



Instruction for use

MK-dent straight and contra angle Handpieces

Version: 2023-06-20-RevE

CE 0123

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1 About this Instruction for use

This Instruction Manual applies to all MK-dent straight handpieces and angle pieces (see Chapter 4 **Product description**).

All products listed in this document are intended exclusively for dental medical treatments in the field of dentistry. Any kind of use for unrelated purposes or modifications of the product are prohibited and can cause danger. All products referred to in this document may be used exclusively by skilled users according to Chapter 2.5 **Intended users** within the scope of the intended use defined for each of them and in observation of the Instruction Manual.

1.1 Explanation of warnings

This Instruction Manual is meant to explain the safe and effective operation of the described product. Before you use the product, you have to read this Instruction Manual, and notice and strictly observe all safety information and warnings. Pay particular attention to all information and procedures that are described in chapter 3 **Safety and requirements**.

This Instruction for use is part of the product and must be kept within reach of the product so that they are accessible at any time.

To prevent personal injuries and property damages, please notice the warnings and safety information contained in this document. These are specially marked:



WARNING

A WARNING alerts you to a potentially serious outcome, unwanted result or safety risk. Failure to observe a warning can result in death or serious injury of the user or patient.



CAUTION

CAUTION alerts you to situations requiring particular care for the safe and effective use of the product. Disregard for a precautionary measure can result in minor or moderately severe personal injuries or damages to the product or other property, and potentially cause a remote risk of serious injuries and/or environmental pollution.

NOTICE

NOTICE

This identifies special tips, for example, as help to the user or for the improvement of a work process.

1.2 Compliance

This medical device fulfils the requirements of Directive 93/42/EEC.

CE 0123

This product complies with the following international standards:

- ISO 14971 Application of risk management to medical devices
- IEC 62366-1 – Application of usability engineering to medical devices

If you have further questions regarding the applicable national or international standards, please direct them to the manufacturer:



MK-dent GmbH
Marie-Curie-Str. 2
22941 Bargteheide
Germany

2 Intended purpose

2.1 Intended use

Straight handpieces (slowly rotating, max. 40,000 rpm): Drives for rotating instruments for used in the preparation of dentures and for polishing tooth and restoration surfaces outside of the oral cavity.

Contra angled handpieces (slowly rotating, 2,703 – 40,000 rpm): Drives for rotating instruments for polishing teeth and dentures as well as for preparing cavities.

Contra angle handpieces (up to 200,000 rpm): Drives for rotating instruments for removal of carious material, preparation of cavities and crowns, removal of fillings.

2.2 Indications

Handpieces and contra angle handpieces are motor-powered preparation instruments with different rotation speed ranges. Depending on the work process, drills (e. g.: rose-head drill, fissure drill), diamonds (actually: steel shafts fitted with diamond grains of different shape and size), grinding bodies (corundum) or rubber polishers can be clamped into the handpiece.

For surgical measures, burs (according to Lindemann) and internally cooled implant drills are used. Parapulpal pins are screwed in mechanically.

For excavating (removal of carious dentine), a rotation speed between 1000 min¹ and 1500 min¹ is recommended; the maximum rotation speed, if necessary, is selected for the preparation (grinding) of enamel and dentine for fitting a crown.

For dental technology work (corrections) on denture parts, a straight handpiece is preferable because these are more robust and the instruments clamped in have a longer HP (handpiece) shaft.

2.3 Contraindications

No contraindications are known to date.

2.4 Intended patient groups

Patients in dental treatment for the removal of caries, preparation of cavities and crowns, and for the removal of fillings. The decision to use a contra angle handpiece, however, is within the sole responsibility of the dentist.

2.5 Intended user

MK-dent handpieces and contra angle handpieces are intended exclusively for use by accredited dentists.

2.6 User environment

Application takes place in dental offices or dental medical centres.

3 Safety and requirements

3.1 General safety regulations



WARNING

- This product is delivered in non-sterile condition. Sterilise it in the autoclave before initial use.
- Sterilisation must be performed before initial use and after each use on a patient in order to prevent direct cross infections.
- This product may be used only by qualified personnel and only for dental treatment.
- Never disassemble or modify this product.
- In case of problems, please do not attempt to repair it on your own. Contact your dealer for the repair.
- Please do not use the product if the performance of the product deteriorates or in case of malfunctions.
- Do not use this product if it has not been serviced properly.
- Observe the precautionary measures for use in order to ensure correct and safe functioning.



CAUTION

- Before initial use and after each treatment, the instrument and accessories must be reprocessed according to the Instruction for use.
- The product may be used exclusively in the field of dentistry with a dental treatment unit, which has a CE-marking or is otherwise certified/approved according to the valid national legal regulations, and which is provided with an appropriate water and compressed air supply in compliance with the applicable standards.
- Test for proper functioning before each use and inspect the instrument visually for external damages.
- A low quantity of spray water can result in the overheating of the instrument and corresponding injuries.

3.2 Reporting obligation

In the event of a serious deterioration in the patient's health during the use of this product, please report this to your specialised dealer or to us as the manufacturer, as well as to the BfArM (Federal Institute for Drugs and Medical Devices).

You can find our contact details in this Instruction for use. We will also inform you of the contact details of the named body upon request.

3.3 Side effects

No side effects are known to date.

3.4 Risk patient groups

No risk patient groups are known to date.

4 Product description

4.1 Description

The MK-dent straight and contra angle handpieces are available in the following variants: PRIME LINE, CLASSIC LINE, ECO LINE, BASIC LINE

Within these product lines, both straight as well as contra angle handpieces (transmission 1:1 = 40,000 rpm) and angled handpieces are available (transmission 4:1 = 5,000 rpm, 1:5 = 200,000 rpm, additional variants generating different rotation speeds with the same input).

The compact shape of the handpieces makes switching between treatment units easy and requires only little space for storage.

The quick coupling system enables easy swapping of the handpieces as well as instant use. No complicated installation is needed, which allows for simple integration in your treatment system.

