Tyscor VS 2 Plus / VS 4

EN Installation and operating instructions

CE 0297

DÜRR DENTAL

71881000021L02 2403V007

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

http://qr.duerrdental.com/7188100021

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 VS 2 Plus
REF: 7188200100
Tyscor VS 4
REF: 7188100100

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

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.


Wear protective gloves.


Disconnect all power from the unit.


Refer to the accompanying electronic documents.

Comply with the lower and upper temperature limits

Comply with the lower and upper humidity limits

CE labelling with the number of the notified body

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

Authorised representative for Switzerland

Order number

Serial number

Medical device

Health Industry Bar Code (HIBC)


Manufacturer


Fragile, handle with care


This way up / store and transport in an upright position


Keep dry


Keep away from sunlight


Stacking limits

1.2 Copyright information

All circuits, processes, names, software programs and units mentioned in this document are protected by copyright.
The Installation and Operating Instructions must not be copied or reprinted, neither in full nor in part, without written authorisation from the copyright owner.

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.
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

- 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 Combining devices safely

Take care when connecting units together or to parts of other systems as there is always an element of risk (e.g. due to leakage currents).

- Only connect units when there can be no question of danger to operator or to patient.
- Only connect units when it is safe to do so and when there is no risk of damage or harm to the surroundings.
- If it is not completely clear from the data sheet of the unit that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the relevant manufacturer) to verify that the setup is safe.

Where applicable, the requirements for medical products have been taken into account in the development and construction of the device. As a result, this device is suitable for installation within medical supply equipment.

- Where this device is integrated in other medical supply equipment, the requirements of European Union Medical Device Regulation 2017/745 and the relevant standards must be observed.

2.6 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.

The following groups are not permitted to operate or use a commercially operated unit:

- People without the necessary experience and knowledge
- People with reduced physical, sensory or mental capabilities
- Children

Installation and repairs

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

2.7 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.

2.8 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.

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.

If required, the original packaging for the unit can be ordered.

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 in its original packaging.
– 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.

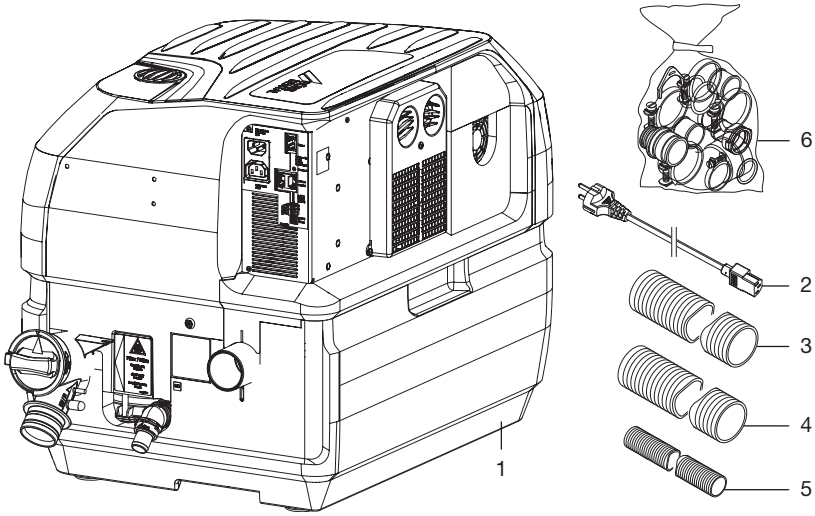
– Decontaminate potentially contaminated parts before disposing of them.
– Uncontaminated parts (e.g. electronics, plastic and metal parts etc.) should be disposed of in accordance with the local waste disposal regulations.
– If you have any questions about the correct disposal of parts, please contact 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 Combination suction unit
2 Mains cable with local mains plug
3 Hose LW 50, 1.5 m
4 Hose LW 50, 0.6 m
5 Waste water hose LW 20
6 Set of connection fittings

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 VS 4 7188100100
Tyscor VS 2 Plus 7188200100

– Combination suction unit
– Mains cable
– Hose LW 50 (0.6 m)
– Hose LW 50 (1.5 m)
– Waste water hose LW 20
– Set of connection fittings
– OroCup
– Short information

3.2 Optional items

The following optional items can be used with the device:

Wall bracket 7188100015
Bacteria filter 0705-991-50
Noise reduction for exhaust air . . . 0730-991-00
Rinsing unit conversion kit for Tyscor 7186100400
Flow accelerator 7560-992-00
Screed frame for flow accelerator . 7560-993-00
Surge tank 7130-991-51
Bracket for floor-mounted installation 7188100017
Radial blower 7188100060
Upgrade kit 7188100075
Installation set for Tyscor V/VS Tandem 7188100300

3.3 Consumables

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

Orotol plus (2.5 litre bottle) CDS110P6150
MD 555 cleaner (2.5 litre bottle) . CCS555C6150

3.4 Wear parts and replacement parts

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

If the mains cable of this unit is damaged it must only be replaced by an original mains cable from the manufacturer.

4 Technical data

Electrical data		7188100100	7188200100
Rated voltage	V	230, 1~	230, 1~
Mains frequency	Hz	50 / 60	50 / 60
Nominal current	A	6.2	
Rated power	kW	1.4	
Fuses		2x T 10.0 AH / 250 V~ (IEC 60127-2)	
Type of protection		IP 21	
Protection class		I	

Control connection electrical data		
Output: Voltage Max. current	 V DC mA	 24 160
Input impedance	kΩ	6.9
Hi level	V	10-30
Lo level	V	0-2.5

Electrical data for connection of the rinsing unit		
Voltage	V DC	24
Max. current	mA	300

Connections		
Vacuum connection (external)	mm	∅ 50
Exhaust air connection (external)	mm	∅ 50
Waste connections (DürrConnect)	mm	∅ 20

Media			
Max. number of users		4	2
Max. rate of flow of fluids	l/min	20	
Max. suction height	cm	80	

Classification in accordance with EN ISO 10637		
Classification based on separation of solids and liquids		Semi-dry suction system
Classification based on flow rate		Type 1

General data		
Radial blower speed (n_v) max.	rpm	24000
Separation stage speed (n_s)	rpm	2780 / 3170
Duty cycle	%	100
Rate of heat generation	kW	1.4

