Instructions for use
COMFORTdrive 200 XDR - REF 1.007.3570

KaVo. Dental Excellence.

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Contents

1 User instructions

Dear user,
KaVo hopes that you enjoy your new high-quality product. Following the instructions below will allow you to work smoothly, economically and safely.

Symbols

	See the section Safety/Warning Symbols
	Important information for users and technicians
	Thermodisinfectable

	Sterilizable with steam up to 135 °C (275 °F)
▶	Action request

Target group

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

1.1 Warranty terms and conditions

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 24 months from data of invoice, subject to the following conditions:
In case of justified complaints, KaVo will honor its warranty with a repair or free replacement. 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 cannot be held liable for defects and their consequences that are or may be due to natural wear, improper handling, cleaning or maintenance, non-compliance with operating 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 specifications. The warranty does not usually cover lamps, light conductors made of glass and glass fibers, glassware, rubber parts and the colorfastness of plastic parts.

No liability is assumed when defects or their consequences are derived from manipulations or changes to the product by the customer or a third party.
Service 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/delivery note. The dealer, purchase date, unit number or type and serial number must be clearly visible on this document.

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 danger.
This section describes the possible consequences of misuse.

- The optional step contains necessary measures for avoiding hazards.

2.1.3 Description of safety instructions: Description of danger levels

The safety instructions cited herein with the three levels of danger will help avert property damage and injury.

⚠ CAUTION

CAUTION
indicates a hazardous situation that can lead to property damage or minor to moderate injury.

⚠ WARNING

WARNING
indicates a hazardous situation that can lead to serious injury or death.

⚠ DANGER

DANGER
indicates a maximum hazardous situation that can directly cause serious injury or death.

2.2 Purpose – Proper use

This medical device is

- Only intended for dental treatment. Any other type of use or alteration to the product is impermissible and can be hazardous. The medical device is intended for the following use: Removal of carious material, cavities and crown preparations, removal of fillings, processing of tooth and restoration surfaces.
- A medical device according to relevant national statutory regulations.

This medical device
- contains a dental electrical low voltage motor according to DIN EN ISO 11498 type 3.
- and is not permitted for use in explosive areas.

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.

2.3 Safety instructions

⚠ CAUTION

Premature wear and malfunctioning from improper storage during long periods of nonuse.
Reduced production time.

- The instrument must be cleaned, serviced and stored dry if it has not been used for a long period.

⚠ WARNING

Hazard to the care provider and patient
Damage, irregular noise during operation, excessive vibration, unusual build-up of heat or if the cutter or grinder cannot be firmly held.

- Stop work and seek service support.

⚠ CAUTION

Hazard from improperly putting away instruments.
Injury and infection caused by chucked cutters or grinders.
Damage to the chucking system when the instrument fails.

- After treatment, place the cutter or grinder properly in the cradle without the tool.

⚠ CAUTION

Burning hazard from hot instrument head or instrument cover.
If the instrument overheats, burns may arise in the oral area.

- Never contact soft tissue with the instrument head or instrument cover.

⚠ CAUTION

Hazard from use as a light probe.
Do not use the device as a light probe since the rotating cutter grinder can cause injury.

- For additional illumination of the oral cavity or preparation site, use a suitable light probe such as the KaVo DIAlux 2300L.

Risks from electromagnetic fields (pacemakers)

⚠ WARNING

Risks from electromagnetic fields.
The functions of implanted systems (such as pacemakers) can be influenced by electromagnetic fields.

- ► Ask patients before treatment and counsel them about the risks.

⚠ CAUTION

Risks from the lack of control equipment.
Hazards can arise if control equipment is not available for changing the speed and the direction of rotation.

- The connected dental treatment unit must have control equipment for changing the speed and direction of rotation.
- In addition, the accompanying documents must refer to them due to responsibilities relating to from safety, reliability and performance.
- The medical device may only be combined with a treatment unit released by KaVo.

⚠ WARNING

Electricity
Electrical shock from incorrectly connecting a non-KaVo system to the medical device.

- When installing the operating the medical device for treatments and equipment from other manufacturers, observe the provisions of "Protection from electrical shock," "Leakage current," and "Not grounding the application part" in accordance with DIN EN IEC 60601-1.
- The medical device may only be combined with a treatment unit released by KaVo.

⚠ CAUTION

Instructions for the safe use of handpieces with electronic micromotors.
Electronic micromotors generate much more energy than conventional pneumatic turbines and motors. Given the higher torque and speed, handpieces that are poorly serviced, damaged or used improperly can overheat which can seriously burn the patient.

