Tyscor V 2 central suction unit

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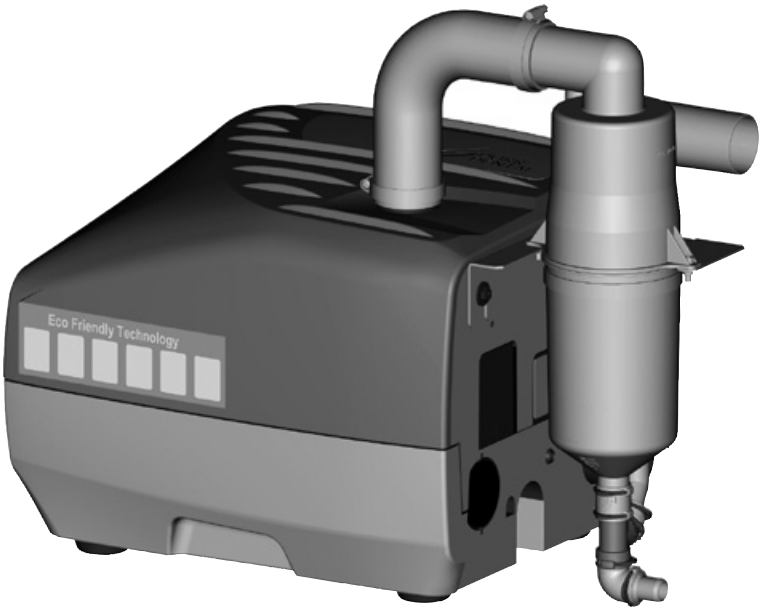

Installation and Operating Instructions

CE 0297

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DÜRR DENTAL

1510V002SE

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1 About this document

These installation and operating instructions form part of the unit.

If the instructions and information in these installation and operating instructions are not followed, Dürr Dental cannot give any warranty or assume any liability for the safe operation and the safe functioning of the unit.

This translation was prepared to the best of our knowledge. The original German language version of the manual is the definitive version.

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 symbols


Warning – risk of dangerous electric voltages


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
– **ATTENTION**
  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 the accompanying electronic documents.


Monitor ambient conditions


Switch off and de-energise the device (e. g. unplug from mains).


Wear protective gloves.


Manufacturer

Item number

Serial number

1.2 Copyright information

All names of circuits, processes, names, software programs and units used 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 Dürr Dental.

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2 Safety

Dürr Dental has designed and constructed this device so that when used properly and for the intended purpose there is no danger to people or property. Nevertheless, residual risks can remain. You should therefore observe the following notes.

2.1 Proper intended usage

The unit is designed to generate a vacuum in order to aspirate saliva, rinsing water and other fluids that are present during dental treatment and need to be transported into the waste water system.

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.

2.2 Improper usage

Any other usage or usage beyond this scope is deemed to be improper. The manufacturer accepts no liability for damages resulting from this. In these cases the user/operator will bear the sole risk.

› Do not use this device to aspirate flammable or explosive mixtures.
› The unit must not be used as a vacuum cleaner.

2.3 General safety notes

› When operating this device always observe all guidelines, laws, and other rules and regulations that are applicable at the site of operation.
› Prior to each use, check condition of the device and make sure it is in perfect working order.
› Do not convert or modify the units.
› Observe the Installation and Operating Instructions.
› Make the Installation and Operating Instructions available to the person operating the device at all times.

2.4 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 there is no risk of damage or harm to the surroundings.
› If it is not 100% clear from the unit data sheet that such connections can be safely made or if you are in any doubt, always get a suitably qualified person (e.g. the 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 installed within other medical supply equipment, the requirements set out in Directive 93/42 EEC and the relevant standards must be complied with.

A copy of the system manufacturer‘s declaration in accordance with Article 12 of Directive 93/42/EEC can be found in our download section at www.duerrdental.com (document no. 9000-461-264).

2.5 Specialist personnel

Operation

Persons who operate the units must ensure safe and correct handling based on their training and knowledge.

› Instruct or have every user instructed in handling the unit.

Installation and repairs

› Installation, readjustments, alterations, upgrades and repairs must be carried out by Dürr Dental or by qualified personnel specifically approved and authorized by Dürr Dental.

2.6 Protection from electric shock

› When working on the units observe all the relevant electrical safety regulations.

› Never touch the patient and unshielded plug connections on the device at the same time.

› Immediately replace any damaged lines and connections.

Observe the EMC rules concerning medical devices

› Observe specific precautionary measures relating to electromagnetic compatibility (EMC) for medical devices, see "16 Information about EMC in accordance with EN 60601-1-2".

2.7 Only use genuine parts

› Only use Dürr Dental parts or accessories and special accessories specifically approved by Dürr Dental.

› Only use only genuine working parts and spare parts.

DÜRR MEDICAL accepts no liability for damages or injury resulting from the use of non-approved accessories or special accessories, or from the use of non-genuine working parts or spare parts.

