Instructions for use

INTRA-L-MOTOR 181 H – 0.535.5200

KAVO
Dental Excellence

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CE 0124

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1 User instructions

Dear User,
Congratulations on purchasing this KaVo quality product. By following the instructions below you will be able to work smoothly, economically and safely.

KaVo, INTRA and INTRAmatic are either registered trademarks or trademarks of KaVo Dental GmbH.

All other trademarks are property of their respective owners.

KaVo Technical Service
Please direct all questions regarding the product, service and maintenance to the KaVo Technical Service:
Toll-free: 1-888-KAVOUSA (888-528-6872)
Email: techservice@kavo.com
Please refer to the serial number of the product in all inquiries.

KaVo Repair Service
For repairs, please contact the KaVo Repair Service. For scheduling or if you have any questions, please contact:
KaVo Dental Technologies, LLC
11727 Fruehauf Drive
Charlotte, NC 28273 USA
Toll-free Direct Customer Service: 1-888-KAVOUSA (888-528-6872)
Email: techservice@kavo.com
www.kavo.com

Target group

The instructions for use are intended for medical professionals, in particular dentists and office personnel.

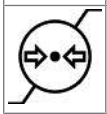
The section on startup is also intended for the service staff.

General marks and symbols

	See Chapter on User Instructions/Hazard Levels
	Important information for users and service technicians
▶	Action request
CE	CE mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
MD	Medical device, labeling of medical devices
135 °C	Sterilizable by steam

Information on the packaging

REF	Material number
SN	Serial number

	UDI symbol
	Manufacturer
	Attention: Please consult the accompanying documents
	Follow the electronic instructions for use
	HIBC Code
	CE mark for medical devices
	EAC conformity mark (Eurasian Conformity)
	UA Mark of conformity
	Medical device, labeling of medical devices
	Transportation and storage conditions (temperature range)
	Transportation and storage conditions (air pressure)
	Transportation and storage conditions (humidity)
	Protect from moisture
	Protect from impact
	Original language German

Hazard levels

The warning and safety notes in this document must be observed to prevent personal injury and property damage. The warning notes are designated as shown below:

⚠ HAZARD

In cases which – if not prevented – directly lead to death or severe injury.

⚠ WARNING

In cases which – if not prevented – can lead to death or severe injury.

⚠ CAUTION

In cases which – if not prevented – can lead to minor or moderate injury.

NOTICE

In cases which – if not prevented – can lead to property damage.

2 Safety

NOTE
All serious events occurring in relation to the product must be reported to the manufacturer and the competent authority of the member state, in which the user and/or patient resides.

The instructions for use are a component of the product and must be read carefully prior to use and be accessible at all times.
The device may only be used in accordance with the intended use, any other type of use is not permitted.

Individual warning notes must be observed in the corresponding chapters.

2.1 Infection hazard

Patients, users or third parties may get infected by contaminated medical devices.

- Take suitable personal protective measures.
- Follow the instructions for use of the components.
- Before initial startup and after each use, process the product and accessories appropriately.
- Carry out the processing as described in the instructions for use. The procedure has been validated by the manufacturer.
- If you deviate from this validated procedure, make sure that the processing procedure is effective.
- Process the product and accessories appropriately before disposal.

2.2 Technical condition

A damaged product or damaged or NOT KaVo original components could injure patients, users or third parties.

- Use the device and components only if there is no damage on the outside.
- Check to make sure that the device is working properly and is in satisfactory condition before each use.
- Have parts with sites of breakage or surface changes checked by the Service.
- If the following defects occur, stop working and have the service personnel carry out repair work:
  - Malfunctions
  - Damage (e.g. caused by being dropped)
  - Irregular running noise
  - Excessive vibration
  - Overheating
  - Imbalance
  - Insufficient retention force

To ensure optimum function and to prevent property damage, please comply with the following instructions:

- Service the medical device with care products and systems regularly as described in the instructions for use.
- The product should be processed and stored in a dry location, according to instructions, if it is not to be used for an extended period of time.

2.3 Accessories and combination with other equipment

Use of un-authorized accessories on the device or un-authorized modifications to the device can lead to injury.