General data			
Dimensions (H x W x D)	cm	51 x 45 x 69	
Weight	kg	24	24
Noise level * ca.	dB(A)	61 / 64	61 / 64

* Noise level in accordance with ISO 3746

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

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

Ambient conditions during operation		
Temperature	°C	+10 to +40
Relative humidity	%	< 70
Altitude above mean sea level	m	< 2000

Classification	
Medical Device Class (MDR)	IIa

4.1 Characteristic curves

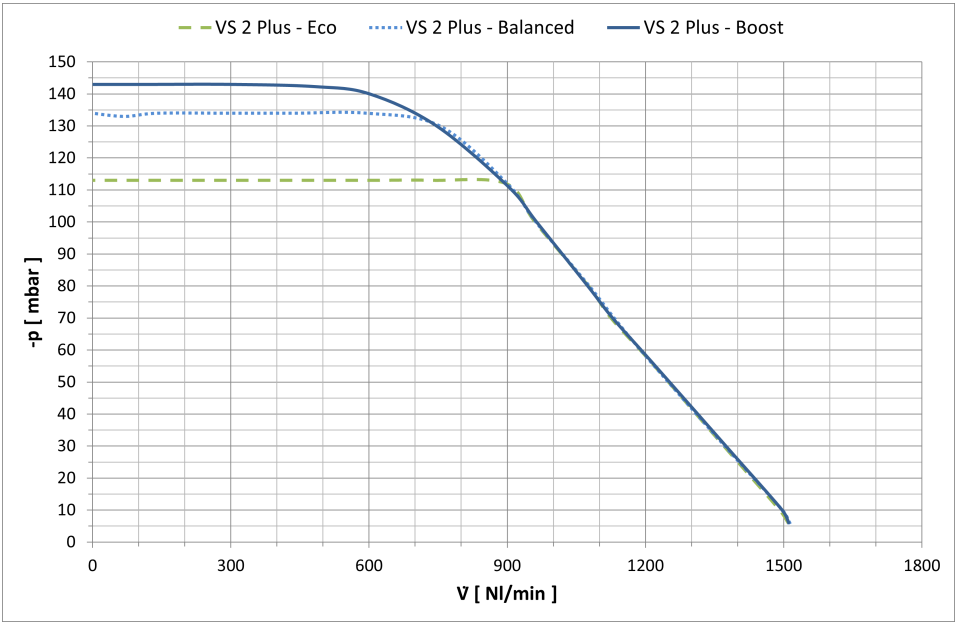


Fig. 1: Characteristic curves for 7188200100, measured in accordance with ISO 10637

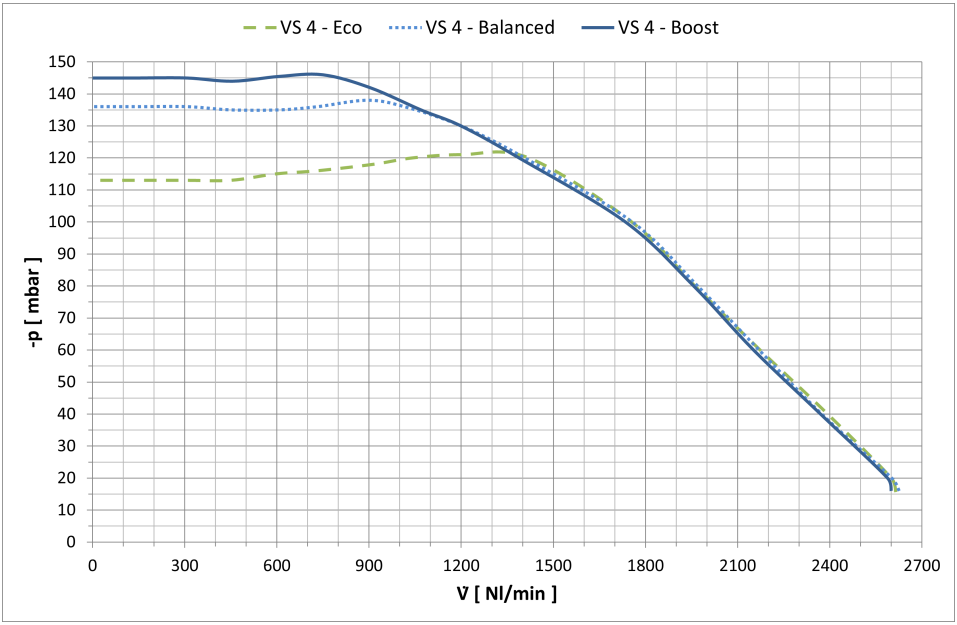
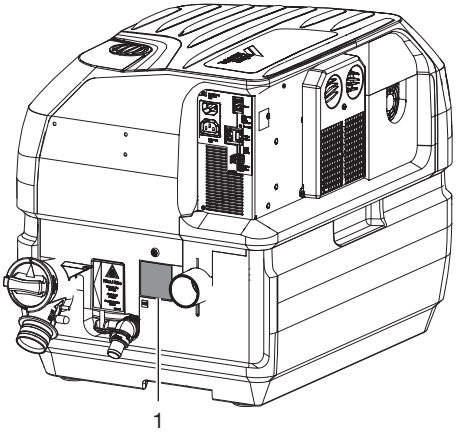


Fig. 2: Characteristic curves for 7188100100, measured in accordance with ISO 10637

4.2 Type plate

The type plate can be found on the housing lower part.

