CanalPro™ Jeni

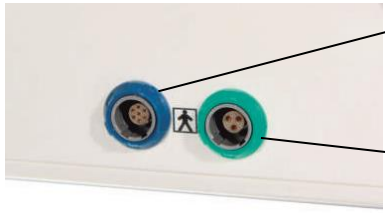
Instructions for use

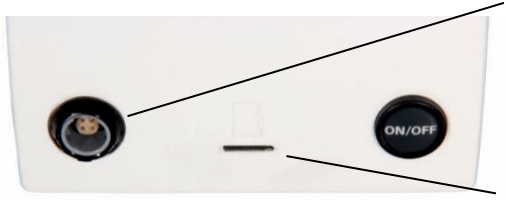
645 2101 v00 - 25.11.2019

COLTENE

Illustration 1
Basic unit

Right side of unit





Rear with microSD card

Illustration 2
Illustration 3

Illustration 4

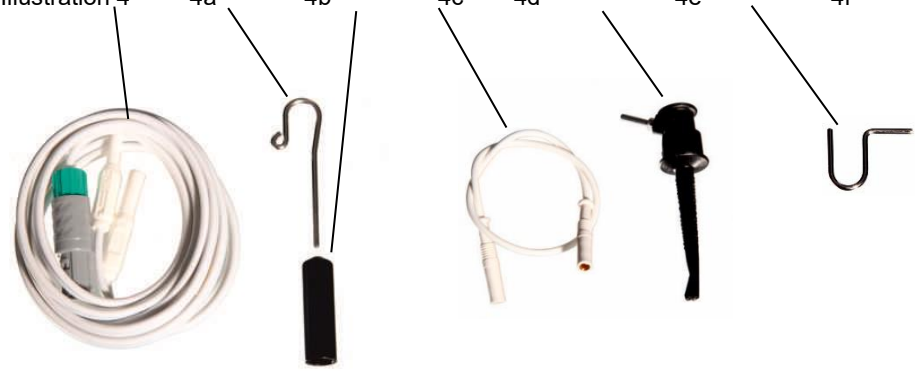
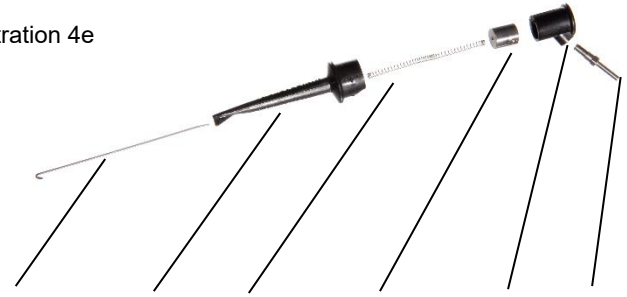


Illustration 4e



Contact bracket, housing, spring, threaded socket, button, contact

The patented file clip (4e) can be disassembled for reprocessing.
A standard ultrasonic universal key with a wrench width of 3.2 mm is used as tool for assembly.

Illustration 5

Illustration 6

Description of the individual parts

Illustration	Ref. No.	Description	#
1	60023660	Basic unit with touch screen, incl. 3 connection sockets and microSD slot (1a to 1d)	A2
2	60023787	Power supply unit with Euro primary plug Input: 100 – 240 V AC Output: 12 V DC 1.50 A	A2 A2
3	60024087	Wireless bluetooth remote foot switch	A2
4	60023788 60023789 60023790 60023791 60023792 60023794 60024252	Apex locator cable set consisting of: 4a – Measuring cable with plug 4b – Lip clip 4c – Cap for socket (for lip clip) 4d – Cable for file clamp 4e – File clamp (can be disassembled) The file clamp can be disassembled (see Image 4e). To disassemble, the contact is unscrewed from the button. This way all parts can be cleaned individually (see reprocessing instructions). After completing assembly the contact is firmly tightened again. Attention: check function! Loose parts can fall out and into the patient's mouth. 4f – Retaining bracket for apex locator cable (mounted on the device)	A2 A1 A1 A1 A1 A1
5	60023661	Contra-angle with integrated apex measurement/ fully insulated Transmission ratio 1:1, with ISO-E clutch	A3

6	60024170	Motor with apex measuring contact, ISO-E connection	A2

(#) refers to the applicable processing instructions, A1-A3 see Section 16

Congratulations!

We are pleased that you have decided to purchase the CanalPro Jeni. You have made an excellent choice. COLTENE is an internationally operating dental company offering a wide range of high quality and innovative endodontic products for sustainable tooth preservation. In cooperation with Prof. Dr. Eugenio Pedullà, the inventor of the patented Jeni mode, COLTENE has both designed and developed the extraordinary and innovative CanalPro Jeni endo motor. For the production of the CanalPro Jeni the cooperation with device manufacturer Schlumbohm was a deliberate decision. Schlumbohm has been successful in the dental market for 50 years and has designed and tested the CanalPro Jeni with great care. The device thus meets very high demands in both function and operation.

- CanalPro Jeni, complete set:
  Basic unit with apex locator, endomotor and contra-angle

- CanalPro Jeni, without contra-angle:
  Basic unit with apex locator, endomotor without angled handpiece

These Instructions for use describe the basic unit including the contra-angle. CanalPro Jeni

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WEEE-Reg. No. DE 88116129

CE 0482

The manufacturer reserves the right to change the information and data contained in these Instructions for use, also without prior notice. The Instructions for use are available in several languages upon request.
These Instructions for use have been prepared with the greatest possible care. However, as errors can unfortunately never be avoided completely, we are always grateful for any comments. In this case, please contact us directly. If you have any further questions, please do not hesitate to contact us at any time.

1. Notes

1.1. Symbols used

Description of the symbols used.