Article no.	Light	Straight handpiece	Contra angle handpiece complete	Contra angle handpiece body	Contra angle handpiece head	Motor connection ISO 3964	HP drill	RA drill	FG drill	Propy cup
LB01	--	X	--	--	--	X	X	--	--	--
LB01W	--	X	--	--	--	X	X	--	--	--
LB02	--	X	--	--	--	X	X	--	--	--
LB1111	--	--	X	--	--	X	--	X	--	--
LB1111C	--	--	X	--	--	X	--	X	--	--
LB11W	--	--	X	--	--	X	--	X	--	--
LB4111	--	--	X	--	--	X	--	X	--	--
LB4111P	--	--	X	--	--	X	--	--	--	X
LBH11	--	--	--	--	X	--	--	X	--	--
LBH11C	--	--	--	--	X	--	--	X	--	--
LBH11P	--	--	--	--	X	--	--	--	--	X
LE01	--	X	--	--	--	X	X	--	--	--
LE01L	X	X	--	--	--	X	X	--	--	--
LE11	--	--	X	--	--	X	--	X	--	--
LE11L	X	--	X	--	--	X	--	X	--	--
LE148	--	--	X	--	--	X	--	X	--	--
LE148L	X	--	X	--	--	X	--	X	--	--
LE148LP	X	--	X	--	--	X	--	--	--	X
LE148P	--	--	X	--	--	X	--	--	--	X
LE15	--	--	X	--	--	X	--	--	X	--
LE15L	X	--	X	--	--	X	--	--	X	--
LE16	--	--	X	--	--	X	--	--	X	--
LE16L	X	--	X	--	--	X	--	--	X	--
LE21	--	--	X	--	--	X	--	X	--	--
LE21L	X	--	X	--	--	X	--	X	--	--
LE21P	--	--	X	--	--	X	--	--	--	X
LE27	--	--	X	--	--	X	--	X	--	--
LE27L	X	--	X	--	--	X	--	X	--	--
LE54	--	--	X	--	--	X	--	X	--	--
LE54L	X	--	X	--	--	X	--	X	--	--
LE54LP	X	--	X	--	--	X	--	--	--	X
LE54P	--	--	X	--	--	X	--	--	--	X
LE74	--	--	X	--	--	X	--	X	--	--
LE74L	X	--	X	--	--	X	--	X	--	--
LC01	--	X	--	--	--	X	X	--	--	--
LC01L	X	X	--	--	--	X	X	--	--	--
LC11	--	--	--	X	--	X	--	--	--	--
LC11L	X	--	--	X	--	X	--	--	--	--
LC27	--	--	--	X	--	X	--	--	--	--
LC27L	X	--	--	X	--	X	--	--	--	--

Article no.	Light	Straight handpiece	Contra angle handpiece complete	Contra angle handpiece body	Contra angle handpiece head	Motor connection ISO 3964	HP drill	RA drill	FG drill	Prophy cup
LC74	--	--	--	X	--	X	--	--	--	--
LC74L	X	--	--	X	--	X	--	--	--	--
LCH11	--	--	--	--	X	--	--	X	--	--
LCH16	--	--	--	--	X	--	--	--	X	--
LCH21	--	--	--	--	X	--	--	X	--	--
LCH21P	--	--	--	--	X	--	--	--	--	X
LP01L	X	X	--	--	--	X	X	--	--	--
LP11L	X	--	X	--	--	X	--	X	--	--
LP15L	X	--	X	--	--	X	--	--	X	--
LP27L	X	--	X	--	--	X	--	X	--	--
LP54L	X	--	X	--	--	X	--	X	--	--
LP74L	X	--	X	--	--	X	--	X	--	--
LPH11	--	--	--	--	X	--	--	X	--	--
LPH16	--	--	--	--	X	--	--	--	X	--
LPH21	--	--	--	--	X	--	--	X	--	--

4.2 Combination with other products

REF MK-dent straight or contra angle handpiece	LB01, LB01W, LB02, LB1111, LB1111C, LB11W, LB4111, LB4111P, LE01, LE01L, LE11, LE11L, LE148, LE148L, LE148LP, LE148P, LE15, LE15L, LE16, LE16L, LE21, LE21L, LE21P, LE27, LE27L, LE54, LE54L, LE54LP, LE54P, LE74, LE74L, LC01, LC01L, LC11, LC11L, LC27, LC27L, LC74, LC74L, LP01L, LP11L, LP15L, LP27L, LP54L, LP74L
REF MK-dent Airmotor (20,000 rpm)	AM0002, AM0004, AM0012, AM0014, AM1002, AM1004, AM1006, AM1116
REF MK-dent electric motor (40,000 rpm)	EM1190K
Connection*	ISO connection*

*The straight and contra angle handpieces are compatible with all motors with a connection according to DIN EN ISO 3964.

4.3 Product components

Not applicable

4.4 Scope of delivery

The scope of delivery of the following components and accessories is part of the delivery unit:

Product variant	AC0001 Nozzle pin	AC0003 Dental brush for maintenance of the spindle	LT1013P Oil adapter for the motor connection according to DIN EN ISO 3964	LT1014P Oil adapter for maintenance of the spindle
Contra angle handpiece, complete	X	X	X	X
Contra angle body / Straight handpiece	X	X	X	--
Contra angle head	--	X	X	X

When you open the delivered package for the first time, be sure that the packaging seal is not broken and that all components are included in the delivery. If something should be missing, please contact your dealer directly.

4.5 Required materials that are not included

NOTICE

NOTICE

The scope of delivery does not include a Motor.

The scope of delivery does not include an instrument holder article no. RT2050.

The scope of delivery does not include a holding force measuring tool article no. RT1020.

The scope of delivery does not include MK-dent Premium Service Oil LU1011.

4.6 Configurations




The configurations of the handpieces and angle handpieces is explained under **4.1 Description** and **5.4 Spare parts**.





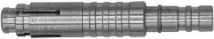
5 Accessories, tools, consumables and spare parts








5.1 Accessories






Holding force measuring tool RT1020	 A black handheld digital force gauge with a small LCD screen at the top. Below the screen are four buttons labeled 'UNIT', 'TARE', 'LIGHT', and 'ON/OFF'. The 'MK-dent' logo is printed in white on the lower part of the black body. A silver metal probe is attached to the bottom.
Instrument holder RT2050	 A grey plastic instrument holder with a grid of 15 cylindrical slots of varying heights. The 'MK-dent' logo is printed in black on the front edge of the base.
MK-dent Premium Service Oil LU 1011	 A blue aerosol can with a white nozzle. The label features the 'MK-DENT' logo at the top, followed by 'PREMIUM SERVICE OIL' in a white box. Below this are three line drawings of dental handpieces. At the bottom of the label, it says 'LU 1011 650', 'Volume = 500ml e', and 'NET 12.20 oz (345g)'.

