VAC 1s

Instructions for use

EN | ZK-58.211/00 | 2021-11

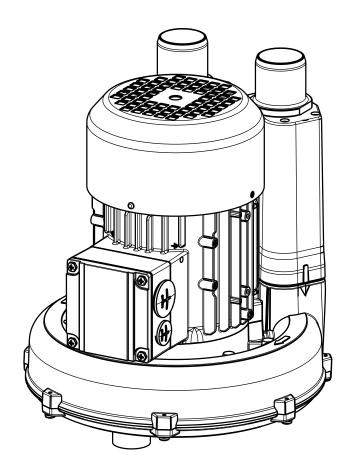






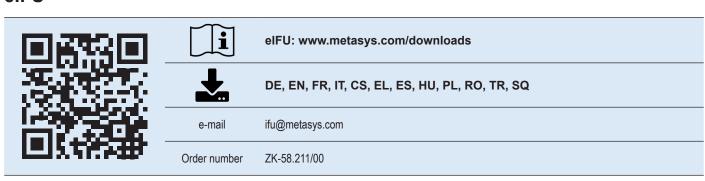




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eIFU



If you would like to request a printed copy of the instructions for use, please contact us at ifu@metasys.com or use the order form at www.metasys.com/downloads A hardcopy of the instructions for use will be made available to you free of charge and within seven calendar days of receipt of the request.

Translations

Translation of the original instructions for use



Tetras GmbH

Sirius Business Park, Rupert-Mayer-Str. 44, 81379 Munich, Germany

Images

The images contained in these instructions for use are for reference and may differ from the actual appearance of the product.

1. Notes

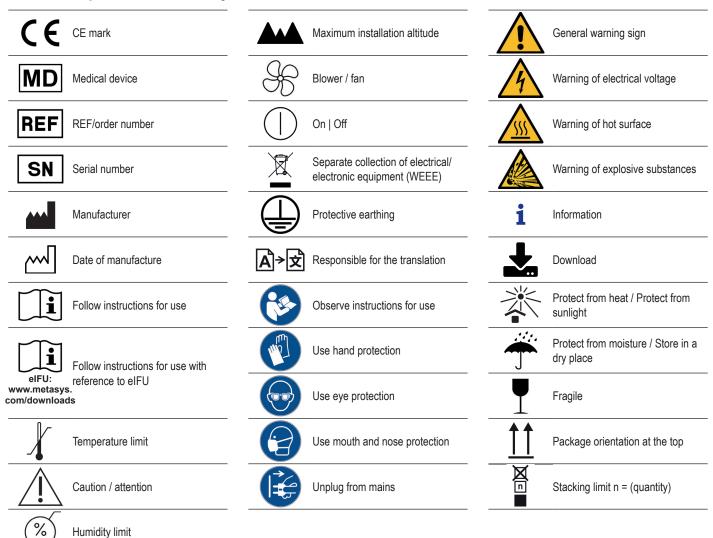
1.1. General instructions

METASYS can only guarantee the safety, reliability and performance of the dental device if the following instructions are adhered to:

- > The product is only to be used in accordance with the instructions for use.
- > During maintenance and service work (inspection, service, repair, replacement), only use original replacement parts.
- > All manufacturer specifications for the treatment units to which the device is connected must be observed.
- > After commissioning, complete the proof of installation and send this to METASYS in order to define the warranty period.
- > All maintenance and service work must be entered into the device logbook.
- > On request by an authorised technician, METASYS will provide all documentation that may be of use to technically qualified personnel during maintenance and service works
- > METASYS accepts no responsibility for damage that may arise due to external influences (defective installation), using incorrect information, improper use of the dental device, or maintenance and service works being carried out improperly.
- > The user must familiarise himself/herself with how to operate the dental device and ensure that the dental device is in good condition each time before operating it.

Important: Read the accompanying documents of the device carefully before installation, commissioning and use and keep them for the entire service life of the product!

1.2. Explanation of the symbols



1.3. Copyright notice

All names and contents are protected by copyright. Distribution, duplication or alternative use of this document is only permitted with the written consent of METASYS Medizintechnik.

2. Intended use

The VAC 1s suction machine is a central suction system for use in dental practices for the generation of central air suction.

