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TCM Endo V

Operation manual GB

Made in Switzerland

Nr. 31943



SWISS QUALITY

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Dental and Medical Equipment

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English

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1 Product description

1.1 Use and operation

The TCM Endo V is a microprocessor- controlled endodontic device with Apex Locator.
The Apex Locator measures the distance between file tip and Apex. If a minimum distance is preselected, the selected auto-control mode is activated, thus ensuring that the minimum distance is reached.
The speed is held constantly under all circumstances until the maximum adjusted torque limit is reached. The Automatic Torque Control (ATC) protection mode reduce the risk of a breakage occurs of the Rimmer. Once the preselected torque limit has been reached, the motor will immediately reverse for one revolution, then returns to forward direction. Which ensures a fast and effective root canal preparation.

1.2 Technical data

Voltage: ..... 100V~/115V~ / 230V~ / 50-60 Hz
Power supply fuse: ..... 2 x T1A
Power: .....60 VA
Device protection class: ..... Class II
Application part type: ..... BF
Rotational speed: .....150 - 2´000 rpm
Precision of measurement: ..... ± 0.2mm
Apex Locator test voltage: ..... 100mV~
Test voltage frequencies: ..... 500Hz and 7.5kHz
Dimensions (H x W x D): ..... 115 x 120 x 185 mm
Net weight: ..... 1.8 kg
File type: .....NiTi-files; shank- Ø 2.35mm (ISO 1797: Typ 1)

1.3 Ambient conditions foroperation

Humidity: ..... max. 90 %
Temperature: ..... 10 to 40°C
Pressure: ..... 800 to 1060 hPa

1.4 Ambient conditions for transport and storage

Rel. air humidity: ..... max. 90%
Temperature: ..... 0 to 60°C
Air pressure: ..... 700 to 1060hPa

1.5 Device labels


: Caution: refer to enclosed documentation


: Application part type BF

CE 1275 : EU conformity symbol


: Certified by the Canadian Standards Association (CSA) for Canada and USA


: Device protection class: II


: Operational earth


: Old electrical and electronic equipment must be disposed separately and may not be included in regular domestic waste.

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2 Supplied equipment

1524	Control unit TCM Endo V	1 unit
1826nou	Micro-motor 20 Endo Apex	1 unit
1292	On / off footpedal	1 unit
22908	Lip connector to Apex Locator	1 unit
1809	Test plug 0.5mm (± 0.2mm)	1 unit

3 Safety instructions

English

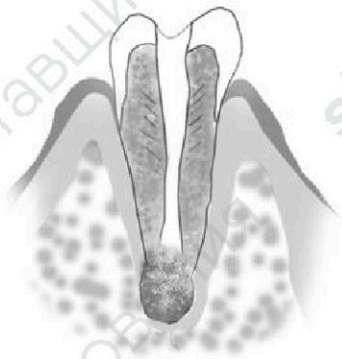
We are very much concerned with your safety, your team's safety and of course your patient's safety. Therefore, it is imperative for you to comply with the following instructions:



- **The TCM Endo V may only be operated by experienced trained personnel!**
- **Please ensure that operating voltage and mains voltage agree!**
- **All sterilisable items must be sterilised before the first use. (see chapter 9, Cleaning, disinfection and sterilisation).**
- **A performance control of the Apex Locator is to be carried out prior to each operation (see chapter 8, performance control of the Apex Locator).**
- **The contact bow must constantly touch the file, respectively be folded up as far as its end position. Otherwise the Apex distance cannot be measured.**
- **The use of third-party products is the responsibility of the operator!**
- **Repairs may only be carried out by authorised NOUVAG service engineers!**
- **Improper use and repair of the device as well as not complying with the instructions relieve us from any obligations regarding guarantee or other claims!**
- **Caution: Federal law restricts this device to sale by or on the order of a physician or dentist**

4 Meausuring Error

Accurate measurement cannot be obtained with the root canal conditions shown below:

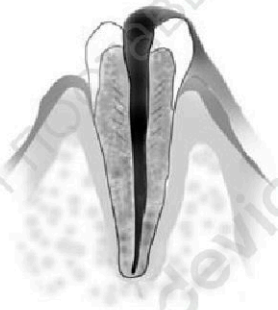


Root Canal with a large apical foramen:

Root canal that has an exceptionally large apical foramen due to a lesion or incomplete development cannot be accurately measured; the results will show shorter measurement than the actual length.