- Observe the following points.

Note

This medical device in conjunction with the dental treatment unit meets the requirements of DIN EN IEC 60601-1-2.

Note

For safety reasons, we recommend that the tool holder system be checked annually after the warranty period expires.

The following guidelines must be observed to ensure save use of the electrically driven handpieces:

- The service instructions of handpieces must be precisely following when using KAVOspray or QUATTROcare care systems.
- Before each use, the handpiece must be checked for external damage.
- In a test run of the handpiece, watch for atypical heating, unusual noise and vibration.
- Immediately stop using handpieces that act unusual.
- Never press the pushbutton during operation. This also includes lifting the cheek or tongue!

We recommend returning the handpieces to KaVo at regular intervals for testing, setup and servicing. The frequency of the care depends on the instruments use. The contra-angle handpieces must be setup according to the KaVo instructions to ensure proper functioning.

The following individuals are authorized to repair and service KaVo products:

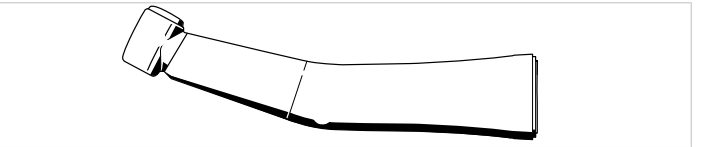
- Technicians at the KaVo branches throughout the world
- Technicians specially trained by KaVo

To ensure proper function, the medical device must be set up according to the methods described in the KaVo instructions for use, and the care products and methods 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 should take into account the frequency of use.

Service may only be provided by repair shops that have undergone training by KaVo and that use original KaVo replacement parts.

The present product is subject to the EC Directive on used electrical and electronic devices and must be disposed within Europe at a special facility. Further information can be obtained from KaVo or a dental distributor.

3 Product description



COMFORTdrive 200 XDR **Mat. no. 1.007.3570**

3.1 Technical data

With integrated electrical motor.

Identification	Red color marking
Motor speed	min./ max. 30,000/ 200,000 rpm

Motor power	30 Watt
COMFORTtronic motor electronics	Mat. No. 1.005.0169
Motor voltage	max. 18 VAC
Output torque	max. 0.45 Ncm

Can be mounted on the COMFORTbase supply hose (**Mat. no. 1.004.9811**).

Information about the connected loads on the device side should be obtained from the manufacturer.

Operating time/intermittent duty	0.5/9 min
Operating voltage of the high-pressure lamp	max. 3.2 V DC

Performance of the high-pressure bulb	max. 2.5 Watt
Air outlet at the coupling (cooling air)	7 to 10 NL/min.
Spray air pressure	1.0 (15) to 2.5 (36) bar (psi)
Spray water pressure	0.8 (12) to 2.0 (29) bar (psi)

3.2 Transportation and storage conditions

⚠ CAUTION

Starting up the medical device can be hazardous after it has been stored in an excessively cold location.
The medical device can malfunction.

- ▶ Prior to start-up, very cold products must be heated to a temperature of 20 °C (68 °F) to 25 °C (77 °F).

	Temperature: -20°C (-4°F) to 50°C (122°F)
	Relative humidity: Non-condensing
	Air pressure: 700 hPa (10 psi) to 1060 hPa (15 psi)
	Protect from moisture.

4 First use

⚠ WARNING

Hazard from nonsterile products.
Infection danger to the care provider and patient.

- ▶ Before first use and after each use, sterilize the medical device.

⚠ WARNING

Damage from soiled and moist cooling air.
Contaminated and moist cooling air can cause malfunctions and lead to premature bearing wear.

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

4.1 Check the amount of water

⚠ CAUTION

Overheating of the tooth due to lack of cooling water.
Thermal damage to the pulp.

- ▶ Adjust the water amount for the spray head to a min. of 50 cm^3/min!

⚠ CAUTION

Hazard from insufficient spray water.
Insufficient spray water can cause the medical device to overheat and damage the tooth.

- ▶ Check the spray water channels and clean the spray nozzles with the nozzle needle **Mat. no. 0.410.0921** if necessary.
- ▶ Check the filter and exchange it if necessary.

5 Operation

5.1 Attach the medical device

⚠ WARNING

Release of the medical device during treatment.
A medical device that is not properly locked in place can release from the supply hose.

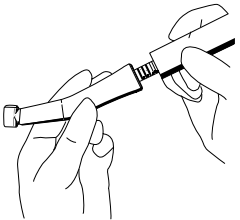
- ► Carefully pull on it before each treatment to ensure that the medical device is securely locked on the supply hose.

