- The connection to the mains supply must be a fixed connection that cannot be disconnected without the use of tools. Plug-in connections (power outlet/plug) are not permissible.
- Install an all-pole disconnection unit (all-pole switch) in the electrical connection to the mains power supply. This must include the clearance and creepage distances defined in IEC 61058-1 for a mains voltage peak of 4 kV.

It must be possible to secure the disconnect switch so that it cannot be inadvertently switched back on again.
The disconnection unit (switch) must be easily accessible without danger.

- Observe the current consumption of the devices that are to be connected.

6.6 Information about connecting cables

The diameter of the connections depends on the current consumption, length of line and the ambient temperature of the unit. Information concerning the current consumption can be found in the Technical Data supplied with the particular unit to be connected.
The following table lists the minimum diameters of the connections in relation to the current consumption:

Current consumption of unit [A]	Cross-section [mm²]
> 10 and < 16	1.5
> 16 and < 25	2.5
> 25 and < 32	4
> 32 and < 40	6
> 40 and < 50	10
> 50 and < 63	16

Mains supply cable

Installation type	Line layout (minimum requirements)
Fixed installation	– Plastic sheathed cable (e.g. type NYM-J)
Flexible	– PVC flexible line (e.g. H05 VV-F) or – Rubber connection (e.g. H05 RN-F or H05 RR-F)

Control cable

Installation type	Line layout (minimum requirements)
Fixed installation	– Shielded sheathed cable (e.g. (N)YM (St)-J)
Flexible	– PVC data cable with shielded cable sheathing, as used for telecommunications and IT processing systems (e.g. type LiYCY) or – Lightweight PVC control cable with shielded cable sheathing

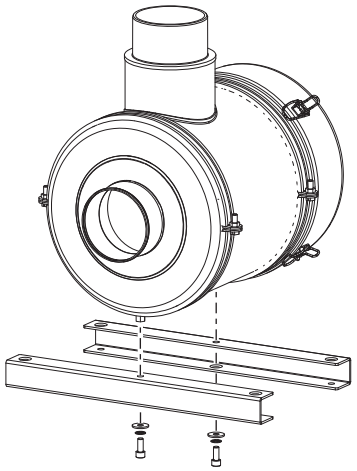
Connect the shielding of the cables in accordance with the regulations.

7 Installation

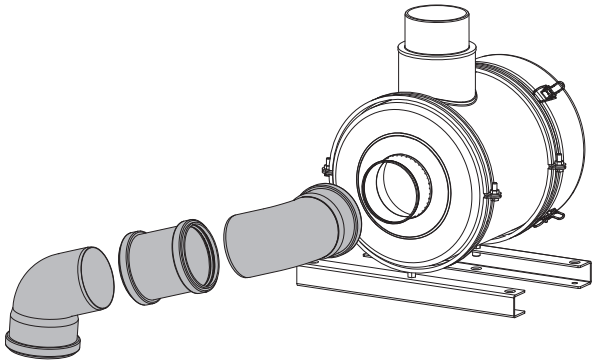
The actual connection can vary depending on the chosen installation option. The connection shown is only an example.

7.1 Installing the exhaust air filter

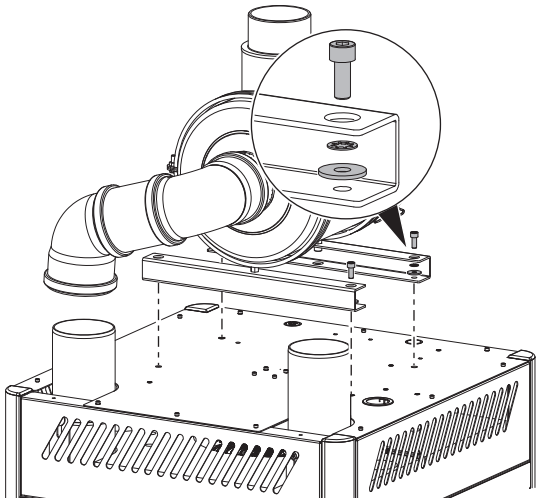
1. Install the exhaust air filter with screws and washers on U-shaped profiles.



2. Plug the elbows and the double sleeve together and then onto the connecting sleeve on the exhaust air filter.

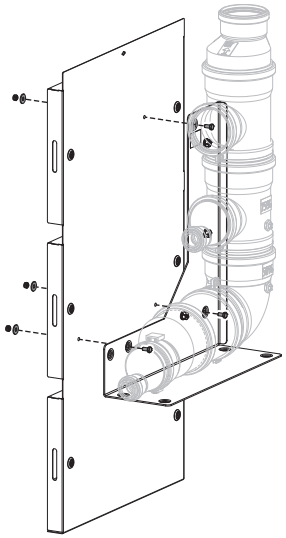


3. Plug the pipes with the exhaust air filter onto the exhaust air connection piece.
4. Position the U-shaped profiles above the threaded bushes.
5. Screw down the U-shaped profiles with screws and washers.

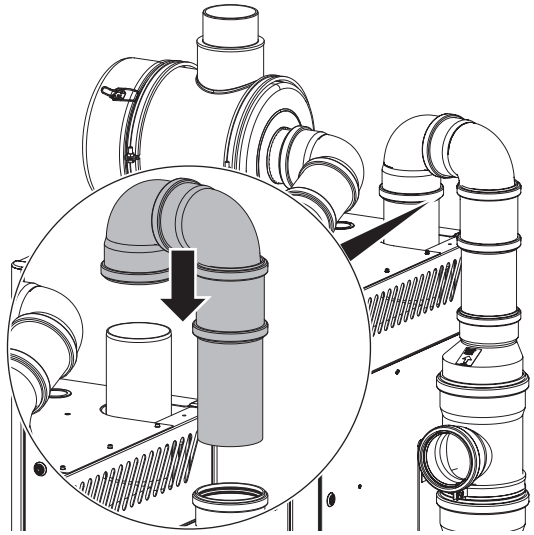


7.2 Dry suction system

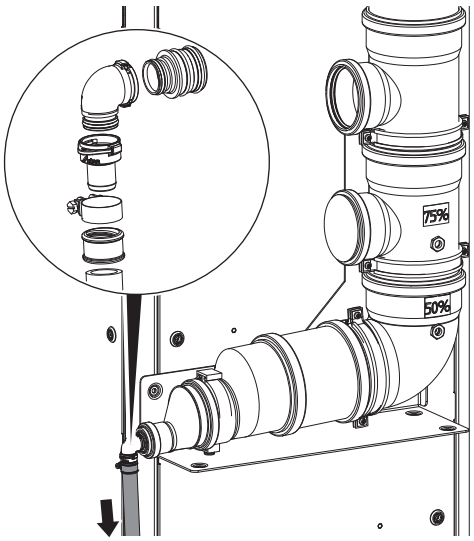
1. Position the suction unit at the intended installation location.
2. Use the adjustable feet to adjust the suction unit so that it is horizontal. In the process, make sure it has a secure and safe footing.
3. Remove the cladding on the rear side.
4. Mark the mounting holes as shown in the drilling plan.
5. Drill the mounting holes (ø 8,4 mm).
6. Punch out the insulation at the holes.
7. Firmly screw the condensation separator onto the cladding.