Symbol	Description
CE 0482	The product complies with the requirements of the EU Directive 93/42
	Warning: observe the accompanying documents! Failure to follow the instructions may result in damage to the equipment during operation or injury to the user or patient.
	Special protection against electric shock (application part)
	This medical device must not be disposed of with normal household waste. The national disposal regulations for waste electrical and electronic equipment must be observed. WEEE Directive (Guideline 2002/96/EG)
	Mechanical processing in the thermal disinfector
	Steam sterilisation
 2019	Manufacturer / Date of manufacture
IP31	Protection against foreign matter with 2.5mm diameter and dripping water
	Manufacturer's type no. of the device
	Serial number of the device or component
	Read the Instructions for use and keep them with the device
 Li-ion 48 Wh	Device contains a lithium-ion battery (power 48Wh) (please observe the current shipping instructions during transport!)
	Insulation Class II device

	China RoHS label for export to China
	Wireless connection
	Protect device from impact
	Different on the outer carton and on the device Carton: Observe temperature during storage / transport (-15 to 60°C) Device sticker: Observe temperature during operation (15° to 40°C)
	Protect the device from moisture
	Observe humidity during storage and transport
	Store packaging upright
	Read Instructions for use and reprocessing instructions

1.2. Proper use

The CanalPro Jeni is a device for the mechanical root canal treatment of teeth. It is intended exclusively for use in dentistry and must not be combined with other devices. The CanalPro Jeni was developed specifically for endodontics.
This device is intended exclusively for use by medical professionals in professional health care facilities.
The CanalPro Jeni is intended exclusively for the following use:

1.2.1. Apex locator

The file position in the root canal is determined by the apex locator. Length determination can either be performed manually using the file clamp (without motor) or during preparation using the contra-angle (integrated length determination with motor).

1.2.2. Motor

Mechanical root canal preparation in conjunction with the pre-programmed nickel-titanium files in standard setting, optionally with integrated length determination.

In the "Jeni mode" the characteristic values are pre-programmed for the respective files used. In the " Doctor's Choice " mode the current characteristic values of the file manufacturers are to be used in principle.

1.3. General precautions

Read these Instructions for use in detail and completely! This is the only way to ensure maximum safety. The most common problems during operation and maintenance result from the fact that basic safety measures are not observed sufficiently and possible accident hazards are not foreseen.
The user and the team must be familiar with the device prior to operation.
Always keep the Instructions for use and the attachments (e.g. reprocessing instructions) with the device.
Always use a cofferdam to prevent the inhalation or swallowing of small parts and the transmission of germs! If you have any questions or concerns about problems, please contact your dealer immediately.

1.3.1. Contraindications

The device must not be used on patients or by clinicians with an active implant (cardiac pacemaker etc.)!

1.3.2. Notes on operation

Use

- The CanalPro Jeni may only be used by certified professionals.
- The application parts must be used sterile. It is essential to observe the disinfection and reprocessing instructions (see Sec. 16).
- Check the device for damage before use.
- Only use the device for its intended purposes.
- Do not combine the device with other devices, such as third-party endo devices.
- Do not modify the characteristics of the product in any way under any circumstances. Schlumbohm® cannot accept any liability in case of modifications to the device.
- The microSD card must be removed from the CanalPro Jeni for shipping! Removal switches off power to the device.

Spatial conditions

- The device must not come into contact with liquids or be installed in damp environments. Keep the foot switch away from spilled liquids.
- Do not expose the device to direct or indirect heat radiation.
- Use of the device in an environment with free oxygen, explosive or flammable gases as well as flammable liquids is not permitted.
- In order not to influence the correct length determination, the CanalPro Jeni should not be installed near devices with electromagnetic radiation. Switch off mobile phones in the immediate vicinity during treatment.
- Do not cover the device with cloths or foils.
- Ensure that the rooms in which the device is used are equipped with smoke detectors. National fire safety regulations must be complied with.
- Never operate the device unattended.
- Make sure that the foot switch cannot be accidentally pressed, for example by a chair or trolley.
- The signal transmission of the wireless foot switch is encrypted, this technology ensures a secure connection between the foot switch and the device. This excludes the unintentional operation of one device with the foot switch of another device. Do not operate mobile phones or devices with strong electromagnetic radiation in the immediate vicinity of the device. In individual cases, the function of the wireless foot switch may be impaired.
- The device does not feature any life-supporting functions. A failure of the device may result in not being able to continue the application. The failure does not endanger the patient. Ensure that treatment can be completed even in the event of a device failure.

Device components and accessories

- The power unit has a safety-relevant function. Only use the supplied, medically approved, original power unit!
- Follow the file manufacturer's instructions for the use and disposal of endodontic files.
- The accuracy of the length determination, the torque as well as the speed is only guaranteed when using the CanalPro Jeni 1:1 contra-angle.
- Accurate length determination may not always be possible due to abnormal or unusual canal morphology (blocked or fractured canal).
- The tolerance for torque and speed is 10%.
- To avoid introducing external voltages, the handpieces and the lip clip must not be placed on electrically conductive surfaces.
- Always remove the lip clip from the patient's mouth unless apex measurement is required. Never place the lip clip, the file clamp and the motor on conductive surfaces. Always place the motor back in the motor holder. Always place the lip clip on the provided retaining bracket.
- Make sure that the contact terminal of the apex locator cable is correctly assembled after reprocessing and that the contact is screwed tight firmly.

Compatibility

- Endo files: in addition to the files for the Jeni mode, all commercially available nickel titanium files with standard ISO shafts can be used in the " Doctor's choice " mode.

The values for speed, torque and operating mode specified by the respective manufacturer must be set and adhered to. As the instrument manufacturers reserve the right to make changes to the file parameters, one needs to check whether the set values correspond to the current specifications of the file manufacturer before operation.

Fundamentals

- Keep these Instructions for use and all information with the device.
- Keep the documentation for the entire lifecycle of the product.
- The operator is obliged to notify the manufacturer of all events within the meaning of MDD 93/42/EEC and of any risks.

2. First steps

2.1. Setup

Please first compare the delivered components with the enclosed shipping documents and the corresponding serial or batch numbers. Check that the glass of the display is not damaged.
Please note that all components are supplied non-sterile and are not disinfected (see Sec. 16).

The following conditions should be taken into consideration during installation:

- The support surface must be flat and made of non-combustible material.
- The device must not be installed in damp places. Do not use the device in areas with liquids on the floor.
- Do not expose the device to direct or indirect heat radiation. Avoid direct exposure to sunlight.
- Only charge or operate the device at room temperature (do not exceed max. 40°C)!
- The ambient temperature must lie within the specified limits.
  (see Sec.14). Avoid heating above 60°C at all times!
- The device must not be installed near free oxygen, flammable gas mixtures or liquids (e.g. in the operating theatre or emergency area).
- In order not to influence the correct length determination, the CanalPro Jeni should not be installed near devices with electromagnetic radiation.
- Position the foot switch such that it is easy to operate.
- Set up the device such that the power supply cable can be pulled from the device if necessary.