2.8 Transport

WARNING
Infection due to contaminated unit

› Disinfect the unit before transport.

› Close all media connections.

The original packaging provides optimum protection for the device during transport.

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

Dürr Dental does not accept any responsibility or liability for damage occurring during transport due to the use of incorrect packaging, even where the unit is still under guarantee.

› Only transport the device in its original packaging.

› Keep the packing materials out of the reach of children.

2.9 Disposal

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

› 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 concerning the correct disposal of parts, please contact your dental trade supplier.

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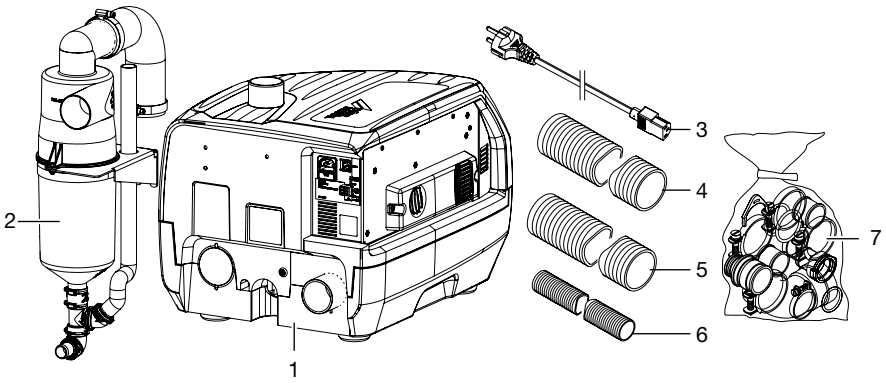
3 Overview



1 Tyscor VS 2 suction unit
2 Condensate separator
3 Mains cable with country-specific mains plug
4 Hose LW 50 (0.6 m)
5 Hose LW 50 (1.5 m)
6 Hose LW 20
7 Set of connection fittings

3.1 Scope of delivery

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

Tyscor V 2 . . . . . 7177-01/. . .

– Suction unit – 230 V, 1~, 50/60 Hz
– Set of connection fittings
– Condensate separator
– Hose LW 20
– Hose LW 50 (suction hose 0.6 m)
– Hose LW 50 (exhaust air hose 1.5 m)
– Tyscor Pulse software (CD)
– Quick-start instructions

3.2 Special accessories

The following optional items can be used with the device:

Wall bracket 7130-190-00
Exhaust air filter 0705-991-53
Noise reduction for exhaust air . . . 0730-991-00
Console for floor-mounted installation. 7130-191-00

3.3 Disposable materials

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

Orotol plus
4 x 2.5 l bottles/carton CDS110P6150
MD 555 special suction unit cleaner
4 x 2.5 l bottles/carton CCS555C6150

3.4 Working parts and spare parts

Information on spare parts can be found on the website portal for authorised specialist dealers under: www.duerrdental.net.

4 Technical data

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Electrical data		
Nominal voltage	V	230, 1~
Mains frequency	Hz	50 - 60
Nominal current	A	2.7
Rated power	kW	0.6
Fuses	A	2x T 4.0 AH / 250 V~ (IEC 60127-2)
Type of protection		IP 21
Protection class		I

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

Media		
Max. unimpeded flow rate	l/min	900
Max. suction system pressure	mbar/hPa	-160

Electromagnetic compatibility (EMC)*		
HF emissions in acc. with CISPR 11		Group 1 Class B
Harmonics in acc. with IEC 61000-3-2		Class A
Voltage fluctuations/flickers in acc. with IEC 61000-3-3		Compliant

*See also: "16 Information about EMC in accordance with EN 60601-1-2"

General data		
Radial blower speed (n_v) max.	rpm	22000
Duty cycle	%	100
Dimensions (H x W x D)		
without condensate separator	cm	34 x 35.5 x 45.5
with condensate separator	cm	49 x 35.5 x 61
Weight	kg	9
Noise level* approx.	dB(A)	58

* Noise levels in acc. with EN ISO 1680 "Noise emissions"; measured in a sound-proofed room. The levels are average values with a tolerance of ± 1.5 dB(A). In rooms with reverberating sound characteristics higher values may be obtained.

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

Classification		
Medical Devices Directive (93/42/EU)		Class IIa

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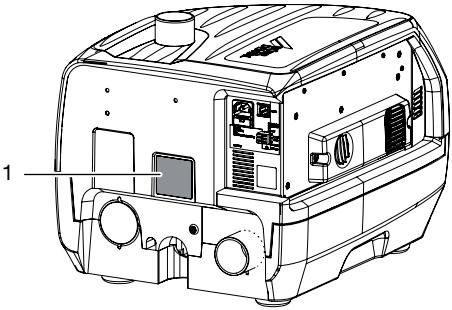
4.1 Model identification plate

The model identification plate can be found on the upper part of the housing.



1 Model identification plate

4.2 Conformity assessment

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.