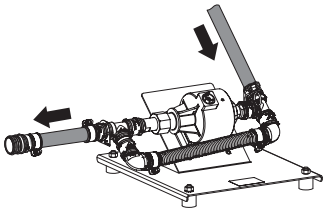
8. Attach the cladding with the condensation separator on the rear side.
9. Connect the suction unit and the condensation separator with high-temperature pipes.



10. Using DürrConnect parts, connect the condensate waste water hose to the waste water system of the condensation separator.

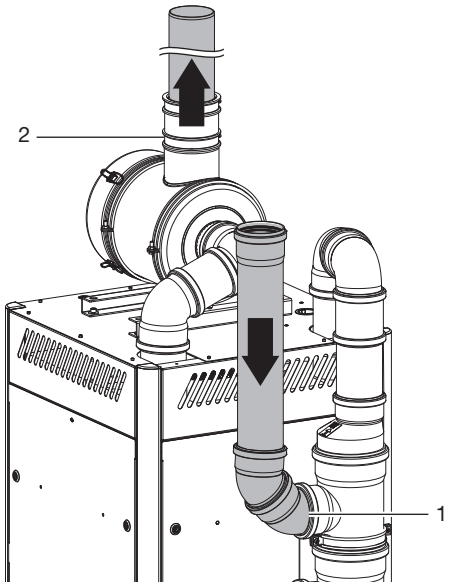


11. Connect the waste water hose of the condensation separator to the condensation pump.
12. Connect the waste water hose of the condensation pump with the building waste water system.



13. Route the suction pipe from the in-house installation to the suction unit and push it onto the suction connection.
14. Route the exhaust air pipe from the in-house installation to the suction unit and plug it onto the connection piece on the exhaust air filter.

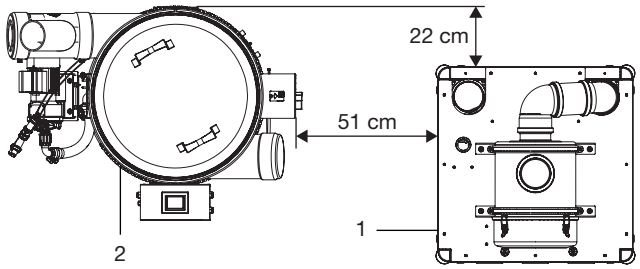
The exhaust air must always be directed out of the building into the open.



1 Suction connection
2 Exhaust air connection

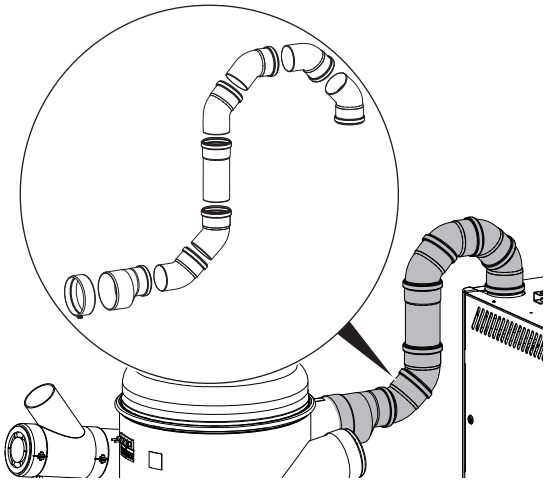
7.3 Semi-dry suction systems

1. Position the suction unit and the central separation tank at corresponding intervals in the intended installation location.



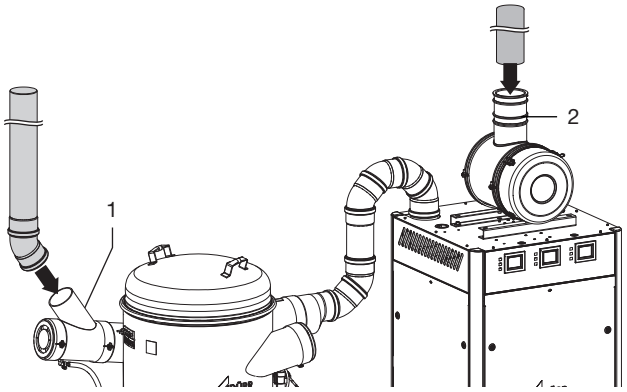
1 Suction unit
2 Central separation tank

2. Use the adjustable feet to adjust the suction unit so that it is horizontal. In the process, make sure it has a secure and safe footing.
3. Push together the high-temperature pipes.
4. Push the assembled pipe onto the suction connection on the suction unit.
5. Push the pipe clamp onto the suction connection piece on the central separation tank.
6. Route the high-temperature pipe to the suction connection piece on the central separation tank.
7. Position the pipe clamp and screw it firmly in place.



8. Route the suction pipe from the in-house installation to the central separation tank and push it onto the suction connection.
9. Route the exhaust air pipe from the in-house installation to the suction unit and plug it onto the connection piece on the exhaust air filter.

The exhaust air must always be directed out of the building into the open.