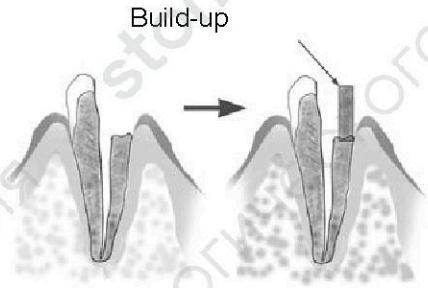
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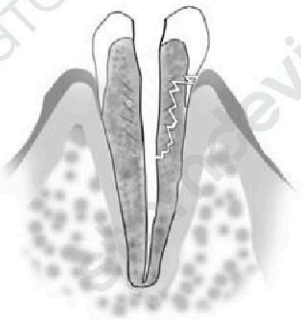
Root Canal with blood or saliva overflowing from the opening:

If blood or saliva over-flows from the opening of the root canal and contacts the gums surrounding the tooth, this will result in electrical leakage and accurate measurement cannot be obtained. Wait for bleeding to completely stop before taking a measurement.



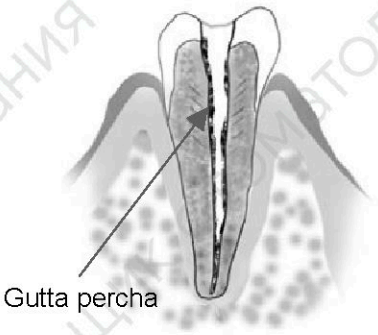
Broken crown:

If the crown is broken and a section of the gingival tissue intrudes into the cavity surrounding the canal opening, contact between the gingival tissue and the file will result in electrical leakage and an accurate measurement cannot be obtained. In this case, build up the tooth with a suitable material to insulate the gingival tissue.



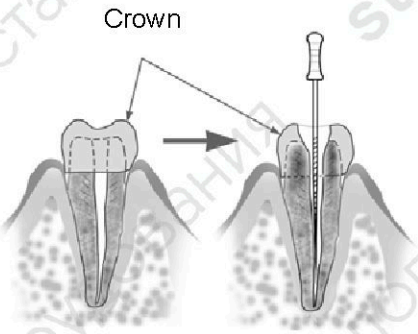
Fractured tooth:

Fractured tooth will cause electrical leakage and an accurate measurement cannot be obtained.



Re-treatment of a root filled with gutta-percha:

In this case, the gutta-percha must be completely removed before a measurement is made. First pass a small file all the way through the apical foramen and then fill the root canal with a saline solution before taking measurement.



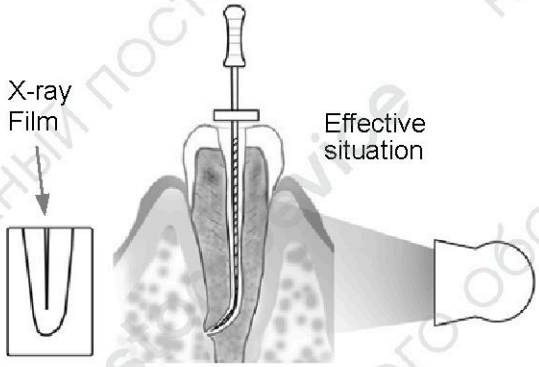
Crown or metal prosthesis touching gingival tissue:

Accurate measurement cannot be obtained if the file touches a metal prosthesis that is touching gingival tissue. In this case, widen the opening at the top of the crown so that the file will not touch the metal prosthesis before taking a measurement.

There may be other cases that an accurate measurement cannot be made.