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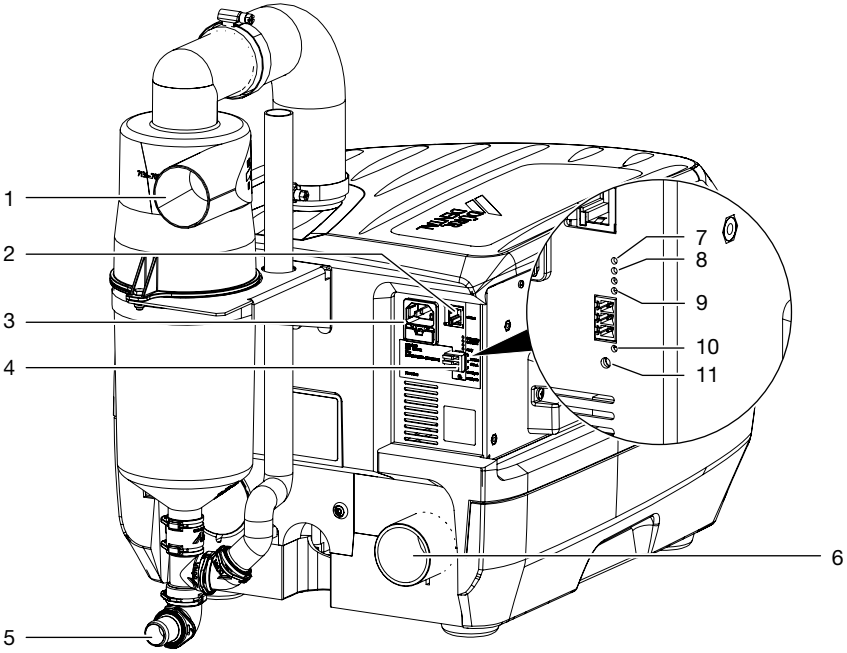
5 Operation



1 Vacuum connection
2 Network connection
3 Mains connection with mains fuses
4 Control connection
5 Condensate connection
6 Exhaust air connection
7 Red LED - radial blower fault
8 Red LED (no function)
9 Green LED - ready for operation
10 Blue LED - "start" signal
11 Start button

The V suction unit is used in "dry" suction systems. The unit comprises a radial compressor and a condensate separator.

5.1 Radial blower

The air that has been separated from the fluids is sucked into the radial blower. The motor in the radial blower is 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 unit.

5.2 Condensate separator

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

5.3 LEDs and settings

LEDs:

– The green LED lights up continuously when the unit is ready for operation.
– The red LED lights up when there is a fault.
– The blue LED lights up when a "start" signal is present from the treatment unit.

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5.4 Tyscor Pulse (optional)

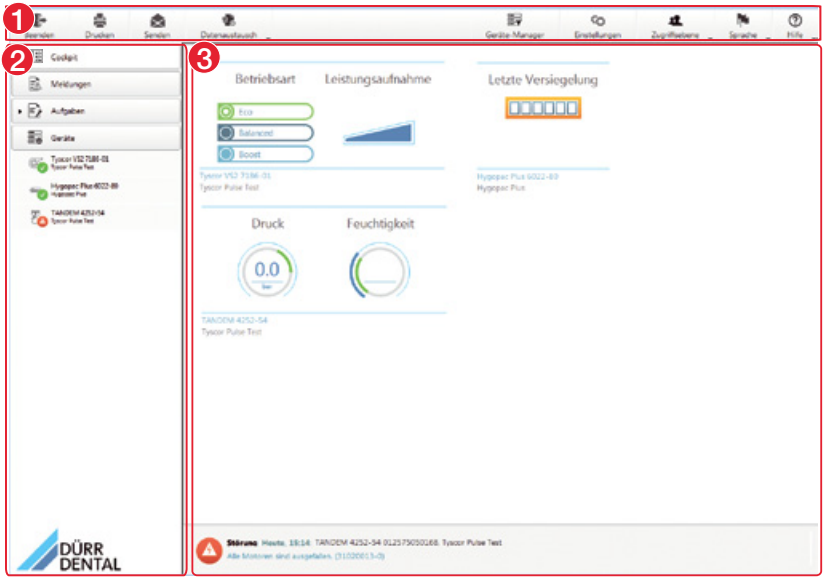
The software is connected via the network to the units from Dürr Dental and displays the current status as well as messages and errors.

All messages are logged and can be printed or sent.

Regular maintenance and upkeep is implemented in the tasks. Reminders signal when a task is due.

The *cockpit* shows the devices with the current characteristic data and provides a quick overview of the functional status of the devices.

The software interface consists of the menu bar, the side bar and the contents area.



1 Menu bar
2 Side bar
3 Contents area

The contents area depends on the tab selected on the side bar. The current messages are always displayed in the lower part of the contents area.

The views and rights depend on the selected access level (User, Administrator or Service Technician).