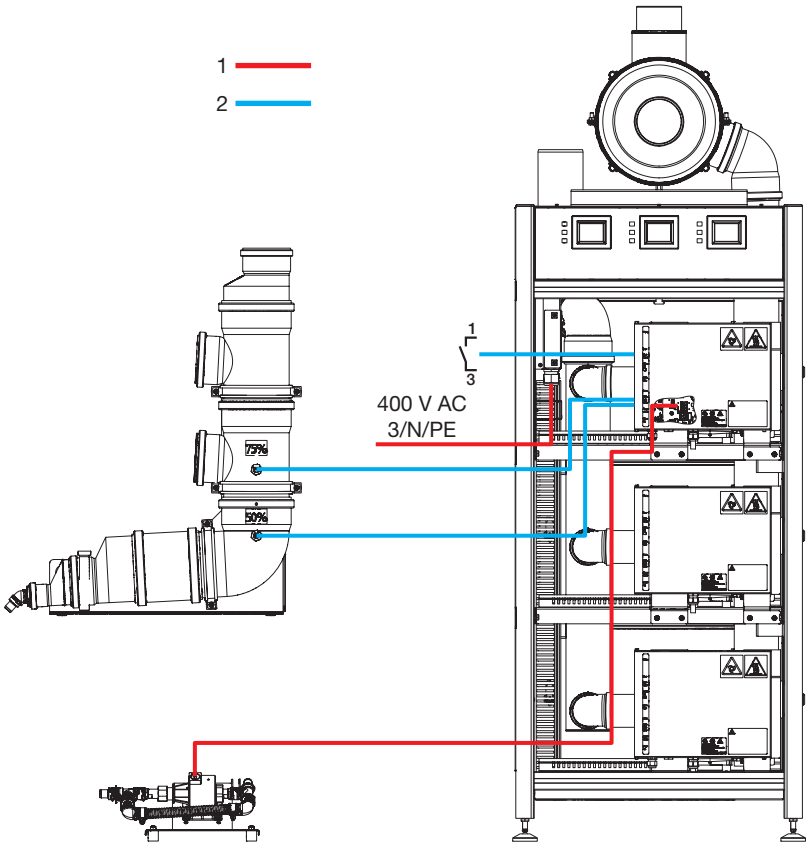


1 Suction connection
2 Exhaust air connection

8 Electrical connections

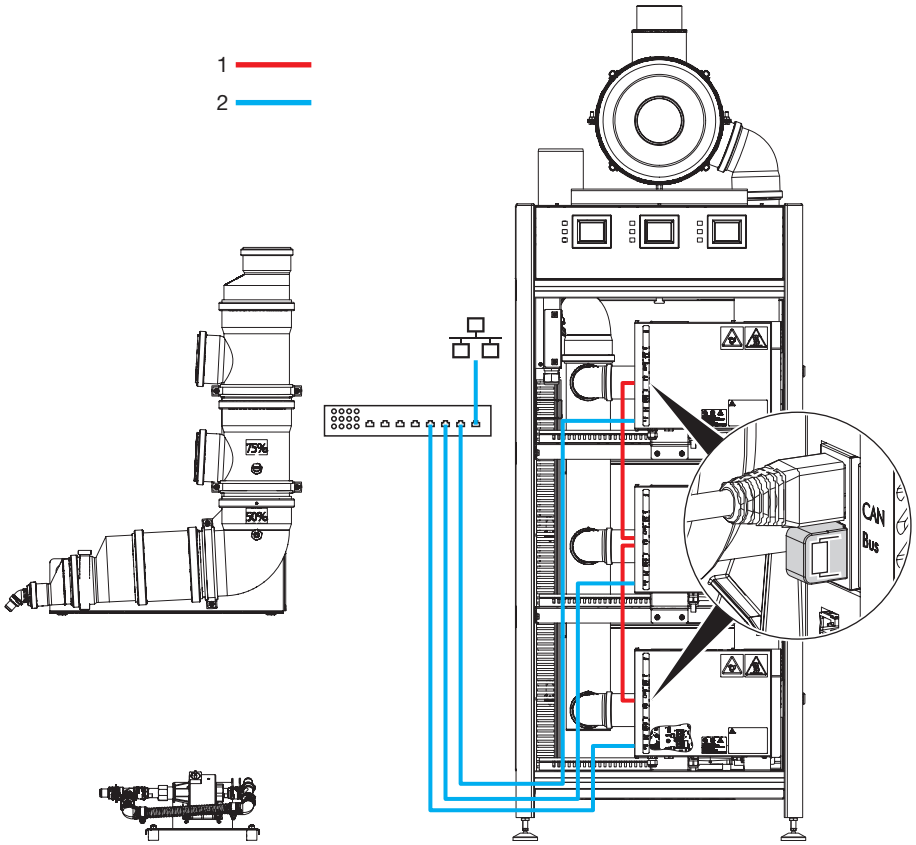
8.1 Connection overview – dry suction system

