Instructions for use

SMARTmatic ENDO S81 - 1.011.6780
SMARTmatic ENDO S321 - 1.011.6790

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.

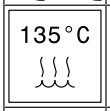
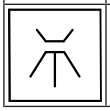
KaVo Repair Service
For repairs, please contact your local dealer or the KaVo Repair Service directly:
+49 (0) 7351 56-1900
service.reparatur@kavo.com

KaVo Technical Service
If you have any questions or complaints, please contact the KaVo Technical service:
+49 (0) 7351 56-1000
service.instrumente@kavo.com

Target group

This document is intended for dentists and their assistants. The startup section is also intended for service technicians.

General marks and symbols

	Refer to the chapter on Safety/Warning symbol
	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.
	Can be steam-sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfectable

Hazard levels

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

⚠ DANGER

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

⚠ WARNING

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

⚠ CAUTION

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

NOTICE

In cases which – if not prevented – could lead to material damage.

2 Safety

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 instructions for use, any other type of use is not permitted.

2.1 Infection hazard

Patients, users or third parties could be infected by contaminated medical devices.

- Take suitable personal protective measures.
- Follow the instructions for using the components.
- Before the initial startup and after each use, prepare and sterilise the medical device and accessories accordingly.
- Carry out the cleaning and sterilisation as described in the instructions for use. The procedure has been validated by the manufacturer.
- It is essential to ensure the effectiveness of the cleaning and sterilisation in the case of deviation in procedure.
- Prior to disposal, the product and accessories must be appropriately prepared or sterilised.
- In the case of injury to soft tissue, do not continue treatment in the oral cavity with instruments driven by compressed air.
- Use gloves or finger guard whenever you test, insert, and remove the tool.

2.2 Technical condition

A damaged device or components could injure patients, users and third parties.

- Only operate devices or components if they are undamaged on the outside.
- Check 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
  - Irregular running noise
  - Excessive vibration
  - Overheating
  - Tool is not seated firmly in the handpiece

Observe the following instructions in order to guarantee optimum functioning and prevent material damage:

- Service the medical device with care products and systems regularly as described in the instructions for use.
- The device should be cleaned, serviced and stored in a dry location, according to instructions, if it will not be used for a longer period.

High torque of micromotors can lead to severe burn injuries.

- Service micromotors regularly.
- Do no use any damaged motors.

- Do not use motors for unauthorised purposes.

2.3 Accessories and combination with other equipment

Use of un-authorised accessories or un-authorised modifications of the device could lead to injury.

- Only use accessories that have been approved for combination with the product by the manufacturer.
- Only use accessories that are equipped with standardised interfaces.
- Do not make any modifications to the device unless these have been approved by the manufacturer of the product.

The lack of control equipment for changing the speed range and the direction of rotation can lead to injury.

- Control facility for changing the speed and the direction of rotation must be present.
- The medical device may only be combined with a treatment centre released by KaVo.
- Comply with the Instructions for Use of the treatment centre.

2.4 Qualification of personnel

Application of the product by users without the appropriate medical training could injure the patients, the users or third parties.

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

The improper use of the device could lead to burns or injuries.

- Never touch soft tissue with the handpiece head or instrument cover.
- After treatment, place the medical device properly in the cradle without the tool.

2.5 Service and repair

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

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

Observe all the following items during servicing work:

- Have the service and testing tasks carried out in accordance with the Medical Product Operator Ordinance.
- Following expiry of the warranty, have the tool holding system checked once a year.
- KaVo recommends specifying in-house service intervals where the medical device is brought to a professional shop for cleaning, servicing and a function check. Defined the service interval depending on the frequency of use.

3 Description of the product

SMARTmatic S81 (Mat. No. 1.011.6780)

SMARTmatic S321 (Mat. No. 1.011.6790)

3.1 Intended use

Indications for use:

This medical device is
- intended for dental treatment only. All other types of use or modifications of the product are not permitted and can be hazardous. The medical device is intended for the following uses: cavity preparation and endodontics.
- A medical device according to relevant national statutory regulations.