2.2. Holders for placing handpieces

The holders provide a secure support for parts requiring handling. The surfaces are easy to clean. The apex locator cable retaining bracket is inserted into the opening on the handpiece holder.

2.3. Connection

All connections are plugged in and must **not** be rotated! Ensure that the groove of the plug fits into the groove of the socket. The "Push and Pull" connections for the handpieces are colour-coded (the numbers refer to the images given on the inside of the cover).

Illustration	Connection	Uses
1a	blue	Motor
1b	green	Apex locator cable, patient connection (lip clip)
1c	black	Power supply
1d	Slot	microSD card

Insert the CanalPro Jeni microSD card into the SD slot before using for the first time. (Insert the card carefully, do not use sharp tools).

2.4. Touch display

Remove the protective transport film before use. All functions of the CanalPro Jeni are called up via the convenient touch display. The touch display enables intuitive and self-explanatory operation. Operate the touch display with a light touch of the finger. Operation with gloves is of course possible.
Under no circumstances may the display be operated with metallic objects (risk of glass breakage)!

With the  button, you will always return to the previous menu or back to the start menu.

2.5. Foot switch

Functions of the wireless foot switch:
- Starting/stopping the motor
- Activating CanalPro Jeni from the sleep mode

To change the batteries (2 pieces 1.5V type AAA), please open the battery compartment under the base plate of the foot switch. Remove the used batteries from the battery compartment. Insert new batteries. Pay attention to the specified pole direction. Dispose of old batteries properly. Do not use rechargeable batteries, these have a lower nominal voltage! Only use branded batteries and batteries of the same type. Important! If the wireless foot switch is not used for an extended period of time, remove the batteries.
Spare batteries should always be available for uninterrupted operation.

The wireless foot switch is already connected to the device on delivery. If a new foot switch is to be connected to the device, this is possible via the service menu (see Section **Fehler! Verweisquelle konnte nicht gefunden werden.**).

2.6. Charging, switching-on, standby mode, switching-off

Make sure to fully charge the device before first use. (The device can only be charged or switched on with the inserted microSD card.)
When charging, please ensure that the device has not been heated by sunlight. Charging is interrupted at a device temperature above 40°C.

To charge, plug the power supply unit into the socket (the green LED in the power supply unit must light up). The device plug of the power supply unit is plugged into the black socket (1c) on the rear of the device. The device is switched on automatically by connecting the power supply unit, the blue LED on the front of the device flashes during charging.
During charging, the display illumination can be switched off with the On/Off switch on the rear of the device, charging continues. When the battery is fully charged, the blue LED lights up continuously. The power supply can be disconnected.

The respective battery status is displayed at the bottom edge of the screen.
If the charge drops to 10% of the capacity, a warning message appears. In this case the battery must be charged immediately. If not charged, the device will switch off to avoid a total discharge of and damage to the battery.

Charge the battery regularly.

If the device is not used for a prolonged period of time, the device automatically switches to sleep mode and the display illumination switches off. The sleep mode is indicated by slow flashing of the blue LED in the display. By briefly pressing the foot switch or the touch display, the device switches on again. The last menu used is displayed again.

After a longer waiting period the device switches off completely. This "Auto off" time can be set in the setup menu.

To avoid unnecessary power consumption in standby mode, the mains plug should be removed from the socket when the CanalPro Jeni is not used for a longer period of time.

In case of malfunctions, the device can be switched off completely by removing the microSD card. Remove the microSD card if the device is to be shipped.

2.7. Preparation of the root canal – motor and contra-angle

The CanalPro Jeni contra-angle (5) is attached to the motor (6). Only use contra-angle handpieces with a transmission ratio of 1:1. The integrated apex length determination (see Sec. 4.5.2) during preparation only works in conjunction with the original CanalPro Jeni contra-angle.

If the contra-angle was changed or sterilised, calibration must be performed as stated in menu item calibration (motor menu, see 24). Calibration compensates friction in the contra-angle. Contra-angles may only be changed when the motor is at a standstill.

Before operation, check whether the motor is firmly engaged in the contra-angle.

During operation of the contra-angle, never exert pressure on its push button, as this could lead to friction or incorrect measurements!

Notes on operation– Jeni mode (for HyFlex EDM, HyFlex CM, MicroMega OneCurve, MicroMega 2Shape). All file parameters are pre-programmed for the Jeni mode In these programs and do not require any further settings. Please follow the instructions below when using these programs.

Note on operation– Jeni mode and Doctor's choice mode
The device is optimised to minimise the risk of file breakage, however it cannot compensate all the factors that may lead to breakage. To avoid file breakage, please observe the following points:

- Nickel-titanium files break due to various factors which lead to material fatigue. Observe the manufacturer's instructions on the reusability of the files.
- Due to the shape of the root canal, the endo files are bent and stressed during use.
- Experience and practice are essential for the successful use of NiTi instruments.

- Practise handling on extracted teeth or endo plastic blocks

The device also reduces the risk of file breakage in the Doctor's Choice mode, but file breakage cannot be ruled out completely. Please make sure that you know the permitted torques of the instruments. Select the correct file. Never use deformed or damaged files!
The menu offers a variety of setting options. The device allows all parameters such as speed, torque and operating mode etc. to be changed individually.
Parameters which deviate from the specifications of the instrument manufacturer can lead to file breakage and other damage. Schlumbohm® will not be liable for any damage resulting from operation other than that specified by the instrument manufacturer.

To avoid file breakage in the Doctor's Choice mode, please observe the following points:

- Never exert great force to insert the file or to move it forward.
- Nickel-titanium files also break due to material fatigue. Only prepare as many canals as specified by the file manufacturer.
- Experience and practice are essential for the effective use of NiTi instruments.
- Practise handling on extracted teeth or endo plastic blocks.