While the software is running (even if the software window is closed), the access level is visible in the task bar (or Mac OS menu bar). The symbol shows the current status of the devices (see "11.2 Querying messages"). If a new message appears, a speech bubble tip also appears.

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 number 9000-617-03/..

6.1 Installation/setup room

The room chosen for set up should 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).
– Take environmental conditions into consideration – see "4 Technical data".

Ambient and environmental conditions must be taken into account. Do not operate the unit in damp or wet conditions.

– 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 and ensure adequate distance for 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:

– Wall installation using a Dürr Dental wall mounting
– In a ventilated cabinet
– In a Dürr Dental noise reducing housing

6.3 Pipe materials

Only use vacuum-sealed HT-waste pipes manufactured from the following pipe materials:

– Polypropylene (PP),
– Chlorinated polyvinyl chloride (PVC-C),
– Unplasticized 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
– Completely PVC hoses
– Hoses that are not sufficiently flexible

6.5 Information about electrical connections

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

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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)
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

7 System components

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

7.1 Exhaust air filter

For reasons of hygiene, we recommend the installation of an exhaust air filter in the exhaust air line.

If the suction unit is installed in the surgery and the exhaust air cannot be directed to the outside, it is essential to install an exhaust air filter.

Depending on the design and condition of the exhaust air filter, it will need to be replaced after 1-2 years at the latest.

The separation unit integrated in the suction unit does not hold back bacteria, which is why we recommend installing a suitable filter in the exhaust air system.

7.2 Noise reduction

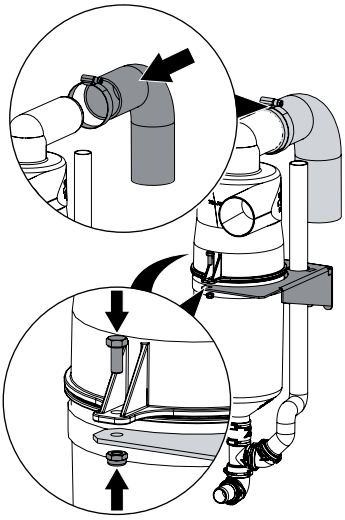
If the noise level from the exhaust air vent or the flow noise generated is too high, noise reduction can be installed in the exhaust air line.

8 Installation

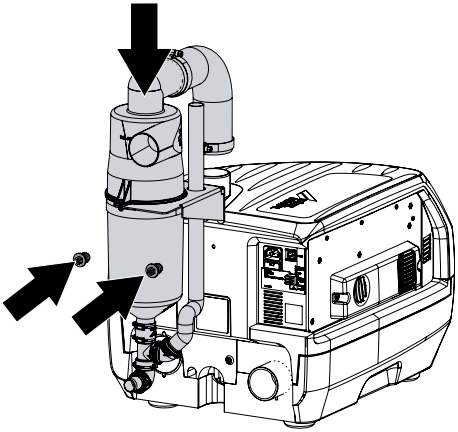
The actual connection can vary depending on the chosen installation option. The connection shown is only an example.

8.1 Mounting the condensate separator

› Attach the condensate separator to the holder with two screws.
› Mount the angled connector piece on the inlet.

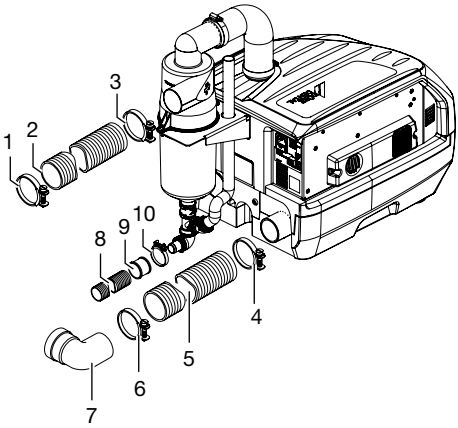


› Attach the condensate separator with the holder to the unit and secure.



8.2 Installation and routeing of hoses and pipes

› Establish connections between the pipe system and the suction unit using the flexible hoses supplied. This will prevent vibrations from being transmitted to the pipe system.
› The connection between the pipe line and suction unit connection should be kept as short as possible and straight, without bends.
› Waste water connections must be implemented in accordance with applicable local and national regulations.

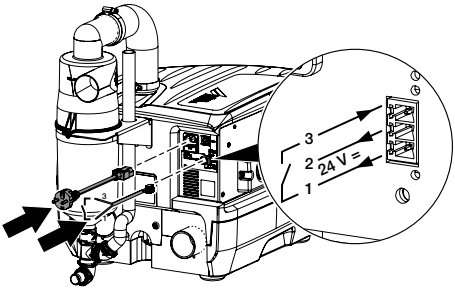


1 Hose clip
2 Suction hose ∅ 50 mm (internal)
3 Hose clip
4 Hose clip
5 Exhaust air hose ∅ 50 mm (internal)
6 Hose clip
7 Angled connector piece DN 50
8 Condensate hose ∅ 20 mm (inside)
9 Hose bushing
10 Hose clip ∅ 28 mm

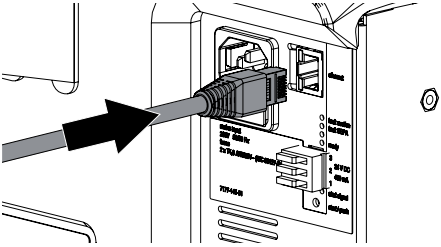
8.3 Electrical connections

› Fasten the socket piece to the control line and connect to the suction unit.