Power supply and control line



1 Power supply
2 Controller

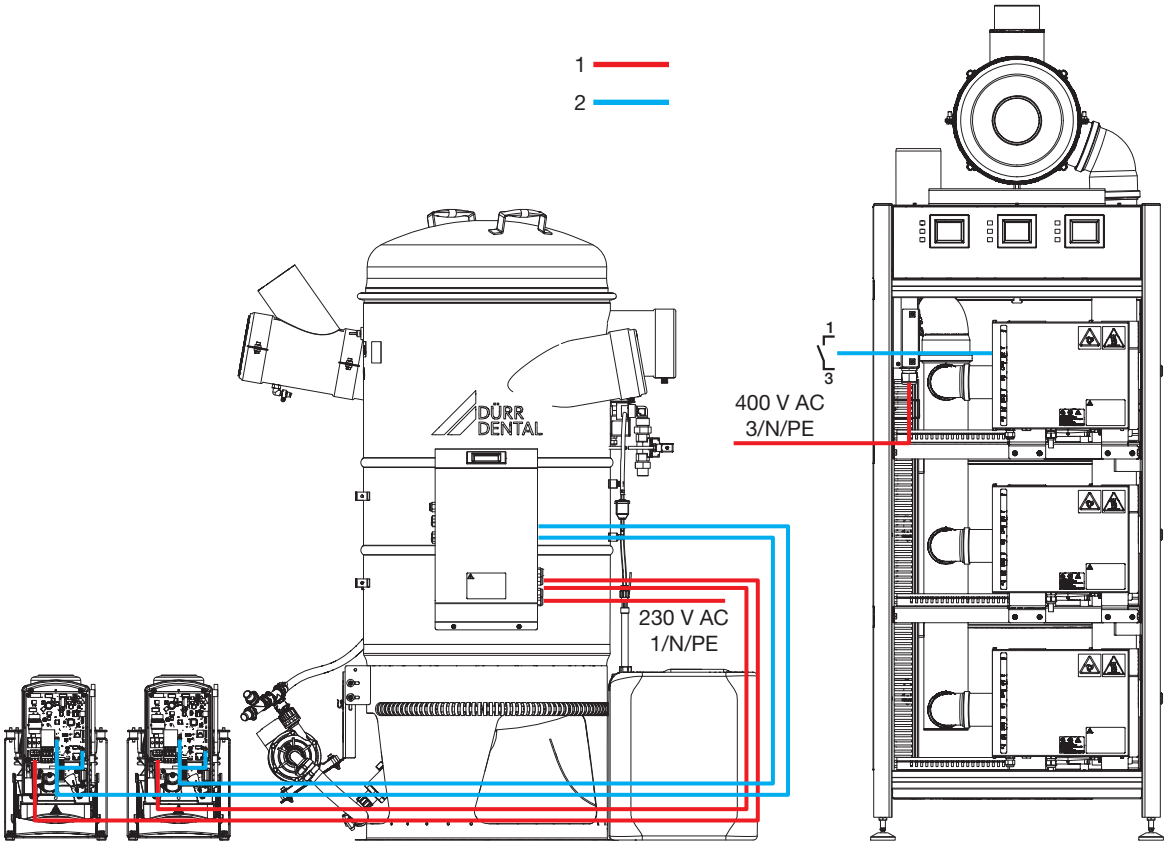
CAN bus and network



1 CAN bus
2 Network

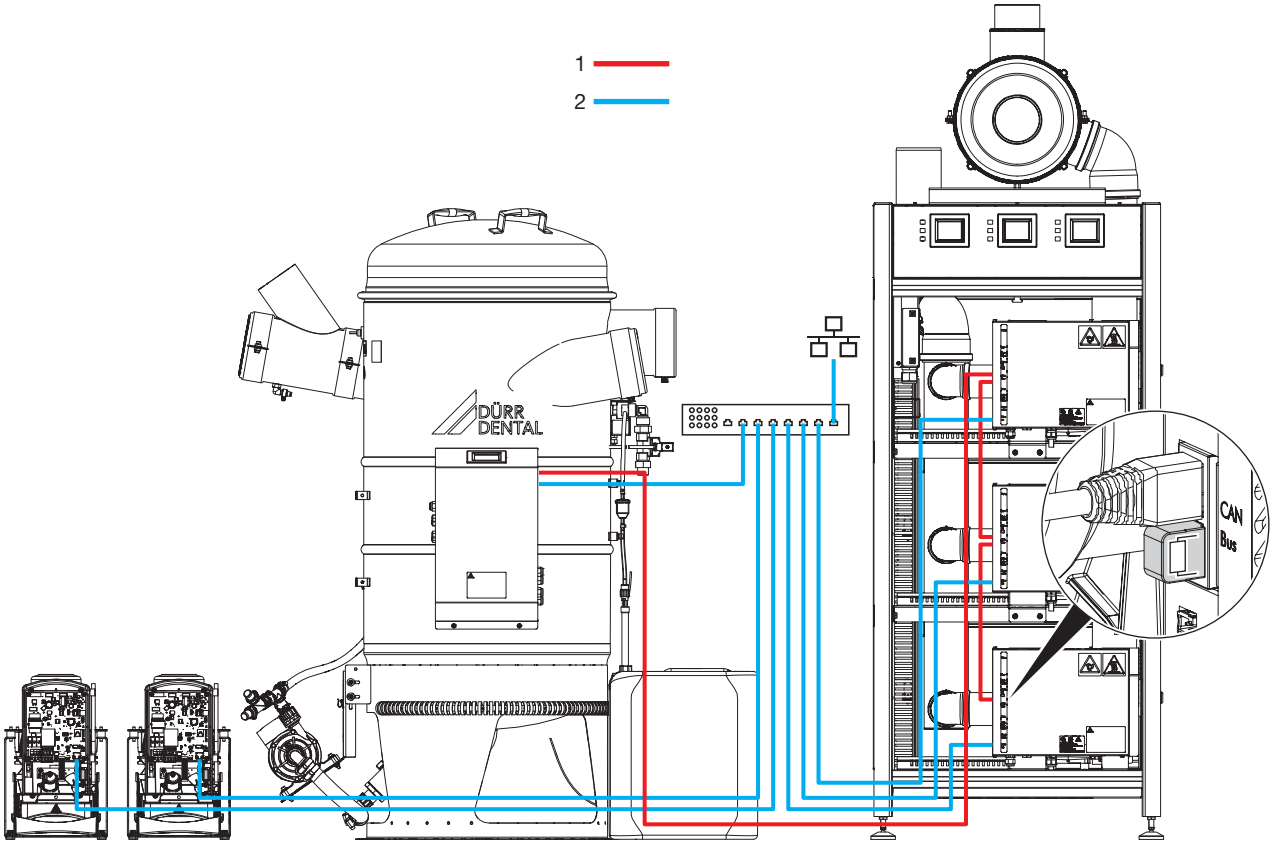
8.2 Connection overview – semi-dry suction system

Power supply and control line



1 Power supply
2 Controller

CAN bus and network



1 CAN bus
2 Network

8.3 Clinic suction system

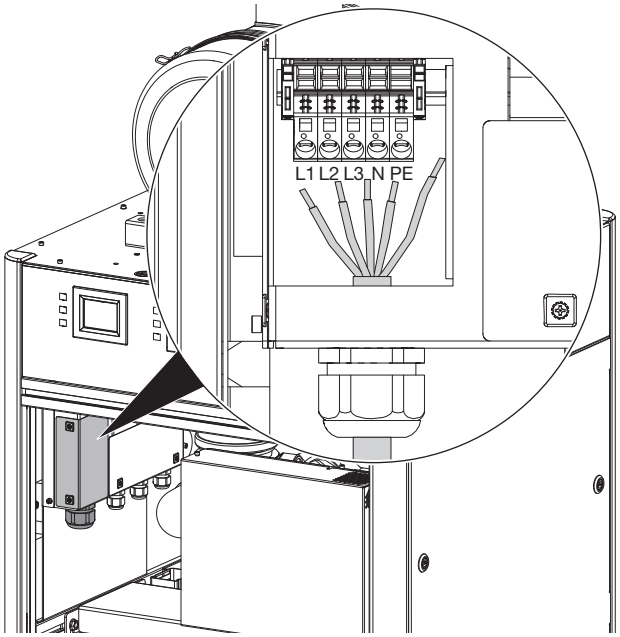
WARNING

Electric shock

› The device may only be connected to a supply system with a earthed power outlet.

For the installation, a main power switch must be available in the building installation that satisfies the requirements for the separation of medical devices from the mains power supply.

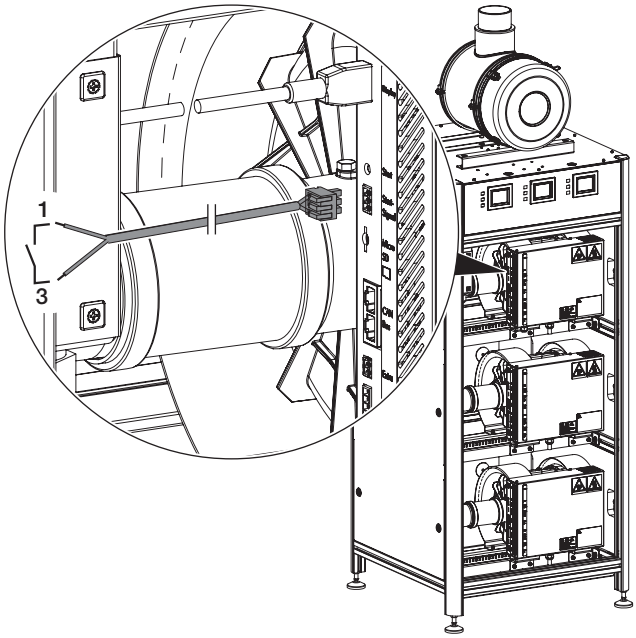
1. Remove the cover from the terminal box.
2. Route the mains supply cable into the unit and to the terminal box.
3. Guide the mains supply cable through the strain relief and tighten the strain relief.
4. Connect the mains supply cable to the corresponding terminals.
5. Close the cover on the terminal box.



8.4 Control cable

Keep the cable long enough so that it can be plugged into another device in the event of a fault.

1. Guide the control cable for starting the suction units into the unit and route it through the provided channels to the suction unit.
2. Fasten the plug socket to the control cable and connect it to the suction unit.