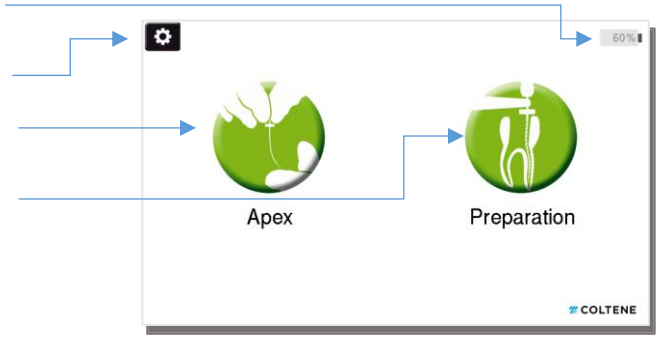
3. - 4. Functions Start menu

Battery status display

Setup button (Sec.5)

Apex locator (Sec.3)

Reprocessing (Sec.4)

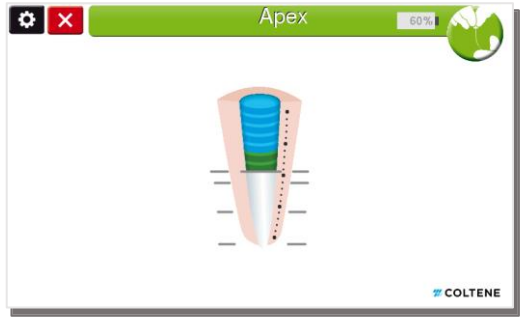


3. Manual apex length determination

In this menu you can pre-probe the canal manually, i.e. with a file guided by hand. Use the lip clip (4b) as well as the file clamp (4e) for this purpose.
The marker (horizontal line) determines the canal position at which the "auto-stop" function is reached during mechanical reprocessing. The marker has already been set by the manufacturer. However, the setting can be changed by the user (if desired) directly on the display by moving the bar (tapping with the finger). With this function it is possible to transfer the X-ray verified position of a pilot instrument to the display.
The marker's setting remains unchanged until the device is switched off. When the device is switched on again, the line is reset to the default value.

Do not place the measuring cables on electrically conductive surfaces, as external voltages could be transferred to the device.

Use the  button to access the settings in the Apex setup menu



The following settings can be configured in this setup menu:

Different sounds as well as the volume for different apical areas can be set. One can choose from 9 different sounds or a mute function

Attention:
If you allow the file to touch the lip clip, this will cause a short circuit. With this short circuit you can test the correct operation of the display and apex locator.

3.1. Tips for length determination

The lip clip (4b) is attached to the patient's cheek pocket on the opposite side of the tooth to be treated.
Place the cap (4c) on the lip clip's socket before use to protect the socket from contamination.
Remove the lip clip from the patient's mouth if you do not need the measurement
Before starting with length determination, the canal should be rinsed briefly with physiological saline solution. The canal entrance must then be dried (e.g. with a cotton pellet) to avoid leakage current and therefore incorrect measurements. It is recommended to wear protective gloves during length determination to avoid dissipation of the measuring current.
During manual measurement, the file is connected to the file clamp below the shaft and slowly inserted into the root canal.
Please bear in mind that the principle of electronic length determination can lead to incorrect measurements due to disturbance variables (conductive residual fillings, cracks, etc.).
Chemicals in the canal can have an influence on the measurement due to different conductivity. The ideal measuring medium is physiological saline solution.

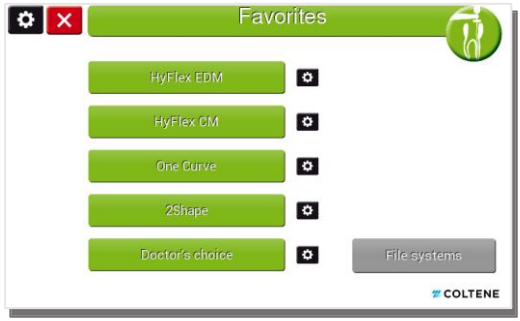
The results should always be compared with an X-ray control image.

4. Motor system

4.1. Favourites

When you call up the "Preparation" menu, the Favourites menu will appear. Use the File Systems“ button to reach the Selection menu (see 4.2).

In this area, one can select one or more file systems to be saved under Favourites so that they can be accessed directly the next time the device is switched on. The values of the four COLTENE file systems - HyFlex EDM, HyFlex CM, MicroMega OneCurve, MicroMega 2Shape - are pre-programmed. After activation, the favourite file systems will be displayed here in the future, this speeds up the selection of file systems



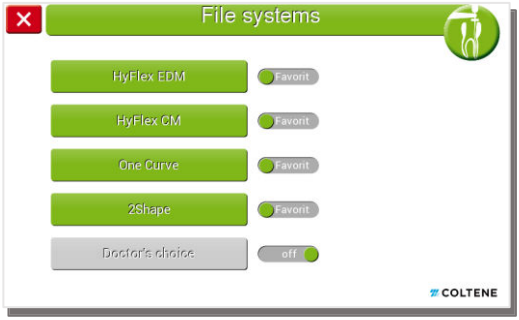
The "Doctor's Choice" program does not feature pre-programmed file systems.
Here the user can create own sequences for each new file by manually setting the values. See Sec. 4.4

The button next to each file sequence can be used to set which files should be displayed per file sequence. For HyFlex EDM you can choose from three file sequences to match the degree of difficulty of the root canal to be treated.

With HyFlex CM, you can choose between a single length sequence and the full HyFlex CM file range.

4.2. Selection of the file systems

Select the file systems to be displayed in the Favourites menu by activating the right button.
You can select a maximum of 5 systems for quick access in the Favourites menu.



4.3. Preparation in the Jeni mode

In the Preparation menu, the endomotor is put into operation via the foot switch after selecting the desired file sequence and a desired file. The selected file appears in the upper line.
Further files are displayed in addition to the currently selected file. They can be selected by direct tapping. With the green arrow below, further files of the sequence can be displayed.

With the  button the "Setup Motor“ menu is called up (see 4.5). Here the motor can be recalibrated (see 4.5.4) and the apex settings can be changed (see 3).

The apex display is always in operation and therefore also allows manual probing with the aid of the file clamp. Please note that the file clamp must be placed insulated, otherwise incorrect measurements may occur when determining the length via the contra-angle.

By pressing the green apex icon on the right side of the screen, the apex measurement can be switched off and on again during preparation.

4.3.1 Details of the Jeni mode

The four COLTENE file systems - HyFlex EDM HyFlex CM, MicroMega OneCurve, MicroMega 2 Shape - were programmed in the Jeni mode. The necessity of setting further parameters is eliminated completely.
The Jeni mode is based on complex algorithms which allow the file movements to be adapted to the treatment situation in extremely short time intervals.

Working in Jeni mode during root canal preparation:

- The file is fed into the canal by applying gentle, continuous pressure
- CanalPro Jeni continuously measures parameters such as pressure, torque, tension or electrical intensity to measure file stress and adapts its motion rotating, forward or backward at different angles.
- No additional up and down movement (pecking) or swiping movement (brushing) should be made regarding the efficiency of CanalPro Jeni, as the motor automatically adjusts its movement.