- Only use accessories that have been approved for combination with the product by the manufacturer.
- Do not make any modifications to the device unless these have been approved by the manufacturer of the product.
- Use original KaVo spare parts only.
- Comply with the Instructions for Use of the treatment center / control unit.

2.4 Qualification of personnel

Application of the product by users lacking appropriate medical training can injure the patient, the user or third parties.

- Make sure that the user has read and comprehends the instructions for use.
- Only employ the device if the user has the appropriate medical training.
- Make sure that the user has read and comprehends the national and regional regulations.

2.5 Service and repair

Repairs, servicing and safety checks may only be performed by trained service personnel. The following persons are authorized to do this:

- Service technicians of KaVo branches after the appropriate product training
- Service technicians of KaVo authorized dealers after the appropriate product training

Comply with the following items during all servicing work:

- Have the service and testing tasks carried out in accordance with the Medical Device Operation Ordinance.
- Have the medical device evaluated by a professional shop with regard to its cleaning, servicing and functional needs according to an in-house service interval. Define the service interval depending on the frequency of use.

As a result of the use of NON-KaVo original spare parts during the repair, parts such as covers may become undone and injure the patient, user or third parties. This may result in aspiration, swallowing of parts and possibly even a risk of suffocation.

- Only use spare parts that comply with the specification for repair; original manufacturer spare parts comply with the specification.

NOTE

If a repair is done with NON-KaVo original spare parts, this may constitute a product modification that leads to the loss of CE conformity. In the event of damage, the responsibility is with the service company or the operator.

The introduction into the market of a modified product, where there is reasonable suspicion that the safety and health of patients or users may be jeopardized, is prohibited by the German medical device law §4, section 1 no. 1 and requires a separate conformity check.

2.6 Property damage

Contaminated and moist compressed air or contaminated water can cause malfunctions and premature wear.

- Make sure to supply dry, clean and uncontaminated compressed air in accordance with ISO 7494-2.

3 Product description

INTRA-L-MOTOR 181 H (**Mat. No. 0.535.5200**)

3.1 Intended use

Indications for use:

The motor is:

- an air motor intended to operate/drive a dental handpiece or contra-angle handpiece
- Intended for dental treatment only. All other types of use or modifications to the product are not permitted and can be hazardous.
- A medical device according to relevant national statutory regulations.

⚠ CAUTION

US Federal law restricts this device to sale by or on the order of a healthcare professional / dentist.

For dental use only.

Proper Use:

According to these regulations, this product may only be used for the described application by a properly trained user. You need to comply with the following:

- the applicable health and safety regulations
- the applicable accident prevention regulations
- these Instructions for use

In accordance with these regulations, the user is required to:

- Only use equipment that is operating properly.
- Comply with the specified intended use.
- Protect himself or herself, the patient and third parties from hazards.
- Prevent contamination by the product.

3.2 Technical Specifications

Operating speed	5,000 to 20,000 rpm
Drive pressure	2.2 to 2.7 bar (32 to 39 psi)
Return air pressure	< 1.1 bar (16 psi)
Spray water pressure	0.8 to 2.5 bar (12 to 36 psi)
Spray air pressure	1.0 to 4.0 bar (15 to 58 psi)
Air consumption	up to 60 Nl/min
Idle torque	2.5 Ncm at 2.2 bar (32 psi)
Connector	4-hole standard connection according to ISO 9168 type 3
Can be attached	Straight and contra-angle handpieces with INTRAmatic connection according to ISO 3964 type 1 and type 2

Air requirements

Air quality in accordance with ISO 7494-2	dry, oil-free, dirt-free, non-contaminated
Air filter, supplied by customer	< 20 µm

Water requirements

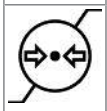
Water quality in accordance with ISO 7494-2	Tap water
pH	7.2 - 7.8
Water filter, supplied by customer	< 80 µm

Ambient conditions

Temperature	+5 °C to +40 °C (41 °F to 104 °F)
Relative humidity	30 % to 75 %
Air pressure	700 hPa to 1060 hPa (10 psi to 15 psi)

3.3 Transportation and storage conditions

- Do not store in a refrigerated environment.