2.1. Indication

Not applicable.

2.2. Contraindication

Not applicable.

2.3. Intended users

The device must only be used by healthcare professionals trained in dentistry. Installation, service and maintenance work may only be carried out by METASYS trained technicians.

3. Safety-related information

3.1. General safety-related information

All serious incidents related to the device must be reported to the manufacturer and the competent authority of the Member State where the user and/or the patient is resident.

3.2. Safety instructions



Warning:

This product is an ME device with external power supply, class I, according to EN 60601-1: To avoid the risk of electric shock, this device must only be connected to a mains supply with a protective earth conductor.

Danger:

Use in explosive or flammable locations is prohibited!

Assembly, modifications or repairs may only be carried out by authorised qualified personnel who guarantee compliance with the EN 60601-1 standard (international standard on Medical Electrical Equipment and Systems, in particular part 1: General requirements for basic safety).

The electrical installation must comply with the regulations of the IEC (International Electrotechnical Commission).

3.3. Warnings

Danger	Warning of a danger that will directly result in serious injury or death
Warning	Warning of a danger that can result in serious injury or death
Caution	Warning of a danger that can result in minor injury
Attention	Warning of a danger that can result in extensive damage to property

3.4. Risks and side effects

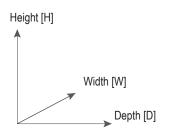
Error message	Possible cause	Countermeasures
Risks	Electronics defective	Main function fails
	Motor faulty	Main function fails
Side effects	Not applicable	Not applicable

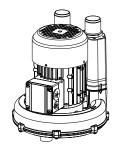
Product description 4.

4.1. **Product description**

The VAC 1s is a single-station dry suction system for the operation of 1 dental treatment unit.

4.2. Technical data / performance data



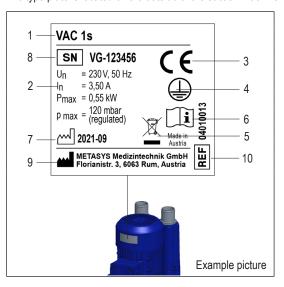




Power supply	230 VCA	230 VCA
Frequency	50 Hz	60 Hz
Max. current consumption	3.5 A	4.5 A
Max. power consumption	0.55 kW	0.63 kW
Max. ambient temperature	35 °C	35 °C
Suction volume	1000 l/min	1000 I/min
Negative pressure range, regulated	120 mbar	140 mbar
Operating time	100%	100%
Weight	11 kg	11 kg
Noise level	53 db(A)	56 db(A)
Dimensions (H x W x D)	280 x 245 x 244 mm	280 x 245 x 244 mm
Protection class	IP 54	IP 54
Class	MD class 1	MD class 1

4.3. Type plate

The type plate is located on the outside of the suction machine.



- Device description
- 2 Connection data
- 3 CE mark
- Protective earthing
- Separate collection of electrical/electronic equipment (WEEE)
- Follow instructions for use
- 7 Date of manufacture
- Serial number
- Manufacturer
- REF/order number

4.4. Construction

Suction machine

The suction machine is a dry vacuum generator with side channel pump. An additional separation unit in the dental unit for the separation of vacuumed liquids and solids from the air stream is required!



Control box (can be retrofit as an option)

The control box includes all electrical components for controlling and monitoring the suction machine.



Condensate separator (can be retrofit as an option)

The condensate separator is used to collect any build up of condensation in the suction line upstream of the suction machine. This can be retrofitted as an option.



4.5. Functional description

The suction process begins when a suction hose is raised from the treatment unit hose rest. The vacuum is generated based on the function principle of a side channel compressor.

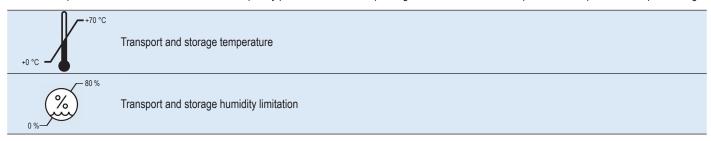
The rotor is mounted directly to the motor shaft and together forms a side channel with the specially shaped housing. The air is sucked in by the rotation of the rotor. In the side channel, the kinetic energy of the rotating rotor transfers the suction air, resulting in compression of the sucked in air. The compressed suction air is conveyed after a rotation and subsequently compressed again and then discharged. This causes a high differential pressure and thus generates a vacuum.