Proper use:

According to these provisions, this medical device 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

According to these regulations, the user is required to:
- to only use equipment that is operating correctly,
- adhere to the specified intended use
- to protect him or herself, the patient and third parties from hazards, and
- to prevent contamination from the product

3.2 Technical Specifications

Drive speed	max. 40,000 rpm
Speed transmission S81:	8:1
Speed transmission S321:	32:1
Cooling air flow	5.5 to 9.5 Nl/min

With press-button chuck.

Contra-angle drills and root canal instruments can be inserted.

The contra-angle handpiece can be mounted on all INTRAmatic (LUX) motors, and motors with a connection in accordance with ISO 3964 / DIN 13940.

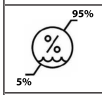
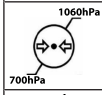
3.3 Transportation and storage conditions

NOTICE

Startup after refrigerated storage.

Malfunction.

- Prior to startup, strongly refrigerated products must be allowed to warm up to a temperature of 20 °C to 25 °C (68 °F to 77 °F).

	Temperature: -20°C to +70°C (-4°F to +158°F)
	Relative humidity: 5% RH to 95% 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 non-sterile products.

Infection hazard for dentist and patient.

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

⚠ WARNING

Dispose of the product in appropriate manner.

Infection hazard.

- Reprocess and sterilise the product and accessories before disposal.

NOTICE

Damage from soiled and moist cooling air.

Contaminated and moist cooling air can cause malfunctions.

- Make sure that the supply of cooling air is dry, clean, and uncontaminated according to EN ISO 7494-2.

NOTICE

Damage to the contra-angle handpiece caused by spray air and spray water.

Property damage

- Un-select spray air and water on the supply unit before startup!

5 Operation

5.1 Attaching the medical device

⚠ CAUTION

Detachment of the medical device during treatment.

Injury or property damage

A medical device that is not properly locked in place can become disconnected from the motor coupling and fall off.

- Carefully pull on the medical device before each treatment to ensure that it is securely locked onto the motor coupling.

NOTICE

Removing and attaching the contra-angle handpiece while the drive motor is rotating.

Damage to the driver.

- Never attach or remove the contra-angle handpiece while the drive motor is rotating.

NOTICE

Pressing the foot switch while attaching or detaching the medical device.

Property damage to the medical device.

- Do not connect or remove the medical device while pressing the foot switch.

- Lightly spray O-rings on motor coupling with KaVo Spray.

- Place the medical device on the motor coupling and lock it into place.

- Pull on the medical device to make sure that it is securely affixed to the coupling.

5.2 Removing the medical device

- Unlock the medical device from the motor coupling by twisting it slightly and then pulling it along its axis.

5.3 Inserting the dental bur or diamond grinder

Note

Only use root canal instruments with shafts that comply with ISO 1797-1 type 1 and ISO 3630-1:

- Shaft diameter: Ø 2.334 to Ø 2.350 mm
- Shaft clamping length: at least 12 mm

⚠ WARNING

Use of unauthorised dental burs or diamond grinders.

Risk of injury.

- Comply with the instructions for use and use the dental bur or diamond grinder properly.
- Only use dental burs or diamond grinders that do not deviate from the specified data.

⚠ WARNING

Hazard from rotating bur or diamond grinder.

Lacerations.

- Do not touch the bur or diamond grinder when it is rotating!
- Remove the bur/diamond grinder from the medical device after treatment to avoid injury and infection when putting it away.

⚠ CAUTION

Use of dental burs or diamond grinders with worn or damaged shafts.

Risk of injury, tool may fall out during treatment.

- Never use dental burs or diamond grinders with damaged or worn shafts.

⚠ CAUTION

Hazard from defective chuck system.

The tool can fall out and cause injury.

- Pull on the tool to check if the chucking system is functioning properly and that the tool is firmly clamped. Wear gloves or a thimble when you check, insert, or remove the bits to prevent injury and infection.

NOTICE

Tool shaft slips inside the chuck due to excessive speed of the tool or abrupt engagement of the tool.

Material damage to tool shaft and chuck system, reduction of the service life of tool and chuck system.

- Do not operate the tool at a higher speed than recommended by the manufacturer.

NOTICE

Use of dental burs or diamond grinders with worn or damaged shafts.

