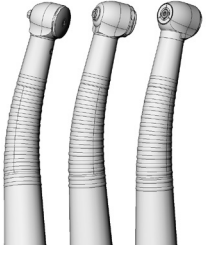
Instructions for use



CE
0297

Turbine

RC-90 BC/RM

RC-95 BC/RM

RC-98 BC/RM

Contents

Symbols

in the Instructions for use

WARNING!
(risk of injury)

ATTENTION!
(to prevent
damage occurring)

General explanations,
without risk to
persons or objects

Do not dispose of with
domestic waste

Symbols

on the medical device / packaging

CE XXXX — CE marking with identification number of the Notified Body

REF — Catalogue number

SN — Serial number

Date of manufacture

Manufacturer

Consult Instructions for use

DataMatrix Code for product information including UDI (Unique Device Identification)

MD — Medical Device

c UL us — UL Component Recognition Mark indicates compliance with Canadian and U.S. requirements

℞ only — Caution! Federal law restricts this device to sale by or on the order of a dentist, physician, veterinarian or with the descriptive designation of any other practitioner licensed by the law of the State in which the practitioner practices to use or order the use of the device.

HIBC — Data structure in accordance with Health Industry Bar Code

135°C — Sterilizable up to the stated temperature

1. Introduction

Customer satisfaction has absolute priority in the W&H quality policy. This medical device has been developed, manufactured and subjected to final inspection according to legal regulations, quality and industry standards.

For your safety and the safety of your patients
Prior to initial use please read the Instructions for use. These explain how to use your medical device and guarantee a smooth and efficient operation.


Observe the safety notes.

Intended use
The dental turbine handpiece is intended for the following applications: Removal of decayed materials, cavities and crown preparation, removal of fillings, finishing of tooth and restoration surfaces.


Misuse may damage the medical device and hence cause risks and hazards for patient, user and third parties.

Qualifications of the user
We have based our development and design of the medical device on the dentists, dental hygienists, dental employees (prophylaxis) and dental assistants target group.

Responsibility of the manufacturer
The manufacturer can only accept responsibility for the safety, reliability and performance of the medical device when it is used in compliance with the following directions:

> The medical device must be used in accordance with these Instructions for use.
> Only the components approved by the manufacturer may be replaced (rotor, water filter).
> If it proves impossible to correct the malfunction, please contact an authorized W&H service partner.

Skilled application
The medical device is intended only for skilled application according to the intended use as well as in compliance with the valid health and safety at work regulations, the valid accident prevention regulations and in compliance with these Instructions for use.

The medical device should be prepared for use and maintained by staff who have been trained in procedures for infection control, personal safety and patient safety.

Improper use, (e.g., through poor hygiene and maintenance), non-compliance with our instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.

Any serious incident that has occurred in relation to the medical device should be reported to the manufacturer and the competent authority!

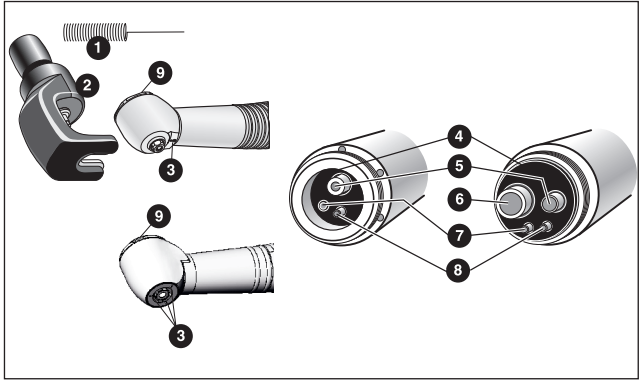
- Before using the medical device for the first time, store it at room temperature for 24 hours.
- The operation of the medical device is permitted only on supply units which correspond to the standards IEC 60601-1 (EN 60601-1) and IEC 60601-1-2 (EN 60601-1-2).
- Use only the supply hoses as specified by EN ISO 9168
- Always ensure the correct operating conditions and cooling function.
- Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction.
- In case of coolant supply failure, the medical device must be stopped immediately.
- Use only the filtered, oil-free and cooled air supplied by dental compressors for drive air
- Check the medical device for damage and loose parts each time before using (e.g. push-button).
- Do not operate the medical device if it is damaged.
- Perform a test run each time before using.