Coarse particles must first be collected in a prefilter (e.g. in the hose rest) in order to prevent deposits in the suction machine. The suction flow is then guided through a separation unit (normally in the treatment unit) which separates the air from the solid and liquid parts of the suction flow. After the separation unit, the suction machine only conveys a dry air flow.

5. Preparation for use

5.1. Transport and storage

The device is shipped in a box. The suction machine is fixed in this box using EPS half shells and can be removed from the box via a cardboard strap. This original packaging must be used and thus stored for any onward and return transport. The device must always be transported and stored in an upright position. The device must be transported to the installation location in a completely packed state. After unpacking the device, check for completeness and possible transport damage.



5.2. Installation requirements





Operating temperature: 10°C to 35 °C

For room temperatures above +35° C, an additional ventilation system must be installed in the installation room!



Humidity limit max. 70 %



Max. 3,000 m above sea level

- Only set up in dry, adequately ventilated rooms (recommendation: air-conditioned rooms)
- the device can be installed in a technical room on the same floor as the treatment unit or one floor below it
- To avoid vibrations, place the appliance only on a firm surface
- for the hose routing on the connection side, a wall clearance of min. 150 mm must be maintained
- the front of the device must be freely accessible

Attention:

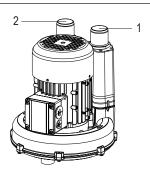


The main switch must not be switched off during the suction process!

Danger:

Use in explosive or flammable locations is prohibited!

5.2.1. Pipe and hose connections



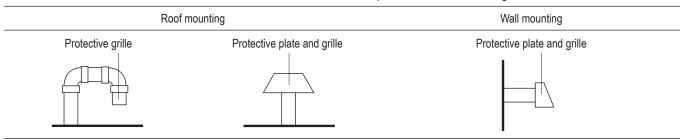
	1	2
Suction hose length	under 5 m	over 5 m
Air inlet Ø	40 mm	40 mm
Exhaust air Ø	≥ 40 mm	≥ 50 mm

Requirements for hose and pipeline assemblies and connections:

- > Use only vacuum-tight pipe material (e.g. HT drainage pipes made of PP, PVC-C, PVC-U, PEHD) that is resistant to all chemicals commonly used in dental practice
- > Use flexible spiral hoses made of PVC or equivalent material
- > Make hoses and pipelines as short as possible: The suction line should not exceed a maximum length of 25 m!
- > Recommended pipe cross-section of 40 mm to minimise suction losses
- > Avoid 90° bends (recommendation: 2 x 45° bends),



- For hygienic reasons and due to possible noise pollution, we recommend fitting the exhaust air connection with a germ filter.
- > The exhaust air connection must be guided outdoors. Precautions must be taken (such as protective covers for the exhaust air shaft) to protect the device or the device room from rain or condensation water and other weather influences and to prevent animals from entering.



> The Ø connection for the exhaust air must be greater than or equal to the Ø connection of the suction line.



Warning:

All hose connections must be secured with hose clamps!

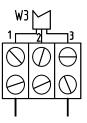
Only heat-resistant (≥ 130 °C) hose and pipe materials may be used for the exhaust air connections!

5.3. Installation, assembly and commissioning

Read the instructions carefully before installation and commissioning! Meet spatial requirements

2	Remove the plug on the suction air and exhaust air connection	
3	Mount grommets on the connections.	
4	Mount the rubber buffers.	
5	Connect high temperature hose (not included in scope of delivery), exhaust air connection	
6	Possible installation of a condensation water outlet (exhaust air side)	
7	Connection of the suction line, air inlet	

8 Connect contacts 1 and 3 to the dental unit (only with control box)



Connect the device to the power supply according to EN 60601-1 (comply with all country-specific standards and safety requirements!)

Inform the dentist about product function, operation, care and warranty conditions.