	Temperature: -29 °C to +50 °C (-20 °F to +122 °F)
	Relative humidity: 5% RH to 85% RH absence of condensation
	Air pressure: 700 hPa to 1060 hPa (10 psi to 15 psi)
	Protect from moisture

4 Startup and shut-down

⚠ WARNING

Hazard from contaminated products.

Patients, users or third parties may get infected by contaminated medical devices.

- Prior to initial startup and after each use, process the product and accessories.

⚠ WARNING

Dispose of the product in the appropriate manner.

Patients, users or third parties may get infected by contaminated medical devices.

- Process the product and accessories before disposal.

Also refer to:
7 Processing steps in accordance with ISO 17664-1 / ISO 17664-2, Page 17

Current packaging law

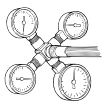
Dispose of the packaging properly in accordance with the current packaging law using disposal companies/recycling firms. Comply with the comprehensive return system. KaVo has had its packaging licensed for this purpose. Please comply with the regional public waste-disposal system.

4.1 Checking the pressures

NOTICE

Damage from soiled and moist cooling air/compressed air.
Contaminated and moist cooling air can cause malfunctions.

- Make sure that the supplied cooling air is dry, clean and free of contamination in accordance with ISO 7494-2.



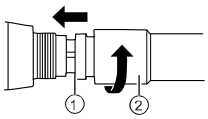
- Insert the pressure gauge (**Mat. No. 0.411.8731**) between hose and motor and check the following pressures according to the technical data:
  - Drive pressure
  - Return air pressure
  - Spray water pressure
  - Spray air pressure

Also refer to:
3.2 Technical Specifications, Page 11

5 Operation

NOTE
At the beginning of each workday, the water-conducting systems should be rinsed for at least 2 minutes (without transmission handpieces being attached) and if there is a risk of contamination from reflux or back suction, the system may also need to be rinsed for 20 to 30 seconds after each patient.

5.1 Connecting the motor to the supply hose



- Attach plug-in fitting ① to the motor connection and screw it tight in clockwise direction using the sleeve ②.

NOTE
Details on the hose coupling can be obtained from the manufacturer.

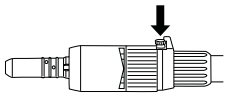
5.2 Regulating the spray water

⚠ CAUTION

Hazard from insufficient amount of spray water.

Damage to the cog due to overheating.

- Make sure that the motor speed is appropriate for the preparation on hand.
- Use the requisite minimal amount of spray water.



- Rotate the regulating screw of the motor to regulate the water portion of the spray.

5.3 Attaching an instrument to the motor

All straight and contra-angle handpieces with INTRAmatic connection according to ISO 3964 type 1 and type 2 can be attached.

⚠ CAUTION

Make sure that the handpiece is firmly seated on the motor.

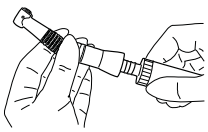
The handpiece detaching inadvertently from the motor during treatment can cause a hazard to the patient and user.

- Pull on the handpiece before each treatment to check that it is engaged and locked in place.

NOTICE

Attaching and removing instruments during rotation.
Property damage to the product.

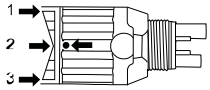
- Do not attach or remove the instruments during rotation.
- Only use reliable handpieces.



- Attach instrument to motor and snap into place.
- Pull on it to make sure that the handpiece is securely attached to the motor.

5.4 Removing an instrument from the motor

- Pull the instrument off the motor in axial direction.



5.5 Regulating the speed and changing the direction of rotation

- Rotate the regulating sleeve to regulate between idle ② in clockwise rotation ① or counterclockwise rotation ③ and maximal speed in a continuous manner.

6 Troubleshooting

⚠ WARNING

Use of NON-KaVo original spare parts in repairs.

Parts can become undone and cause injury. Aspiration, swallowing of parts, danger of suffocation.

- Only use spare parts that comply with the specification for repair; original KaVo spare parts comply with the specification.

NOTE

If a repair is done with NON-KaVo original spare parts, this may constitute a product modification that leads to the loss of CE conformity. In the event of damage, the responsibility is with the service company or the operator.