Step by step with the Jeni mode

1. Select the appropriate sequence in the menu and from this the appropriate file which you would like to use for the preparation step in question and start the motor via the foot pedal.
2. Apply gentle and continuous pressure to the file during preparation - do not move the file up and down or back and forth (no pecking or brushing) - the motor adapts its movement automatically (see description above)
3. In Jeni mode, the motor decides independently on type of movement and speed
4. Hold the pressure until an acoustic signal sounds (long tone), which indicates that the canal must be irrigated
5. Remove the file from the canal, irrigate the canal and then proceed with preparation as described above
6. When the automatic, acoustic signal for file change sounds (several short tones), please change the file

Automatic irrigation signal

During preparation in Jeni mode, the motor automatically signals when and how often the canal should be irrigated. A prolonged tone sounds and the motor automatically switches to reverse motion.

Signal for automatic file change

The motor automatically signals when a file should be changed to prevent file deformation or breakage. Several short tones indicate that the file used should be replaced.

4.4. Doctor's Choice

The Doctor's Choice program offers a sequence for free design. In this program the values for 8 files can be individually set and saved.

By clicking the  button you can change and save the file parameters (speed, torque, operating mode). Parameters which deviate from the specifications of the instrument manufacturer can lead to file breakage and other damage. Schlumbohm® will not be liable for any damage resulting from operation other than that specified by the instrument manufacturer.

Menu items:
Speed:

- selectable from 200 to 1000 rpm

Torque:

- from 0.2 – 5.0 Ncm

Movement:
- Twist off (clockwise movement, motor stops at overload)
- Twist (clockwise rotation with "loosening vibration" in case of jamming)
- Counterclockwise rotation
- Reciprocal (angle settings over time and pause)

Note:
Please keep in mind that the file manufacturers reserve the right to make changes and adjustments to the instrument characteristics. Future changes can be adapted individually by the user.

4.4.1. Notes on Doctor's Choice

Unlike the conventional rigid drives, the CanalPro Jeni offers a free choice of parameters. The movement parameters of the instrument can be adapted individually by the user. As no data from the file manufacturers have been published yet, it is necessary for the user to define the parameters which suit him/her and his/her file system. In concrete terms, this can be performed by experimenting with trial preparation on practice blocks. The default values should be adjusted in every case.

It should be noted that this technique requires experience and practice.

The user should gain experience with extracted teeth. It can be assumed that the use of different file systems leads to differing results. To avoid distortion of the file, always set the same values for the clockwise and anticlockwise rotation. The pause time provides intermittent operation and reduces the pulsed load on the file.

Please ensure that chips are removed regularly during the work process.

The torque is also monitored in this operating mode. However, as there is no pronounced starting phase when starting the motor with this technology, torque control can already be triggered at high speed settings when the motor is started. In this case a higher torque limit should be set.

The cyclic drive.

This function provides an incremental drive in the direction of rotation. To set this function, one of the parameters left or right is set to zero, the other parameter in each case determines the increment size. The pause between the movements allows the instrument to partially reset the torsion.

4.5. Setup motor

4.5.1. File data

For the preset programs - HyFlex EDM, HyFlex CM, MicroMega OneCurve and MicroMega 2Shape - all file parameters are saved in the Jeni mode and cannot be changed. The Jeni mode is based on complex algorithms which allow the movements to be adapted to the treatment situation in extremely short time intervals.

It is necessary to adjust the file data in the Doctor' s choice mode, which can be adjusted in the menu File Setup (see Point XX).
Further settings for apex measurement in combination with preparation can be made under Apex Setup (see information under 3.). The apical stop is set here in the lower right area and not on the touch screen.

Under Calibration the motor is tested with the contra-angle. Leave the motor and the contra-angle in the holder and start calibration.

4.5.2. Apex functions in motor operation

The settings that apply to preparation can be selected in the Apex Setup menu.
(see also Section 3)

Various sounds and the volume of the apex signal can be set here.

Here it is also determined how the motor responds when reaching the apex position. The stopping time of the motor can be set. Stopping the motor at the apex can also be switched off. The following apex functions can be selected:

1. Apex function Apex Stop **0.5 sec./ 1 sec./ 2 sec.**
The position of the file in the canal, or its advance, is shown on the display via the symbolised apex during preparation and manual probing. It is not possible to enter or change the parameters while the motor is being operated via the foot switch.
1. When the preparation line is reached, which may have been set by manual probing, the motor stops for the selected time unit (0.5; 1 or 2 seconds).
2. A tone signal indicates that the max. torque limit of the file will be further reduced with immediate effect.

2. Apex function Apex Stop off
The position or the advance of the file in the canal is depicted on the apex image on the display during preparation and manual probing.
An acoustic signal sounds when the preparation line is exceeded. The motor does not stop and the torque is not reduced.
Note: Electronic length determination is only possible with conductive tool shafts. There are instruments with insulating shafts. In this case it is therefore not possible to determine the length during preparation.

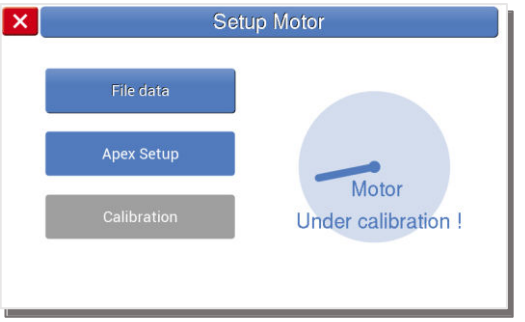
Check the apex locator cable and the correct connection by briefly touching the lip clip with the clamped file. The error message **short circuit** must be displayed (see Section 12). A convenient function of CanalPro Jeni is length determination during mechanical preparation. In principle, all notes already mentioned in Section 3 (Manual apex length determination) apply. During measurement during preparation, the file clamp's function is taken over by the contra-angle. The measuring signal is transmitted to the file through the insulated contra-angle. The lip clip is still necessary to close the circuit.

The results should always be compared with an X-ray control image.

4.5.3. Calibration

Always calibrate after every sterilisation. Calibration compensates for the friction of the contra-angle.

Marginal torque losses at the contra-angle can be compensated through calibration. This function always enables safe operation at low torque limits.