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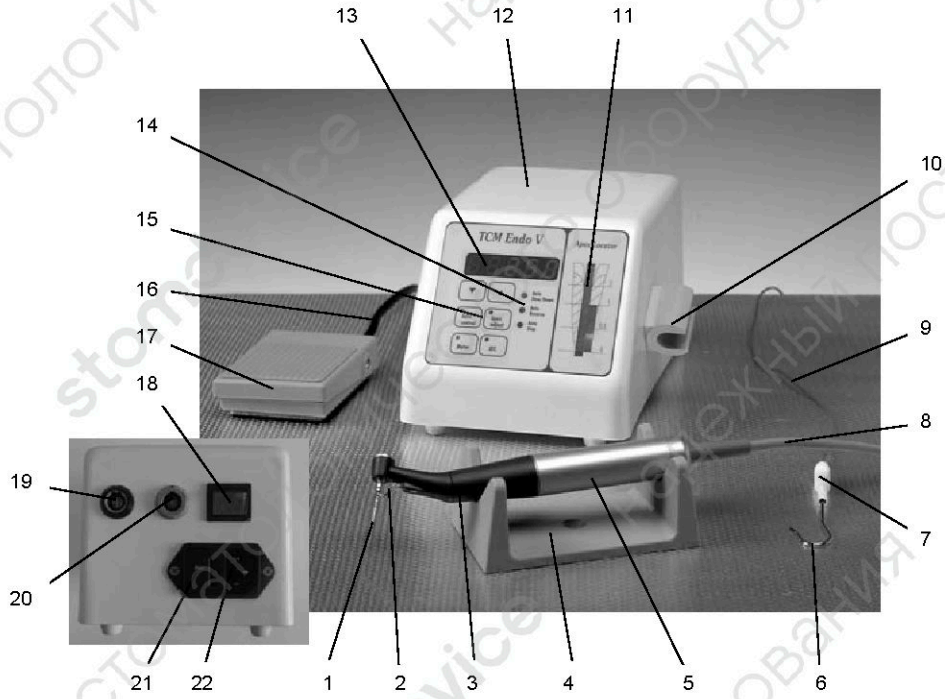
Apex-Locator and Radiography



Sometimes the EMR and the x-ray image do not correspond. This does not mean that the unit is not working properly or that the x-ray exposure is inaccurate.
Frequently the actual apical foramen and anatomical apex do not correspond exactly. The actual apical foramen may be located towards the crown. In this case, the x-ray image will seem to indicate that the file has not reached the apex..

English

5 Device overview



1. Tool tip
2. Contact bow
3. Contra angle
4. Hand piece surface (not included)
5. Endo micro-motor
6. Lip connector
7. Lip connector socket
8. Motor cable
9. Lip connector cable
10. Motor support
11. Root canal display
12. Control unit
13. Display
14. LED Auto-Control Mode
15. Key panel
16. Footpedal cable
17. On/off footpedal

Back:

18. Main switch
19. Motor jack
20. Footpedal jack
21. Fuse casing
22. Mains cable socket

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6 Commissioning

6.1 Adjusting the operating voltage



If the set operating voltage of the device does not agree with the local mains voltage (back), the operating voltage can be switched over on the fuse casing.

1) Pull out mains plug.
2) Open fuse compartment with a screwdriver.
3) Pull out grey fuse holder together with the fuse from the fuse drawer.
4) Insert back grey fuse holder according to local mains voltage. →The correct mains voltage should now appear in the small window of the fuse drawer!
5) Insert grey fuse holder again and close fuse compartment.
6) Check displayed mains voltage on fuse compartment.
7) Plug in mains plug again.

6.2 Commissioning

1) Connect on/off footpedal on footpedal jack (back!)
   (→ If motor control through footpedal is required)
2) Connect motor on motor jack (back).
3) Couple contra angle on motor until it locks into place and check fit by slightly pulling in the opposite direction.
4) Put file onto contra angle (also see **chapter 7.10 Replacing the file**):
   - Adjust file with slight pressure and rotation until it locks into place.
   - Check whether the file is correctly fixed with a slight pull.
   - Fold up contact bow, so that the file lies between the labial bars.
   - Fold up contact bow up to the end position of the file.
   - Check fit of the contact bow.