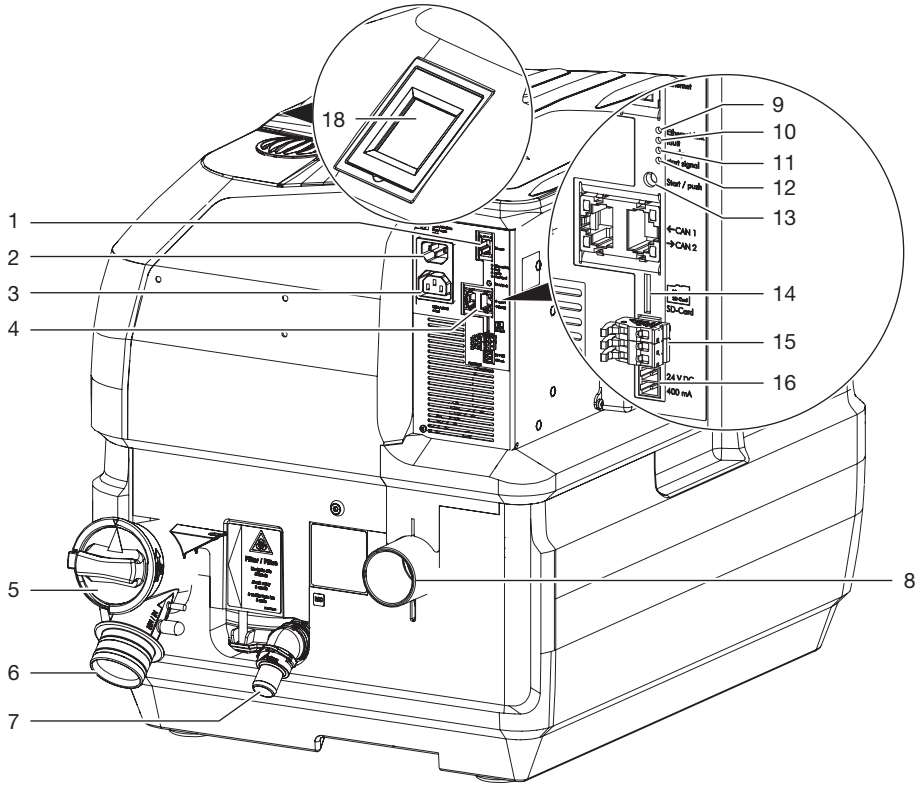


1 Type plate

4.3 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 Operation



1 Network connection
2 Mains connection (power plug)
3 Connection to amalgam separator (appliance power inlet)
4 CAN bus
5 Protective strainer
6 Inlet connection
7 Waste water connection
8 Exhaust air connection
9 Orange LED – Ethernet
10 Red LED – fault
11 Green LED – ready for operation
12 Blue LED – start signal
13 Manual start button
14 SD card slot (Micro SD)
15 Control connection
16 Voltage supply for the rinsing unit
18 Touch screen

The VS suction unit is used in "wet" suction systems. The device contains two radial blowers and a separation system. The radial blower and the separation system are each driven by their own motor.

5.1 Separation system

In the separation system the aspirated fluids and the solid particles are separated from the suction air. The separation system has two stages. It consists of a cyclonic separator and a separation turbine. The suction process runs continuously.

Stage 1:

The mixture drawn in, consisting of fluids, solid particles and air, passes through the inlet connection into the device. The coarse filter holds back the solid particles. The rest of the mixture passes to the cyclonic separator, where it is set into a spiral motion. In the first stage the resulting centrifugal forces force the fluid constituents and any remaining solid particles against the outside wall of the separation chamber of the cyclonic separator. This initially creates a coarse separation of the fluid waste.

Stage 2:

The subsequent second stage comprises a separation turbine. Fine separation takes place in the separation turbine, where the remaining fluid is separated out.

The waste water pump in the separation system feeds the fluid together with the finer solid particles through the waste water system connection into the central waste water network.

5.2 Radial blower

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.

The antibacterial treatment of the surfaces of the radial blower with silver phosphate glass helps impede the growth of bacteria for a hygienic surface of the components.

5.3 LEDs

- The orange-coloured LED lights up when the unit is connected to the network.
- The red LED lights up when there is a fault.
- The green LED lights up continuously when the unit is ready for operation.
- The blue LED lights up when a "start" signal is present from the treatment unit.

EcoStop:

- Green LED flashes. The unit has been switched off by the EcoStop function. To switch it on, lift a suction hose up out of the hose manifold or briefly disconnect the power supply from the unit.

5.4 Operating modes

Three different operating modes are available for Tyscor V/VS 2 Plus and Tyscor V/VS 4. 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 Quick Start

The Quick Start function is used to hold the unit in standby mode for a certain length of time, which ensures fast availability of the suction flow when required. Since the motor remains switched on at a very low speed when the unit is in standby mode, this option consumes slightly more energy.

5.6 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.

5.7 Eco Stop

The Eco Stop function is used to protect the unit if it is operated inadvertently with no flow rate or with a flow rate that is too low. If the unit is operated under these conditions without the manifold signal being actuated in the mean time, the unit will switch off automatically after a pre-defined period of time (it is possible to set this up so that it can be adjusted via the monitoring software). To switch it on, lift a suction hose up out of the hose manifold or briefly disconnect the power supply from the unit.

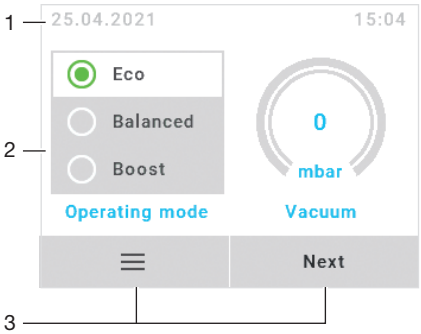
5.8 Grouping of multiple devices

Up to three devices can be operated together as a group. Here, one device takes on the role of the main unit (main unit), which can control up to two further devices (auxiliary units). 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 device is permitted to be configured as the main unit; additional devices must be configured as auxiliary units.

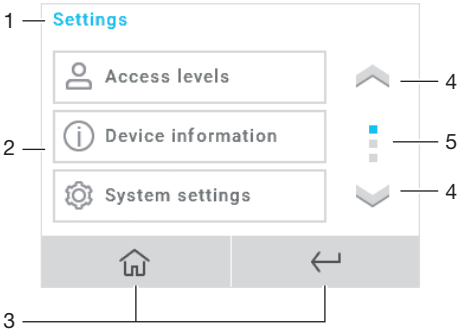
5.9 Overview of the touch screen user interface

Display window



1 Context range (e.g. date, time)
2 Content area
3 Navigation buttons

Menu window



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

Assembly

6 Requirements

The unit can be installed on the same level as the surgery room or in a floor below.

Further information can be found in our suction planning information leaflet.
Order number9000-617-03/..

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)
- When installing in a cabinet the inlet and outlet ventilation slots must be present; minimum free cross-section at least 120 cm^2.
- Forced ventilation (fan) must be provided if there is a risk that the recommended room air temperature could be exceeded. The air flow performance must be at least 2 m^3/min.
- Do not cover cooling slots or openings with housing installations; ensure sufficient clearance to the openings to permit sufficient cooling.
- Mains cable plug connections must be freely accessible so they can be quickly disconnected if there is any danger.

