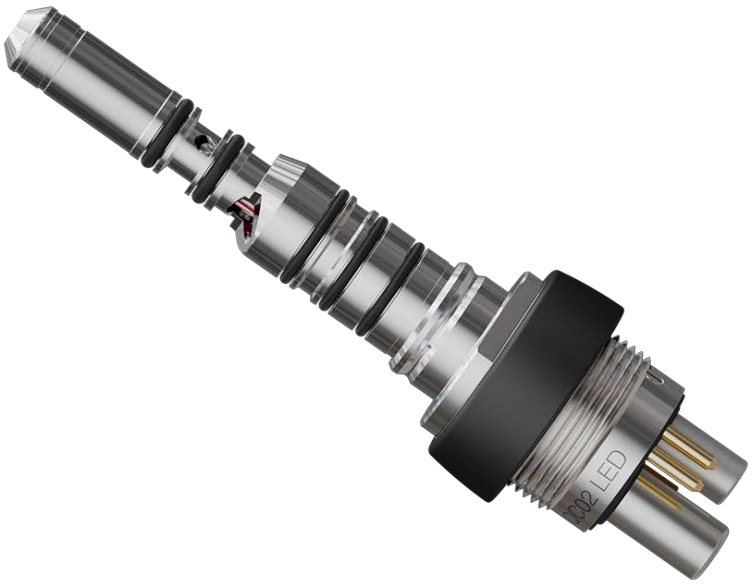
Instructions for use

QC02 LED REF 055501



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1 User instructions

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

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KaVo Original Factory Repair

In the event of a repair, please ship your product to the KaVo Original Factory Repair using www.kavobox.com/faro.

FARO Technical Service
+39 039 6878245
service@faro.it

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

Target group

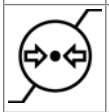
The instructions for use are intended for medical professionals, in particular dentists and dental practice personnel.

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 directives.
MD	Medical device, labelling of medical devices
135 °C	Can be steam sterilised at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
	Thermodisinfectable

Information on the packaging

REF	Material number
SN	Serial number
	Manufacturer
	Manufacturing date
	Note: Please note accompanying documents
	Follow the electronic instructions for use
	HIBC Code
	CE mark for medical devices
MD	Medical device, labelling of medical devices
UDI	UDI symbol
	Transportation and storage conditions (temperature range)
	Transportation and storage conditions (air pressure)
	Transportation and storage conditions (Humidity)
	Protect from moisture (Keep dry)
	Protect from impact
	Do not dispose of with household waste
	Original language German

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:

⚠ 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.

CAUTION

In cases which – if not prevented – can lead to material 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 an integral part of the product and must be read carefully prior to use and must 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 could be 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, reprocess the product and accessories appropriately.
- Carry out the reprocessing 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 reprocessing procedure is effective.
- Reprocess the product and accessories appropriately before disposal.

2.2 Electrical shock

Connecting a non-KaVo system to the medical device can lead to electrical shock and injury to patient, user and third parties.

- During installation and operation of the product on treatment devices and equipment from other manufacturers, comply with the provisions of "Protection from electrical shock," "Leakage current," and "Not grounding the applied part" in accordance with DIN EN IEC 60601-1.
- Make sure to combine the product only with a treatment centre / control unit that has been released by KaVo.
- Make sure that the product combined with the dental treatment unit / control unit meets the requirements in accordance with DIN EN IEC 60601-1.

2.3 Use

Direct exposure to the lamp or blue light might cause damage or blinding to the eyes of the patient, user or third parties.

- Do not look directly into the lamp.
- Do not look into the lamp for any extended period of time when it is in operation.

2.4 Technical condition

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

- Only operate devices or components if they show no signs of 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 personnel.

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

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

2.5 Accessories and combination with other equipment

Use of non-authorised accessories or non-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 product.

2.6 Qualification of personnel

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

- Make sure that the user has read and fully comprehends the instructions for use.
- Make sure that the user has read and comprehends the national and regional regulations.
- The device may be used only if the user has completed the appropriate medical training.

2.7 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

Observe all the following items during servicing work:

- Have the service and testing tasks carried out according to the Medical Device Operator Ordinance.
- KaVo recommends specifying in-house service intervals where the medical device is brought to a professional shop for cleaning, servicing and a function check. 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 other people. 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 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 of a modified product in the market, in which the reasonable suspicion exists to endanger the safety and health of patients or users, is prohibited by Medical Device Law §4, Abs.1 No. 1 and therefore requires its own conformity check.

2.8 Disposal

This product is subject to the EC directive governing waste electrical and electronic devices and must be submitted to special disposal in Europe.

- For further information, please contact KaVo or a specialised dental dealer.