5.2 Tools

LB01, LB01W, LB02, LE01, LE01L, LC01, LC01L, LP01L			
 Torque wrench: RT2026	 Key: KE2011BT	 Internal adapter remover: RT2015	 Key: RT2011

LB11W, LB1111, LB1111C, LB4111, LB4111P			
 Torque wrench: RT2025	 Torque wrench: RT2026	 Key: KE2011T	 Key: KE2011BT
 Internal adapter remover: RT2015			

LE11, LE11L, LE148, LE148L, LE148LP, LE148P, LE16, LE16L, LE21, LE21L, LE21P, LE27, LE27L, LE54, LE54L, LE54LP, LE54P, LE74, LE74L, LC11, LC11L, LC27, LC27L, LC74, LC74L, LP11L, LP27L, LP54L, LP74L			
 Torque wrench: RT2025	 Torque wrench: RT2026	 Key: KE2011T	 Key: KE2011BT
 Internal adapter remover: RT2015	 Conical sleeve: RT2012	 Screwdriver: RT2016	

LE15, LE15L, LP15L		
 Torque wrench: RT2025	 Torque wrench: RT2026	 Key: KE2011T
 Key: KE2011BT	 Internal adapter remover: RT2015	 Screwdriver: RT2028

LBH11, LBH11C, LBH11P, LCH11, LCH16, LCH21, LCH21P, LPH11, LPH16, LPH21		
 Torque wrench: RT2025	 Key: KE2011T	 Screwdriver: RT2016

5.3 Consumables

Not applicable

5.4 Spare parts



CAUTION

Use of unapproved accessories or making impermissible modifications on the product can result in injuries or malfunctions of the instrument.

→ Combine the product only with spare parts and components that are approved by MK-dent.

	Straight handpiece
Prime Line replacement handpiece	LP01L
Classic Line replacement handpiece	LC01, LC01L
Eco Line replacement handpiece	LE01, LE01L, LE01, LE01L
Basic Line replacement handpiece	LB01, LB01W, LB02

	Contra angle handpiece, complete	Replacement body	Replacement head
Prime Line replacement contra angle handpiece	LP11L LP15L LP27L LP54L LP74L	-- -- -- -- --	LPH11 -- LPH11 LPH21 LPH11
Classic Line replacement contra angle handpiece	--	LC11, LC11L, LC27, LC27L LC74, LC74L	LCH11, LCH16, LCH21, LCH21P, LPH11, LPH16, LPH21
Eco Line replacement contra angle handpiece	LE11/L LE15/L LE16/L LE21/L LE21P LE27/L LE54/L LE54P/LP LE74/L LE148/L LE148P/LP	-- -- -- -- -- -- -- -- -- -- --	LCH11 -- LCH16 LCH21 LCH21P LCH11 LCH21 LCH21P LCH11 LCH21 LCH21P
Basic Line replacement contra angle handpiece	LB1111 LB1111C LB11W LB4111 LB4111P	-- -- -- -- --	LBH11 LBH11C -- LBH11 LBH11P

6 Installation

6.1 Requirements for the environment

To supply the products with clean and dry air, clean the compressor air filter in your dental office. Do not lead in any moist compressed air. Please read the instruction manual of your air compressor for draining water from your compressor and for its regular maintenance. Be sure the compressor is serviced according to its operating manual.

6.2 Unpacking

When opening the package for the first time, confirm that the content according to **4.4 Scope of delivery** is enclosed with the product. Make sure that the straight or contra angle handpiece has no defects or damages such as cracks.

6.3 Assembly

Not applicable

6.4 Preparation for use



WARNING

Danger of infection for patients and users due to unsterile instruments

→ Before initial use and after each treatment, the instrument and accessories must be processed according to this Instruction for use (see Chapter **8 Reprocessing according to ISO 17664-1**).

Malfunction and/or danger of infection from moist and contaminated compressed air and contaminated water for cooling

→ The product may be used exclusively in the field of dentistry with a dental treatment unit, which has a CE-marking or is otherwise certified/approved according to the valid national legal regulations, and which is provided with an appropriate water and compressed air supply in compliance with the applicable standards.



CAUTION

A damaged instrument or damaged components can injure the patient, the user and third parties.

→ Test for proper functioning before each use and inspect the instrument visually for external damages.

→ Do not use the instrument and components if there are any abnormalities.

If a straight or contra angle handpiece is removed, water and oil will stay behind on the motor contact. Remove the water and oil completely. Be sure that no water or oil is left behind in your hose connection. If there are still any residues left, remove them with a dry cloth.

Be sure that there are no water or oil residues left in the connection of the instrument. Remove residues with a cotton swab.

6.4.1 Connecting to the motor



WARNING

Malfunction caused by decoupling the instrument during the treatment.

An instrument that has not interlocked correctly can come loose during the treatment.

→ Pull on the instrument to check before each treatment if it sits firmly on the motor

Damages from inexact coupling.

Inexact coupling can destroy the high-pressure lamp or LED of the coupling or shorten its usage life.

→ Pull on the handpiece to check whether it is firmly secured on the motor

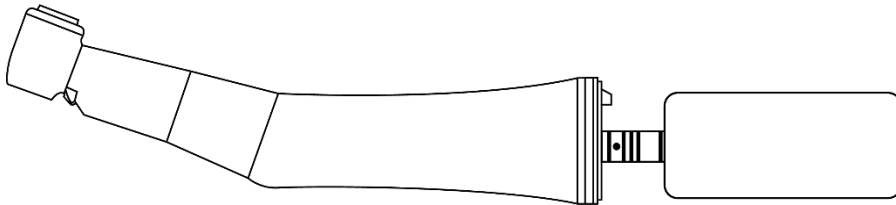


CAUTION

Damages caused by pulling off and putting on the instrument while the motor is rotating.

→ Damage to the driving pin

→ Never put on or take off the body while the motor is rotating



- Place the instrument exactly onto the motor coupling and press it down firmly until you can hear the connection snap in.
- On handpieces with light, set the correct position of the light conductor by turning the instrument firmly until the lock for the correct seat of the light guide snaps in.
- Pull on the instrument to check whether it is firmly secure on the motor coupling.
- To remove it, hold the instrument and pull it off by turning it carefully.

6.5 Putting into service and operation

6.5.1 Before use

NOTICE

NOTICE

Before the start of every working day, the systems conducting water must be flushed for at least 2 minutes without any instruments attached. Another flushing process must be performed for 20 to 30 seconds after each patient.