> Avoid overheating at the treatment site.
> Do not use the medical device if there are soft tissue wounds in the mouth. The air pressure can cause septic substances to enter the tissue or trigger embolisms.
> Do not lift the cheek or tongue with the medical device. Risk of burning due to the push-button heating up! (RC-95, RC-98).
> It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the treatment water decontamination system, as well as its handling.

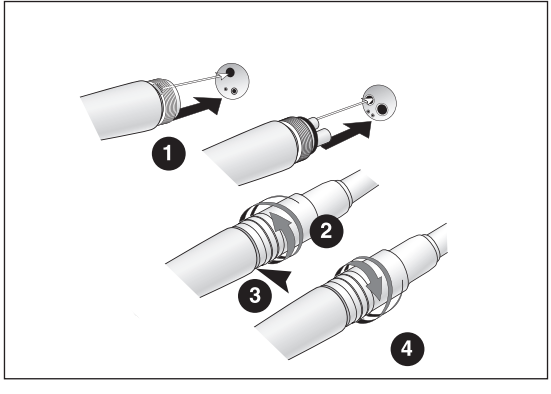
Hygiene and maintenance prior to initial use

> The medical device is sealed in PE film and not sterilized when delivered.
> The PE film and the packaging are non-sterilizable.

> Clean, disinfect and lubricate the medical device.
> Sterilize the medical device, the bur changer and the nozzle cleaner.



1. Nozzle cleaner
2. Bur changer
3. Spray nozzles
4. Seal
5. Drive air
6. Exhaust air
7. Spray air
8. Coolant
9. Back cap (RC-90)
   push-button (RC-95, RC-98)



Do not assemble or remove the medical device during operation!

1. Insert the medical product with BC/RM connection into the apertures of the supply hose.
2. Screw the union nut on.

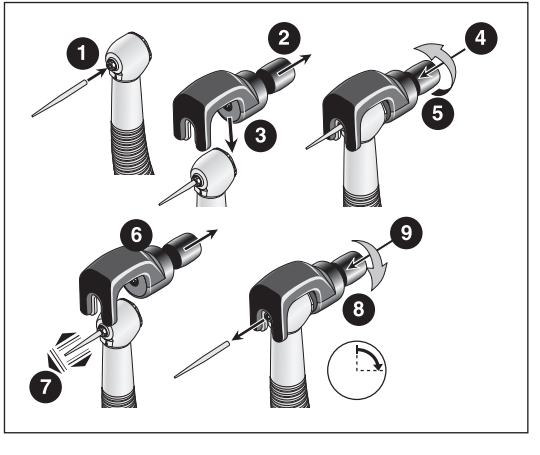
3. Verify full engagement.
   Check the leak tightness.

or

4. Unscrew on the union nut. Remove the turbine handpiece from the supply hose.

Rotary instruments

- > Use only rotary instruments which are in perfect condition. Follow the operating instructions of the manufacturer.
- > Insert the rotary instrument only when medical device is stationary.
- > Never touch the rotary instrument while it is still rotating.
- > Do not activate the medical device without a rotary instrument in place, or if the bur changer is still attached. (RC-90)
- > Do not activate the push-button of the medical device during operation. This leads to detachment of the rotary instrument, damage to the chucking system and/or heating up of the medical device. Risk of burning! (RC-95, RC-98)
- > Only use rotary instruments up to the maximum operating speed stipulated by the manufacturer.



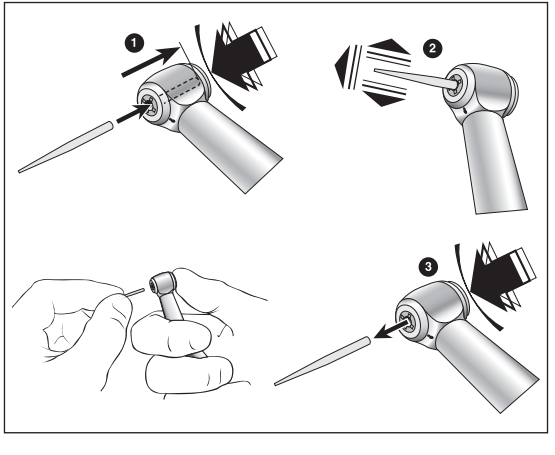
To change rotary instruments
RC-90 BC/RM

❶ Insert the rotary instrument.
❷ Pull out the button and push the bur changer onto the turbine head ❸
❹ Release the button and turn until the rotary instrument is clamped tightly ❺
❻ Pull out the button and remove the bur changer from the turbine head.