3 Description of the product

QC02 LED REF 055501

The QC02 LED coupling transfers the following media from a dental treatment centre to dental instruments:

- Spray water
- Spray air
- Drive air
- Return air

The QC02 LED coupling has a built-in non-return valve that prevents spray water from being suctioned back into the coupling and the hose system of the treatment centre.

The QC02 LED coupling has a built-in LED lamp.

3.1 Intended use

Indications for use:

The medical device is:

- Intended for dental treatment only. All other types of use of or modifications to the product are not permitted and can be hazardous.
- The medical device is designed for coupling of the standard supply hose (DIN EN ISO 9168) to MULTIflex-compatible dental handpieces, turbine handpieces, air motors, scalers, prophylaxis handpieces etc.
- A medical device according to relevant national statutory regulations

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

According to these regulations, the user is required:

- to only use equipment that is operating correctly
- to comply with the specified intended use
- to protect him or herself, the patient and third parties from hazards
- to prevent contamination from the product

3.2 Technical Specifications

Connector	in accordance with DIN EN ISO 9168 type 3
Anti-retraction valve	with Anti-retraction valve
Rated voltage of the KaVo MULTI LED lamp	3.4 V DC
Voltage range of the KaVo MULTI LED lamp	3.0 - 3.6 V DC
Maximum current	120 mA
Can be attached to	all instruments with original MULTIflex connector

NOTE
Please comply with the Instructions for Use of the product to be connected to the QC02 LED coupling. Check the suitability of the product for operation with the QC02 LED coupling.

NOTE
Operation on KaVo units:
- 1042: on the unit, set the cold light intensity to the lowest intensity level and increase the brightness level maximally to intensity level 4.
- 1065 / 1060: If the QC02 LED coupling is used on these units, have a technician adjust the voltage.
- E80 / E70 / E50 / 1058 / 1080 / 1066 / 1062: The QC02 LED coupling can be used on these units with any further measures being required.

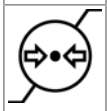
NOTE
Do not exceed the specified upper voltage limit of 3.6 V DC on the QC02 LED coupling MULTI LED lamp.

3.3 Transportation and storage conditions

CAUTION

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: -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 (Keep dry)

4 Startup and shut down

⚠ WARNING

Hazard from contaminated products.

Infection hazard to the 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 the product and accessories before disposal.

Also refer to:
7 Reprocessing steps in accordance with ISO 17664, Page 19

CAUTION

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

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

5 Operation

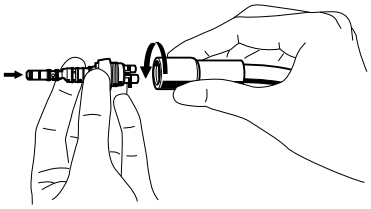
NOTE
At the beginning of each workday, the water-conducting systems should be rinsed for at least 2 minutes (without transmission handpieces being attached) and if there is a risk of contamination from reflux or back suction, the system may also need to be rinsed for 20 to 30 seconds after each patient.

5.1 Connecting the coupling to the hose

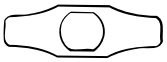
CAUTION

Malfunction from grasping the regulating ring.
Product defects.
- Do not grasp the regulating ring.

- Plug the QC02 LED coupling onto the turbine hose and secure it tightly with the union nut screw of the hose.



- Re-tighten with the enclosed wrench.



- Apply a small amount of KaVo Spray to the O-rings on the supply hose.

The coupling remains screwed onto the hose.

5.2 Removing the coupling from the hose

NOTE
The coupling remains screwed to the hose, use the wrench to remove it.

5.3 Attaching instruments

⚠ WARNING

Detaching the medical device during treatment.

A medical device that is not properly locked can detach from the coupling during treatment.

- Before each use, check if the medical device is securely locked onto the coupling.

CAUTION

Inexact coupling.
Reduces the service life of the lamp.
- Avoid inexact coupling.
- Check the secure fit of the (LUX) handpieces on the coupling by pulling on them.

- Accurately attach the MULTIflex (LUX) instrument to the QC02 LED coupling and push it to the rear until the coupling audibly locks into the medical device.

- Check the secure fit of the (LUX) instrument on the coupling by pulling on it.

5.4 Pulling the handpiece off

- Grasp the coupling and pull the instrument forward while twisting it slightly.

6 Checking for malfunctions and troubleshooting

6.1 Checking for malfunctions before initial start-up

⚠ CAUTION

Danger from hot lamp.

Risk of burn injury.

- Do not touch lamp after previous operation. Allow the lamp to cool down.

CAUTION

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

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

NOTE
Stop working if the O-ring is missing or damaged.