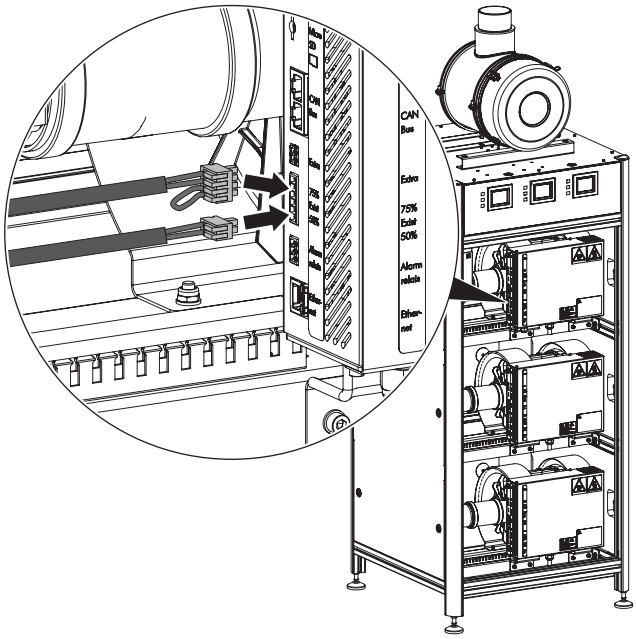
8.5 Condensate separator

Connect the power supply of the condensation pump and the float switch of the condensation separator to the same suction unit.

Keep the cable long enough so that it can be plugged into another device in the event of a fault.

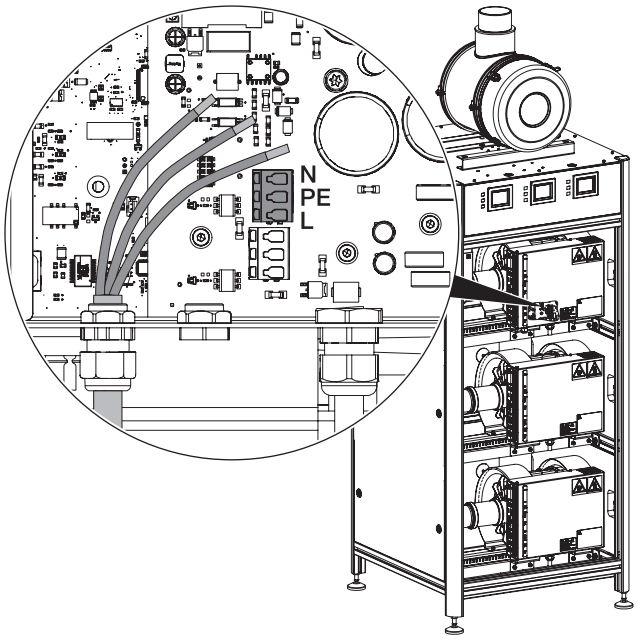
Float switch

1. Route the connecting cables of the float switches in the cable ducts to the suction unit.
2. Plug the connector of the float switches into the corresponding position on the suction unit.



Condensation pump

1. Remove the housing cover of the electronics.
2. Attach the cable gland to the electronics housing of the suction unit.
3. Guide the electric cable to the suction unit and through the cable gland.
4. Connect the stranded wire ends at the terminal strip X7 to N, PE and L.



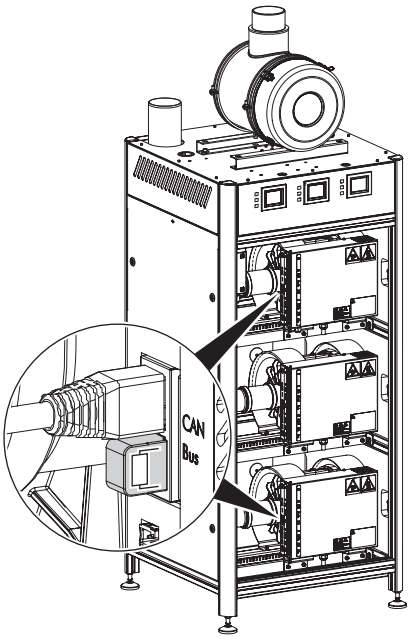
8.6 CAN bus

Purpose of the CAN bus connection

The CAN bus is used to enable mutual controlling and information exchange between the combined devices.

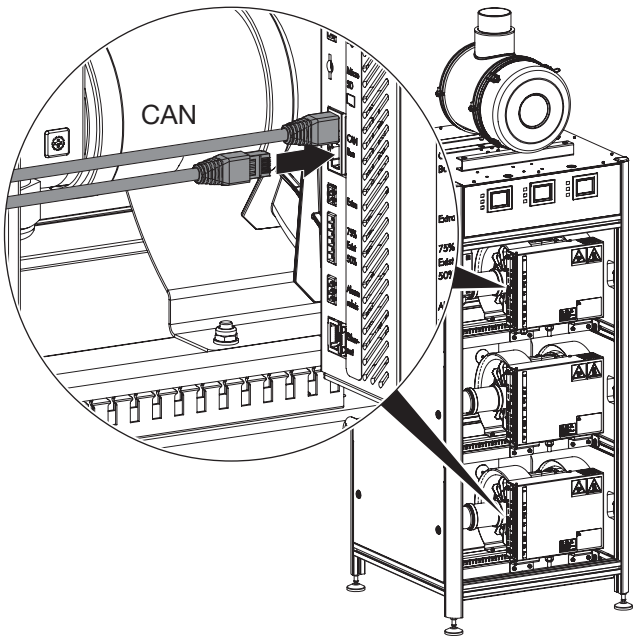
Terminating the CAN bus

For ideal operation of the CAN bus, it must be terminated at the first and last participants in the chain via a resistor. The resistor is located in a special RJ45 plug. If the suction system is extended, e.g. with a central separation tank, remove the corresponding RJ45 plug.



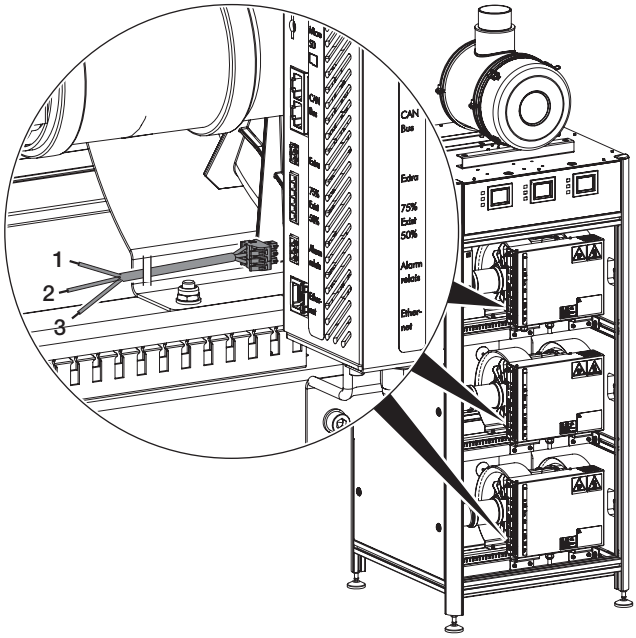
Keep the cable long enough so that it can be plugged into another device in the event of a fault.

1. Guide the patch cable into the unit and route it through the provided channels to the suction unit.
2. Plug the patch cable into a free CAN bus plug socket on the suction unit.



8.7 External fault display (optional)

Each suction system has a connection (Alarmrelais) with a relay for an external fault indicator. As long as the suction system is supplied with power and ready for operation, contacts 1 and 2 are connected (switch closed).