❼ Verify full engagement.

or

❽ To remove the rotary instrument turn it counterclockwise (max. 1/4 turn) ❾.



To change rotary instruments
RC-95 BC/RM, RC-98 BC/RM

❶ Insert the rotary instrument.
Activate push-button, at the same time insert the rotary instrument until back stop.

❷ Verify full engagement.

or

❸ Remove the rotary instrument by pushing the push-button.

Test run

Do not hold the medical device at eye level!

> Insert the rotary instrument.
> Operate the medical device.

In the event of operating malfunctions (e.g., vibrations, unusual noise, overheating, coolant failure or leakage) **stop the medical device immediately** and contact an authorized W&H service partner.

Follow your local and national laws, directives, standards and guidelines for cleaning, disinfection and sterilization.

The information on the validated reprocessing procedures serves as an example of an ISO 17664 compliant processing of the medical device.

> Wear protective clothing, safety glasses, face mask and gloves.
> Use only oil-free, filtered compressed air with a maximum operating pressure of 3 bar for manual drying.

Cleaning agents and disinfectants

- > Read the notes, follow the instructions and heed the warnings provided by the manufacturers of cleaning agents and/or disinfectants.
- > Use only detergents which are intended for cleaning and/or disinfecting medical devices made of metal and plastic.
- > It is imperative to comply with the concentrations and exposure times specified by the manufacturer of the disinfectant.
- > Use disinfectants which have been tested and found effective by, for example: the Verbund für Angewandte Hygiene e.V (VAH = Association for Applied Hygiene), the Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin (ÖGHMP = Austrian Society for Hygiene, Microbiology and Preventive Medicine), the Food and Drug Administration (FDA) or the U.S. Environmental Protection Agency (EPA).

The user is responsible for validating its process if the specified cleaning agents and disinfectants are not available.

The product lifetime and the medical device's ability to operate correctly are mainly determined by mechanical stress during use and chemical influences due to processing.

> Decommission worn or damaged medical devices and/or medical devices with material changes.Send those to an authorized W&H service partner.

Processing cycles

> Safe use is guaranteed until at least 1,000 reprocessing cycles.
> For this W&H medical device we recommend to change the rotor after 1,000 recprocessing cycles or after one year.

Clean the medical device immediately after every treatment, to flush out liquid (e.g., blood, saliva etc.) and to prevent settling on the internal parts.

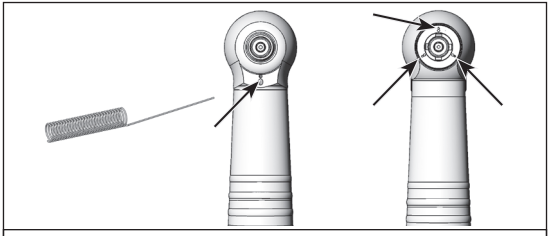
> Operate the medical device for at least 10 seconds at idle speed.
> Ensure that all outlets are rinsed out.

> Wipe the entire surface of the instrument with disinfectant.
> Remove the rotary instrument.
> Remove the medical device.

Note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfection step after cleaning.

Do not place the medical device in liquid disinfectant or in an ultrasonic bath.

> Clean the medical device under running tap water (<35°C / 95°F).
> Rinse all surfaces.
> Move moving parts back and forth several times.
> Remove any liquid residues using compressed air.



Cleaning of the spray nozzles

> Clean spray nozzles carefully with the nozzle cleaner to remove dirt and deposits.

Clean and disinfect the nozzle cleaner in an ultrasonic bath / disinfection bath.

Cleaning of the coolant tubes

> Blow through the coolant tube using compressed air.

In case of blocked coolant outlets or coolant tubes contact an authorized W&H service partner.