- If there is no O-ring on the motor coupling, replace the O-ring.
- If the intensity of the KaVo MULTI LED lamp is low, increase the cold light intensity on the unit.
- If the KaVo MULTI LED lamp glows red or not at all, turn the KaVo MULTI LED lamp by 180° and insert it.

Also refer to:
6.2.1 Replacing the LED lamp, Page 16

6.2 Troubleshooting

⚠ WARNING

Repair WITHOUT using KaVo original spare parts.

Parts such as the cover can come loose and cause injury. Aspiration, swallowing of parts and 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 of a modified product in the market, in which the reasonable suspicion exists to endanger the safety and health of patients or users, is prohibited by Medical Device Law §4, Abs.1 No. 1 and therefore requires its own conformity check.

6.2.1 Replacing the LED lamp

⚠ CAUTION

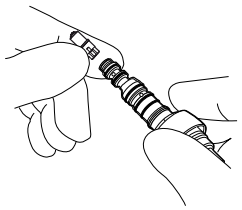
Danger from hot lamp.

Risk of burn injury.

- Do not touch lamp after previous operation. Allow the lamp to cool down.

NOTE
Inserting the lamp, make sure that the contacts in the coupling are not damaged. Screw-on the screw cap.

- Unscrew the screw cap in anticlockwise direction.



- Push the old KaVo MULTI LED lamp out of the mount with your fingernail and remove it.
- Insert the new KaVo MULTI LED lamp into the recess such that the contact surfaces align with those of the mount.

NOTE
The LED lamp is a semiconductor element and must be operated with direct voltage only. The lamp must be inserted with the poles in the correct orientation for the lamp to work properly.

- **Case 1:** KaVo MULTI LED lamp is on
- **Case 2:** KaVo MULTI LED lamp is faint
- Increase the cold light intensity on the unit until the desired illuminance is reached.
- **Case 3:** KaVo MULTI LED lamp is red or off
- Insert KaVo MULTI LED lamp after rotating it 180° about its axis.
- Screw-on the screw cap in clockwise direction.

6.2.2 Replacing the O-rings

CAUTION

Missing or damaged O-rings.
Malfunction and premature failure.
- Make sure that all O-rings are on the coupling and are undamaged.

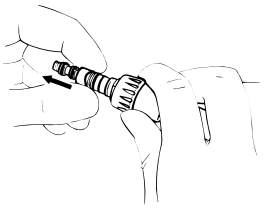
NOTE
Stop working if the O-ring is missing or damaged.

CAUTION

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.

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

- 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 Reprocessing steps in accordance with ISO 17664-1 / ISO 17664-2

7.1 Preparations at the site of use

⚠ WARNING

Hazard from contaminated products.

Contaminated products are associated with an infection hazard.

- Take suitable personal protective measures.

- To minimise the risk of infection during reprocessing, always wear protective gloves.
- Reprocess the medical device right after treatment.
- Remove all residual cement, composite or blood immediately.
- Wipe-disinfect the medical device before transport.
- Remove instrument from the medical device.
- Do not place in solutions or similar substances.

CAUTION

Never reprocess the medical device with chloride-containing products.
Malfunction and material damage.

- Reprocess it in a washer disinfector only.

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

Approved disinfectants:

- CaviWipes and CaviCide made by Metrex
- Mikrozid AF made by Schülke & Mayr (Liquid or wipes)
- 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.

7.2 Manual Reprocessing

This product is not designed for manual internal and external cleaning and manual internal and external disinfection.

For effective reprocessing, automated internal and external cleaning as well as automated internal and external disinfection with a cleaning and disinfection unit in accordance with EN ISO 15883-1 is required.

CAUTION

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

- Reprocess it in a washer disinfector only.

7.3 Automated reprocessing

CAUTION

Never reprocess the medical device with chloride-containing products.
Malfunction and material damage.
- Reprocess it in a washer disinfector only.

CAUTION

Never reprocess this medical device in an ultrasonic cleaner.
Malfunction and material damage.
- Reprocess it in a washer disinfector only.

NOTE
Adapters are needed for automated cleaning.
Order adapter separately.

Also refer to:
8 Components and miscellaneous, Page 23

7.3.1 pre-cleaning

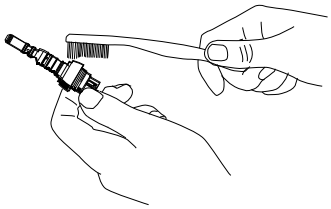
CAUTION

Never reprocess this medical device in an ultrasonic cleaner.
Malfunction and material damage.
- Reprocess it in a washer disinfector only.

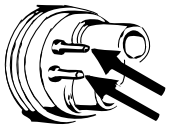
The non-fixing preliminary cleaning is a central constituent and must be carried out prior to the automatic reprocessing.