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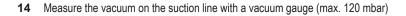
Fill in the installation proof and device logbook and return them to METASYS (installation@metasys. com)

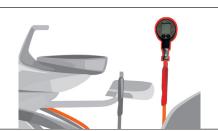


Commissioning

- For devices without control box: Switch on practice main switch For devices with control box: Switch on the practice and device main switches
- Remove the suction hose from the hose tray of the treatment unit







Installation and assembly of optional accessories, retrofit parts and spare parts 5.3.1.



Assembly, modifications and repairs may only be carried out exclusively by authorised specialist personnel (see 3.2. Safety instructions)! The METASYS technical customer service is also available for further information and assistance in carrying out repairs, retrofitting, fault analyses, etc.

5.3.1.1. Connection of the control box

Scope of delivery



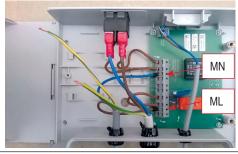
Work preparation



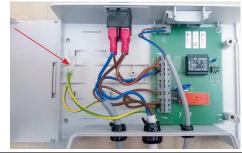
Insert motor cable



Connect motor cable (blue cable on MN, brown cable on ML)



Connect protective earth



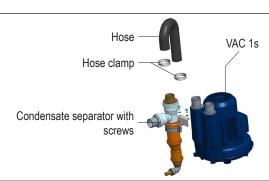
Close control box cover, insert screws into the openings and screw in.



For more information, see also 5.4 Electronics.

5.3.1.2. Mounting the condensate separator

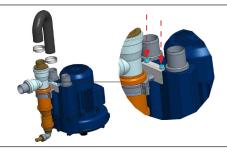
Part designations



Position the condensate separator.



Fasten the condensate separator using 2x screws and 2x spring washers.



Fix the hose in place using the hose clamps.



5.3.2. Connecting to other devices

When connecting the METASYS device to other devices or systems, hazards can arise. It must therefore be ensured that no hazards arise for the user or the patient and that the environment is not affected. The specifications of the manufacturer of the device or system to be connected must be observed.

5.4. **Electronics**

The mains connection may only be carried out by a qualified electrician. The electrical installation must be carried out in accordance with the applicable local regulations. Before connecting to the mains, compare the rated voltage on the device type plate with the mains voltage.

5.4.1. **Electrical connections**

Mains connection

The mains cable may only be replaced by an authorised person in accordance with EN 60601-8.11.3.

The suction machine is controlled via the controller on the external control box:

Attention:



The electrical connection must be made in compliance with the technical regulations for the installation of low-voltage systems in areas used for medical purposes

Danger:

The suction machine may only be connected to the power supply using the mains cable provided.

Extension cables must not be used!



Danger:

The motor connection cable must be laid in such a way that it cannot come into contact with hot surfaces

Electrical circuit protection (only on devices with control box)

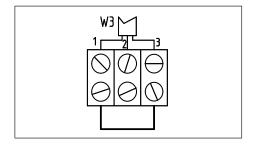
Circuit breaker 16 A, characteristic C according to EN 60898

Main switch (only on devices with control box)

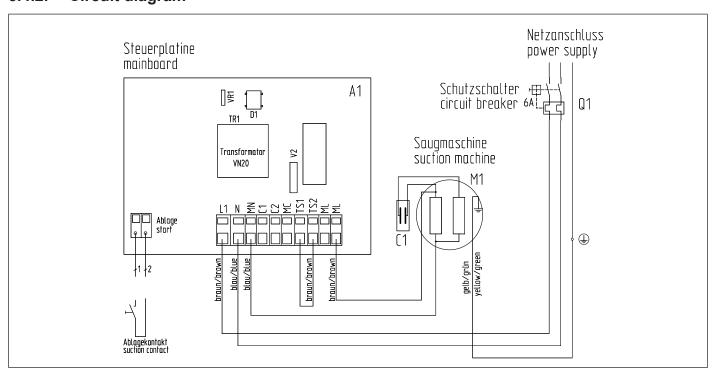
The connection to the mains (230 V) must be made after the practice's main switch. The suction machine is controlled by the electronics located in the switchbox. The suction machine must be positioned so that the circuit breaker is easily accessible. The switchbox must be easily accessible for switching off the suction machine.