Material damage to the chuck system, tool is difficult or impossible to remove from the chuck system.

- Do not use dental burs or diamond grinders with damaged or worn shafts.

- Insert the bur or diamond grinder into the segment of the head drive by twisting the tool slightly, and push to the stop.

- Check that the dental bur or diamond grinder is securely attached by pulling on it.

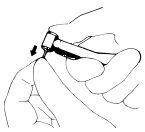
5.4 Removing the dental bur or diamond grinder

⚠ WARNING

Hazard from rotating bur or diamond grinder.

Lacerations and damage to the chuck system.

- Do not touch the bur or diamond grinder when it is rotating!
- Do not press the push-button while the cutter or grinder is rotating.
- Remove the cutter/grinder from the contra-angle handpiece after treatment to avoid injury and infection when putting it away.



- After the dental bur or diamond grinder has stopped rotating, firmly press the press-button with your thumb and simultaneously pull out the dental bur or diamond grinder.

6 Troubleshooting

6.1 Check for malfunctions

NOTICE

Missing or damaged O-rings.

Malfunction and premature failure.

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

⚠ CAUTION

Product heats up.

Burn injury or product damage due to over-heating.

- Do not continue working if the product heats up irregularly.

- The medical device is too hot while idling:
  Check the amount of cooling air.
- The medical device is too hot while working:
  Service the medical device.
- When the speed drops or is uneven:
  Service the medical device.
- An O-ring is missing on the motor coupling:
  Replace O-ring.

6.2 Troubleshooting

6.2.1 Replacing the O-rings on the motor coupling

NOTICE

Improper care of the O-rings.

Malfunction or complete failure.

- Do not use Vaseline or other grease or oil.

Note

The O-rings on the motor coupling may only be lubricated with a cotton ball wetted with KaVo spray.

- Press the O-ring between your fingers to form a loop.
- Push the O-ring to the front, and remove it.
- Insert new O-rings into the grooves.

7 Reprocessing steps in accordance with ISO 17664

7.1 Preparations at the site of use

⚠ WARNING

Hazard from incorrectly reprocessed products.

Contaminated products are associated with an infection hazard.

- ▸ Take suitable personal protective measures.

- ▸ Remove the tool from the medical device.
- ▸ Remove all residual cement, composite or blood immediately.
- ▸ Reprocess the medical device as soon as possible after treatment.
- ▸ The medical device must be dry when transported to reprocessing.
- ▸ Do not place in solutions or similar substance.

7.2 Cleaning

NOTICE

Never reprocess this medical device in an ultrasonic device.

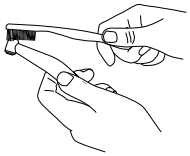
Malfunction and material damage.

- ▸ Clean manually or in a washer disinfector only.

7.2.1 Manual external cleaning

Accessories required:

- Tap water 30 °C ± 5 °C (86 °F ± 10 °F)
- Brush, e.g. medium-hard toothbrush



- ▸ Brush off under flowing tap water.

7.2.2 Automated external cleaning

KaVo recommends washer disinfectors in compliance with EN ISO 15883-1 that are operated with alkaline cleaning agents.
The validations were conducted with the VARIO-TD program, the cleaning agent neodisher® MediClean and the neutralisation agent neodisher® Z.

- ▸ The program settings and cleansers and disinfectants that must be used can be found in the instructions for use of the thermodisinfector.
- ▸ Directly after automated cleaning/disinfection, treat the medical device with the KaVo care products and systems provided by KaVo.

7.2.3 Manual internal cleaning

Validated internal cleaning (removal of residual protein) can be accomplished with KaVo CLEANspray and KaVo DRYspray.

- Cover the medical device with the KaVo CLEANpac bag, and place it on the corresponding care adapter. Press the spray button three times for 2 seconds each time. Remove the medical device from the spray attachment and let the cleanser act for one minute.
- Afterwards, rinse for 3-5 seconds with KaVo DRYspray.

See also:

KaVo CLEANspray / KaVo DRYspray Instructions for Use

Note

KaVo CLEANspray and KaVo DRYspray for manual interior cleaning are only available in the following countries:
Germany, Austria, Switzerland, Italy, Spain, Portugal, France, Luxembourg, Belgium, Netherlands, United Kingdom, Denmark, Sweden, Finland and Norway.
In other countries interior cleaning can only be carried out with thermodisinfectors in accordance with EN ISO 15883-1.