RISK OF INJURY!
The contact bow must constantly touch the file, respectively be folded up as far as its end position. Otherwise the Apex distance cannot be measured.

5) Insert lip connector on lip connector socket.

Please make sure that the operating voltage and the local voltage are in agreement!

6) Establish mains connection.

The device is now operational!

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7 Operation

7.1 Operatin sequence

1) Turn on control unit with main switch (back panel):
see **chapter 7.3 Switching on the control unit**

2) Adjust speed:
see **chapter 7.4 Adjusting the rotational speed**

3) Adjust the torque limit:
see **chapter 7.5 Adjusting the torque limitation**

4) "Auto Control"-Modus adjustment:
see **chapter 7.6 Adjust "Auto Control" mode**

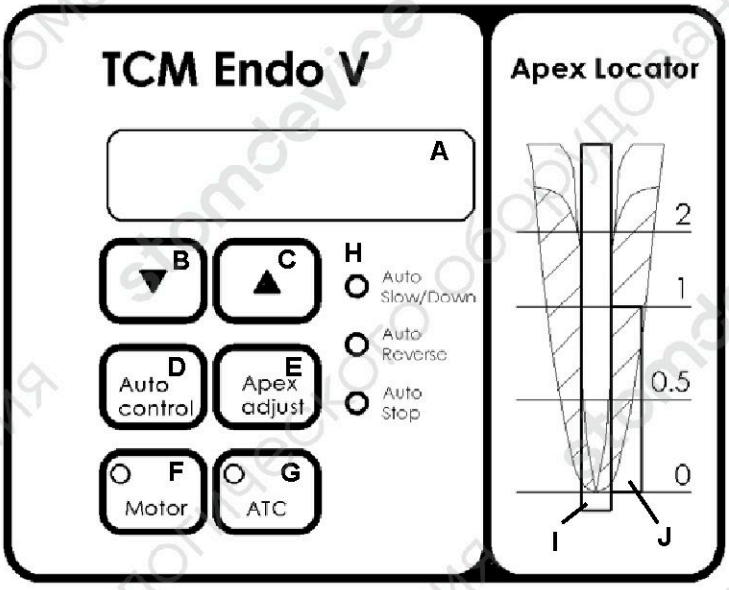
5) To activate the function control of the Apex- Locator:
see **chapter 8 Performance control Apex-Locator**

6) Hanging the lip connector in the patient's lower lip:
see **chapter 7.7 Hanging up the lip connector**

7) Start the Motor:
see **chapter 7.8 Switching on the motor**

The device is now ready for use!

7.2 Overview of the control devices



A) **Display:** Speed or torque display.

B) **Button "▼":**
Speed or torque reduction.

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C) **Button "▲":**
Increase speed or torque.

D) **Button "Auto control":**
Selection of mode which is activated when the adjusted distance of the file to the Apex has been reached.

E) **Button "Apex adjust":**
Adjustment of distance to Apex for which the selected mode is activated.

F) **Button "Motor":**
Switch on-off (LED is illuminated when motor is switched on!).
→ Button only works if device is operated without footpedal!

G) **Button "ATC":**
Display switches over: Rotational speed / torque limitation.

H) **LED "Auto Slow/Down", "Auto Reverse" and "Auto Stop":**
Display of current Auto-Control-Modus → LED illuminated if relevant mode activated!

I) **LED long bar:**
Displays current distance from tool tip to Apex (1LED = 0.1mm).

J) **LED short bar:**
Displays distance at which the adjusted Auto-Control-Mode is activated (1LED = 0.1mm).

7.3 Switching on the control unit

The control device can be switched on or off with the main switch (at the back!).

7.4 Adjusting the rotational speed

1) If necessary, switch over to speed display **"ATC"** in the display.
2) Select desired rotational speed with **"▼"** and **"▲"**.

Adjustable speed values:

150, 200, 250, 300, 350, 400, 450, 500, 600, 700, 800, 900, 1000, 1200, 1400, 1600, 1800 and 2000 [rpm].