⚠ CAUTION

Loss of function
If the footswitch is pressed while you are connecting and removing the medical device, you can damage the medical device and supply hose.

- ▸ Do not connect or remove the medical device while pressing the footswitch.

- ▸ Slightly wet the O-rings on the connection hose with KAVOspray.



- Connect the medical device with the supply hose until it locks into place and twist it until the catch audibly locks in place.

5.2 Remove the medical device

- Remove the medical device from the supply hose in an axial direction.

5.3 Insert the milling cutters or diamond grinders

Note

Only use cutters or grinders that correspond to ISO 1797-1 type 3, are made of steel or hard metal and meet the following criteria:
- shaft diameter: 1.59 to 1.60 mm
- Overall length: max. 25 mm
- Shaft clamping length: min. 11 mm
- Cutting diameter: max. 2 mm

⚠ DANGER

Use properly in conformance with the cutter or grinder instructions for use.
Never use metal cutters or burrs with worn shafts can fall out during treatment and injure the patient.

- Never use cutters or grinders with worn shafts.

⚠ WARNING

Use of impermissible cutters or grinders.
Injury to the patient or damage to the medical device.

- Only use cutters or grinders that do not deviate from the indicated data.

⚠ CAUTION

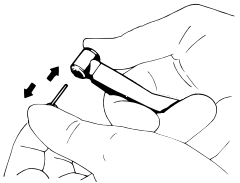
Injury hazard from cutters or grinders.
Infections or cuts.

- Wear gloves or thimbles.

⚠ DANGER

Hazard from defective chucking system.
The cutter or grinder can fall out and cause damage.

- Pull on the cutter or grinder to check if the chucking system is okay and the cutter or grinder is securely held. Fur checking, inserting and removing, use gloves or a thimble to prevent an injury or infection.



- Firmly press the pushbutton with your thumb. Simultaneously push the cutter or grinder in all the way.

- Check that the cutter or grinder is seated by pulling on it.

5.4 Removing the milling tool or diamond grinder

⚠ CAUTION

Hazard from rotating cutter or grinder.
Cuts.

- Do not unintentionally touch rotating cutters or grinders.

⚠ WARNING

Do not press the pushbutton while the cutter or grinder is rotating.
If you press the pushbutton when the cutter or grinder is rotating, it can damage the chucking system and cause injury.

- Never touch soft tissue with the head or tip since it may be hot and cause a burn.
- After treatment is over, remove the cutter or grinder from the contra-angle handpiece since injury and infection may result from putting it away when the cutter or grinder are inserted.

- After the cutter or grinder has stopped rotating, press the push button with your thumb and pull out the cutter or grinder.

6 Troubleshooting

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

⚠ CAUTION

Missing or damaged O-rings
If the O-rings are missing and damaged, malfunctions and premature failure can occur.

- ▶ Check if all O-rings are on the coupling and undamaged.

Number of available O-rings: 3

6.1 Exchanging the O-rings on the supply hose

⚠ CAUTION

Hazard from improper care of O-rings.
The medical device can malfunction and completely fail if the O-rings do not receive proper care.

- ▶ Do not use Vaseline or any other grease or oil.

Note

The O-ring on the supply hose may only be lubricated with cotton ball wet with KAVOspray.

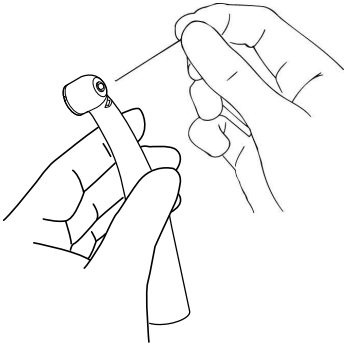
Press the O-ring between your fingers to form a loop. Shove the O-ring to the front, and remove it. Insert new O-rings into the grooves.

6.2 Cleaning the spray nozzle.

⚠ CAUTION

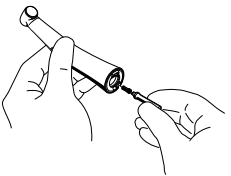
Hazard from insufficient spray water.
The medical device can overheat and the tooth can become damaged.

- ▸ Check the spray water channels and clean the spray nozzles with the nozzle needle **Mat. no. 0.410.0931** if necessary.
- ▸ Check the water filter and exchange it if necessary.



- Use the nozzle needle **Mat. no. 0.410.0921** to free the water passage in the spray nozzles.