The introduction into the market of a modified product, where there is reasonable suspicion that the safety and health of patients or users may be jeopardized, is prohibited by the German medical device law §4, section 1 no. 1 and requires a separate conformity check.

6.1 Changing O-rings on the coupling

NOTICE

Improper care of the O-rings.
Malfunction or complete failure.

- Do not use Vaseline or other grease or oil.
- Spray a lint-free cloth with KaVo Spray and apply it to the O-rings on the coupling.

- Press the O-ring between your fingers to form a loop.
- Push the O-ring to the front, and remove it.
- Spray a lint-free cloth with KaVo Spray, apply it to the new O-rings and insert them in the recesses.

7 Processing steps in accordance with ISO 17664-1 / ISO 17664-2

7.1 Preparations at the site of use

⚠ WARNING

Hazard from contaminated products.

Patients, users or third parties may get infected by contaminated medical devices.

- Take suitable personal protective measures.

- To minimize the risk of infection during processing, always wear protective gloves.
- Process the medical device right after treatment.
- Remove all residual cement, composite or blood immediately.
- Disinfect the medical device by wiping before transport.
- Remove straight and contra-angle handpieces from the medical device.
- Do not immerse in solutions or the like.

7.2 Manual processing

⚠ CAUTION

The dental motor is an integral part of the water-conducting system of the treatment center. Germs and bio-films may be formed in the lines. This is associated with an infection risk.

This results in the following requirements for the workflow at the practice:

- Rinse all withdrawal sites of the water-conducting systems for 2 minutes at the start of the workday (without any transfer handpieces attached).
- After each treatment of a patient, purge/rinse the cooling water withdrawal sites with air and/or water for at least 20 seconds.
- The permanent/intensive germ reduction of the water-conducting systems is managed through the unit. Please note the compatibility of the materials with the disinfectants used.

NOTICE

Never process this medical device in an ultrasonic device.
Malfunction and material damage.

- Process by hand only.

7.2.1 Manual external cleaning and manual external disinfection

⚠ WARNING

Incomplete disinfection.

Patients, users or third parties may get infected by contaminated medical devices.

- Only use disinfection procedures that are verified to be bactericidal, fungicidal and virucidal.
- If the disinfectants/disinfection procedures fail to meet the mandatory national requirements, perform a final sterilization applying the sterilization parameters as described.

NOTICE

Use of the disinfection bath or chloride-containing disinfectants.
Malfunction and material damage.
- Do not disinfect the device in the disinfection bath or with chloride-containing disinfectants.

- CaviWipes and CaviCide made by Metrex

The validations for efficacy and material compatibility were carried out using CaviWipes cleaning and disinfection wipes from Metrex.

Manual external cleaning

- Thoroughly wipe the outer surfaces of the medical device with a CaviWipes cleaning and disinfecting wipe to remove all visible deposits.
- Thoroughly wipe the outer surfaces of the medical device with a second CaviWipes cleaning and disinfecting wipe to remove any remaining impurities that are not visible.

Manual external disinfection

- Finally wipe the outer surfaces of the medical device with a third CaviWipes cleaning and disinfecting wipe and allow to act according to the disinfectant manufacturer's instructions (3 min.).
- Comply with the instructions for use of the disinfectant.

NOTE
Cleaning and servicing of the site of coupling.
To maintain uninterrupted operation, it is recommended to clean the grooves for the O-rings semi-annually.
- For this purpose, take all O-rings off the coupling peg and remove all adhering particles and lime scale from the grooves using a wet, lint-free cotton cloth.

NOTE
If the connection to the instrument is not leak-proof, replace all O-rings.

7.2.2 Manual internal cleaning

Not applicable.

7.2.3 Manual internal disinfection

Not applicable.

7.2.4 Manual drying

NOTICE

Moisture.
Corrosion and other product damage.
- Store motors in a dry place.

- If there is any residual moisture after cleaning and disinfecting, soak up the residual moisture with a soft cotton cloth and then wipe dry.
- Immediately after drying, lubricate the KaVo medical device with care agents from the care system.

Also refer to:
7.4 Care products and systems - Servicing, Page 19

7.3 Automated processing

Not applicable.

7.4 Care products and systems - Servicing

⚠ CAUTION

Improper service and care.

Risk of injury.