7.2.4 Automated internal cleaning

KaVo recommends washer disinfectors in compliance with EN ISO 15883-1 that are operated with alkaline cleaning agents.
The validations were conducted with the VARIO-TD program, the cleaning agent neodisher® MediClean and the neutralisation agent neodisher® Z.

- For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector.
- In order to prevent damage to the medical device due to residual fluid, make sure that the inside and outside of the device is dry after the end of the cycle. Remove any residual liquids from the interior and exterior of the medical device using compressed air.
- Immediately after drying, lubricate the medical device with care agents from the KaVo care system.

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

Note

Please observe the instructions for use of the thermodisinfector.

7.3 Disinfection

⚠ WARNING

Incomplete disinfection.
Infection hazard.

- Principally, KaVo recommends carrying out an final disinfection of the unpackaged item to guarantee the complete disinfection.

NOTICE

Using the disinfectant bath or chlorine-containing disinfectants.
Malfunction and material damage.

- Do not disinfect the device in the disinfection bath or with chlorine-containing disinfectants.

7.3.1 Manual external disinfection

KaVo recommends the following products based on compatibility of the materials. The microbiological efficacy must be ensured by the disinfectant manufacturer and proven by an expert opinion.

- Mikrozid AF made by Schülke & Mayr (liquid or cloths)
- FD 322 made by Dürr

Consumables required:
Cloths for wiping the medical device.

- ▸ Spray the disinfectant on a cloth, then wipe down the medical device and allow the disinfectant to act according to the instructions of the disinfectant manufacturer.
- ▸ Follow the instructions for use of the disinfectant.

7.3.2 Manual internal disinfection

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 with care agents from the KaVo care system.

7.3.3 Automated external and internal disinfection

KaVo recommends washer disinfectors in compliance with EN ISO 15883-1 that are operated with alkaline cleaning agents.
The validations were conducted with the VARIO-TD program, the cleaning agent neodisher® MediClean and the neutralisation agent neodisher® Z.

- ▸ For program settings as well as cleansers and disinfectants to be used, please refer to the Instructions for Use of the thermodisinfector.
- ▸ In order to prevent damage to the medical device due to residual fluid, make sure that the inside and outside of the device is dry after the end of the cycle. Remove any residual liquids from the interior and exterior of the medical device using compressed air.
- ▸ Immediately after drying, lubricate the medical device with care agents from the KaVo care system.

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

Note
Please observe the instructions for use of the thermodisinfector.

7.4 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 cleaning program of the thermodisinfector.

- Follow the instructions for use of the thermodisinfector.

7.5 Care products and systems - Servicing

⚠ WARNING

Sharp dental bur or diamond grinder in the medical device.

Risk of injury from sharp and/or pointed dental bur or diamond grinder.

- Remove dental bur or diamond grinder.

NOTICE

Improper service and care.

Premature wear and reduced product service life.

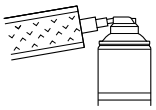
- Service regularly with suitable agents.

Note

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

7.5.1 Servicing with KaVo Spray

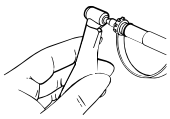
KaVo recommends servicing the product as part of the reprocessing after each use, i.e. after each cleaning, disinfection, and before each sterilisation.



- Remove the insert.
- Cover the product with the Cleanpac bag.
- Plug the product onto the cannula, and press the spray button for one second.

Servicing the chucking system

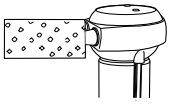
KaVo recommends cleaning and servicing the chuck system once a week.



- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.
- Carry out the servicing according to the instructions in the section, "Servicing with KaVo Spray".

7.5.2 Servicing with KaVo SPRAYrotor

KaVo recommends servicing the product as part of the reprocessing after each use, i.e. after each cleaning, disinfection, and before each sterilisation.



- Place the product on the appropriate coupling on the KaVo SPRAYrotor and cover it with the Cleanpac bag.
- Service the product.