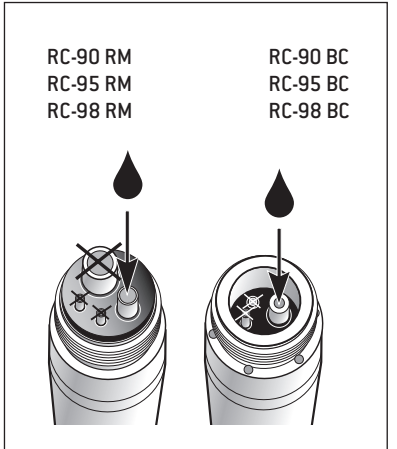
> W&H recommends wiping down with disinfectant.

Evidence of the medical device's basic suitability for effective manual disinfection was provided by an independent test laboratory using the disinfectants "mikrozid® AF wipes" (Schülke & Mayr GmbH, Norderstedt) and "CaviWipes™" (Metrex).

> Ensure that the medical device is completely dry internally and externally after cleaning and disinfection.
> Remove liquid residues using compressed air.

Inspection

> Check the medical device after cleaning and disinfection for damage, visible residual soiling and surface changes.
> Reprocess any medical devices that are still soiled.
> Sterilize the medical device following cleaning, disinfection and lubrication.



Lubrication

> Lubricate the dry medical device immediately after cleaning and/or disinfection.
> Direct the medical device downwards.

Recommended lubrication cycles

> Essential after every internal cleaning
> Before each sterilization

or

> After 30 minutes of use or at least once daily

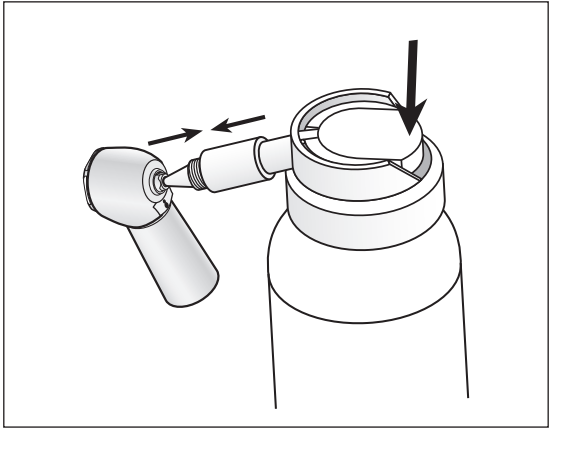
With W&H Service Oil F1, MD-400

> Follow the instructions on the oil spray can and on the packaging.

or

With W&H Assistina

> Follow the instructions in the Assistina Instructions for use.



Lubrication of the chucking system

With W&H Service Oil F1, MD-400

> Fit the spray adaptor REF 02036100 onto the spray can.
> Hold the medical device firmly.
> Press the tip of the spray adaptor firmly into the chucking system.
> Spray for approx. 1 second.

or

With W&H Assistina

> Follow the instructions in the Assistina Instructions for use.

Test after lubrication

> Direct the medical device downwards.
> Operate the medical device so that excess oil can escape.
> Remove any oil that has escaped.

Pack the medical device and the accessories in sterilization packages that meet the following requirements:

> The sterilization package must meet the applicable standards in respect of quality and use and must be suitable for the sterilization method.
> The sterilization package must be large enough for the sterilization goods.
> The filled sterilization package must not be under tension.

W&H recommends sterilization according to EN 13060, EN 285 oder ANSI/AAMI ST55.

> Read the notes, follow the instructions and heed the warnings provided by the manufacturers of steam sterilizers.
> The program selected must be suitable for the medical device.

Recommended sterilization procedures

> “Dynamic-air-removal prevacuum cycle” (type B) / “Steam-flush pressure-pulse cycle” (type S)*/**
> 134°C (273°F) for at least 3 minutes, 132°C (270°F) for at least 4 minutes
> “Gravity-displacement cycle” (type N)**
> 121°C (250°F) for at least 30 minutes
> Maximum sterilization temperature 135°C (275°F)

Evidence of the medical device's basic suitability for effective sterilization was provided by an independent test laboratory using the LISA 517 B17L* steam sterilizer (W&H Sterilization S.r.l., Brusaporto (BG)), the Systec VE-150* steam sterilizer (Systec) and the CertoClav MultiControl MC2-S09S273** steam sterilizer (CertoClav GmbH, Traun).