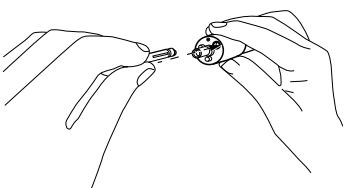
6.3 Change the water filter



Push out and remove the filter with the wrench **Mat. no. 1.002.0321** .
Insert the new filter **Mat. no. 1.002.0271** and screw it in with the wrench.

6.4 Changing the high-pressure lamp

	**⚠ CAUTION** **Danger due to hot high-pressure bulb.** Burning hazard. ► Do not touch the high pressure bulb after use. Let the lamp cool off.



Push the accompanying lamp changer on the lamp and pull the lamp off axially. Insert the new lamp into the lamp changer, and introduce it into the hole in the face of the supply hose. Carefully shove the lamp into the socket by twisting slightly. Remove the lamp changer by quickly twisting it and simultaneously pulling it out in an axial direction.

7 Preparation methods according to ISO 17664

7.1 Preparations at the site of use

⚠ WARNING

Hazard from nonsterile products.
An infection hazard exists from contaminated medical devices.

- ▸ Observe suitable personal protective measures.

- ▸ Remove residual cement, composite or blood at the site of use .
- ▸ The medical device must be dry when transporting it to be prepared. (Do not place it in a solution or the like).
- ▸ Prepare the medical device directly before treatment.
- ▸ Remove cutters or burs from the medical device.

7.2 Cleaning

⚠ CAUTION

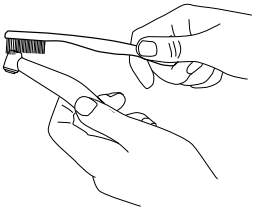
Malfunctions from cleaning in the ultrasonic unit.
Defects in the product.

- ▶ Only clean in a thermodisinfector or manually.

7.2.1 Cleaning: Manual cleaning - external

Required accessories:

- Tap water 30 °C ±5 °C (86 °F ± 10 °F) or a 60 to 70% alcohol solution
- Brush such as a medium hard toothbrush



- Brush off under flowing tap water, or clean with a 60 - 70% alcohol solution.

7.2.2 Cleaning: Automated external cleaning

KaVo recommends thermodisinfectors in accordance with ISO 15883-1 e.g. Miele G 7781/G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutralizer "neodisher® Z" and rinse "neodisher® mielclear") and only refers to material compatibility with KaVo products.)

- 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, treat the medical device with the care products and systems provided by KaVo.

7.2.3 Cleaning: Manual cleaning of the inside

For a medical device 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 cleaner work for one minute.
- Then rinse for 3-5 seconds with KaVo DRYspray.

Instructions for use for the KaVo CLEANspray/KaVo DRYspray.

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,only automated interior cleaning with thermodisinfectors in accordance with ISO 15883-1.

7.2.4 Cleaning: Automated internal cleaning

KaVo recommends thermodisinfectors in accordance with ISO 15883-1 e.g. Miele G 7781/G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutralizer "neodisher® Z" and rinse "neodisher® mielclear") and only refers to material compatibility with KaVo products.)

- 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, treat the medical device with the care products and systems provided by KaVo.

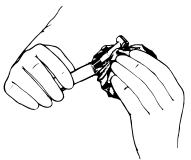
7.3 Disinfection

⚠ CAUTION

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

- Only disinfect in a thermodisinfector or manually.

7.3.1 Disinfection: Manual disinfection - external



KaVo recommends the following products based on material compatibility. The microbiological efficacy must be ensured by the disinfectant manufacturer.

- CaviCide by Metrex

Required tools:

- Cloths for wiping down 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.

Note

Observe the instruction for use for the disinfectant.

7.3.2 Disinfection: Manual disinfection - internal

To effectively set up, the inside of the machine must be cleaned automatically in a cleaning and disinfection unit in accordance with ISO 15883-1. (The inside of this product should not be disinfected manually.)

7.3.3 Disinfection: Machine disinfection - external and internal

KaVo recommends thermodisinfectors in accordance with ISO 15883-1

e.g. Miele G 7781/G 7881.

(Validation was performed with the program "VARIO-TD", the cleaner "neodisher® mediclean", the neutralizer "neodisher® Z" and rinse "neodisher® mielclear") and only refers to material compatibility with KaVo products.)

- 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, treat the medical device with the care products and systems provided by KaVo.

7.4 Drying

Manual drying

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

Machine drying

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

Note

Follow the instructions for use of the thermodisinfector (compressed air quality: see the warning the section "Startup").