6.5.2 Check of correct operation



WARNING

Check the safe connection to the motor after you have heard a locking sound. An instable connection leads to injuries caused by the instrument and other parts falling off.

Check that there are no damages, cracks, ruptures or any corrosion on the product and that it is safe to use.

If you encounter any problems, please read Chapter **11 Troubleshooting**. To set the water supply, use the water volume regulator of your treatment unit.

6.5.3 Testing the water quantity



WARNING

Injury to the pulp and tooth.

A low quantity of spray water can result in the overheating of the instrument and corresponding injuries.

→ Set the water quantity for the spray cooling to min. 50 ml/min.

Check the water quantity with a measuring cup. Check the spray water tubes. If the water output is too low or a nozzle is clogged, clean the spray nozzle with the enclosed nozzle pin. Also see **8.1.2 Manual pre-cleaning of the spray nozzle**.

6.5.4 Insertion of rotating instruments



WARNING

Danger of injury to patients caused by the instrument falling out.

→ After each use of rotating instruments, check the holding force of the collet by pulling on the rotating instrument. Please ensure that this is done while the actuator is stopped.

Danger of injury to patients caused by damages on the instrument. Use of rotating instruments other than those listed below.

→ Use only rotating instruments with specifications that are equivalent of the data listed below.

→ Observe the Instruction for use and intended use of the rotating instruments.

Risk of injury from use of worn-out rotating instruments. Rotating instruments can fall out during the treatment and injure the patient.

→ Do not use any rotating instruments with worn-out shafts.

Risk of injury to users from rotating instruments. Cuts and potential infections can be caused as a result.

→ Use gloves or finger guards

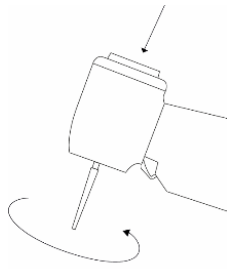
NOTICE

NOTICE

Use only rotating instruments made of steel or tungsten carbide that comply with DIN EN ISO 1797 and meet the following criteria:

	Shaft diameter			Maximum clamping length		Snap-on prophy cups
	Type 1 (CA, RA): 2,334 to 2,350 mm with groove	Type 2 (HP): 2,334 to 2,350 mm cylindrical	Type 3 (FG): 1,590 to 1,600 mm cylindrical	12 mm	30 mm	
REF MK-dent straight or angle handpiece						
LB1111, LB1111C, LB11W, LB4111, LBH11, LBH11C, LE11, LE11L, LE148, LE148L, LE21, LE21L, LE27, LE27L, LE54, LE54L, LE74, LE74L, LCH11, LCH21, LP11L, LP27L, LP54L, LP74L, LPH11, LPH21	X	--	--	X	--	--
LB01, LB01W, LB02, LE01, LE01L, LCO1, LCO1L, LP01L	--	X	--	--	X	--
LE15, LE15L, LE16, LE16L, LCH16, LP15L, LPH16	--	--	X	X	--	--
LB4111P, LBH11P, LE148P, LE148LP, LE21P, LE54P, LE54LP, LCH21P	--	--	--	--	--	X

6.5.4.1 Contra angle handpieces



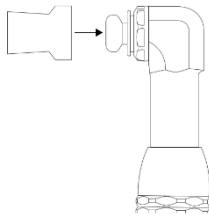
- Press button firmly with your thumb and simultaneously insert the rotating instrument with short rotating movements until it stops.
- Pull on the drill to check that it sits firmly.
- Check the holding force of the spindle at least once a week, using the MK-dent holding force measuring tool RT1020 or another suitable device according to ISO 8325. The holding force of the spindle must not fall below 2.5 kg. MK-dent recommends replacing the spindle when the holding force is below 3 kg.

6.5.4.2 Straight handpieces



- Turn the tension ring in the direction of the arrow up to the stop and insert the rotating instrument into the spindle.
- Turn the tension ring back to the starting position.
- Pull on the rotating instrument to check that it is secure.

6.5.4.3 Insert prophyl cups or polishing brushes



Snap-on and screw-type polishing bits (prophy cups and brushes) according to DIN EN ISO 13295 can be used.

- Screw the bit into the head or slide it onto it.
- Check that the bit is securely firm.

7 Treatment

7.1 Patient, operator and assistant protection



WARNING

The product must be processed correctly before bringing it into contact with the patient the first time in order to prevent infection. See Chapter 8 Reprocessing about this.

Protect the patient appropriately before use.

During the treatment, the user and assistants must wear gloves, safety goggles and masks to prevent infections.



CAUTION

Stop working in all cases whenever operating noises get louder or irregular, or there are stronger vibrations, or in any case of overheating or visual damages. In these cases, contact a repair workshop authorised by the manufacturer or your dealer.

MK-dent recommends lubricating the instrument after a treatment duration of 30 minutes, using the MK-dent Premium Service Oil LU1011; see Chapter 8.3.3 Maintenance, checks and testing. If the instrument is to be used again directly after it is lubricated, it must run in idle for 15–20 seconds to remove excess oil. If the instrument is to be used again later on the same patient, retain it in an instrument holder (Art. no. RT2050) so that any excess oil can drain.

7.2 Removing rotating instruments

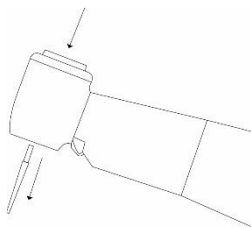


WARNING

Risk of injury from rotating instruments. Cuts and damages on the clamping system.

- Never touch rotating instruments.
- Never use the push button while the instrument is rotating.
- Remove the rotating instrument after each treatment to prevent injuries and infections when putting it down

7.2.1 Contra angle handpieces



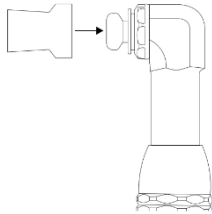
- Use your thumb to press the button firmly after the rotating instrument has come to a complete stop and pull it out at the same time.

7.2.2 Straight handpieces



- After the rotating instrument has come to a complete stop, turn the tension ring in the direction of the arrow up to the stop and take out the rotating instrument.
- Never lock the handpiece without rotating instrument or test pin.

7.2.3 Remove prophy cups or polishing brushes



- Screw the bit out of the head or take it off.