"Dynamic-air-removal prevacuum cycle" (type B):	134°C (273°F) – 3 minutes*, 132°C (270 °F) – 4 minutes*/**
"Steam-flush pressure-pulse cycle" (type S):	134°C (273°F) – 3 minutes*, 132°C (270 °F) – 4 minutes*/**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

Drying times:

"Dynamic-air-removal prevacuum cycle" (type B):	132°C (270°F) – 30 minutes**
"Steam-flush pressure-pulse cycle" (type S):	132°C (270°F) – 30 minutes**
"Gravity-displacement cycle" (type N):	121°C (250°F) – 30 minutes**

* EN 13060, EN 285, ISO 17665
** ANSI/AAMI ST55 , ANSI/AAMI ST79

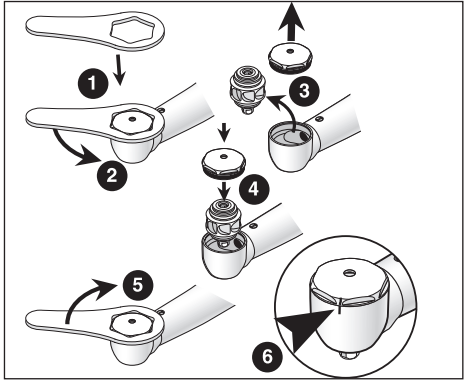
> Store sterile goods dust-free and dry.
> The shelf life of the sterile goods depends on the storage conditions and type of packaging.

6. Servicing

Returns

In the event of operating malfunctions immediately contact an authorized W&H service partner.

> Ensure that the medical device has been completely processed before returning it.

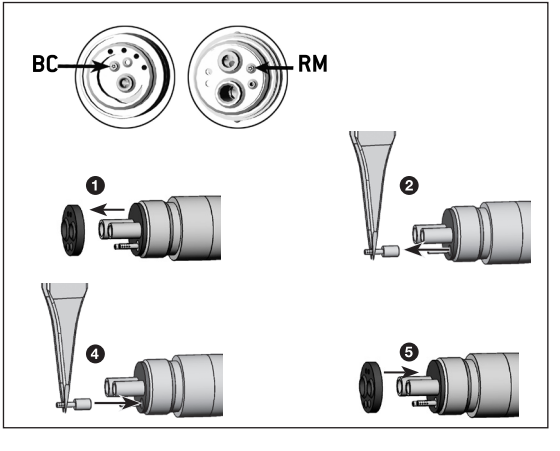


RC-90 BC/RM, RC-95 BC/RM, RC-98 BC/RM

1. Place the cap spanner on the cap.
2. Open the cap anticlockwise.
3. Change the rotor and screw the cap on tightly 4.
5. Close the cap with the cap changer, turning it clockwise up to the mark 6!

> Perform a test run.

> Repeat the complete hygiene and maintenance process.



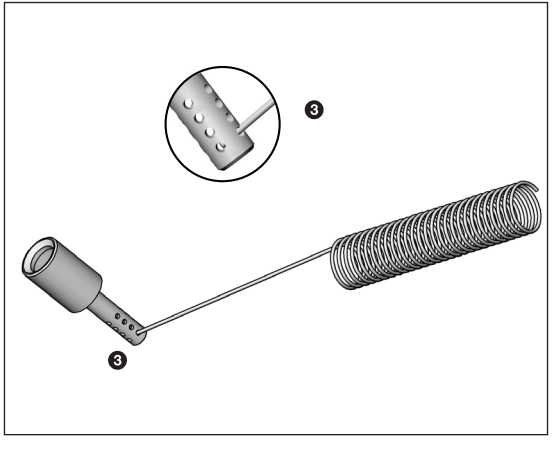
Removal/assembly of the water filter RC-98 BC/RM

1. Remove the gasket.
2. Pull the water filter out using a pair of tweezers.
3. Clean the water filter (see page 37).

or

4. Insert a new water filter.
5. Slide on the gasket.

> Repeat the complete hygiene and maintenance process.