Rest signal (only on devices with control box)

The control line for the stacking signal is already connected internally and implemented via a 3-pole cable 3 m in length. Connecting wires 1 and 3 starts the suction system. The control line must be properly connected in a junction box



5.4.2. Circuit diagram



6. Use

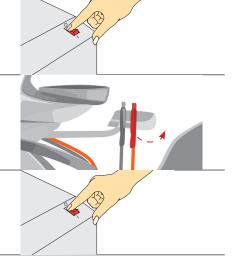
6.1. Normal operation

Switch on the practice or unit main switch (only on devices with control box) at the start of the workday*, machine starts automatically.

Remove suction hose from the treatment unit hose rest in order to automatically start the suction process (only on devices with control box).

The suction process stops as soon as the suction hose is placed back on the hose rest (only on devices with control box).

3 Switch off the practice or unit main switch (only on devices with control box) at the end of the workday.*



*Depending on the installation situation, the device can be used for daily operation:

- > Can be switched on and off directly at the device switch
- > Switched on and off at the practice main switch. In this case, the device switch is always on and the power supply is controlled centrally via the practice main switch.
- > Be permanently switched on and ready for use. It does not affect the device in any way.

6.2. Error messages



Assembly, modifications and repairs may only be carried out exclusively by authorised specialist personnel (see 3.2. Safety instructions)! The METASYS technical customer service is also available for further information and assistance in carrying out repairs, retrofitting, fault analyses, etc.

Error message	Possible cause	Countermeasures
Device does not start	No mains voltage	Check mains voltage. Check fuses (mains fuse, fuse in the control box or on the circuit board).
	Mains voltage too low	Check the mains voltage, contact an electrician if necessary
	Capacitor defective	Measure capacitor capacitance and replace if necessary
	Start signal (suction contact) (only on devices with control box)	Check and measure start signal (suction contact), establish if necessary
	Thermal protection in motor winding triggers	Measure current; check fine running of motor; allow to cool down - restart
Suction power too low	Suction line leaking	Check suction line for leaks and repair/replace if necessary.

7. Care and maintenance

7.1. Maintenance and service

The VAC 1s is a maintenance-free suction system. Regular cleaning measures or maintenance is therefore not required.

8. Decommissioning

8.1. Disassembly



Warning

Remove from power source before disassembly!







Warning:

Risk of contamination: To avoid infection, wear personal protective equipment (hand, eye, nose and mouth protection) and disinfect and clean the device!

If it is necessary to return the device to the depot or to METASYS, the original METASYS packaging must be used. Before packing the METASYS device to be transported, clean and disinfect it. Possible openings where residual fluids could escape must be closed.

8.2. Recycling and disposal



The device may be contaminated! Advise the disposal company of this so that appropriate precautions can be taken. Parts that are contaminated with amalgam, such as sieves, filters, hoses, etc., must also be disposed of in accordance with the national regulations.

Uncontaminated plastic parts of the device can be recycled as normal plastics. The integrated electronic components (including circuit board) are to be disposed of as electronic waste. Metal parts are to be disposed of as scrap metal.

Alternatively, the device can be returned to the manufacturer for proper disposal. Before packing the METASYS device to be transported, clean and disinfect it. Possible openings where residual fluids could escape must be closed. The original METASYS packaging must be used for shipping.

The proof of installation and the device logbook must be kept for 5 years after the device has been disposed of.

9. Annex

9.1. REF numbers and scope of delivery

REF	Designation	Scope of delivery
04010013	VAC 1s, 1 station 0.55 kW, 230 V, 120 mbar, ready for connection	Suction machine (ready for connection) and instructions for use
04010013 + 50060208 or 50060209	VAC 1s with control 1s, 1 station 0.55 kW, 230 V, 120 mbar, ready for connection	Suction machine (ready to connect), control and instructions for use

9.1.1. Accessories, service kits, collection containers and spare parts

REF	Designation
40060002	EXCOM hybrid 1s germ filter, A1/1, A2/2, VAC 1s, diameter 40 mm
50060208	1s for EXCOM hybrid 1s control, VAC 1s
50060209	1s 3-Pin for EXCOM hybrid 1s control, VAC 1s
50060312	Control board for EXCOM hybrid 1s/VAC 1s
50070019	VAC 1s condensate separator, diameter 40 mm

9.2. Warranty conditions

METASYS grants a guarantee of 12-36 months for specific products (duration of guarantee depends on the product according to the information in the current price list).