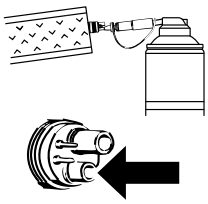
- Perform regular proper care and servicing.

NOTE

KaVo guarantees the proper function of KaVo products only if the care products listed by KaVo as accessories are used, since these were tested for proper use on our products.

7.4.1 Servicing with KaVo Spray

KaVo recommends servicing the product as part of the reprocessing after each use, i.e. after each cleaning, disinfection, and before each sterilization, but no later than after 30 minutes of operation.



- Unscrew the motor from the hose.
- Cover the medical device with the KaVo Cleanpac bag, and place it on the corresponding care adapter.
- Press the spray key once for 1-2 seconds.

7.4.2 Servicing with KaVo QUATTROcare PLUS

KaVo recommends servicing the product as part of the reprocessing after each use, i.e. after each cleaning, disinfection, and before each sterilization, but no later than after 30 minutes of operation.

- Unscrew the motor from the hose.
- Service the device in the QUATTROcare PLUS.

Also refer to:
Instructions for use KaVo QUATTROcare PLUS

7.5 Packaging

NOTE

The sterile goods package must be large enough to accommodate the product without stretching the packaging. The quality and use of the sterilization packaging must comply with applicable standards and be suitable for the sterilization procedure!

- Seal the medical device separately in a sterile pack.

7.6 Sterilization

Sterilization in a steam sterilizer (autoclave) in accordance with ISO 17665-1

Sterilization has to be performed using a steam sterilizer (autoclave) approved by the U.S. Food and Drug Administration (FDA).

⚠ CAUTION

Improper service and care.

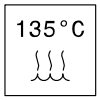
Risk of injury.

- Perform regular proper care and servicing.

NOTICE

Contact corrosion due to moisture.
Damage to the product.

- Remove the product from the steam sterilizer immediately after the sterilization cycle.



The medical device has a maximum temperature resistance up to 138 °C (280.4 °F).

Sterilization parameters:

Sterilization of the product is approved for the following "wrapped" steam sterilization cycles:

- Sterilizer with triple pre-vacuum:
  - 3 minutes at 135 °C (275 °F)
    Drying time: 16 min.
- Remove the medical device from the sterilizer immediately after completion of the sterilization cycle.
- Use in accordance with the manufacturer's Instructions for Use.

7.7 Storage

Processed products must be stored, protected from bacteria, to the extent possible, and dust, in a dry, dark, cool room.

NOTE
Observe the expiration date of the sterilized item.

8 Optional aids and consumables

Available from dental suppliers.

Material summary	Mat. no.
Spare washer	**0.553.1872**
O-ring 8.3 x 0.68	**0.200.6120**
Cleanpac 10 units	**0.411.9691**
Spray head INTRA (incl. nipple)	**0.411.9911**
KaVo Spray American region and Canada 2113 A	**0.411.9660**
QUATTROcare plus Spray USA and Canada 2141 P	**1.005.4524**

9 Terms and conditions of warranty

This KaVo medical device is subject to the following warranty conditions:
KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and workmanship for a period of 12 months from the date of the invoice, subject to the following conditions:
With regard to justified complaints KaVo will fulfil the terms and conditions of the warranty either through a free-of-charge repair or delivery of a replacement product. Other claims of any nature whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply in the absence of mandatory legal regulations to the contrary.
KaVo shall not be liable for defects and their consequences that have arisen or may arise from natural wear, improper handling, cleaning, maintenance or servicing, non-compliance with operating, maintenance or connection instructions, calcination or corrosion, contaminated air or water supplies or chemical or electrical factors deemed abnormal or impermissible in accordance with the KaVo instructions for use or other manufacturer's instructions. The warranty granted does not usually extend to lamps, optical fibers made of glass and glass fibers, glassware, rubber parts, and the colorfastness of plastic parts.
All liability shall be excluded if defects or their consequences are caused by the customer or third parties not authorized by KaVo making manipulations or changes to the product.
Warranty claims shall be accepted only if the product is submitted along with proof of purchase in the form of a copy of the invoice or note of delivery. The dealer, purchase date, type, and serial number must be clearly evident from this document.

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