Accessories required:
- Tap water (drinking water)
- Brush, e.g. medium-hard toothbrush

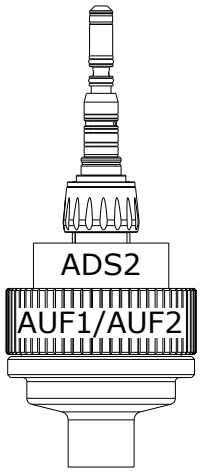
- Brush off under flowing tap water at least 10 seconds.



- Rinse the spray air and spray water tube with potable water.



7.3.2 Preparation for automated internal and external cleaning as well as internal and external disinfection

Miele Series G 7881/7891	
Reprocessing with Miele AUF1/AUF2 adapter and silicone adapter ADS2 with a diameter of 16 mm	

7.3.3 Automated internal and external cleaning and internal and external disinfection

KaVo recommends washer disinfectors in accordance with EN ISO 15883-1, which are operated using alkaline cleaning agents.

The validations were performed using a Miele washer disinfector and the "VARIO-TD" programme and a mild alkaline cleaner made by Dr. Weigert.

In addition, KaVo recommends the use of a rinsing agent.

- For programme settings as well as cleansers and disinfectants, please refer to the Instructions for Use of the washer disinfector.
- For adaptations, unless otherwise specified, refer to the Instructions for Use of the washer disinfector.

7.3.4 Automated drying

The drying procedure is usually part of the cleaning programme of the washer disinfector.

NOTE
Please comply with the instructions for use of the washer disinfector.

- In order not to affect the KaVo medical device, make sure that the product is dry on the inside and outside after completion of the cycle.

7.4 Care products and systems - Servicing

CAUTION

Improper care.
Malfunction or property damage.

- Do not service the medical device with oil or maintenance spray.

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 packaging of the items to be sterilised must meet the applicable standards and be appropriate for the sterilisation process!

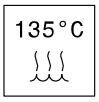
- Seal the medical device separately in a sterile pack.

7.6 Sterilisation

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

CAUTION

Contact corrosion due to moisture.
Damage to product.
- Immediately remove the product from the steam steriliser after the sterilisation cycle.



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

Sterilisation parameters:

Select a suitable process from the following sterilisation processes (depending on the available steriliser):

- Steriliser with triple pre-vacuum:
  - at least 3 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
- Autoclave using the gravity method:
  - at least 10 minutes at 134 °C -1 °C / +4 °C (273 °F -1.6 °F / +7.4 °F)
  - at least 30 minutes at 121 °C -1 °C / +4 °C (250 °F -1.6 °F / +7.4 °F)
- Remove the medical device from the steam steriliser immediately after the sterilisation cycle is completed.
- Use according to the manufacturer's Instructions for Use.

7.7 Storage

Reprocessed products must be stored appropriately protected from dust in a dry, dark and cool space with a low germ level.

NOTE
Comply with the expiry date of the sterilised items.

8 Components and miscellaneous

Available from authorised KaVo dealers.

Components

Description	KaVo material number
KaVo MULTI LED lamp	**1.007.5372**

Miscellaneous

Description	KaVo material number
Key	**0.411.1563**
Spare washer	**0.553.5262**
O-ring 6.65x0.8	**1.004.2776**
O-ring 3.8x1.1	**1.004.2775**
O-ring set MULTIflex couplings	**1.010.7024**

Additional tools and consumables are available from specialised dental dealers.

9 Terms and conditions of warranty

This KaVo medical device is subject to the following warranty conditions:
KaVo grants the end customer a warranty of proper function and guarantees zero defects in respect of material and workmanship for a period of 18 months from the date of the invoice, subject to the following conditions:
With regard to justified complaints KaVo grants warranty in the form of a free of charge repair or delivery of a replacement. Other claims of any kind whatsoever, in particular with respect to compensation, are excluded. In the event of default, gross negligence or intent, this shall only apply insofar as this does not conflict with mandatory statutory provisions.
KaVo shall not be liable for defects and consequences thereof that have arisen or may arise from natural wear, improper handling, cleaning, servicing 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 the KaVo instructions for use or other manufacturer's instructions. The warranty granted does, in general, not extend to lamps, optical fibres made of glass and glass fibres, glassware, rubber parts, and the colourfastness of plastic parts.
Any liability is excluded if defects or the consequences thereof are due to the customer or third parties not authorized by KaVo interfering with or modifying the product.
Warranty claims can only be asserted if proof of sale in the form of a copy of the invoice or delivery note is presented with the product. The dealer, purchase date, type, and serial number must be clearly evident from this document.

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