6.2 Setup options

The following options for setting up the unit are available:
- On the floor with a console for floor-mounted installation
- Wall installation using a Dürr Dental wall mounting
- In a ventilated cabinet

6.3 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).

6.4 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

1. Ensure that electrical connections to the mains power supply are carried out in accordance with current valid national and local regulations and standards governing the installation of low voltage units in medical facilities.
2. Observe the current consumption of the devices that are to be connected.

6.6 Information about connecting cables

Mains supply cable

Only use the supplied mains cable to connect the device.

Control cable

Installation type	Line layout (minimum requirements)
Fixed installation	– Shielded sheathed cable (e.g. (N)YM (St)-J)

Installation type	Line layout (minimum requirements)
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 System components

The system components listed below are required or recommended for various procedures or for installation.

7.1 Rinsing unit

It is recommended that the suction system is equipped with a rinsing unit, e.g. in the treatment unit. The rinsing unit provides a small amount of water during aspiration. This dilutes the aspirated fluids (blood, saliva, rinsing water etc.), which can then be transported more effectively.

7.2 Exhaust air filter / bacteria filter

For hygienic reasons, we recommend the installation of a bacteria filter in the exhaust air line. If the unit is installed in the surgery and the exhaust air cannot be discharged to the outdoors, it is essential to install a bacteria filter. Depending on the type and condition of the bacteria filter, it will need to be replaced every 1-2 years at the latest.

The separation integrated in the system does not retain bacteria; this is why we recommend installing a suitable filter in the exhaust air system.

7.3 Noise reduction

If the noise level from the exhaust air vent or the flow noise generated is too high, noise reduction can be installed in the exhaust air line.

7.4 Surge tank

If the suction unit is combined with an amalgam separator, this requires the installation of a surge tank. The surge tank reduces pressure peaks caused by the waste water pump of the suction unit and acts as a buffer against temporary rises in the volume of water.
The surge tank can also be used if the waste water is fed directly into the building waste water system. this case the waste water from the suction unit is diverted to the building drainage system under zero pressure.

7.5 Flow accelerator

In order to keep the suction system free of deposits, a flow accelerator can be fitted in conjunction with a spittoon valve. When using a bowl rinse system, water will collect before the flow

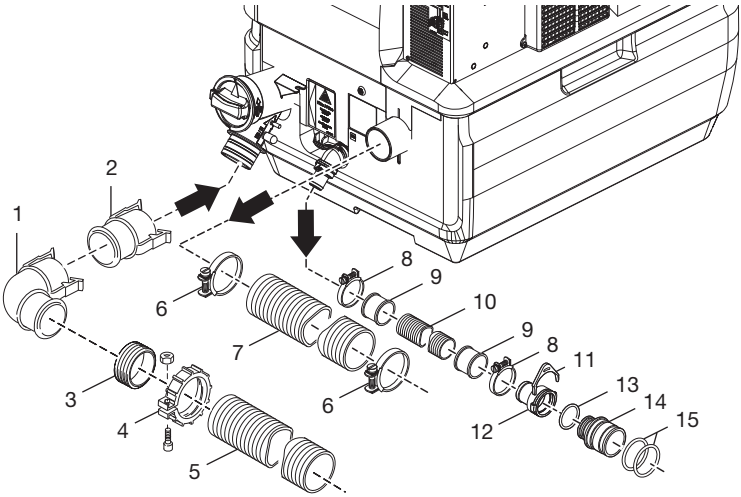
accelerator. The next time suction takes place using the large cannula, the collected fluid is transported in surges and at high speed to the suction system. This ensures automatic cleaning of the suction pipes.

8 Installation

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

8.1 Installation and routeing of hoses and pipes

– Establish connections between the pipe system and the unit using the flexible hoses supplied. This will prevent vibrations from being transmitted to the pipe system.
– The connection between the pipe line and unit suction connection should be kept as short as possible and straight, without bends.
– Install the drain hoses with a downward gradient so that the waste water can drain off.
– Waste water connections must be implemented in accordance with applicable local and national regulations.



1 Curved adaptor bush
2 Straight adaptor bush
3 Sealing sleeve
4 Union nut
5 Suction hose ∅ 50 mm (internal)
6 Hose clamp ∅ 55 mm
7 Exhaust air hose ∅ 50 mm (internal)
8 Hose clamp ∅ 28 mm
9 Hose sleeve
10 Waste water hose ∅ 20 mm (internal)
11 Securing ring
12 Hose sleeve ∅ 20 mm
13 O-ring 20 x 2.0
14 Connector ∅ 36 mm (external)
15 O-ring 30 x 2

8.2 Installing the group of devices

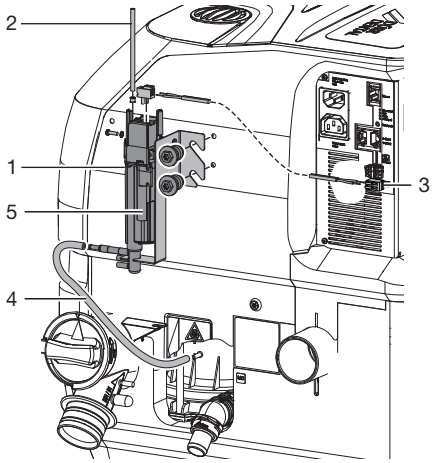
To install the devices and combine them as a group, use the *Installation Kit Tyscor V/VS Tandem* (see "Optional equipment"). The installation kit contains various parts (pipes, moulded sections, hose clamps etc.) and corresponding installation information required for the installation of two or more devices.

Setup and installation must be carried out in accordance with the requirements of Dürr Dental. Corresponding installation information is enclosed with the installation kit, but it can also be downloaded from the Dürr Dental homepage.

All suction units in the group must be on the same level, and the supply manifold must be slightly lower than the suction inputs.