Alarm connection circuit diagram

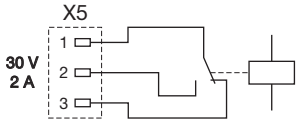


Fig. 1: Alarm relay in idle state, suction system de-energised

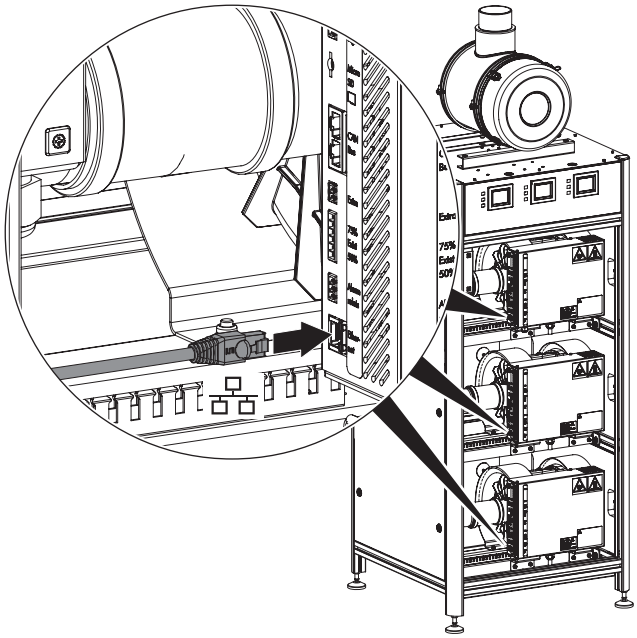
8.8 Network connection

Purpose of the network connection

The network connection is used to exchange information or control signals between the unit and a software installed on a computer, in order to, e. g.:

– Display parameters
– Select operating modes
– Indicate messages and error situations
– Change unit settings
– Activate test functions
– Transmit data for archiving
– Provide documents concerning the units

1. Plug the patch cable into the network plug socket on the suction unit.
2. Route the patch cable through the provided channels in the unit.
3. Route the patch cable to a network switch and plug it in there



9 Commissioning

In many countries technical medical products and electrical devices are subject to regular checks at set intervals. The owner must be instructed accordingly.

1. Turn on the unit power switch or the main surgery switch.
2. Carry out an electrical safety check in accordance with applicable local regulations (e.g. the German Ordinance on the Installation, Operation and Use of Medical Devices / Medizinprodukte-Betreiberverordnung) and record the results as appropriate, e.g. in the technical log book.
3. Carry out a functional inspection of the system and check the connections for leaks.
4. Attach and screw on the covers.
5. Carry out and document the instruction and handover for the unit.

A sample handover report is included in the attachment.

9.1 Setup wizard

A setup wizard is displayed on the touch screen when the device is started for the first time or after a firmware update. To ensure trouble-free operation, please follow the instructions displayed in the setup wizard.

9.2 Settings on the touch screen

Buttons

The buttons at the bottom edge of the screen can be used to switch between the different menus.

Switches to the menu *Settings*

Next — Switches between the two start screens (only when a device is configured as the "main unit")

Switches to the start screen

Switches to the next higher menu level

Changing to the Administrator user level:
In the display screen, use the *Settings* button to switch to the menu screen. Use the *Access Level* button to switch to the selection for *User*, *Administrator* and *Service Technician [PIN]*. Then tap *Administrator* and confirm. Afterwards use the *Main Menu* button to go back.

Selecting the operating mode

Depending on the installation, the operating mode (suction power) of the device can be adjusted. Before changing the operating type, the suction power should be checked at the cannulas.
The operating mode can be adjusted in the display screen by tapping the buttons *Eco*, *Balanced* or *Boost*. The selected operating mode is highlighted with a different colour.

Setting up the group settings

If two clinic suction systems are operated in combination, one system must be defined as tower 1 and the second system must be defined as tower 2. The devices must be connected to each other via CAN bus here. The group settings can only be adjusted from the user level *Administrator* or higher.

On delivery each device is preconfigured as tower 1.

Setting up the group settings:

To adjust the group settings, use the *Settings* button to change from the display screen to the menu screen. Then use the *Parameter* and *Tower number* buttons to go to the selection list. In the list choose whether the device is tower 1 or tower 2.

Setting the afterrun delay time

Depending on the installation, the lag time of the device can be adjusted. The lag time can only be adjusted from the user level *Administrator* or higher.

When operating devices as a group, always adjust the lag time on the main unit.

Adjusting the lag time:
To adjust the lag time, switch from the display screen to the menu screen via the *Settings* button. Then use the *Parameters* and *Lag Time* buttons to adjust the time. Tap the *Save* button to save the time.

9.3 Monitoring the unit via the network

The following requirements must be met in order to monitor the unit on the computer:
– Unit connected to the network
– Current monitoring software installed on the computer

Combining devices safely

– The overall safety of the unit and its main performance features are independent of the network. The device is designed for operation independent of a network. However, some of the functions are not available in this case.
– Incorrect manual configuration can lead to significant network problems. The expert knowledge of a network administrator is required for configuration.
– The data connection utilises part of the bandwidth of the network. Interactions with other medical devices cannot be completely ruled out. Apply the IEC 80001-1 standard for risk assessment.
– The device is not suitable for direct connection to the public Internet.

Network configuration

Various options are available for network configuration:

✓ Automatic configuration via DHCP (recommended).
✓ Automatic configuration via Auto-IP for direct connection of unit and computer.
✓ Manual configuration.

1. Configure the network settings of the unit using the software or, if available, the touch screen.
2. Check the firewall and release the ports, if applicable.

Network protocols and ports

Port	Purpose	Service
45123 UDP, 45124 UDP	Unit recognition and configuration	
502 TCP	Device data	
514[1)] UDP	Event log data	Syslog
23 TCP	Diagnosis	Telnet
123 UDP	Time	NTP

1) The port may vary depending on the configuration.

Usage

10 Operation

Once the system is switched on, the display will show the standard display. The navigation buttons can be used to jump to a different screen or to select further menu items for adjustment of the system. The menu structure is shown below in a table.

Changes to the settings of the system should only be made by properly trained personnel.

10.1 Overview on the touch screen

The buttons at the bottom edge of the screen can be used to switch between the different menus.

Switches to the menu *Settings*

Next — Switches between the two start screens (only when a device is configured as the "main unit")

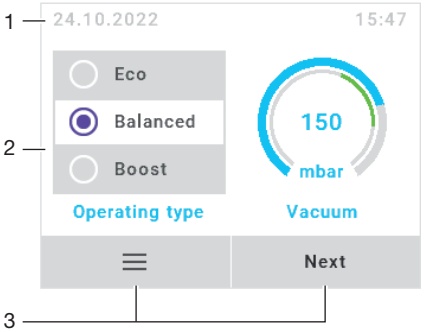
Switches to the start screen

Switches to the next higher menu level

10.2 "Home" screen

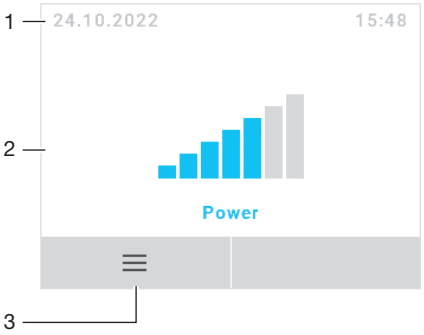
The selected operating mode and the current negative pressure are displayed on the Main Menu of the main unit. The operating mode can be changed by tapping one of the operating modes.
The *Next* button can be used to scroll to another page.
The power consumption is shown on the Main Menu of the auxiliary unit.