7.5 Adjusting the torque limitation

The Automatic Torque Control (ATC) is a special function to prevent file breakage. Once the preselected torque limit has been reached, the motor switches to reverse for one revolution. After one revolution of the file, it returns to forward motion automatically.
Values in the display are always to be indicated in Nmm (e.g. the file is stressed with a maximum of [AP 20] →20 Nmm).

1) If necessary **switch to torque display in the display with "ATC"** (e.g. [AP 20]).
2) Select desired torque with **"▼"** and **"▲"**.

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Adjustable torque values:
2, 4, 6, 10, 15, 20, 25, 30, 40 and 50 Nmm

7.6 Adjust "Auto Control" mode

Various modes can be adjusted for controlled root canal treatment. They are activated when the file reaches the adjusted distance to the Apex. Which ensures that the set minimum distance to the Apex is reached.

Settings:
The desired mode can be selected with the **"Auto control"** button → LED of activated mode is illuminated.

- **"Auto Slow / Down"**

If the set minimum distance is reached during drilling, an acoustic signal is heard and the motor speed is reduced by half.
If the distance from the tool tip to the Apex is increased again, the motor begins to run at the adjusted speed again.

- **"Auto Reverse"**

If the set minimum distance is reached, an acoustic signal is heard and the motor switches to reverse mode.
If the distance from the tool tip from the Apex is reached, the motor returns to normal mode.

- **"Auto Stop"**

If the set minimum distance is reached during drilling, an acoustic signal is heard and the motor stops.
If the distance from the tool tip to the Apex is increased again, the motor begins to run again.

7.7 Hanging up the lip connector

The lip connector act as contact for the Apex-Locator. It is plugged into the lip connector socket and it is placed in the patient's lower lip.

Check the Apex-Locator function before hanging up the lip connector in the patient's lower lip!
(see chapter 8. Function control of the Apex- Locator)

7.8 Switching on the motor

The TCM Endo V can be operated with or without foot pedal:

- **Without footpedal:**

The motor can be swithed on and off with the key „Motor"→ If the motor is on, the LED illuminates.

- **With footpedal:**

When using the footpedal, the motor is started and stopped with the step:

Step not pressed: .....Motor switched off
Step pressed down:.....Motor switched on

The speed of the tool corresponds to the speed which is adjusted on the control unit.

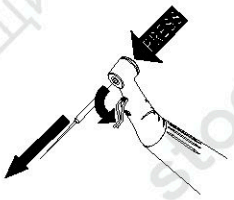
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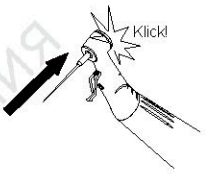
7.9 Storage of settings

When switching on the unit, the settings of the last session appear automatically.

7.10 Replacing the file



1) Fold down contact bow.
2) Press push-button.
3) Remove drill.
4) Release push button.



5) Insert new file with slight pressure and rotation until it locks into place.
6) Check whether the file is correctly fixed with a slight pull.



7) Fold up contact bow until the file lies between the labial bars.
8) Fold up contact bow up to end position of the file.
9) Check fit of the contact bow.

RISK OF INJURY!
When operating the device, the contact bow must constantly touch the tool tip, respectively be folded up as far as its end position. Otherwise, the Apex-distance cannot be measured and the drilling depth cannot be controlled !

8 Function control Apex-Locator

The function control of the Apex-Locator is to be checked prior to each use:

1) Plug out motor cable from motor socket.
2) Insert test plug (art. 1809) into motor socket.
3) Switch on device.
4) Apex-Locator has to indicate 0.5mm (± 0.2mm)

If the display deviates more than 0.2mm the unit has to be looked-over. Please contact your supplier in this case.

5) Plug out test plug from motor socket.
6) Insert motor cable into motor socket.
7) Check file fit.
8) Check contact bow fit.
9) Hold file to lip connector → Acoustic signal is heard and "LED bar long " is fully illuminated!

If no acoustic signal is heard or if the "LED bar long" is not illuminated, please read chapter **11. Faults and fault detection**.