8.3 Fitting the rinsing unit

1. Securely screw the rinsing unit onto the retaining plate.
2. Securely screw the rinsing unit and the retaining plate onto the housing upper part.
3. Connect the hose for the water supply to the rinsing unit and to the water supply.
4. Push the rinse hose onto the rinse connection of the separation unit.
5. Shorten the rinse hose to the required length and connect it to the rinsing unit.
6. Connect the waste water hose to the overflow connection piece and to the waste outlet.
7. Connect the voltage supply of the rinsing unit at the suction unit.



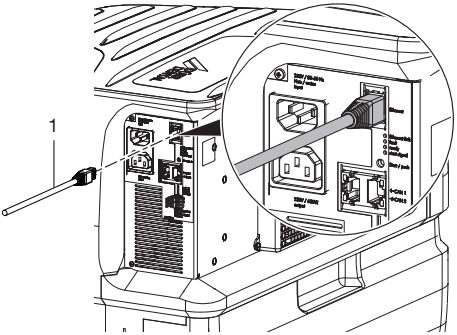
1 Rinsing unit
2 Water connection
3 Voltage supply for the rinsing unit
4 Rinsing hose
5 Overflow connection piece

8.4 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 in the network cable at the network connection on the unit (optional when using monitoring software).
2. Plug in the network cable at the network socket.

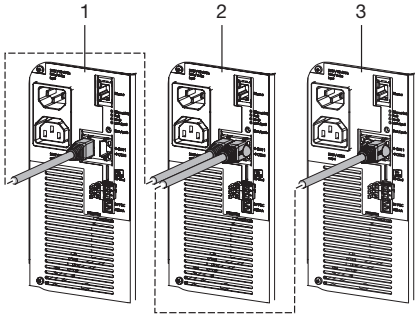


1 Network cable

8.5 CAN bus

Purpose of the CAN bus connection
In a grouping of up to three devices, the CAN bus is used to enable mutual controlling and information exchange between the devices.

1. Connect the network cable between the devices at the CAN bus.



1 Main unit
2 Auxiliary unit 1
3 Auxiliary unit 2

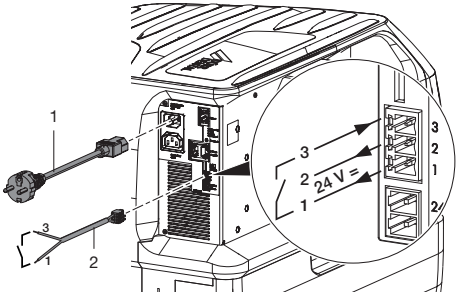
8.6 Electrical connections

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

1. Fasten the plug socket to the control line and connect to the device.

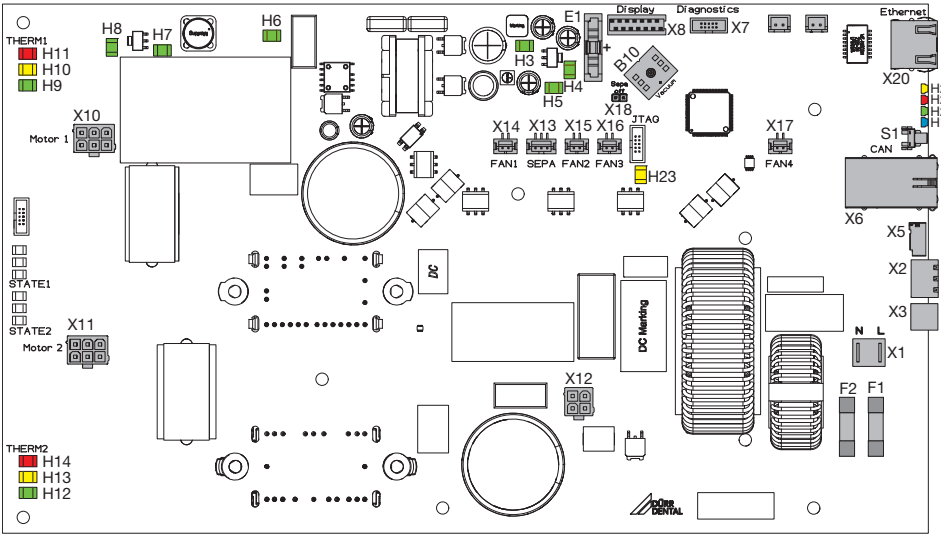
In a grouping of devices connect the control cable to the main unit.

2. Connect the mains cable to the unit and to the power outlet.



1 Mains cable with socket and country-specific mains plug
2 Control line

8.7 PCB (main board) electrical connections



X1 Supply voltage 230 V
X2 Control voltage output, 24 V DC, control voltage input
X3 Voltage supply for the rinsing unit, 24 V DC
X5 SD card holder (for Micro SD)
X6 CAN bus
X7 Service interface
X8 Connection for the display
X10 Supply voltage for suction motor 1
X11 Supply voltage for suction motor 2
X12 Separation motor supply voltage (VS only)
X13 Separation motor RPM monitor (VS only)
X14 Fan connection for housing fan
X15 Motor control fan connection 1
X16 Motor control fan connection 2
X17 Connection for cooling air fan (optional)
X18 Jumper (V = closed, VS = open)
X20 Network connection
F1 Mains fuse T10.0AH
F2 Mains fuse T10.0AH
H1 Blue LED – start signal
H2 Red LED – fault
H3 Green LED – voltage supply +24 V
H4 Green LED – voltage supply +3.3 V
H5 Green LED – voltage supply +5 V

H6 Green LED – HV voltage supply +15 V
H7 Green LED – HV voltage supply +5V
H8 Green LED – HV voltage supply +3.3 V
H9 Green LED – temperature indicator for radial blower 1, temperature OK
H10 Yellow LED – line to radial blower 1, short circuit or open circuit
H11 Red LED – temperature indicator for radial blower 1, temperature too high
H12 Green LED – temperature indicator for radial blower 2, temperature OK
H13 Yellow LED – line to radial blower 2, short circuit or open circuit
H14 Red LED – temperature indicator for radial blower 2, temperature too high
H21 Green LED – ready for operation
H22 Orange LED – network
S1 Start button
B10 Vacuum sensor
E1 Battery (CR2032 button cell)

8.8 Testing suction power after installation

The following procedure is recommended in order to measure the maximum negative pressure of the suction system so that it can be compared with the performance curve:

1. Select the operating mode "Boost"
2. At a treatment unit lift off a suction hose and connect a pressure gauge (relative pressure). The connection adapter to the pressure gauge must be leak tight.
3. Read off the displayed negative pressure and compare it against the performance curve.