If calibration is not possible, the contra-angle is heavily soiled or damaged. In this case, please contact the manufacturer.

5. - Fehler! Verweisquelle konnte nicht gefunden werden.. Setup functions

5. Software status and updates

Here you will find the device data and the software status.
Updates can be performed via the microSD c

6. Brightness / volume

Setting brightness

Setting volume

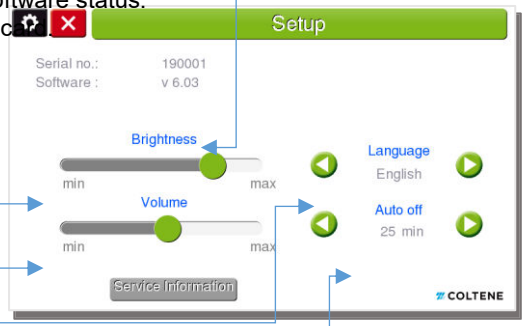
7. Setting language

Here you can select the language

8. Auto Off time

Setting the switch off time

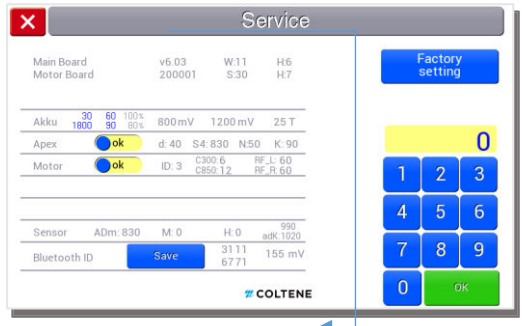
Open Service menu with further information (Sec. 9)



9. Service Information / Bluetooth

These data indicate the device status.
These data are helpful in case of an error.

The memory button is used to store a foot switch.
- The right pair of values shows a pressed switch from the environment.
- The left pair of values indicates a foot switch that has already been saved.



The keypad can be used to enable further functions or to query settings.

By resetting, all file parameters are reset to the default settings. Important! Changes made by the user are deleted.

Updates are easy to perform with the aid of the microSD card.
Important! Never insert microSD cards with unknown content into the device.

10. - 16. Appendices

10. Maintenance, transport and disposal

10.1. Regular checks

In some countries, the national legal authorities oblige the operators of certain electrical medical devices to carry out regular inspections.

The legal authorities in Germany oblige the operator of specific medical electrical devices to carry out regular inspections.within the context of §11 of the Medical Device Operator Ordinance. Appendix 1 of the Ordinance on Medical Devices Operators specifies the equipment groups for which so-called safety inspections are mandatory. The objective is to ensure operational safety and to avoid safety risks.
No safety inspections are prescribed by the legal authorities in Germany for the CanalPro Jeni.

However, in connection with maintenance pursuant to § 7 of the Medical Device Operator Ordinance, we as a manufacturer recommend carrying out an annual inspection of the device in accordance with DIN EN 62353 "Medical electrical devices - Repeat inspections and testing after repair of medical electrical devices" (VDE 0751), in particular of the power supply unit.

The scope of testing should include the following test steps:

- Is the power supply unit the original power supply unit?
(REF. number matches the number in the Instructions for use)
Attention, the power supply unit is safety-relevant, no other power supply units may be used!
- Measurement of the leakage current at the power supply unit
- Visual inspection of the power supply unit and the entire device
  (Special attention must be paid to the integrity of the cables, the plug connections as well as the insulation!)
- Functional testing of all components:

The device corresponds to Protection Class II, the application parts to type BF (see Instructions for use Sec. 14 "Technical Data").

The tests must comply with the international standard IEC 62353 (or DIN EN 62353 / VDE 0751-1), they must be carried out by persons and organisations with appropriate expertise (in accordance with § 7 Sec.4 MPBetreibV).

10.2. **Maintenance**

Detailed information on the reprocessing of individual components can be found in the reprocessing instructions given in the Section16 (Cleaning / Disinfection / Sterilisation).
It is imperative that you observe the following notes:
- Check the connection cable as well as the plug connections every 6 months
- If the wireless foot switch is not used for an extended period of time, remove the batteries.
- Do not use rechargeable batteries for the foot switch (only AAA type 1.5V batteries)
- The CanalPro Jeni does not contain any components which can be repaired on site.
- The warranty expires if the device is modified or opened.
- Repairs can only be carried out by the manufacturer!
- If the device is not used regularly, it should still be charged every 6 months. Only use the designated power supply unit!
- A battery replacement is scheduled after 4 years. Highly aged batteries can pose a safety risk. Attention, a battery replacement is only possible via the manufacturer or authorised partner.

Important! Under no circumstances must the motor be lubricated or oiled! During maintenance of the contra-angle, make sure that no lubricants or cleaning agents penetrate into the motor! Allow excess oil to drip from the contra-angle before use. To do this, place the contra-angle in a vertical position.
The contra-angle should be oiled immediately after use (before actual reprocessing) with maintenance oil spray for contra-angles in order to remove penetrated treatment fluids such as sodium hypochlorite.

10.3. **Transport**

Avoid dropping the device. The device contains a lithium-ion battery (Li-Ion battery) Power: 48Wh. A hard impact can cause mechanical damage to the device and the battery unit. The battery used can cause fires and injuries if handled incorrectly. The device must not be heated above 60°C, burnt, immersed in liquids or disassembled.

When shipping the device, please use the manufacturer's packaging as far as possible or other packaging that is sufficiently strong and damping. Please observe the applicable shipping regulations.

Switch off the device before shipping and remove the microSD card. Include same clearly visible. Pack the device such that the On/Off switch on the rear of the device cannot be operated unintentionally during transport.

Ensure that all components have been reprocessed before shipping (see reprocessing instructions in Section 16).
Soiled and contaminated products must not be shipped.
When shipping, please observe the applicable transport regulations for devices with lithium-ion batteries (UN3481).

10.4. **Disposal**

Dispose of all generated waste and used disposables properly. National regulations must be observed.

The device is a high-quality medical device with a long service life. At the end of the product's service life, the device must be disposed of properly. Observe country-specific disposal regulations.
It must be assumed that the device is contaminated at the end of its service life. The device and accessories must be decontaminated before disposal; pathogens pose a hazard. Before disposal or transport, all handling parts and cables must be thoroughly cleaned, disinfected or sterilised. The device itself and the foot switch must be subjected to all-round surface disinfection. Also spray the plugs and sockets during this final reprocessing. Remove the used batteries from the foot switch.