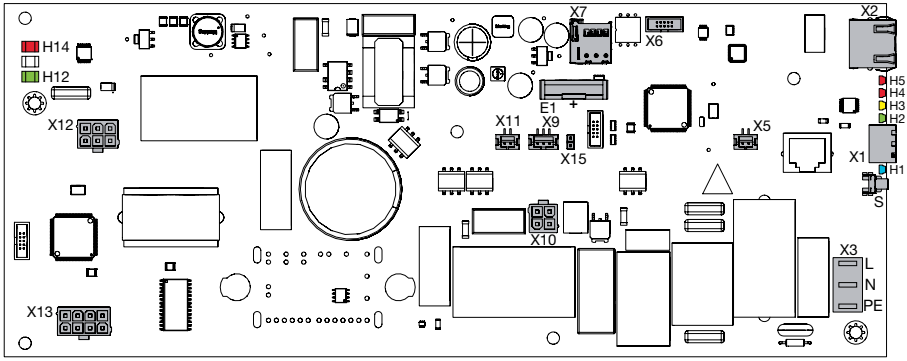
› Connect the mains cable to the suction unit and plug it into the socket-outlet.



› Plug the network cable for the Tyscor Pulse into the network connection (optional when using Tyscor Pulse).



8.4 PCB electrical connections



X1 Control voltage output, 24 V DC, 25 VA, control signal input
X2 Network connection
X3 Supply voltage 230 V
X5 Motor control fan connection 2
X6 Service interface
X7 SD card holder (for Micro SD), optional
X9 Separation motor RPM monitor
X10 Separation motor supply voltage
X11 Motor control fan connection 1
X12 Suction motor supply voltage
X13 Suction motor RPM monitor
X15 Jumper (plugged)
H1 Blue LED - "start" signal
H2 Green LED - ready for operation
H3 Yellow LED - reserve
H4 Red LED (no function)
H5 Red LED - radial blower fault
H12 Green LED - radial blower temperature indicator, temperature OK
H14 Red LED - radial blower temperature indicator, temperature too high
S Start button
E1 Battery (CR2032 button cell), optional

9 Commissioning and first start-up

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› Carry out a functional inspection of the system and check the connections for leaks.
› Attach and screw on the covers.

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

› Turn on the unit power switch or the main surgery switch.
› Carry out an electrical safety check in accordance with applicable local regulations (e.g. concerning set up, operation and application of medical products) and record the results as appropriate, e.g. in the technical log book.

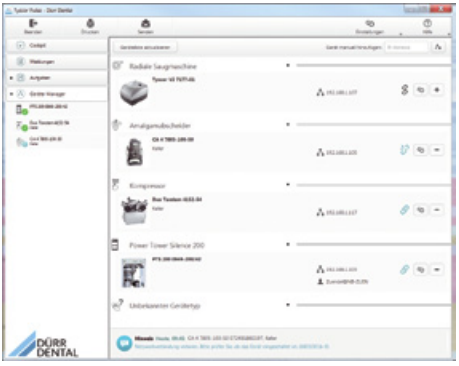
9.1 Monitoring the device with Tyscor Pulse

Further information on Tyscor Pulse can be found in the software help and in the Tyscor Pulse manual, order number 9000-619-22.

The following requirements must be met in order to monitor the unit with the software on the computer:

– Unit connected to the network
– Tyscor Pulse (version 3.0 or higher) installed on computer

Add device



Requirements:

– Unit switched on and connected to the network
– Administrator or service technician access level selected in the software

› Click on *Unit manager* in the side bar.

The list of units appears. A symbol displays the connection status to the software:

The device is present in the network and connected to the software.

The device is present in the network but not connected to the software.

The network connection between the software and the device is interrupted, e.g. the device is switched off.

The new unit that is not yet connected is displayed with the connection status .

› Select the device and click + in the menu bar.

The unit appears in the side bar.

Adding the device in the cockpit

All devices that are connected to the software can be added to the cockpit. When the unit is first connected to the software, the unit is automatically added to the cockpit.

Requirements:

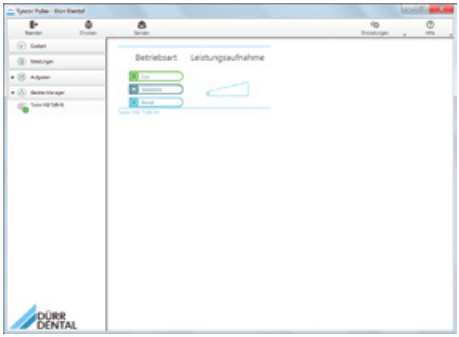
– Administrator or Service Technician access level selected.