7.5 Care products and systems - Servicing

⚠ CAUTION

Sharp cutters or grinders in the medical device.
Injury hazard from sharp and/or pointed cutters or grinders.

- ▶ Remove the cutter or grinder.

⚠ CAUTION

Premature weary and malfunctions from improper servicing and care.
Reduced production time.

- ▶ Regularly perform proper care.

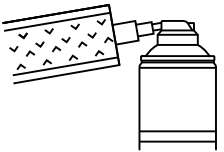
Note

KaVo only guarantees that its products will function properly when the care products are used that are listed as accessories since they were tested for proper use on our products.

7.5.1 Care products and systems - Servicing: Care with KAVOspray

KaVo recommends servicing the project twice daily (at noon and in the evening after hours), after each time the machine is cleaned, and before each sterilization.

- ▸ Remove the cutter or grinder and close the chuck.

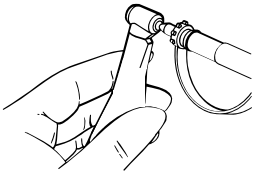


- Cover the product with the Cleanpac bag.

- Place the product on the cannula, and press the spray button for one second.

Care for the chuck of the KAVOspray

KaVo recommends cleaning and maintaining the chucking system once a week.



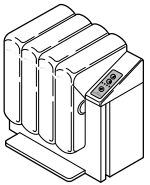
- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

Note

For the care procedure, see the section "Care with KAVOspray."

7.5.2 Care products and systems - Servicing: Care with KaVo QUAT-TROcare

Cleaning and care unit with expansion pressure for thorough cleaning and care.



KaVo recommends servicing the project twice daily (at noon and in the evening after hours), after each time the machine is cleaned, and before each sterilization.

- Remove the cutter or grinder.
- Servicing the product.

KaVo QUATTROcare plus spray can

KaVo recommends cleaning and maintaining the chucking system once a week.

See also: Instructions for use **KaVo QUATTROcare**.

- Remove the cutter or grinder, place the spray nipple tip in the opening and spray.

- Subsequently treat with the care products and systems listed below.

7.6 Packaging

Note

The sterilization bag must be large enough for the instrument so that the bag is not stretched.
The quality and use of the sterilized product packaging must satisfy applicable standards and be suitable for the sterilization procedure.

- Individually weld the medical device in the sterilized item packaging (such asKaVoSTERIclave bags **Mat. no. 0.411.9912**.

7.7 Sterilization

Sterilize in a steam sterilizer (Autoclave) EN 13060/ISO 17665-1

⚠ CAUTION

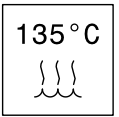
Premature weary and malfunctions from improper servicing and care.
Reduced production time.

- Before each sterilization cycle, treat the medical device with KaVo care products.

⚠ CAUTION

Contact corrosion from moisture.
Damage to product

- After the sterilization cycle, immediately remove the product from the steam sterilizer .



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

Autoclave with prevacuum for at least 4 minutes at 134°C ± 1°C (273°F ± 1.8°F)
Drying time: 20 min.

Autoclave using the gravitation method for at least 10 minutes at 134°C ± 1°C (273°F ± 1.8°F)
Drying time: 30 min.
Autoclave using the gravitation method for at least 60 minutes at 121 °C ± 1°C (250 °F ± 1.8°F)
Drying time: 30 min.
Follow the manufacturer's instructions for use.

7.8 Storage

Prepared products must be stored germ-free and protected from dust in a dry, dark and cool room.

Note

Observe the expiration date of the sterilized item.

8 Tools

Available from dental and medical suppliers

Material summary	Mat. No.
Airflow measuring tube	0.411.4441
Adapter for the airflow measuring tube	1.005.1702
Nozzle needle	0.410.0921
Bulb changer	1.005.1773
Replacement filter	1.002.0271
COMFORTdrive service coupling	1.005.1707
Wrench	1.002.0321
COMFORTdrive spray head	1.005.3154
High-pressure bulb	1.002.2928
Place the O-ring	1.005.0327

Material summary	Mat. No.
Cellulose pad 100 units	0.411.9862
Cleanpac 10 units	0.411.9691
CLEAN/DRYspray adapter COMFORTdrive	1.007.3350

Only for the USA

Material summary	Mat. No.
KAVOspray America 2113 A	0.411.9660
QUATTROcare plus Spray America 2141 P	1.005.4524

1.007.3590 · kb · 20090702 - 04 · en-US

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