Please note that the device contains a powerful Li-Ion battery. In case of incorrect handling (e.g: overheating, mechanical damage, use of liquids and short circuits) this can lead to fires and injuries. Please do not disassemble the control unit yourself. Avoid dropping and unnecessary damage.

Disposal within the EU: According to the EU directives (WEEE and RoHS), the device must not be disposed of with general household waste. Please observe the laws and regulations applicable in the respective country which apply to the disposal of used equipment.

Disposal in Germany: In the Federal Republic of Germany, the Electrical and Electronic Equipment Act (ElektroG) regulates the disposal of used electrical equipment.

The CanalPro Jeni is an exclusively commercially used product (B2B). Disposal is effected by returning to the manufacturer. The sender bears the costs for shipment. In case of questions please contact your dealer.

11. Troubleshooting

If the CanalPro Jeni does not seem to function properly, it does not necessarily need to be a fault of the device! Please check the device first using the following table to exclude operating errors or unwanted variables (such as anatomical peculiarities in apex measurement).

Problem	Possible cause	Solution
Device in general		
The device exhibits no function and the display remains switched off.	No power supply, battery possibly not charged	Is the power supply unit plugged in correctly (LED on the power supply unit must light up).
Operation of the touch display is not possible, device does not react.	Display damaged	Return to manufacturer.
No sound signals	Sound is switched off	Switch sound on again.
Endo motor		
The instrument does not rotate.	Calibration not performed	Perform calibration with contra-angle
	Motor damaged	Check the cable connection and the plugs for damage. Check whether the motor works without the contra-angle.
	Angle-piece damaged	Check whether the axis can be rotated freely.
Apex locator		
Measurement not possible. Signal missing or weak and interrupted	Contact problems	Are the lip clip and measuring cable connected properly? Are the lip clamp and file clamp completely blank? Check whether a short circuit is depicted on the display when the lip clip and file clamp or the instrument in the contra-angle touch each other.
	Lip clip on wrong plug	The lip clip must be inserted into the socket of the measuring cable, not into the short cable for the file clamp!
	wrong angle-piece	Check whether the CanalPro Jeni contra-angle is attached. Is it engaged properly? Connect the lip clip and NiTi file. Is a short circuit displayed?
	Root canal calcified or obliterated	Check X-ray image, if necessary create a glide path up to the working length with a suitable file.
	Root canal very dry	Interim irrigation with saline solution. Dry access cavity with cotton pellet
	Blocked by old filling / medical insert	Comparative X-ray! Complete removal of old gutta-percha remnants, or remains of the medical insert.

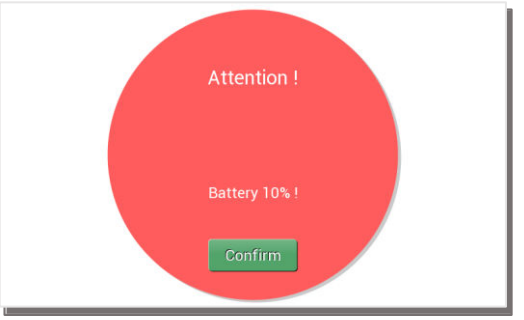
Measurement tends to indicate apex too early or signal is at maximum	Secondary currents or high conductivity	Remove moisture from the crown or "cavity base". Are there any side canals? Irrigate with saline solution if necessary.
Wireless foot switch		
No function	The batteries are flat	Open the battery compartment under the base plate of the switch and change the batteries. Do not use rechargeable batteries.
No function	Switch not detected.	Connect switch to device / see Setup -> Service information
No function	Signal is disrupted by strong electromagnetic radiation. (EMC)	Switch off other devices (such as mobile phones) in the vicinity. Check environment. (a cable switch can be used in particularly exposed areas)

If the problem cannot be resolved, please contact your dealer.
Avoid mechanical damage. Do not open the device yourself.

12. Error messages

For certain operating errors or malfunctions, the device outputs information texts.
For example, the following errors are detected automatically:

- Battery only has 10% charge left.
  By confirming you confirm that you have read the message. The device must be charged immediately.
- External voltage on the apex locator cable or contra-angle. With this function, the device indicates that an electrical voltage is present at the apex connections. The external voltage can be caused by defective devices or electrical installations.



13. Warranty / Liability

Schlumbohm® guarantees the warranty for material and manufacturing defects of this product for one year from the date of the original invoice. The Schlumbohm® product warranty includes the repair or replacement of the entire device or individual parts. The decision whether to replace or repair is made solely by the manufacturer.
In the event of suspected damage subject to warranty, the customer must notify Schlumbohm® Customer Service immediately. Customer Service will provide further instructions. Normally you will be asked to return the complete unit. The costs of returning the goods shall be borne by the sender.

Application errors preclude any warranty.
Schlumbohm® does not provide warranty for wear and contamination of handpieces and contra-angles. Schlumbohm® does not provide warranty for glass breakage of the display or damage to the battery.

Schlumbohm® does not accept any responsibility for damage caused by unattended operation of the device.

Schlumbohm® does not accept any responsibility for damage caused by improper packaging or shipping of the device.

Schlumbohm® does not accept any responsibility for damage caused by the clinical use of its products. Irrespective of whether the use is accidentally connected with other medical devices (e.g. cardiac pacemakers) or not.

14. Technical data

Type:	**CanalPro Jeni**
Power supply[1]:	Input: 100-240V/AC (50-60Hz) Output: 12V/1,25A /DC or 12V/1,5A/DC Power supply unit according to IEC 60601 for medical devices (Only use the original CanalPro Jeni power supply unit) Charge the device regularly, at least every 6 months
Electrical protection class:	II
Transmission Bluetooth	2,402-2,480 GHz, TX Power: +7dBm
Output: basic unit	Max. 3V/5A bzw.12V/1,25A (direct current)
Use:	The device is intended for short-time operation Motor: 30 seconds full load/ 1 minute pause
Sped endo motor:	200-1000 rpm +/- 10%
Torque:	0.2 - 5 Ncm +/- 10%
Device class:	Class acc. to EN 60601-1: Application part type BF
IP protection class:	The device must not be operated in potentially explosive environments. Keep the device away from flammable substances. IP31 CanalPro Jeni and wireless foot switch IP31 Ultrasound extension and pump extension IP40 Power supply unit
MP / EU class:	IIa
Conditions of the environment	Atmospheric pressure 800hPa to 1060hPa
For operation:	+15°C to +40°C / humidity: 20-80%, non-condensing
For transport:	- 15°C to+60°C / humidity: 20-80%, non-condensing
Type of battery:	Li-Ion battery, 7.2V, output: 48Wh
Weight:	1200 g CanalPro Jeni basic unit,
Dimensions height x width x depth:	23 x 16.5 x12.8 cm (basic unit)

Subject to technical changes!