› Click on the device in the device list with the left mouse button and keep the mouse button pressed.
› With the mouse key pressed, drag the unit onto the cockpit.
› Release the mouse key.

The block with the current characteristic data and the name of the device appear in the cockpit.

› To change the position of the device block, click on the block and, with the mouse key pressed, drag it to the required location.

Selecting the operating mode



The suction unit can be used in various operating modes. Depending on the installation situation and power requirements, one of the following operating modes can be selected: Eco, Balanced or Boost. On delivery, the suction machine is set to Balanced.

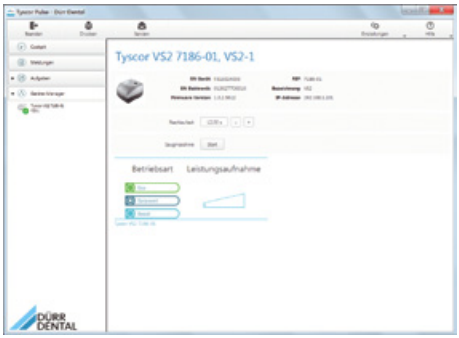
Requirements:

– Administrator or Service Technician access level selected.

› Select the suction machine in the side bar.

› Click on the desired operating mode with the left mouse key.

Manually starting the device



Manually starting the device for testing.

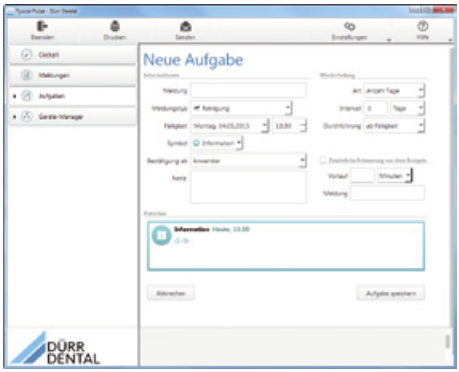
Requirements:

– Service technician access level selected.

› Select the device in the device list.

› Click on the Start button with the left mouse key; on some devices you will need to keep it pressed.

Transferring the maintenance schedule to the software



We recommended transferring the tasks from the maintenance schedule (see "13 Maintenance") into the maintenance schedule of the software.

› Select the *Tasks* view in the software.

› Adding a task.

Result:

The task appears on the side bar and in the maintenance schedule.

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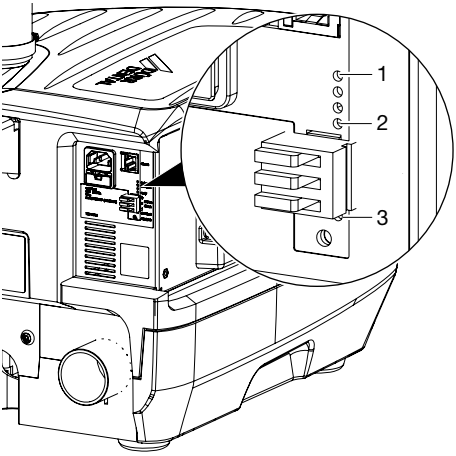
10 LEDs



1 Red LED - fault
2 Green LED - ready for operation
3 Blue LED - "start" signal

10.1 Ready for operation

Green LED is on

10.2 Hose manifold start signal

BLUE LED is on
Manifold signal active and machine running.

10.3 Fault

RED LED is on

If there is a fault in the unit, the red LED lights up.

11 Monitoring the device with Tyscor Pulse

Further information on Tyscor Pulse can be found in the software help and in the Tyscor Pulse manual, order number 9000-619-22.

11.1 Monitoring operation

The device must have been added to the cockpit for the graphical device block to be shown in the cockpit.

The following are shown in the device block of the suction unit:
– Operating mode
– Power consumption of the suction stage

11.2 Querying messages

Trouble-free operation

Fault
Operation of the device interrupted

Warning
Operation of the device restricted

Note
Important information about the device

Information

Establishing a connection to the device

Connection to the device interrupted

If a message occurs for an device, the symbol next to the device in the side bar changes. The message appears in the cockpit and in the device details.

If several messages occur, the symbol of the highest message level in each case is displayed.

As soon as a message concerning a device occurs, the symbol in the task bar (or Mac OS menu bar) also changes to the relevant message symbol. If required by the message an acoustic signal also sounds.

› To query the message details, switch to the cockpit or to the device.

11.3 Completing the task

Due tasks appear as a message in the cockpit.

The task can be assigned to an access level (operator, administrator or service technician), which then means that it can only be confirmed from this access level.

› Perform the task.

› Confirm the task in the software.

Result:

The due date of the task is set to the next date.

11.4 Creating a report

A current report can be printed out or sent via e-mail.

The report contains all messages and a screenshot of the view that is displayed when the report is created.

