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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.
<table>
<thead>
<tr>
<th>Symbols</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Refer to the Chapter on Safety/Warning symbol</td>
</tr>
<tr>
<td>i</td>
<td>Important information for users and service technicians</td>
</tr>
<tr>
<td>➡</td>
<td>Action request</td>
</tr>
<tr>
<td>135°C</td>
<td>Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)</td>
</tr>
<tr>
<td>-------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Thermodisinfektable</td>
</tr>
</tbody>
</table>

CE mark (European Community). A product bearing this mark meets the requirements of the applicable EC directive.
Target group

This document is intended for dentists and their assistants. The section on starting up is also intended for service technicians.
2 Safety

2.1.1 Description of safety instructions: Warning symbol

Warning symbol
2.1.2 Description of safety instructions: Structure

DANGER
The introduction describes the type and source of the hazard. This section describes the potential consequences of non-observance.

▶ The optional step includes necessary measures for hazard prevention.
2.1.3 Description of safety instructions: Description of hazard levels

The safety instructions listed here, together with the three levels of danger will help avert property damage and injury.

<p>| CAUTION |
| CAUTION indicates a hazardous situation that can cause damage to property or mild to moderate injuries. |</p>
<table>
<thead>
<tr>
<th>WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>WARNING</td>
</tr>
<tr>
<td>indicates a hazardous situation that can cause death or serious injury.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DANGER</th>
</tr>
</thead>
<tbody>
<tr>
<td>DANGER</td>
</tr>
<tr>
<td>indicates a hazardous situation that can directly cause death or serious injury.</td>
</tr>
</tbody>
</table>
2.2 Safety instructions

**WARNING**

Hazard to the care provider and patient.
Stop working in case of damage, irregular noise during operation, excessive vibration, unusual build-up of heat or if the SonicFill Unidose Tips cannot be firmly held.

- Before extended periods of non-use, the instrument must be cleaned, serviced and stored in dry condition according to the instructions.
CAUTION

Premature wear and malfunctioning from improper storage during long periods of nonuse.
Reduced product life.

▶ The medical device should be cleaned, serviced and stored in a dry location, according to instructions, before long periods of nonuse.
CAUTION

Injury or damage due to wear.
Irregular operating noise, excessive or very low vibrations or if the SonicFill Unidose Tip becomes detached.

▶ Stop working and contact service support.
<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure that the SonicFill Unidose Tips are firmly attached to the SONICfill 2010. Before each treatment, pull on the SonicFill Unidose Tips to see if it is securely attached to the handpiece.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swallowing or aspiration of the SonicFill Unidose Tip by the patient.</td>
</tr>
<tr>
<td>- Before each treatment involving the SONICfill 2010, insert a rubber dam for safety reasons.</td>
</tr>
</tbody>
</table>
The following individuals are authorized to repair and service KaVo products:

- Technicians at KaVo branches throughout the world
- Technicians specially trained by KaVo

To ensure proper function, the medical device must be set up according to the reprocessing methods described in the KaVo Instructions for Use, and the care products and care systems described therein must be used. KaVo recommends specifying a service interval at the dental office for a licensed shop to clean, service and check the functioning of the medical device. This service interval depends on the frequency of use and should be adjusted accordingly. Service may only be carried out by KaVo-trained repair shops using original KaVo replacement parts.
3  Product description

SONICfill 2010, Mat. no. 1.007.7400
The SONICfill 2010 is a dental handpiece in accordance with ISO 15606. The handpiece can be used to automatically dispense rheologically-matched filling materials (contained in SonicFill Unidose Tips) into a dental cavity by the action of sound and pressure.

### 3.1 Purpose – Proper use

**Purpose:**

The SONICfill 2010 is a dental delivery system intended to be used to dispense SonicFill Unidose Tips, a dental restorative resin, directly into dental cavities.
This medical device is

▪ intended for dental treatment only. Any other type of use or alteration to the product is impermissible and can be hazardous.

The SONICfill 2010 must be used exclusively in combination with the SonicFill Unidose Tip for filling dental cavities with composite materials.

▪ A medical device according to relevant national statutory regulations.
Proper use:

According to these provisions, the medical device is only for the described use in conformance with:

▪ the applicable health and safety regulations,
▪ the applicable accident prevention regulations
▪ and these instructions for use.