8 Reprocessing according to ISO 17664-1

NOTICE

NOTICE

The lifecycle of the medical device is validated for 250 reprocessing cycles. After 250 reprocessing cycles, no significant negative effect on the product condition from processing could be detected. The possible number of applications does not depend on the reprocessing cycles but rather on the application of the device and the wear and tear caused by this. The product lifetime is therefore determined by signs of wear and tear and damages that occur during use.

Dispose of damaged products according to chapter **10 Disposal**. Do not use products with visible signs of wear and tear or damages.

Use only cleaning agents/disinfectants that are approved for the processing of medical devices. Notice the manufacturer's instructions for the cleaning agents/disinfectants. If unsuitable cleaning agents or disinfectants are used, this can have negative effects on the instruments:

- Damage or corrosion
- Discolouration of the product
- Corrosion of metal parts
- Reduced lifetime

Notice the information of the cleaning agent/disinfectant manufacturer. Do not use any abrasive cleaning agents/disinfectants.

The manufacturer recommends only using cleaning agents/disinfectants compliant with EN ISO 15883-1 and -2 for mechanical cleaning/disinfecting.

The instruments can be sterilised. Do not use any sterilisation temperatures above 135°C.

Ultrasonic cleaning is not recommended for processing the instruments, as the ball bearings can be damaged and the product lifetime could be reduced by this.

8.1 Processing at the location of use



WARNING

Risk of infection from non-sterile instruments. Always wear protective gloves.



CAUTION

Using disinfecting baths and disinfectants containing chlorine can cause defects and malfunctions of the instrument.

The cleaning result is diminished by surface-drying of residues.

→ Flush the transfer instrument immediately when you finish working on the patient.

→ Immediately remove any cement, blood or composite residues.

Do not submerge the instrument in solutions or similar.

NOTICE**NOTICE**

Clean the connectoin hose and on the inside of the instrument connector according to **6.4 Preparation for use** before reconnecting the instrument.

- Flush the inner tubes of the product according to the RKI specifications for 20 seconds while it is still connected to the treatment unit.
- The instruments should be pre-cleaned directly after the treatment in consideration of personal safety. The aim is to prevent organic material and chemical residues from drying in the lumen or on the outer parts of the instruments and to avoid contaminating the environment.
- Remove adhering dirt, body fluids and tissue using a disposable cloth/paper tissue.
- Rinse the product with water after use (temperature below 35°C).
- Do not use any abrasive cleaning agents or water with temperatures above 35°C, as this can lead to increasing adhesion of the dirt and thereby complicate the further processing steps.
- Clean the instrument within one hour after each treatment to prevent surface drying.
- Ensure the instrument is stored safely and transported in dry condition in a closed container to the place of reprocessing.

8.1.1 Preparation for cleaning

Take the drill out of the spindle and pull off the instrument from the motor or quick coupling. Take off all removable parts (if any) and wash each part under running water.

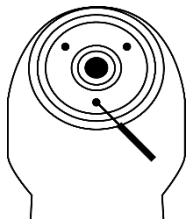
Manual pre-cleaning is also recommended for mechanical processing, such as to remove clogging in the spray tubes.

8.1.2 Manual pre-cleaning of the spray nozzle

**WARNING**

Injury to the pulp and tooth. A low quantity of spray water can result in the overheating of the instrument and corresponding injuries.

→ Check spray water tubes and, if necessary, clean the spray nozzles with the nozzle pin (AC0001) included in the delivery.



Carefully remove clogging in the spray tubes with the enclosed nozzle pin.

8.1.3 Manual pre-cleaning of the instrument



CAUTION

Insufficient cleaning of the surface and water and air tubes.

To ensure successful cleaning, it is necessary to perform thorough manual pre-cleaning. The application of manual pre-cleaning requires training of the employees who implement this reprocessing instruction. This is necessary to ensure successful cleaning.

Tools:

- Drinking water¹ 30°C ± 5°C min. 100 ml
- Brush or soft toothbrush
- Dental brush (AC0003)
- 50 ml syringe or cannula
- Soft lint-free cloth



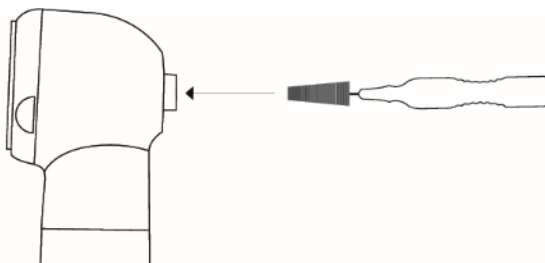
CAUTION

Risk of infection from dental brushes reused multiple times

→ To avoid cross infection, use a new dental brush for each instrument to be cleaned

Malfunctions can occur if cleaning is done in the ultrasonic machine

→ Clean the instrument exclusively as described below.



→ Carefully brush the complete instrument under running drinking water¹ using a brush or soft toothbrush to pre-clean the instrument.

→ To pre-clean the spindle, insert the enclosed dental brush (AC0003) into the collet and carefully loosen/remove any deposits and dirt in rotating movements.

→ Repeat this process several times and flush the dental brush with drinking water¹ each time.

→ To pre-clean the water and air tubes, apply the syringe to the bottom end of the handpiece and flush out the hollow spaces at least five times.

NOTICE

NOTICE

Repeat these steps several times in case of heavy dirt.

¹ Drinking water quality according to the EU Drinking Water Directive (total germ count max. 100 CfU/ml)

8.1.4 Manual pre-cleaning of the glass rod of handpieces with light



CAUTION

Risk of scratching and defects on the glass rod of the instruments if not handled with care.

→ Be extremely careful when you clean the glass rod

Conduct a visual inspection after each cleaning of the glass rod. Do not use the handpiece or angle handpiece if the glass rod is damaged and contact your dealer or the MK-dent repair service.

Wash the glass rod with warm drinking water¹ using a soft lint-free cloth.

Dry the light guide using a compressed air gun or do so carefully using a soft lint-free cloth.

8.2 Manual processing

Tools:

- ALPRO® WL-clean cleaning solution
- ALPRO® WL-cid disinfectant solution
- ALPRO® WL-dry drying spray
- ALPRO® cleaning adapter, depending on the connector
- Lint-free disposable cloth

NOTICE

NOTICE

Use alcohol-based instrument disinfectant with short residence time that does not cause any relevant adhesion of proteins on the handpieces. The instrument disinfectant must be bactericidal, fungicidal and antiviral according to RKI requirements. Generally no disinfectants containing chlorine are to be used, as these can damage the handpieces. Do not use aldehydic disinfectants, as they are incompatible with the material. Generally only use disinfectants with microbiological efficacy confirmed or guaranteed by the manufacturer (e.g. VAH/DGHM registration or CE marking).