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, e.g. household cleaning agents or instrument disinfection agents.

› Do not use abrasive cleaners.

› Do not use agents containing chlorine.

› Do not use any solvents like acetone.

12.1 After every treatment

› 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:

– Material-compatible, non-foaming disinfection/cleaning agents that have been approved by Dürr Dental, e.g. Orotol® plus.

– Unit care system, e.g. OroCup

› To pre-clean, suck up 2 litres of water with the care system.

› 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 prophylaxis powders) 1x daily before the midday break

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The following are required for cleaning:

– Material-compatible, non-foaming special cleaning agents that have been approved by Dürr Dental, e.g. MD 555 Cleaner
– Unit care system, e.g. OroCup

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

13 Maintenance

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

Maintenance interval	Maintenance work
Every 1-2 years	› Replace the exhaust air filter (where fitted).

14 Tips for operators and service technicians

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Any repairs above and beyond routine maintenance must only be carried out by suitably qualified personnel or by one of our service technicians.

Before working on the device or in case of danger, disconnect it from the mains (e. g. pull the mains plug).

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

14.1 General faults

Problem	Probable cause	Solution
Unit 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 electronics
Water leaking from the exhaust air connection	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	Leak in the suction line	› Check and if necessary establish leak-tightness of suction system and connections.
	Poor pipe routeing	› Use higher operating mode level.
No suction power	Radial blower defective	› Replace radial blower

14.2 Error messages in Tyscor Pulse

The error messages are displayed in Tyscor Pulse. If the device is not connected to the network, the messages can be read via a terminal client (e. g. PuTTY).

Problem	Probable cause	Solution
Vacuum motor overheated	Motor suction stage defective	› Replace the suction stage.
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.

15 Transporting the unit

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

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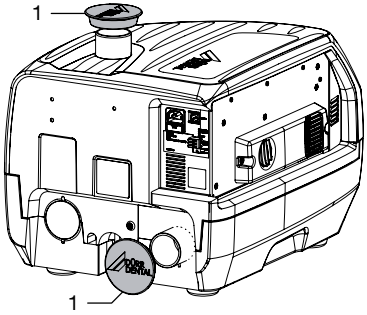
› Before disassembly clean and disinfect the suction unit and the suction system using a disinfectant approved by Dürr Dental.
› Disinfect a defective unit using a suitable surface disinfection agent.
› Disassemble the condensate separator.
› Use caps to close off all connections.



1 Sealing cap (order number 7186100070)
Sealing cap set (order no. 7186100071)

› Pack the unit securely in preparation for transport.

16 Information about EMC in accordance with EN 60601-1-2

16.1 General notes

This information contains excerpts from the international standards for electrical medical devices. It must be observed when installing Dürr Dental devices or combining them with products of other manufacturers. If you are uncertain about anything, please refer to the complete standard.

16.2 Abbreviations

EMC	Electromagnetic compatibility
HF	High frequency
U_T	Rated voltage of the device (supply voltage)
V_1, V_2	Compliance level for the test in acc. with IEC 61000-4-6
E_1	Compliance level for the test in acc. with IEC61000-4-3
P	Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer
d	Recommended safety distance in metres (m)

16.3 Guidelines and manufacturer's information

Electromagnetic emissions for all devices and systems

The device is designed for operation in an electromagnetic environment as specified below. The customer or operator of the device should ensure that the device is operated in such an environment.

Interference emission measurements	Compliance	Electromagnetic environment - guidelines
HF emissions in accordance with CISPR 11	Group 1	The device uses HF energy exclusively for internal functions. As a result, HF-transmissions are very low and it is highly unlikely that any interference will be caused to neighbouring electronic devices.
HF emissions in accordance with CISPR 11	Group 2	The device needs to emit electromagnetic energy in order to perform its intended function. Neighbouring electronic devices could be affected.
HF emissions in accordance with CISPR 11	Class [A or B]	The device is suitable for use in all facilities including those in living areas and areas that are directly connected to the public mains electricity supply that also supplies buildings used for residential purposes.
Harmonics in acc. with IEC 61000-3-2	[Class A, B, C, D or Not Applicable]	
Voltage fluctuations/flickers in acc. with IEC 61000-3-3	[Compliant or Not Applicable]	

Table 1: Electromagnetic emissions for all devices and systems

Resistance to electromagnetic interference (immunity) for all devices and systems

The device is designed for use in electromagnetic environments specified below. The customer or operator of the device should ensure that the device is operated such an environment.