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9 Cleaning, disinfection and sterilisation

For care of the material, please do not fail to comply with the following important points:



- **The device parts will be not supplied in a sterile condition and have to be sterilized before the first use!**
- **Carry out cleaning, disinfection and sterilisation after each treatment!**
- **Do not use cleaning agents containing solvents, especially cleaning agents composed of substances like methylenedichloride and trichlorethane!**
- **Always autoclave material in sterile individual packaging!**
- **Sterilisation packaging may only be filled up to 80%!**
- **Autoclave material up to maximum 134°C!**
- **Should the sterilised material not be used immediately, it should be labelled on the packaging with sterilisation indicator and sterilisation date!**

English

9.1 Control unit and footpedal

The patient should not come into contact with the control unit and the footpedal:
Use only external wipe disinfection with microbiologically tested surface disinfectants or 80% ethylic alcohol.



Only wipe control unit with cloth. No spray disinfection, because device not sealed!

9.2 Micromotor Endo, contra angle, lip connector and file

1) After each treatment, free micromotor, cable, contra angle and drill from residues and clean. For this, use damp cloth with cleaning or disinfection agents for wiping.
2) Remove file from Contra angle (see **chapter 7.10 Exchanging the file**).
3) Remove lip connector from lip connector socket.
4) Decouple contra angle from motor.
5) Spray contra angle with "Nou-Clean". → For handling, see spray label!
6) Pack motor, contra angle, lip connector and file in sterile goods individual packaging (see DIN 58953).
7) After packing the above mentioned items, autoclave them at **maximum 134°C**.
8) When autoclaving without vacuum, there must be a drying phase whereby the items in the transparent bag is dried for at least 1 hour at room temperature.



- **Do not clean components with compressed air!**
- **Cool micromotor after autoclaving!**
- **Do not bend motor cable, this may lead to possible cable rupture!**

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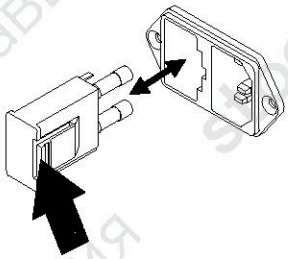
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10 Maintenance

10.1 Replacement of control unit fuse

Defective control unit fuses can be replaced by the user without outside help. They can be found at the back of the device in the fuse compartment next to the main switch:

1) Pull out mains plug
2) Open fuse compartment with a screwdriver.
3) Replace defective fuse T 1A.
4) Insert fuse holder again and close fuse compartment.
5) Check displayed mains voltage on fuse compartment.
6) Plug in mains plug again.



When setting the fuse compartment, please mind that the displayed voltage agrees with the local mains voltage!

11 Faults and fault detection

Fault:	*Cause:*	*Elimination:*
Device does not run:	Mains connector not plugged	Plug in mains plug
	Wrong operating voltage	Check mains voltage →See marking on fuse casing!
	Defective device fuse	Replace defective fuse
Footpedal does not function:	Footpedal not connected properly	Correctly insert footpedal cable at the back of the control unit on footpedal jack
	Control unit not switched on	Switch on control unit with main switch at the back
End motor does not run:	No motor connection	Connect motor cable to control unit
	Motor not installed properly	Press micro-motor firmly at the handle until it locks into place
	Do not switch motor	Switch on "Motor" button or footpedal
File is not rotating:	File is not well inserted into contra angle	Insert file with slight pressure and rotation into contra angle until file locks into place and check fit with a slight pull in the opposite direction
	Contra angle not correctly coupled to motor	Couple contra angle to motor until it snaps into place and check fit with a slight pull in the opposite direction
"LED long bar" not illuminated:	No contact between contact bow and file	Clamp contact bow on file firmly
	Contact pin on motor broken off.	Send device for repair (incl. motor and contra angle)
No acoustic signal:	No contact between contact bow and file	Clamp contact bow on file firmly
	Contact pin on motor broken off.	Send device for repair (incl. motor and contra angle)

If a fault cannot be eliminated, please contact the supplier or an authorised service agent. Relevant addresses can be found on the last page of the operating instructions.

12 Discarding instructions

When discarding the device, device components and accessories, please comply with the issued statutory regulations.
With regard to the preservation of the environment old equipment may be returned to the distributor or manufacturer.

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