According to these regulations, the user is required to:

▪ only use properly operating equipment,
▪ use the equipment for the proper purpose,
▪ to protect himself, the patient and third parties from danger,
▪ to avoid contamination from the product.
3.2 Technical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drive pressure</td>
<td>3 – 4.2 bar</td>
</tr>
<tr>
<td>Air consumption</td>
<td>10 – 40 NL/min</td>
</tr>
<tr>
<td>Frequency</td>
<td>5 – 6 kHz</td>
</tr>
<tr>
<td>Ejection force</td>
<td>0 to 170 N</td>
</tr>
</tbody>
</table>

Please note that the values mentioned above relate to the pressure in the handpiece and not to the pressure of the treatment centre itself. No adjustment should be required if the treatment centre is set at 2.1 - 3.5 bar, (which is normally the case when a turbine is used. However, if correction is
required, please observe the instructions for the proper measurement and calibration of the hand-piece pressure in Chapter "4.4 Testing pressures" of these instructions for use.

The SONICfill 2010 can be mounted on all MULTIflex couplings.
3.3 Transportation and storage conditions

CAUTION

It is hazardous to start up the medical device after it has been stored strongly refrigerated. This can cause the medical device to malfunction.

- Prior to start-up, very cold products must be heated to a temperature of 20°C to 25°C (68°F to 77°F).
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature</td>
<td>-20°C to +70°C (-4°F to +158°F)</td>
</tr>
<tr>
<td>Relative humidity</td>
<td>5% RH to 95% RH absence of condensation</td>
</tr>
<tr>
<td>Air pressure</td>
<td>700 hPa to 1060 hPa (10 psi to 15 psi)</td>
</tr>
<tr>
<td>Protect from moisture</td>
<td></td>
</tr>
</tbody>
</table>
4 First use

The SONICfill 2010 can be connected to any turbine hose of a treatment centre through a MULTIflex coupling.

⚠️ WARNING

Hazard from non-sterile products.
Infection hazard for care provider and patient.

- Sterilise the medical product before its first use and reprocess it after each use in accordance with the medical application, national regulations, and legal provisions.
### 4.1 Connection to devices

<table>
<thead>
<tr>
<th>![WARNING]</th>
<th><strong>WARNING</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Damage from soiled and moist cooling air. Contaminated and moist cooling air can cause malfunctions and lead to premature bearing wear.</td>
<td></td>
</tr>
<tr>
<td>▶ Always make sure that the supply of cooling air is dry, clean and uncontaminated according to ISO 7494-2.</td>
<td></td>
</tr>
</tbody>
</table>
4.2 Installing the MULTIflex coupling

▶ Screw the MULTIflex LUX/MULTIflex LED coupling onto the turbine hose and tighten with the wrench.
4.3 Checking the O-rings

**CAUTION**

Missing or damaged O-rings.
Malfunctions and premature failure.

- Make sure that all O-rings are on the coupling and undamaged.

Number of available O-rings: 5
4.4 Checking the pressures

A minimum drive pressure of 3 bar \textit{measured on the handpiece} is required to operate the SonicFill handpiece. \textit{3.5 bar is ideal}. The drive air in the SonicFill handpiece is automatically reduced at a setting between 3.5 - 4.2 bar. The air consumption is approximately 20 - 40 NI/min. Insert the test manometer between the MULTIflex coupling and the SonicFill handpiece. Set the regulating ring at stage 5.
Pressure displayed:

- Drive air T.R. = 3 - 4.2 bar
- Return air R.L. < 0.4 bar
- No water or spray air are needed, though.
5  Operation

5.1  Attaching the SONICfill 2010

CAUTION
Ensure that the SONICfill 2010 is firmly seated on the coupling. The SONICfill 2010 can be a hazard for patient and user if it inadvertently comes undone from the coupling during the treatment.

▶ Before each treatment, pull on the SONICfill 2010 to check if it is securely seated on the coupling.
Damage from inaccurate coupling. Inaccurate coupling (especially during the afterglow period) can destroy the high-pressure lamp or the LED of a MULTiflex (LUX) / MULTiflex LED coupling or reduce its service life.

▶ Make sure that the coupling is accurate.
Place the SONICfill 2010 exactly on the MULTIflex / MULTIflex LUX coupling and push it to the rear until it audibly locks.
5.2 Pulling off the SONICfill 2010

- Hold the MULTIflex (LUX) / MULTIflex LED coupling tight, and pull the SONICfill 2010 forward while twisting slightly.
### 5.3 Inserting the SonicFill Unidose Tips

<table>
<thead>
<tr>
<th>DANGER</th>
</tr>
</thead>
<tbody>
<tr>
<td>The SonicFill handpiece must be used exclusively in combination with SonicFill Unidose tips. Non-compliance may lead to product damage.</td>
</tr>
</tbody>
</table>
If the SonicFill Unidose tips is difficult to screw-on, this is due to a defect and the SonicFill Unidose tips must not be used since it may come off during use. Inspect threads before use to ensure no debris is preventing proper tip attachment.