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Interference immunity tests	IEC 60601 - test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge (ESD) in acc. with IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be made of wood or cement, or covered with ceramic tiles. If the floor is covered by synthetic material, then the relative humidity must be at least 30%.
Electrical fast transient/burst immunity test in accordance with IEC 61000-4-4	±2 kV for mains cables ±1 kV for input and output cables	±2 kV for mains cables ±1 kV for input and output cables	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage surge in accordance with IEC 61000-4-5	±1 kV voltage outer conductor/outer conductor ±2 kV voltage outer conductor/earth	±1 kV push-pull voltage ±2 kV common mode voltage	The quality of the supply voltage should correspond to a typical commercial or hospital environment.
Voltage drops, short-term interruptions and fluctuations of the supply voltage in accordance with IEC 61000-4-11	0% U_T for 1/2 period 0% U_T for 1 period 70% U_T for 25/30 periods 0% U_T for 250/300 periods	< 5% U_T (> 95% drop in U_T) for 1/2 period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	The quality of the supply voltage should correspond to a typical commercial or hospital environment. If the operator of the device needs the unit to continue working even if the mains power supply is interrupted, we recommend powering the device from an uninterruptible power supply (UPS) or from a battery.
Magnetic field for a supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m	30 A/m	The magnetic fields at mains frequency should be within the range of typical values encountered in a commercial or hospital environment.

Table 2: Resistance to electromagnetic interference (immunity) for all devices and systems

Electromagnetic interference immunity for devices or systems that are not life-sustaining

Portable and mobile communication devices should not be used any closer to the unit (including cables) than the recommended safety distance, which is calculated based on the applicable formula for the transmission frequency.

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distance
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	$[V_1]$ V	d = $[3.5 / V_1] \cdot \sqrt{P}$ d = $1.2 \cdot \sqrt{P}$
Emitted HF disturbance variables in accordance with IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	$[E_1]$ V/m	d = $[3.5 / E_1] \cdot \sqrt{P}$ for 80 MHz to 800 MHz d = $1.2 \cdot \sqrt{P}$ for 80 MHz to 800 MHz d = $[7 / E_1] \cdot \sqrt{P}$ for 800 MHz to 2.7 GHz d = $2.3 \cdot \sqrt{P}$ for 800 MHz to 2.7 GHz

Table 3: Electromagnetic interference immunity for units or systems that are operated in healthcare facilities

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

d Recommended safety distance in metres (m)

The field strength of stationary communication devices should be lower than the compliance level for all frequencies based on inspections on site[a].[b]

Interference is possible in the environment of units that have the following symbols.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic radiation is affected by absorption and reflection on the building, objects and people.

[a] The field strength of stationary transmitters, such as the base stations of mobile phones and land mobile radios, amateur radio stations, AM and FM radio and television broadcasters, for example, cannot be accurately predicted. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of electromagnetic phenomena at the site should be considered. If the measured field strength at the location where the unit is used exceeds the compliance levels stated above, the unit should be monitored to verify that it works as intended. If unusual performance characteristics are observed additional measures may be required, such as a changing the orientation of the unit or moving it to a different location.

[b] Over the frequency range of 150 kHz to 80 MHz, the field strength should be less than $[V_1]$ V/m.

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Recommended safety distance between portable and mobile HF communication devices and the unit

The device is designed for use in the electromagnetic environments specified below, in which the HF disturbance variables are controlled. The customer or the operator of the device can help to prevent electromagnetic interference by maintaining the minimum distances between mobile HF communication equipment (transmitters) and the device as recommended below in accordance with the maximum output line of the communication equipment.

Keep a minimum distance of 30 cm between the device and mobile communication devices.

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \cdot \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \cdot \sqrt{P}$
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

Table 4: Recommended safety distance between portable and mobile HF communication devices and the unit

For transmitters whose maximum rated power is not specified in the table shown above, the recommended safety distance d in metres (m) can be determined from the formula that belongs to the respective column where P is the maximum rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer.

Comment 1 The higher frequency range applies for 80 MHz and 800 MHz.

Comment 2 These guidelines may not apply in all cases. The propagation of electromagnetic waves is affected by absorption and reflection on the building, objects and people.

16.4 Calculation table

If the measured values deviate from the standard, the values are specified in chapter "4 Technical data".

The safety distances can then be calculated in the tables shown below.

P: .....

V_1: .....

E_1: .....

P Rated power of the transmitter in Watts (W) in accordance with the specifications of the transmitter manufacturer

V_1 Compliance level for the test in acc. with IEC61000-4-6

E_1 Compliance level for the test in acc. with IEC61000-4-3

Interference immunity tests	IEC 60601 - test level	Compliance level	Recommended safety distances
Conducted HF disturbance variables in accordance with IEC 61000-4-6	3 V_{eff} 150 kHz to 80 MHz	[V_1] V	d = [3.5 / V_1] · √P
Emitted HF disturbance variables in accordance with IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E_1] V/m	d = [3.5 / E_1] · √P for 80 MHz to 800 MHz
			d = [7 / E_1] · √P for 800 MHz to 2.5 GHz

Rated power of the transmitter (W)	Safety distance based on the transmission frequency (m)		
	150 kHz to 80 MHz d = [3.5/V_1] ·√P	80 MHz to 800 MHz d = [3.5/E_1]·√P	800 MHz to 2.5 GHz d = [7 / E_1] ·√P
0.01			
0.1			
1			
10			
100			

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