Cleaning of the water filter

❸ Clean outlets carefully with the nozzle cleaner to remove dirt and deposits.

The water filter can be cleaned in an ultrasonic bath.

> Repeat the complete hygiene and maintenance process.

8. Accessories, consumables, spare parts and other recommended medical devices by W&H

Use only original W&H accessories and spare parts or accessories approved by W&H.
Suppliers: W&H partners

000301xx	W&H Assistina 301 plus
10940021	W&H Service Oil F1, MD-400 (6 pcs)
02015101	Nozzle cleaner
02036100	Spray cap BC/RM
02693000	Assistina adaptor for chucking system
04844900	Bur changer
04753200	Spare rotor RC-90 BC/RM including cap spanner
05421700	Spare rotor RC-95 BC/RM including cap spanner
07507300	Spare rotor RC-98 BC/RM including cap spanner

01000700	Gasket BC
02207300	Gasket RM
05421900	Push-button RC-95
06641900	Push-button RC-98
06226400	Screw cap RC-90
08023630	Water filter (RC-98 RM) (3 pcs)
08024350	Water filter (RC-98 BC) (3 pcs)

9. Technical data

Turbine		RC-90 BC/RM, RC-95 BC/RM, RC-98 BC/RM
Connection	EN ISO 9168	Borden 2/3 -hole / Ritter Midwest
Rotary instruments	ISO 1797 (ø mm)	1.6 – 0.01
Maximum length approved by W&H	(mm)	25*
Minimum chucking length		auf Anschlag
Maximum operating part diameter	(mm)	2
Maximum idle mode speed(± 30,000 min^{-1})	(min^{-1})	330,000
Coolant volume	ISO 14457 (ml/min)	> 50
Water setting range (Recommended water pressure)	(bar/psi)	0.5 – 2** bar / 7.3 – 29** psi
Chip air setting range (Recommended chip air pressure)	(bar/psi)	0.5 – 2** bar / 7.3 – 29** psi
Chip air consumption at 2 bar / 29 psi	(Nl/min)	> 1.5
Exhaust pressure	(bar/psi)	< 0.5 bar / < 7.3 psi
Operating pressure range	(bar/psi)	2.2 – 2.5 bar / 32 – 36.3 psi
Recommended operating pressure	(bar/psi)	2.35 bar / 34.1 psi
Air consumption	(Nl/min)	≤ 45

min^{-1} (Revolutions per minute)

* see page 41

* When using longer rotary instruments the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.
For safe use, follow the respective manufacturer's instructions regarding maximum speed of the rotating instrument.

** Chip air pressure / water pressure must be set at the same time.
The chip air pressure must be higher than the water pressure.

Power and speed data are largely dependent on the quality of the turbine hoses used and may therefore differ from the specified values.

Temperature information

Temperature of the medical device on the operator side:	maximum 55°C (131°F)
Temperature of the medical device on the patient side:	maximum 50°C (122°F)
Temperature of the working part (rotary instrument):	maximum 41°C (105.8°F)

Ambient conditions

Temperature during storage and transport:	-40°C to +70°C (-40°F to +158°F)
Humidity during storage and transport:	8 % to 80 % (relative), non-condensing
Temperature during operation:	+10°C to +35°C (+50°F to +95°F)
Humidity during operation:	15 % to 80 % (relative), non-condensing

10. Disposal

Ensure that the parts are not contaminated on disposal.

Follow your local and national laws, directives, standards and guidelines for disposal.

> Medical device
> Packaging

Authorized W&H service partner

Find your nearest authorized W&H service partner at http://wh.com
Simply go to the menu option “Service” for full details.

Or simply scan the QR code.

Explanation of warranty terms

This W&H medical device has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the Instructions for use have been followed.

As manufacturer, W&H is liable for material or manufacturing defects within the warranty period.
In case of complaint, please contact your nearest W&H service partner.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H!

Claims under warranty – accompanied by proof of purchase – must be sent to the vendor or to an authorized W&H service partner. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

warranty

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Form-Nr. 50566 AEN
Rev. 008 / 17.07.2023
Subject to alterations