Main unit standard display



1 Context area (e. g. messages)
2 Content area
3 Navigation buttons

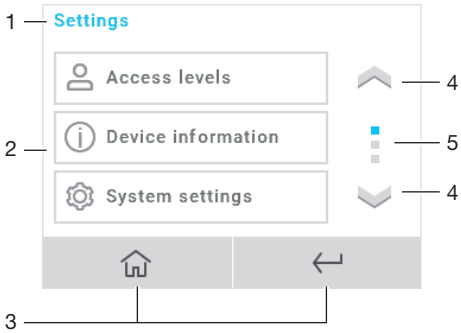
Auxiliary unit standard display



1 Context area
2 Content area
3 Navigation buttons

10.3 "Settings" display

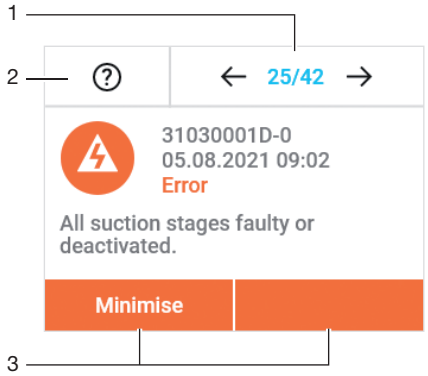
In the Settings screen you can query information and adjust settings.
To access the individual menu items, tap the relevant button. If there are multiple pages, the arrow buttons are used to scroll through the pages.



1 Title bar / submenus
2 Content area
3 Navigation buttons
4 Scroll button
5 Page indicator

10.4 "Messages" screen

Any incidents that occur in the unit are shown in the Messages screen. The messages can be confirmed by tapping the navigation button. The messages are then displayed in the context area of the Home screen until the incident has been remedied.



1 Scrolling between messages
2 Detailed information about the message
3 Navigation buttons

Severity of the messages:

Information

Note
Important information about the device

Notice
Operation of the device restricted

Fault
Operation of the device interrupted

11 Disinfection and cleaning

The following tasks are required for the disinfection and cleaning of the suction system:

"11.1 Suctioning water"	After every treatment
"11.2 Disinfection"	Daily in the evening after the end of treatment, With increased workloads, before the midday break and after the end of treatment
"11.3 Cleaning"	Allow to act for at least 2 x per week before the start of treatment or during the midday break Alternatively, 5 x per week, with short reaction times

NOTICE

Device malfunctions or damage due to use of incorrect media

Guarantee claims may become invalid as a result.

- Do not use any foaming agents such as household cleaning agents or instrument disinfectants.
- Do not use abrasive cleaners.
- Do not use agents containing chlorine.
- Do not use any solvents like acetone.

The following should always be used:

- For disinfection and cleaning:
  - Orotol plus
  - Orotol plus pH 7
- For cleaning:
  - MD 555 cleaner
  - MD 555 cleaner organic

Only these products have been tested by Dürr Dental.

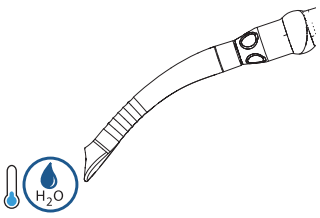
Comply with the instructions for use of the cleaning agent and disinfectant.

11.1 Suctioning water

After every treatment:

1. Suction up cold water (min. 0.5 litres) with the large and small suction hoses. Do this even if only the small suction hose was actually used during treatment.

Suction through the large suction hose causes a large amount of air to be drawn up, thereby considerably increasing the cleaning effect.



11.2 Disinfection

Disinfect and clean the suction system every evening after the end of treatment.

With increased workloads, clean and disinfect twice per day, e.g. before the midday break and after the end of treatment.

The following is required for the disinfection and cleaning of the suction system:

Non-foaming disinfectant/cleaning agent that is compatible with the materials
- Orotol plus
- Orotol plus pH 7

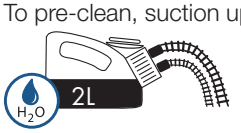
care system
- e.g. OroCup

Disinfection and cleaning are described below with OroCup and Orotol plus.

Wear protective gloves.

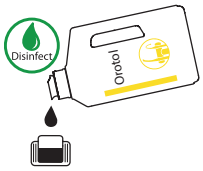
Wear protective goggles.

1. To pre-clean, suction up 2 litres of water with the care system.

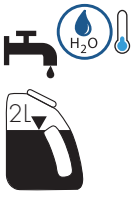


Using the solution in the care system:

1. Pour 2 sealing caps (40 ml) of Orotol plus into the OroCup.



2. Fill the OroCup with 2 litres of cold water.



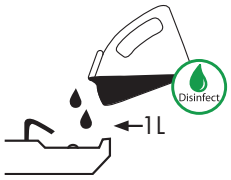
3. Close the lid of the care system.

4. Mix the solution.

Using the solution:

1. Attach suction hoses to the care system and suction up 1 litre of solution.

2. Pour the remaining solution into the spittoon.



3. Allow to work for a minimum of one hour or leave overnight.
4. When placing the system back into operation, suction up 2 litres of water.

The instructions are also available as a video:

11.3 Cleaning

Clean the suction system regularly:
– Allow to act for at least 2 x per week in the morning before the start of treatment or during the midday break, reaction time 30–120 minutes
– Alternatively: 5 x per week before the start of treatment, reaction time 5–15 minutes

The following is required for cleaning the suction system:

Special non-foaming detergent for suction systems that is compatible with the materials
– MD 555 cleaner
– MD 555 cleaner organic

care system
– e.g. OroCup

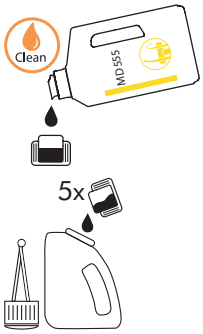
Cleaning is described below with OroCup and MD 555 cleaner.

Wear protective gloves.

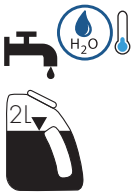
Wear protective goggles.

1. To pre-clean, suction up 2 litres of water with the care system.

2. Use the solution in the care system.
Pour 5 caps (100 ml) of MD 555 cleaner into the care system.



3. Fill the OroCup with 2 litres of cold water.



4. Close the lid of the care system.

5. Mix the solution.

6. Attach suction hoses to the care system and suction up one litre of solution.

7. Pour the remaining solution into the spittoon.

8. Allow the solution time to act.
   For 2 x per week: 30–120 minutes
   For 5 x per week: 5–15 minutes

9. Suction up 2 litres of water after the reaction time has elapsed.

The instructions are also available as a video:

12 Maintenance

All maintenance work must be performed by a qualified expert or by one of our Service Technicians.