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.

NOTICE

Interference caused by larger particles such as pieces of tooth or fillings

› Do not operate the unit without a coarse filter

1. Check that the coarse filters are installed in the suction system (e.g. in the spittoon).
2. Turn on the unit power switch or the main surgery switch.
3. Carry out a function check of the device.
4. Check all connections for leak tightness.
5. Carry out an electrical safety check in accordance with applicable regulations (e.g. regulations concerning set up, operation and application of medical devices) and record the results as appropriate, e.g. in the technical log book.
6. 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 multiple devices are operated in a group then one of the devices needs to be defined as the main unit. Each additional device is then defined as auxiliary unit 1 or auxiliary unit 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 a main unit.

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 *Parameters* and *Group Settings* buttons to switch to the selection list. In the list choose whether the device is a main unit or auxiliary unit.

Control strategy in group operation

If required, you can change the control strategy of the device or device group.
Adjusting the control strategy:
To change the control strategy, switch from the display screen to the menu screen by pressing the *Settings* button. Then use the *Parameters* and *Control Strategy Options* buttons to go to the selection list. Select the required control strategy from the list:

- Adaptive operation
- Parallel operation

In parallel operation, increased power consumption and increased wear are to be expected.

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.

Quick Start

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

When operating devices as a group, set up the Quick Start function on the main unit.

Activating Quick Start:
To activate the Quick Start function, switch from the display screen to the menu screen by tapping the *Settings* button. Then switch to the submenu via the buttons *Parameters* and *Start*/*Stop*. The function can now be enabled or disabled via the *Quick Start* slider. If the function is active then the slider is shown in blue.

Eco Stop

The Eco Stop function can be set to either a short time (enabled) or long time (disabled). This setting can be adjusted from the user level *Administrator* or higher.

When operating devices as a group, set up the Eco Stop function on the main unit.

Enabling the Eco Stop:

To activate the Eco Stop function, switch from the display screen to the menu screen by tapping the *Settings* button. Then switch to the submenu via the buttons *Parameters* and *Start/Stop*. The function can now be enabled or disabled via the *Eco Stop* slider. If the function is active then the slider is shown in blue.

Exhaust air filter

If an exhaust air filter is used, this will need to be set up in the controller. This is the only way to ensure that a corresponding maintenance message is displayed at the right time.

Settings for the exhaust air filter:

To activate the maintenance counter for the exhaust air filter, switch from the display screen to the menu screen by tapping the *Settings* button. Then use the *Parameters* and *Exhaust Air Filter* buttons to switch to the selection list. In the list, select whether or not an exhaust air filter is fitted.

Emergency mode

In emergency mode the device or group of devices can continue to be operated even if one of the device components is defective. Once the device component has been repaired, emergency mode will need to be reset. This can be done from user level *Administrator* or higher.

Resetting emergency mode:

To reset emergency mode, switch from the display screen to the menu screen with the *Settings* button. Then use the *Service* and *Emergency Mode* buttons to switch to the submenu. Use the button to reset emergency mode.

Device components

In the *Device Components* menu you can deactivate one or possibly both radial blowers for maintenance purposes. The menu is available in the user level for Administrators.

Deactivating/activating radial blower(s):

To deactivate/activate radial blowers, switch from the display screen to the menu screen with the *Settings* button. Then use the *Service* and *Device Components* buttons to switch to the submenu. The desired motor can be deactivated/activated via the sliders for the top motor and bottom motor. If the motor is active then the slider is shown in blue.

In normal operation both of the radial blowers should be activated.

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.
– Protect the network with antivirus and firewall tools.
– Only allow authorised users to access the devices.
– Only allow authorised users to access the device network.
– Block access to the device network via the guest WiFi.
– Only download firmware updates from recognised, secure sources, e.g. directly from the manufacturer's website.

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.

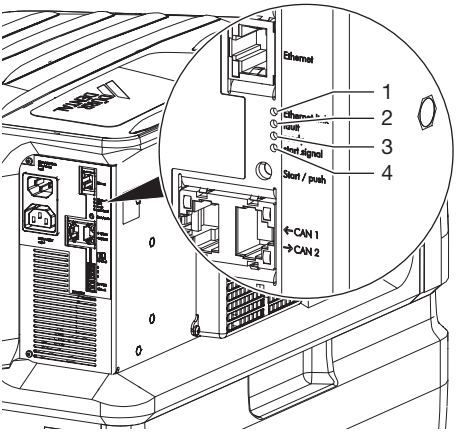
Network protocols and ports

Port	Purpose	Service
45123 UDP, 45124 UDP	Unit recognition and configuration	
1900 UDP	Service indicator	SSDP / UPnP
502 TCP	Device data	
514[1)] UDP	Event log data	Syslog
22 TCP, 23 TCP	Diagnosis	Telnet, SSH
123 UDP	Time	NTP

1) The port may vary depending on the configuration.

Usage

10 LEDs



1 Orange LED – network
2 Red LED – fault
3 Green LED – ready for operation
4 Blue LED – start signal

10.1 Ready for operation

Green LED lights up

10.2 Eco Stop

Green LED flashes
The unit has been switched off by the EcoStop function. To switch it on, lift a suction hose up out of the hose manifold or briefly disconnect the power supply from the unit.

10.3 Hose manifold start signal

BLUE LED illuminates
Manifold signal active and machine running.

10.4 Network

ORANGE display is illuminated
The machine is connected to the network.

10.5 Fault

Red display flashes
– Fault/failure of a radial blower

RED LED illuminates
– Failure of both radial blowers
or
– Failure of separation (VS only)

11 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*

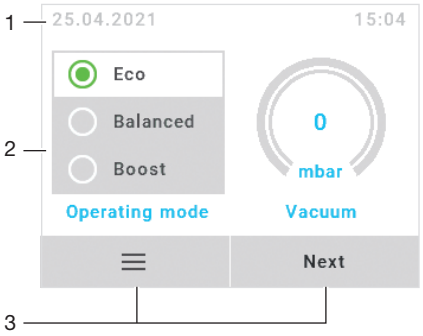
Next — Switches between the two start screens (only when a device is configured as the "main unit")

Switches to the start screen

Switches to the next higher menu level

11.1 "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 the next page, where the power consumption and temperature of the electronics are displayed.
The power consumption and temperature of the electronics are displayed on the Main Menu of the auxiliary unit.