Check if the SonicFill Unidose tips are firmly connected by briefly starting-up the SonicFill hand-piece outside the mouth.
Push the SonicFill Unidose tips by hand into the corresponding opening of the SonicFill hand-piece using moderate pressure and screw them finger-tight through a clockwise rotation.

5.4 Removing the SonicFill Unidose Tips

Unscrew the SonicFill Unidose Tips by hand from the SONICfill 2010 through a counterclockwise rotation.
5.5 Power setting

- Use the regulating ring of the SONICfill 2010 to adjust the dispensed quantity.

  Level 1 = low
  Level 5 = high
Note

Dispensing with a variable foot control (e.g. KaVo multi-function foot control):
Variable foot controls allow the dispensing rate to be controlled with different foot pedals. With a KaVo foot control, the maximal dispensed volume is reached with the pedal position towards the right, whereas a pedal position towards the left reduces the volume. In this case, it is recommended to set the regulating ring on the handpiece to 5.
6 Reprocessing methods according to ISO 17664

Note
The reprocessing procedures described in the following apply to the SONICfill 2010.
6.1 Preparations at the site of use

**WARNING**

Hazard from nonsterile products.
There is a risk of infection from contaminated medical devices.

- Take suitable personal protective measures.
- Remove all residual cement, composite or blood without delay.
- The medical device must be dry when transported for reconditioning.
- Do not place it in a solution or similar.
Recondition the medical device as soon as possible after treatment.

6.2 Preparations before cleaning

- Remove the SonicFill Unidose Tips by hand from the SONICfill 2010.
## 6.3 Cleaning

<table>
<thead>
<tr>
<th>CAUTION</th>
</tr>
</thead>
</table>
| Malfunctions from cleaning in the ultrasonic unit.  
| Defects in the product. |
| ▶ Only clean manually or in a thermodisinfector. |
6.3.1 Cleaning: Manual external cleaning

Accessories required:
- Tap water 30 °C ± 5 °C (86 °F ± 10 °F)
- Brush, e.g. medium-hard toothbrush
Brush it off under running tap water using for example a medium-hard toothbrush.
6.3.2 Cleaning: Automated external cleaning

KaVo recommends thermodesinfectors in accordance with EN ISO 15883-1 that are operated with alkaline cleaning agents at a pH value of max. 10 (e.g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" program, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent and "neodisher® mielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).
In order to prevent negative effects on the medical device, make sure that the interior and the exterior of the medical device are dry, and then lubricate immediately with care agents from the KaVo care system.

6.3.3 Cleaning: Manual internal cleaning

Not applicable.
6.3.4 Cleaning: Automated internal cleaning

KaVo recommends thermodesinfectors in accordance with EN ISO 15883-1 that are operated with alkaline cleaning agents at a pH value of max. 10 (e.g., Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" program, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent and "neodisher® miielclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).

▶ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).
In order to prevent negative effects on the medical device, make sure that the interior and the exterior of the medical device are dry, and then lubricate immediately with care agents from the KaVo care system.

6.4 Disinfection

CAUTION

Malfunctioning from using a disinfectant bath or disinfectant containing chlorine. Defects in the product.

- Only disinfect in a thermodisinfector or manually.
6.4.1 Disinfection: Manual external disinfection

KaVo recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer.
Reprocessing methods according to ISO 17664

- Mikrozid AF Liquid made by Schülke & Mayr
- FD 322 made by Dürr
- CaviCide made by Metrex

Consumables required:
Cloths for wiping off the medical device.

Spray the disinfectant on a cloth, then thoroughly wipe down the medical device and leave the disinfectant to soak in according to the instructions from the disinfectant manufacturer.
6.4.2  Disinfection: Manual disinfection - internal

The efficacy of manual internal disinfection must be demonstrated by the manufacturer of the disinfection agent. With KaVo products, use only disinfection agents that have been released by KaVo with respect to the compatibility of materials (e.g. WL-cid / made by ALPRO).
Immediately after internal disinfection, lubricate the KaVo medical device immediately with care agents from the KaVo care system.

6.4.3 Disinfection: Machine disinfection - external and internal

KaVo recommends thermodesinfectors in accordance with EN ISO 15883-1 that are operated with alkaline cleaning agents at a pH value of max. 10 (e. g. Miele G 7781 / G 7881 – validation was performed with the "VARIO-TD" program, "neodisher® mediclean" cleaning agent, "neodisher® Z" neutralisation agent and "neodisher® mieleclear" rinsing agent and extends only to the compatibility of materials with respect to KaVo products).
For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector (complying with max. pH value of 10).

In order to prevent negative effects on the medical device, make sure that the interior and the exterior of the medical device are dry, and then lubricate immediately with care agents from the KaVo care system.