According to the RKI recommendation, thermal disinfection in a steam steriliser must follow to the manual cleaning and disinfecting of medical devices of the “semi-critical B” class, especially if the instrument disinfectant used for the manual disinfection does not simultaneously have bactericidal, fungicidal and antiviral efficacy. Alternatively, the manual cleaning can serve as preparation for mechanical cleaning.

8.2.1 Manual cleaning

Connect the adapter to the Alpro® WL-clean spray bottle and insert it into the handpiece on the motor side. Clean the instrument with 3 spray puffs for 2 seconds and with 1 minute residence time, respectively.

8.2.2 Manual disinfection, rinsing and drying

Disinfect the outer surfaces of the instrument using a disposable cloth drained with Alpro® WL-cid. Connect the adapter to the Alpro® WL-cid spray bottle, insert it into the handpiece on the motor side, then spray for 3 seconds. After 5 minutes of residence time, dry the instrument with Alpro® WL-dry spray.



CAUTION

The residence time after the last spray puff is 5 minutes.

8.3 Automatic cleaning

8.3.1 Cleaning, disinfection and rinsing

NOTICE



NOTICE

MK-dent recommends thermal disinfection devices that satisfy the requirements of EN ISO 15883-1 and are approved by the manufacturer for dental handpieces and turbines. The cleaning should be performed at min. 55°C for min. 6 minutes and disinfection at min. 90°C for min. 5 minutes (for A0 value > 3000). A mildly alkaline cleaning agent with pH 9 to 11, e.g. Dr. Weigert Neodisher® MediClean Forte is recommended.

The automatic cleaning and disinfection was validated using the device WD BHT INNOVA® M3 in program no. 03 thermal disinfection, with Dr. Weigert Neodisher® MediClean forte 0.5% as the cleaning agent. The instruments were connected with a silicon hose to a Luer-Lock adapter of the machine.

Parameters for automatic cleaning and disinfection:

- Pre-rinsing for 1 minute with Neodisher® MediClean forte 0.5% cleaning agent at 30°C
- Cleaning for 6 minutes with Neodisher® MediClean forte 0.5% cleaning agent at 55°C
- Rinsing for 1 minute with demineralised water
- Thermal disinfection for 5 minutes with demineralised water at 90°C (for an A0 value > 3,000).

NOTICE

NOTICE

The final rinsing water must have drinking water quality according to the EU Drinking Water Regulation (total germ count max. 100 CfU/ml).

If there is still a visible contamination after processing in the thermal disinfection device, the process must be repeated.

8.3.2 Mechanical drying

The drying process is normally part of the cleaning process of your thermal disinfection device. Please follow the instructions for your thermal disinfection device.

To avoid any kind of interference with the instrument, ensure after each cycle that the instrument is dry on the inside and outside. If moisture remains on or in the instrument after the cleaning process, dry it off again with a lint-free cloth and check the lumen of the instruments for dryness. If necessary, dry it again with medical compressed air.

8.3.3 Maintenance, checks and testing



CAUTION

Premature wear and tear and malfunctions from improper maintenance and care

- Reduced product lifetime
- Perform appropriate maintenance and care at regular intervals

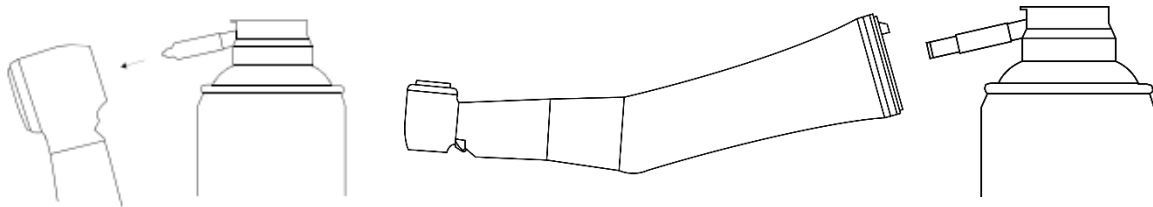
NOTICE

NOTICE

The instrument requires maintenance after each processing and before each sterilisation. Use the MK-dent Premium Service Oil LU1011 for this purpose.

The instrument requires maintenance after each processing and before each sterilisation. Perform the following steps in the order indicated below:

- Screw the included LT1014P oil adapter for maintenance of the spindle onto the oil can. Spray into the spindle for 2 seconds.
- Screw the included LT1013P oil adapter for the motor connection onto the oil can. Insert it into the instrument on the motor side and spray into the connection for 2 seconds.



8.4 Sterilisation in an autoclave

8.4.1 Wrapping

NOTICE

NOTICE

The sterilisation bag must be big enough for the instrument so that the packaging does not get stretched. The sterilisation packaging must conform to EN ISO 11607-1 and be suitable for the sterilisation process. Pack each instrument separately into a single sterilisation bag and check the weld seam for tightness.

8.4.2 Sterilization in a steam sterilizer according to EN 13060 / EN ISO 17665-1



WARNING

Premature wear and tear and malfunctions from improper maintenance and care

→ Reduced product lifetime

→ Maintenance of the instrument with the MK-dent Premium Service Oil is required before each sterilisation.

Contact corrosion from moisture can cause damages on the product.

→ Take the instrument out of the steam steriliser directly after the sterilisation cycle.

This medical device has a temperature resistance of max. 135°C.



CAUTION

Discolouration of the product may occur depending on the conditions for use of your steriliser or your sterilisation methods.

NOTICE**NOTICE**

The instructions of the sterilizer manufacturer for operation and the loading configuration should always be followed. If you sterilize several instruments in one sterilization cycle, ensure that the instruments cannot touch each other in order to allow the best possible penetration of the steam. Notice the information in the sterilizer manufacturer's instruction manual.

After sealing it in the sterilization bag, place the instrument onto a sterilization tray to avoid direct contact with the surface of the sterilizer's interior chamber and put it into the autoclave. MK-dent recommends using a sterilizer according to EN 13060, EN ISO 17665-1 or EN 285. Sterilization must be performed in packaging suitable for the sterilization process. The packaging should comply with EN ISO 11607-1 (e.g. paper/laminate film).