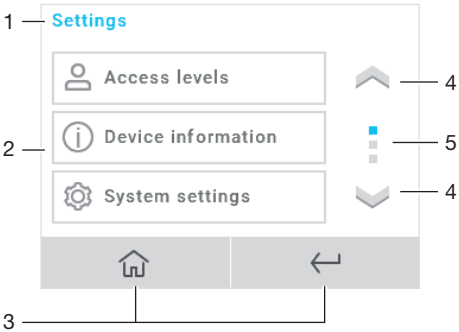


1 Context range (e.g. date, time)
2 Content area
3 Navigation buttons

11.2 "Settings" display

In the Settings screen you can query information and adjust settings.

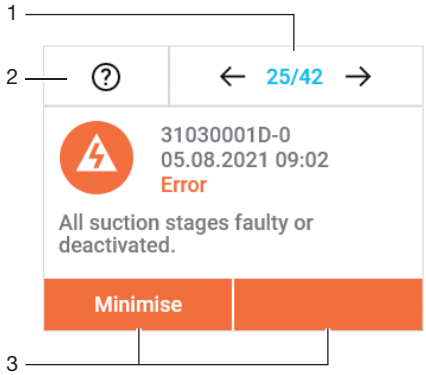
To access the individual menu items, tap the relevant button. If there are multiple pages, the arrow buttons are used to scroll through the pages.



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

11.3 "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

12 Disinfection and cleaning

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.

As a general rule use:
– for disinfection and cleaning:
Orotol plus or Orotol ultra
– for cleaning:
MD 555 cleaner

Only these products have been tested by Dürr Dental.
When using prophy powders, water-soluble Lunos Prophy Powders are recommended in order to protect the suction systems (Dürr Dental).

12.1 After every treatment

1. Aspirate a glass of cold water through the large and the 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.

12.2 Daily after the end of treatment

After higher workloads before the midday break and in the evening

The following are required for disinfection/cleaning:

✓ Non-foaming disinfectant/cleaning agent that is compatible with the materials.
✓ Unit care system, e.g. OroCup

1. To pre-clean, suck up 2 litres of water with the care system.
2. Aspirate the disinfection/cleaning agent with the care system.

12.3 Once or twice a week before the midday break

Under harsher conditions (e.g. hard water or frequent use of prophy powders) 1x daily before the midday break

The following are required for cleaning:

✓ Special non-foaming detergent for suction units that is compatible with the materials.
✓ Unit care system, e.g. OroCup

1. To pre-clean, suck up 2 litres of water with the care system.
2. Aspirate the cleaning agent with the care system.
3. Rinse with ca. 2 l water after the application time.

13 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.

Maintenance interval	Maintenance work
Every three months	› Check the filter at the device suction connection and clean if necessary.
Annually	› Replace the waste water valve. * › Check the nonreturn valves upstream of the radial blowers for correct operation and replace as required. *
Every 1-2 years or when prompted if the maintenance counter is activated	› Replace the exhaust air filter (where fitted). *

* Only to be performed by service technicians.

The device informs the user about any pending maintenance. Once the maintenance is performed, this can be confirmed in the menu so that the counter can be reset.

Resetting the maintenance for the waste valve and the exhaust air filter can be done at the user level Administrator or higher.

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.

Resetting the counter:
To reset the maintenance counters, switch from the display screen to the menu screen with the *Settings* button. Then use the *Maintenance* button to switch to the submenu. In this menu select which maintenance was performed and confirm this via the display.

Troubleshooting

14 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.

WARNING

Electric shock due to capacitor discharge

- Wait for the discharge time.
- Watch for the LEDs going out.

14.1 General faults

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. *
The unit has been switched off, the green LED is flashing	The EcoStop function has been activated	› Lift up a suction hose from the hose manifold. › Briefly disconnect the power supply from the unit. › Check the switch in the hose manifold and replace as required. *

Error	Possible cause	Remedy
Water leaking from the exhaust air connection	Membrane valve defective	› Check the membrane valve at the waste water connection and if necessary clean or replace.
	Foam in turbine due to use of incorrect cleaning and disinfectant agents	› Use non-foaming cleaning and disinfectant agents.
	Build-up of condensate in the exhaust air line	› Check the pipe system; avoid over-cooling. *
Suction performance too low	Coarse filter blocked	› Clean the coarse filter at the intake connection.
	Leak in the suction pipe	› Check and if necessary establish leak-tightness of suction pipe and connections. *
	Soiling in the suction pipe	› Check the pipe system and clean it as required. *
	Soiling in the separation stage	› Check the separation stage and clean it as required *
	Membrane valve defective	› Check the membrane valve at the waste water connection and if necessary clean or replace.
	One radial blower defective	› Replace the radial blower. *
No suction power	Radial blower defective	› Activate emergency mode by confirming the alarm message. › Replace radial blower. *
	Controller defective	› Replace the controller. *
	Separation system defective	› Check the separation system and clean or replace it as required. *
	Main unit defective in group	› Take the defective main unit out of operation and reconfigure an auxiliary unit as the main unit.
Water not being pumped away	Separation system defective	› Replace separation system. *
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. *

Error	Possible cause	Remedy
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.

14.2 Error messages

Error messages are displayed on the touch screen. If there is a network connection, the messages can be forwarded to the monitoring software. If the device is not connected to the network, the messages can be read via a terminal client (e. g. PuTTY).