The guarantee covers all material faults that more than negligibly affect the function of the device. The guarantee does not cover damages caused by incorrect or improper handling as well as normal wear. Furthermore, the guarantee does not apply to the replacement of the amalgam collection container or to fragile parts such as glass, plastic, hoses, filters, condensate filters or membranes. Any incurred working and travel times are excluded from the warranty.

In order to determine the validity of the guarantee, the installation proof accompanying the device must be returned to METASYS immediately after proper assembly has taken place. In this case the warranty period begins with commissioning. In the event of installation without returning the installation proof to METASYS, any warranty claim is forfeited. Installation and return of installation proof must be completed within 24 months from the date of sale from METASYS.

Furthermore, any warranty claims of the customer expire if only one of the following circumstances arises, regardless of whether the circumstances arise for the customer of METASYS or a later owner or operator:

- > Improper installation, operation, maintenance or transport of the device. If METASYS parts have to be returned, the original METASYS packaging must be used for shipping. Prior to packaging and shipping, the METASYS device must be cleaned and disinfected. Any openings where residual fluids could leak must be closed.
- > Installation and return of installation proof have not been completed in the aforementioned 24 months.
- > Failure to send the Installation Proof to METASYS.
- > Installation and use of non-original METASYS parts.
- > Installation of the device by personnel who are neither trained nor authorized by METASYS.
- > Occurrence of damages through improper handling and operation or use of unapproved cleaning and/or disinfecting material, as well as non-compliance with the instructions for use.
- > Execution of repairs by unauthorised repair shops or unathorised personel.
- > Failure to comply with the prescribed maintenance intervals. Maintenance must be carried out 11-12 / 23-24 / 35-36 months after installation of the respective METASYS item.
- > Missing entries in the Equipment Logbook regarding the installation as well as prescribed servicing by technicians trained by METASYS.
- > Failure to take reasonable immediate measures to avoid further damages in the event of a malfunction.
- > Shipping of devices or components to METASYS without proper accompanying paperwork, in particular without error description or invoice for the purchase of the device.
- > Failure to provide visual images (photos, video clips ...) of the METASYS item complained about, as well as of its installation situation and ambient conditions.

METASYS reserves the right to demand the documentation supplied with the device to check the maintenance intervals for the assertion of warranty claims. The processing of warranty claims takes place exclusively according to the following method:

In the event of malfunctions, the device must be opened by an authorized technician, the relevant component taken out and sent to METASYS unopened and cleaned. The customer sends the device or component in question to METASYS at his own expense. METASYS checks whether there is a warranty claim. METASYS will repair the device or component if it is cost-effective. The customer is charged for the costs incurred for the repair, but not the replacement parts covered by the guarantee. The consignment of the device or component to METASYS always represents a repair order for METASYS. For cost estimates for the repair of returned devices, a processing fee* is charged if the warranty period has expired or no warranty case exists. For products inspections only without any cost estimates a processing fee* can be charged. When sending the device or component to METASYS, an error description with all importation information about the device must always be included. The customer of METASYS may only provide payment in advance after consultation with METASYS. Only the affected component is to be sent in (smallest possible unit). If contaminated, intact parts are sent to METASYS without technical necessity, METASYS is entitled to destroy them without separate payment. The new part corresponding to the part to be destroyed is only delivered after a separate order and invoice. In any case, METASYS has the right to handle the guarantee through credit note or the return of new parts without conducting repairs. Guarantee services do not result in an extension of the

warranty period nor do they initiate a new warranty period. The warranty period for installed replacement parts ends with that for the originally delivered device. The METASYS customer is obligated to make his customer aware of the conditions regarding the warranty processing. The statutory warranty rights of the customer remain unaffected.

Change history 9.3.

Revision	Date	Description
ZK-58.211/00	08.11.2021	Newly created.

^{*} The current warranty conditions and fees can be found in the current METASYS price list.