See also:
- Instructions for use KaVo SPRAYrotor

7.5.3 Servicing with KaVo QUATTROcare

Note

QUATTROcare 2104 / 2104 A is no longer included in the current delivery programme.

Follow-up product:
- QUATTROcare PLUS 2124 A

Servicing and cleaning device with expansion pressure for the interior cleaning of inorganic residues and optimum care.
(no validated cleaning of the interior in accordance with German RKI requirements)

KaVo recommends servicing the product as part of the reprocessing after each use, i.e. after each cleaning, disinfection, and before each sterilisation.

- Remove the dental bur or diamond grinder.
- Service the product.

See also:
- Instructions for use KaVo QUATTROcare 2104 / 2104A

Servicing the chuck

KaVo recommends cleaning and servicing the chuck system once a week.

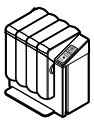
See also:
- Instructions for use KaVo QUATTROcare 2104 / 2104A

- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.
- Subsequently treat with the specified care products and systems.

See also:
- Servicing with KaVo QUATTROcare

7.5.4 Servicing with KaVo QUATTROcare PLUS

Servicing and cleaning device with expansion pressure for the interior cleaning of inorganic residues and optimum care.
(no validated cleaning of the interior in accordance with German RKI requirements)
KaVo recommends servicing the product as part of the reprocessing after each use, i.e. after each cleaning, disinfection, and before each sterilisation.



- Remove the dental bur or diamond grinder.
- Service the product in the QUATTROcare PLUS.

See also:
- Instructions for use KaVo QUATTROcare PLUS

Servicing the chuck

KaVo recommends cleaning and servicing the chuck system once a week using the collet servicing program integrated in the device.

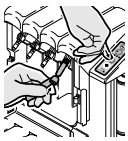
See also:
- Instructions for use KaVo QUATTROcare PLUS

Note
Handpieces must be taken off the service couplings before the chuck service can be started and performed.

- Close the front door and press the chuck service button for at least three seconds until the spray canister control LED flashes three times consecutively.

⇨ The device is in chuck service mode.

- Remove the service coupling of the chuck from the side hatch of the QUATTROcare PLUS and attach it to coupling service point four, on the far right. A MULTIflex adaptor must be mounted there.



- Press the handpiece together with the guide bush of the chuck to be serviced against the tip of the service coupling.
- Press the button marked with the chuck service symbol.

Note
Close the chuck service mode.
Option 1: Place the dental handpieces in the QUATTROcare PLUS 2124 A, close the front door and start theservice procedure.
Option 2: After three minutes with no service procedure running, the device automatically switches back to normal service mode.

See also:
- Servicing with KaVo QUATTROcare PLUS

7.6 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!

- Seal the medical device individually in the sterilised item packaging.

7.7 Sterilisation

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

NOTICE

Improper service and care.

Premature wear and reduced product service life.

- ▸ Before each sterilisation cycle, service the medical device with KaVo care products.

NOTICE

Contact corrosion due to moisture.

Damage to product.

- ▸ Immediately remove the product from the steam steriliser after the sterilisation cycle.

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

Select a suitable procedure (depending on the available autoclave) from the following sterilisation processes:

- Autoclave with three times pre-vacuum:
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- Steriliser using the gravity method:
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- ▸ Use according to the manufacturer's Instructions for Use.

7.8 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.

8 Tools and consumables

Available from dental suppliers.

Material summary	Mat.No.
Instrument stand 2151	0.411.9501
Cleanpac 10 units	0.411.9691
Cellulose pad 100 units	0.411.9862
Spray head INTRA (KaVo Spray)	0.411.9911
INTRA handpiece product care coupling	1.009.6143

Material summary	Mat.No.
Adapter INTRAmatic (CLEANspray and DRYspray)	1.007.1776
KaVo CLEANspray 2110 P	1.007.0579
KaVo DRYspray 2117 P	1.007.0580
KaVo Spray 2112 A	0.411.9640
ROTAspray 2 2142 A	0.411.7520
QUATTROcare plus Spray 2140 P	1.005.4525

9 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, optical fibres made of glass and glass fibres, glassware, rubber parts, and the colourfastness 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.

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