6.5 Drying

Manual Drying

- Blow off the outside and inside with compressed air until water drops are no longer visible.
Automatic Drying

The drying procedure is normally part of the disinfection program of the thermodisinfector.

Note

Please follow the instructions for use of the thermodisinfector (compressed air quality - see the Warning under "Start-up").
CAUTION

Premature wear and malfunctions from improper servicing and care.
Reduced product life.

▶ Perform proper care regularly!
KaVo only guarantees that its products will function properly when the care products used are those listed as accessories, as they were tested for proper use on our products.

6.6.1 Care products and systems - Servicing: Servicing with KaVo Spray

KaVo recommends servicing the product after each automatic cleaning and before each sterilisation.

Note

If the oil leakage is bothersome, once weekly servicing is sufficient.
- Remove the SonicFill Unidose Tips.
- Cover the product with the Cleanpac bag.
- Place the product on the cannula, and press the spray button for one second.
6.6.2 Care products and systems - Servicing: Servicing with KaVo SPRAYrotor

KaVo recommends servicing the product after each automatic cleaning and before each sterilisation.

Note

If the oil leakage is bothersome, once weekly servicing is sufficient.
Place the product on the appropriate coupling of the KaVo SPRAYrotor and cover it with a Cleanpac bag.

Servicing the product.

6.6.3 Care products and systems - Servicing: Servicing with KaVo QUATTROcare

Cleaning and care unit with expansion pressure for thorough cleaning and care.
KaVo recommends servicing the product after each automatic cleaning and before each sterilisation.

Note
If the oil leakage is bothersome, once weekly servicing is sufficient.
Remove the SonicFill Unidose Tips.
Servicing the product.

See also: KaVo QUATTROcare instructions for use.

6.7 Packaging

Note
The sterilisation bag must be large enough for the handpiece so that the bag is not stretched. The quality and use of the sterilisation packaging must satisfy applicable standards and be suitable for the sterilisation procedure!
Individually weld the medical device in the sterilised item packaging (such as KaVo STERI-clave bags Mat. no. 0.411.9912)!
6.8 Sterilisation

Sterilisation in a steam steriliser (autoclave) in accordance with EN 13060/ISO 17665-1

**CAUTION**

Premature wear and malfunctions from improper servicing and care. Reduced product life.

- Before each sterilisation cycle, service the medical device with KaVo care products.
CAUTION
Contact corrosion due to moisture.
Damage to product.
▶ Immediately remove the product from the steamsteriliser after the sterilisation cycle!

Note
Remove the SonicFill Unidose Tip before sterilisation. The SonicFill Unidose Tips are non-sterilisable.
The KaVo medical device has a maximum temperature resistance up to 138 °C (280.4 °F).
(Depending on the available autoclave,) select a suitable procedure from the following sterilisation processes:

- Autoclave with three times initial vacuum:
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)

- Autoclave using the gravitation method:
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F) or alternatively
  - at least 60 minutes at 121 °C -1 °C / +4 °C (250 °F -1.6 °F / +7.4 °F)

▶ Use according to the manufacturer’s Instructions for Use.
6.9 Storage

Prepared products must be stored, protected from germs (as far as possible) and dust, in a dry, dark, cool room.

Note

Comply with the expiry date of the sterilised items.
7 Tools and consumables

Obtainable from the dentalmed. specialist supplier

<table>
<thead>
<tr>
<th>Material summary</th>
<th>Mat. no.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handpiece stand 2151</td>
<td>0.411.9501</td>
</tr>
<tr>
<td>Cellulose pad 100 units</td>
<td>0.411.9862</td>
</tr>
<tr>
<td>Cleanpac 10 units</td>
<td>0.411.9691</td>
</tr>
<tr>
<td>Material summary</td>
<td>Mat. no.</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>KAVO Spray 2112 A</td>
<td>0.411.9640</td>
</tr>
<tr>
<td>ROTA Spray 2142 A</td>
<td>0.411.7520</td>
</tr>
<tr>
<td>QUATTRO care plus Spray 2140 P</td>
<td>1.005.4525</td>
</tr>
</tbody>
</table>
8 Terms and conditions of warranty

The following warranty conditions apply to this KaVo medical device:

KaVo provides the end customer with a warranty of proper function and guarantees zero defects in respect of material and processing for a period of 12 months from the date of the invoice, subject to the following conditions:

In case of justified complaints, KaVo will honour its warranty with a free replacement or repair. 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 or maintenance, 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 KaVo's instructions for use or other manufacturer's instructions. The warranty granted does not usually extend to lamps, light conductors made of glass and glass fibres, glassware, rubber parts, and the colour-fastness of plastic parts.

All liability is excluded if defects or their consequences originate from manipulations or changes to the product made by the customer or a third party that is not authorised by KaVo.
Warranty claims will only be accepted 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.