Error	Possible cause	Remedy
Maintenance required. Clean filter at device suction connection.	Service due	› Clean the filter at the device suction connection. › Reset the maintenance in the menu.
Maintenance required. Check waste valve.	Service due	› Check the waste valve. * › Reset the maintenance in the menu. *
Maintenance required. Replace exhaust air filter.	Service due	› Replace the exhaust air filter * › Reset the maintenance in the menu. *
Severe fault detected. Confirm to enter emergency mode.	A radial blower is defective	› Confirm to enter emergency mode. › Immediately repair or replace the radial blower. * › Reset emergency mode in the menu. *
Severe fault detected. Call service.	A radial blower is defective. Emergency mode unavailable.	› Immediately repair or replace the radial blower. *
This device is running in emergency mode. Call service.	Device is running in emergency mode	› Immediately repair or replace the radial blower. * › Reset emergency mode in the menu. *
An Aux device has a severe failure. Confirm at affected device.	A radial blower on an auxiliary unit is defective	› Confirm to enter emergency mode. › Immediately repair or replace the radial blower. * › Reset emergency mode in the menu. *
An Aux device is running in emergency mode. Call service.	An auxiliary unit is running in emergency mode	› Immediately repair or replace the radial blower. * › Reset emergency mode in the menu. *
Driver overcurrent TRIP	Radial blower motor defective	› Replace the radial blower. *
Speed of Sepa is low	Motor defective	› Replace the separation stage. *
	Hall sensor PCB (main board) defective	› Replace the Hall sensor PCB (main board), check the magnets in the Sepa fan. *
	Centrifuge soiled or damaged	› Check the centrifuge and clean or replace if necessary. *
Vacuum motor overheated	Radial blower motor defective	› Replace the radial blower. *

Error	Possible cause	Remedy
DC bus overvoltage	Control error	› Replace the electronics. *
DC bus undervoltage	Mains power supply fault	› Check the mains connection and supply voltage. *
	Machine was disconnected from the mains while running	› No action required.
	Control error	› Replace the electronics. *
No Ready Signal from vacuum machine	Control error	› Replace the electronics. *
Internal board communication disturbed	Failed firmware update	› Perform/repeat the firmware update. *
	Control error	› Replace electronics. *
Unexpected re-initialization	Firmware error	› Perform/repeat the firmware update. *
Short circuit to earth	Radial blower motor defective	› Replace radial blower. *
Vacuum motor sensor shorted	Radial blower motor defective	› Replace radial blower. *
Vacuum motor sensor open circuit	Radial blower motor defective	› Replace radial blower. *
	Motor cable not correctly connected to the control board	› Check the plug connection. *
Firmware mismatch	Different firmware versions on the two processors after a firmware update	› Perform/repeat the firmware update. *
Speed Feedback Failure	Motor speed detection defective	› Replace radial blower. *
MC Lib failure	Control error	› Replace the electronics. *
CPU overheated	Insufficient ventilation or poor set-up conditions	› Check the setup conditions, ensure adequate ventilation.
	Fan in the foam housing soiled	› Clean the fan and ventilation slots for supply and exhaust air. *
	Fan in foam housing defective	› Replace the fan. *
	Control electronics defective	› Replace electronics. *
Power Pack overheated	Insufficient ventilation or poor set-up conditions	› Check the setup conditions, ensure adequate ventilation.
	Fan on the electronics housing soiled	› Remove the cover on the electronics housing, clean the fan and heat sink. *
	Fan on electronics housing defective	› Replace the fan. *
	Control electronics defective	› Replace electronics. *

Error	Possible cause	Remedy
Eco Stop. Switch start signal off and on again to restart	Unit has been switched on unintentionally for too long.	› Check whether all suction hoses are correctly hung up. › Briefly disconnect the unit from the mains. › Check whether a permanent start signal is present at the unit. * › Check the control cable. *
All devices failed or deactivated	Radial blower defective	› Replace the radial blower. *
	Radial blower deactivated	› Inform a Service Technician.
More than one main control unit detected. Wrong configuration!	Configuration error. More than one main unit found	› Make sure that only one device is configured as the main unit. *
No main control unit detected. Check system.	No main unit found. Check the system.	› Configure one device as the main unit. *
Auxiliary unit has error.	Fault on auxiliary unit	› Check the fault on the affected auxiliary unit *

* Only to be done by service technicians.

15 Transporting the unit

WARNING

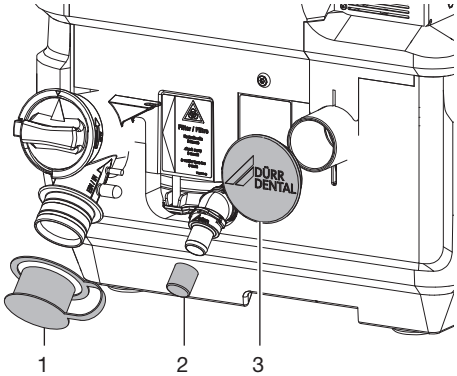
Infection due to contaminated unit

› Disinfect the unit before transport.

› Close all media connections.

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

1. Prior to disassembly, clean and disinfect the suction unit and the unit via aspiration of a suitable disinfectant approved by the manufacturer.
2. Disinfect a defective unit using a suitable surface disinfection agent.
3. Seal all connections with sealing caps.
4. Pack the unit securely in preparation for transport.



1 Suction connection sealing cap (order number 7130-100-19)

2 Waste water connection sealing cap (order number 9000-412-98)

3 Sealing cap (order number 900041298)

Appendix

16 Menu structure

Setup wizard	*Language*			
	Operating mode			
	Exhaust air filter			
	Finished			
Start screen	*Operating mode, vacuum*			
	Performance, temperature			
Settings	Access level	Operator		
	Device information	Administrator		
		Service Technician [PIN]	XXXXXX	
		Device data	REF	
			SN	
			Firmware	
			Upgrade	
			Library version	
			PCB_SN	
			File	
		Device usage data	Operating hours	
			Number of starts	
	System settings	Language	Deutsch, English, . . .,	
		Date, time [2]	Automatic	
			Date	DD MM YYYY
			Time	HH MM
			Time zone	UTC
		Network [2]	DHCP	
			IP address	
			Netmask	
			Gateway	
			MAC	
		Factory settings [1]	Delete message history	

Settings (continued)	Parameters [2]	Cluster settings	Main unit
			Auxiliary unit 1
			Auxiliary unit 2
		Lag time [3]	XX s
		Start / stop [3]	Quick Start
			Eco Stop
		Exhaust air filter	Present/not present
		Control strategy options [3]	Adaptive operation / parallel operation
	Message history [2]	List of alarms	Alarm information
	Maintenance	Filter maintenance	Maintenance completed
		Waste valve maintenance [2]	Maintenance completed
		Exhaust air filter maintenance [2]	Maintenance completed
	Service [2]	Emergency mode	Reset
		Device components	Motor 0 (top)
			Motor 1 (bottom)

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

17 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:**

18 Country representatives

Country	Address
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