8.4.3 Sterilization parameters

Only apply the following sterilization parameters:

Autoclave with triple pre-vacuum (recommended): at least 5 minutes at min. 134°C.
Drying time: 10 minutes

The sterilization was validated with the device Tuttnauer 3870 EHS, type B autoclave, in a double pre-vacuum process at 134°C for 2.5 minutes (half-cycle) with a drying time of 10 minutes. The instruments have been double-bagged in sterilization bags and sealed.

The instructions given above for processing a medical device for reuse have been validated and found to be suitable by the medical device manufacturer. The user is responsible for ensuring that the actually performed processing, including the devices and materials used in the processing system as well as the personnel, will render the intended result. This requires verification and/or validation as well as routine monitoring of the process.

8.4.4 After sterilization

When the sterilization cycle is finished, take the instrument out of the autoclave. When doing so, notice that the instruments are hot and be sure to use appropriate personal protective equipment for this.

8.5 Storage

After sterilization and drying, check that there are no drops of residual water. Store the processed instruments in a dry, dark and cool room, protected from dust and with the lowest possible microbial load.

Temperature	-20°C to +70°C (-4°F to +158°F)
Relative humidity	5% to 95%, non-condensing
Air pressure	700 hPa to 1060 hPa (10 psi to 15 psi)

**CAUTION**

Malfunction of the instrument during operation after heavily cooled storage conditions

→ Let heavily cooled instruments warm up to room temperature before starting to use them.

The instrument must be completely dried before storage. Remaining water can result in discolouration or rust.

Never store the instrument in a place where it could be exposed to water.

Do not store the instrument in places where chemicals are stored or where corrosive gases occur.

9 Maintenance

9.1 Regular maintenance and checks



WARNING

Improper maintenance or servicing can result in malfunctions and/or deterioration. Always conduct proper maintenance and servicing.



CAUTION

For safe use of the product, perform checks and maintenance of the instrument according to this Instruction for use.

9.2 Cleaning in case of problems

In case of problems with the air or water tubes, clean each part of the instrument. The instrument must be disconnected from the hose coupling for cleaning. You can find instructions in chapter **6.4 Preparation for use**.

10 Disposal

Dispose of this instrument according to your local rules and regulations or clean the instrument according to chapter **8 Reprocessing** in this Instruction for use and return it to the manufacturer.

11 Troubleshooting

NOTICE

NOTICE

This instrument must never be repaired by the user in the event of a malfunction. Contact your dealer for repair.

If this instrument does not function as described in this manual, check the list below for your problem. If your problem is not resolved or if your problem is not listed below, please contact your dealer.

Symptom	Possible causes	Countermeasures
1) No water	<ul style="list-style-type: none"> The water supply system of your treatment unit is switched off No water gets into the hose Water tubes are clogged O-ring(s) on your motor is (are) damaged 	<ul style="list-style-type: none"> Activate the water supply system of your treatment unit Check the water supply system of your treatment unit Check the hose for potential soiling Replace the O-rings on your motor Request repair by your dealer
2) Water leak on the hose connection	<ul style="list-style-type: none"> O-ring(s) on your hose connection is (are) damaged. 	<ul style="list-style-type: none"> Replace the O-rings on your hose connection. Request repair by your dealer
3) No light	<ul style="list-style-type: none"> Glass rod is defective Contact of the light guide is defective 	<ul style="list-style-type: none"> Replace the tube Repair/replace the connector Request repair by your dealer
4) Irregular operating noises	<ul style="list-style-type: none"> Ball bearing is dry, not lubricated sufficiently Ball bearing defective Corrugated spring washer are worn out O-rings are worn out 	<ul style="list-style-type: none"> Lubricate/replace angle handpiece Replace the corrugated spring washer Replace O-rings Request repair by your dealer
5) Strong vibrations	<ul style="list-style-type: none"> Ball bearing defective Ball bearing worn out 	<ul style="list-style-type: none"> Request repair by your dealer.
6) Strong heat development	<ul style="list-style-type: none"> Handpiece is dry, not lubricated sufficiently O-rings are worn out Ball bearing defective 	<ul style="list-style-type: none"> Lubricate the instrument Replace O-rings Request repair by your dealer
7) Optical damages	<ul style="list-style-type: none"> Drop damage Deformation 	<ul style="list-style-type: none"> Replacement Request repair by your dealer
8) Rotation speed inadequate	<ul style="list-style-type: none"> Air supply to the air-powered motor is insufficient Supply voltage of the e-motor is too low Ball bearing defective 	<ul style="list-style-type: none"> Check the compressed air supply Check the supply voltage Request repair by your dealer

12 Repair











Please ship the instrument to your dealer or directly to the manufacturer in case of defects.

13 Technical data

Article no.	Type	Transmission/ Reduction	Marking	Max. rotation speed [U/min]	Max. motor speed	Coating	Operating sound [dB(A)]
LB01	Straight handpiece	1:1	blue	20,000	20,000	chrome	≤ 70
LB01W	Straight handpiece	1:1	blue	20,000	20,000	chrome	≤ 70
LB02	Straight handpiece	1:1	blue	20,000	20,000	chrome	≤ 70
LB1111	Contra angle handpiece	1:1	blue	20,000	20,000	chrome	≤ 70
LB1111C	Contra angle handpiece	1:1	blue	20,000	20,000	chrome	≤ 70
LB11W	Contra angle handpiece	1:1	blue	20,000	20,000	chrome	≤ 70
LB4111	Contra angle handpiece	4:1	green	5,000	20,000	chrome	≤ 70
LB4111P	Contra angle prophy handpiece	4:1	green	5,000	20,000	chrome	≤ 70
LBH11	Contra angle head	1:1	blue	20,000	20,000	chrome	-
LBH11C	Contra angle head	1:1	blue	20,000	20,000	chrome	-
LBH11P	Contra angle prophy head	1:1	blue	20,000	20,000	chrome	-
LE01	Straight handpiece	1:1	blue	40,000	40,000	chrome	≤ 70
LE01L	Straight handpiece	1:1	blue	40,000	40,000	chrome	≤ 70
LE11	Contra angle handpiece	1:1	blue	40,000	40,000	chrome	≤ 70
LE11L	Contra angle handpiece	1:1	blue	40,000	40,000	chrome	≤ 70
LE148	Contra angle handpiece	14.8:1	green	2,703	40,000	chrome	≤ 70
LE148L	Contra angle handpiece	14.8:1	green	2,703	40,000	chrome	≤ 70
LE148LP	Contra angle prophy handpiece	14.8:1	green	2,703	40,000	chrome	≤ 70
LE148P	Contra angle prophy handpiece	14.8:1	green	2,703	40,000	chrome	≤ 70
LE15	Contra angle handpiece	1:5	red	200,000	40,000	chrome	≤ 70
LE15L	Contra angle handpiece	1:5	red	200,000	40,000	chrome	≤ 70
LE16	Contra angle handpiece	1:1	blue	40,000	40,000	chrome	≤ 70
LE16L	Contra angle handpiece	1:1	blue	40,000	40,000	chrome	≤ 70
LE21	Contra angle handpiece	2:1	green	20,000	40,000	chrome	≤ 70
LE21L	Contra angle handpiece	2:1	green	20,000	40,000	chrome	≤ 70
LE21P	Contra angle prophy handpiece	2:1	green	20,000	40,000	chrome	≤ 70
LE27	Contra angle handpiece	2.7:1	green	14,814	40,000	chrome	≤ 70