WARNING
Infection due to contaminated unit
› Clean and disinfect the suction before working on the unit.
› Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Prior to working on the unit or in case of danger, disconnect it from the mains.

12.1 Clinic suction system

Maintenance interval	Maintenance work
12 months	› Inspection of the nonreturn valves on the exhaust air side of the suction units, replacement as required › Inspection of the nonreturn valve upstream the suction unit, replacement as required
24 months or 3500 hours	› Replacement of the filter cartridge of the exhaust air filter

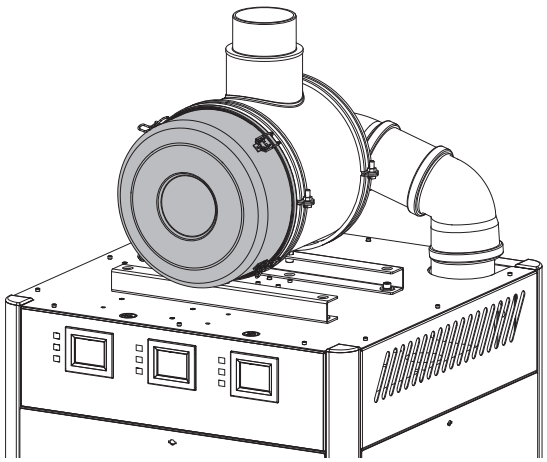
12.2 Condensate separator

Maintenance interval	Maintenance work
12 months	› Inspection of the condensation separator › Check and clean the level switch in the condensation separator, replacement as required › Check and clean the filter upstream of the condensation pump › Check the nonreturn valves of the condensation pump, replacement as required

12.3 Change the filter cartridge of the exhaust air filter

Wear protective equipment to avoid any risk of infection (e.g. liquid-tight protective gloves, protective goggles, face mask).

1. Release the four clamps on the lid of the exhaust air filter.
2. Remove the cover.
3. Pull out the cartridge.
4. Insert a new cartridge in the filter housing.
5. Position the lid and fasten it with the clamps.



Troubleshooting

13 Tips for operators and service technicians

Any repairs exceeding routine maintenance may only be carried out by qualified personnel or our service.

WARNING
Infection due to contaminated unit
› Clean and disinfect the suction before working on the unit.
› Wear protective equipment when working (e. g. impermeable gloves, protective goggles and mouth and nose protection).

Prior to working on the unit or in case of danger, disconnect it from the mains.

DANGER
Electric shock due to capacitor discharge
› Wait for the discharge time.
› Watch for the LEDs going out.

Error	Possible cause	Remedy
Device does not start	No mains voltage	› Check the mains supply voltage. * › Check the fuses and replace if necessary. *
	Undervoltage	› Measure the supply voltage; call an electrician if necessary. *
	Control electronics defective	› Replace the electronics. *
Suction performance too low	Leak in the suction pipe	› Check and if necessary establish leak-tightness of suction pipe and connections. *
	One radial blower defective	› Replace the radial blower. *
	Membrane valve defective	› Check the membrane valve at the waste water connection and if necessary clean or replace.
No suction power	Radial blower defective	› Activate emergency mode by confirming the alarm message. › Replace radial blower. *
	Controller defective	› Replace the controller. *
	Main unit defective in group	› Take the defective main unit out of operation and reconfigure an auxiliary unit as the main unit.
Nothing shown on the display	Cable defective or not connected	› Check the cable connection and replace the cable if necessary. *
	Display defective	› Replace the display. *
Display does not respond to touches	Display not calibrated	› Calibrate the display. – Disconnect and reconnect the mains plug. Within 8 seconds of the device being started, start the calibration process with a long press (5 s) on the display. Follow the instructions on the display.
	Display defective	› Replace the display. *

* Only to be done by service technicians.

13.1 Vorgehen bei defektem Hauptaggregat

In the case of a fault or defect in the main unit of the suction system, proceed as follows.

1. Check whether the circuit breaker of the main unit on the distribution box has tripped. If the circuit breaker has not tripped, switch it off.
2. Reconnect connections (e.g. control line, condensate separator, CAN bus, etc.) to an auxiliary unit.
3. Set the auxiliary unit as the main unit in the menu on the touchscreen.
4. Repair or replace the defective unit.
5. Restore the initial state.

Appendix

14 Menu structure

Start screen	*Operating mode, vacuum*			
	Output			
Settings	Access levels	Operator		
		Administrator		
		Service Technician [PIN]	XXXXXX	
	Device information	Device data	REF	
			SN	
			Firmware	2.0.x
			Library version	
			PCB serial number	
			File	
		Device usage data	Operating hours	
			Number of starts	
	System settings	Language	Deutsch, English, . . .,	
		Date, time [1]	Automatic	
			Date	DD MM YYYY
			Time	HH MM
			Time zone	UTC
		Network [1]	DHCP	
			IP address	
			Netmask	
			Gateway	
			MAC	
		Factory settings [2]	Delete message history	
	Parameters [1]	Main / auxiliary unit	Main unit	
			Auxiliary unit	
		Tower number	Tower 1	
			Tower 2	
		Unit position	Top	
			Middle	
			Bottom	
		Lag time [3]	XX s	
		System selection[3]	Semi-dry system	
			Dry system	
	Message history [1]	List of alarms	Alarm information	
	Maintenance[3]	Waste valve maint.	Maintenance completed	
		Exhaust filter maint.	Maintenance completed	

1 only as Administrator
2 only as Service Technician
3 only as Administrator and only on the main machine

15 Handover record

This document confirms that a qualified handover of the medical device has taken place and that appropriate instructions have been provided for it. This must be carried out by a qualified adviser for the medical device, who will instruct you in the proper handling and operation of the medical device.

Product name	Order number (REF)	Serial number (SN)

- ☐ Visual inspection of the packaging for any damage
- ☐ Unpacking the medical device and checking for damage
- ☐ Confirmation of the completeness of the delivery
- ☐ Instruction in the proper handling and operation of the medical device based on the operating instructions

Notes:

Name of person receiving instruction:	Signature:

Name and address of the qualified adviser for the medical device:

Date of handover:	Signature of the qualified adviser for the medical device:

16 Country representatives

Country		Address
GB	UKCA XXXX	**UK Responsible Person:** Duerr Dental (Products) UK Ltd. 14 Linnell Way Telford Way Industrial Estate Kettering, Northants NN 16 8PS
UA	UA.TR.099	**Уповноважений представник в Україні:** Приватне підприємство “Галіт” вул. 15 квітня, 6Є, с. Байківці, Тернопільський р-н, 47711, Україна тел.: 0800 502 998; +38 050 338 10 64 www.galit.te.ua; e-mail: office@galit.te.ua Виробник: Дюрр Дентал ЕсЕ Хьопфігхаймер Штрассе 17, Д-74321 Бітігхайм-Біссінген, Німеччина email: info@duerrdental.com

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