Article no.	Type	Transmission/ Reduction	Marking	Max. rotation speed [U/min]	Max. motor speed	Coating	Operating sound [dB(A)]
LE27L	Contra angle handpiece	2.7:1	green	14,814	40,000	chrome	≤ 70
LE54	Contra angle handpiece	5.4:1	green	7,407	40,000	chrome	≤ 70
LE54L	Contra angle handpiece	5.4:1	green	7,407	40,000	chrome	≤ 70
LE54LP	Contra angle prophy handpiece	5.4:1	green	7,407	40,000	chrome	≤ 70
LE54P	Contra angle prophy handpiece	5.4:1	green	7,407	40,000	chrome	≤ 70
LE74	Contra angle handpiece	7.4:1	green	5,406	40,000	chrome	≤ 70
LE74L	Contra angle handpiece	7.4:1	green	5,406	40,000	chrome	≤ 70
LC01	Straight handpiece	1:1	blue	40,000	40,000	chrome	≤ 70
LC01L	Straight handpiece	1:1	blue	40,000	40,000	chrome	≤ 70
LC11	Contra angle body	1:1	blue	40,000	40,000	chrome	-
LC11L	Contra angle body	1:1	blue	40,000	40,000	chrome	-
LC27	Contra angle body	2.7:1	green	14,814	40,000	chrome	-
LC27L	Contra angle body	2.7:1	green	14,814	40,000	chrome	-
LC74	Contra angle body	7.4:1	green	5,406	40,000	chrome	-
LC74L	Contra angle body	7.4:1	green	5,406	40,000	chrome	-
LCH11	Contra angle head	1:1	blue	40,000	40,000	chrome	-
LCH16	Contra angle head	1:1	blue	40,000	40,000	chrome	-
LCH21	Contra angle head	2:1	green	20,000	40,000	chrome	-
LCH21P	Contra angle prophy head	2:1	green	20,000	40,000	chrome	-
LP01L	Straight handpiece	1:1	blue	40,000	40,000	Titanium	≤ 70
LP11L	Contra angle handpiece	1:1	blue	40,000	40,000	Titanium	≤ 70
LP15L	Contra angle handpiece	1:5	red	200,000	40,000	Titanium	≤ 70
LP27L	Contra angle handpiece	2.7:1	green	14,814	40,000	Titanium	≤ 70
LP54L	Contra angle handpiece	5.4:1	green	7,407	40,000	Titanium	≤ 70
LP74L	Contra angle handpiece	7.4:1	green	5,406	40,000	Titanium	≤ 70
LPH11	Contra angle head	1:1	blue	40,000	40,000	Titanium	-
LPH16	Contra angle head	1:1	blue	40,000	40,000	Titanium	-
LPH21	Contra angle head	2:1	green	20,000	40,000	Titanium	-

14 Explanation of symbols

	See Chapter 1 Explanation of warnings
	See Chapter 1 Explanation of warnings
	Product can be sterilised in a steam steriliser (autoclave)
	Product can be used in thermal disinfectors for automatic cleaning
CE 0123	CE marking – confirms that this product fulfils all applicable requirements of the valid EU legislation
	Reference number
	Serial number
	Legal manufacturer
	Manufacturing date
	Consult instruction for use
	Unique Device Identifier

15 Warranty

MK-dent grants the end consumer a warranty that is valid from purchase for correct functioning as well as defect-free material and workmanship. The invoice date is decisive for this.

The manufacturer additionally grants a full-service carefree guarantee valid in Germany for the Eco Line, Classic Line and Prime Line.

The following periods must be noted for this:

Designation	Germany		International
	Warranty	Full-service carefree guarantee	Warranty
Prime Line – straight handpiece and contra angle handpiece, complete	24 months	24 months	24 months
Prime Line – contra angle head	24 months	24 months	24 months
Classic Line – straight handpiece and contra angle body	24 months	18 months	24 months
Classic Line – contra angle head	24 months	18 months	24 months
Eco Line – straight handpiece and contra angle handpiece, complete	24 months	12 months	24 months
Basic Line – contra angle body, straight handpiece and contra angle handpiece, complete	12 months	-	12 months
Basic Line – contra angle head	12 months	-	12 months

In the event of justified complaints, MK-dent will perform repair free of charge or deliver a free replacement if necessary. This decision is at the discretion of MK-dent. Further claims of any kind, in particular for damage compensation, are excluded. In the event of default, gross negligence or intent, this applies only insofar as no compulsory legal regulations apply.

MK-dent has no liability for occurred defects and their consequences, which can result from natural wear and tear, improper handling, improper cleaning or maintenance, failure to observe operating or other instructions, calcination or corrosion, contaminated air and water supply, or chemical or electrical influences that are extraordinary or impermissible according to the MK-dent Instruction Manual or other instructions of the manufacturer.

The warranty usually does not cover rubber parts and colour fastness of plastic parts.

Any liability is excluded for defects or their consequences resulting from any manipulation or modifications of the product by the end consumer or a third party not authorised by MK-dent.

Warranty claims will be accepted only if the product is returned with purchase receipt in the form of an invoice or a copy of the delivery slip. The name of the dealer, the purchase date, model and serial number must be clearly legible.