[1] No other power supply units may be used. The power supply unit is safety-relevant!

15. EMC manufacturer's declaration

Medical electrical equipment is subject to special EMC precautions and must be installed and commissioned in accordance with the EMC instructions contained in the accompanying documentation.
Portable and mobile RF communication installations can affect medical electrical devices.

Warning
Use of other accessories, other transducers and leads than those specified, with the exception of the transducers and leads sold by the manufacturer of the medical electrical device or system as replacement parts for internal components, may result in increased emissions or reduced interference immunity of the medical electrical device or system.

Medical electrical equipment or systems must not stand directly side by side or be stacked with other equipment and, if operation is required close to or stacked with other equipment, the medical electrical equipment or system should be observed to verify its proper operation in that configuration. A minimum distance of 30 cm should be presumed.

This device is intended exclusively for use by medical professionals in professional health care facilities. This equipment may cause radio interference or may disrupt the operation of nearby equipment.

It may be necessary to take appropriate corrective measures, such as new orientation or new positioning of the device.
The CanalPro Jeni device may be impaired in its function by interference from other devices. The device does not feature any life-supporting functions. A failure of the device may result in not being able to continue the application. The failure does not endanger the patient.

Guidelines and manufacturer's declaration Electromagnetic emissions		
The CanalPro Jeni device is designed to operate in an environment as specified below. The customer or user of the device should ensure that it is operated in such an environment.		
Interference emissions	**Compliance**	**Electromagnetic environment – Guideline**
RF Emissions CISPR 11	Group **1**	The CanalPro Jeni device uses RF energy exclusively for its internal function. Therefore, its RF emission is very low and it is unlikely that adjacent electronic equipment will be interfered with.
RF emissions CISPR 11	Class **B**	The CanalPro Jeni device is suitable for use in all facilities, including those in domestic areas and those directly connected to a public utility network that also supplies buildings used for residential purposes.
Emission of harmonics IEC 61000-3-2	Class **A**	
Emission of voltage fluctuations IEC 61000-3-3	Complies	

Guidelines and manufacturer's declaration Electromagnetic interference immunity			
The CanalPro Jeni device is designed to operate in an environment as specified below. The customer or user of the device should ensure that it is operated in such an environment.			
Interference immunity tests	**IEC 60601:2007 testing levels**	**Compliance level**	**Electromagnetic environment – Guidelines**
Discharge of static electricity IEC 61000-4-2	**± 6 kV** Discharge on contact **± 8 kV** Air discharge	**± 8 kV** Discharge on contact **± 15 kV** Air discharge	Floors should be made of wood or concrete, or covered with ceramic tiles. If the floor is covered with synthetic material, the relative humidity must be at least 30 %.
Fast transient electrical interferences (bursts) IEC 61000-4-4	**± 2 kV** Mains lines **± 1 kV** Input and output lines	**± 2 kV** Mains lines Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Surge voltages (surges) IEC 61000-4-5	**± 1 kV** differential mode **± 2 kV** common mode	**± 1 kV** differential mode Not applicable	The quality of the supply voltage should correspond to that of a typical business or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines	**> 95 %** drop/ 0.5 periods dip in U_T/ 0.5 cycles **60 %** drop/ 5 periods dip in U_T/ 5 cycles	**> 95 %** drop/ 0.5; 1 period dip in U_T/ 0.5; 1 cycles **60 %** drop/ 5 periods dip in U_T/ 5 cycles	The quality of the supply voltage should correspond to that of a typical business or hospital environment. If the user of the CanalPro Jeni device also requires continued operation in the

	30 % drop/ 25 periods dip in U_T/ 25 cycles **> 95 %** drop/ 5 periods. dip in U_T/ 5 cycles	**30 %** drop/ 25 periods dip in U_T/ 25 cycles **> 95 %** drop/ 5 periods. dip in U_T/ 5 cycles	case of power supply interruptions, it is recommended that the device be powered from a UPS or a battery.
Magnetic fields at the supply frequency (50/60) Hz IEC 61000-4-8	3 A/m	30 A/m	Magnetic fields at the mains frequency should correspond to the typical value found in business and hospital environments.
Conducted RF disturbances IEC 61000-4-6	V_1 = 3 V 150 kHz – 80 MHz	V_1 = 6 V 150 kHz – 80 MHz 80 % AM, 1 kHz	Portable and mobile radios should not be used at a distance from the CanalPro Jeni device (including lines) less than the recommended protective distance: d= 1.17 √P for V1 = 3 V d = 1.2 √P for V_1 =10 V
Radiated RF disturbances IEC 61000-4-3	E_1 = 3 V/m 80 MHz – 2.5 GHz	E_1 = 3 V/m 80 MHz – 2.7 GHz 80 % AM, 1 kHz E_1 = 28 V/m 385; 450; 810; 870; 930 MHz 50 % PM, 18 Hz E_1 = 28 V/m 1720; 1845; 1970; 2450 MHz 50 % PM, 217 Hz E_1 = 9 V/m 710; 745; 780; 5240; 5500; 5785 MHz 50 % PM, 217 Hz	d = [12/E_1] √P 80 MHz to 800 MHz d = [12/E_1] √P 800 MHz to 2.5 GHz The field strength of stationary radio transmitters should be less than the compliance level at all frequencies measured during an on-site investigation. Interference may occur in the vicinity of devices bearing the following symbol: 

16. Cleaning, disinfection, sterilisation (reprocessing)

Reprocess the product immediately after each application or after each patient.
The brand-new device must also be reprocessed before being used for the first time.

Information is provided in the enclosed reprocessing instructions.

Different reprocessing instructions apply to the individual components depending on their condition and durability. The applicable instructions are specified in the list of components in the front section of this manual, see (# A1-A3).
(# -) means: reprocessing is not planned.

The following reprocessing instructions are available from the manufacturer:

# A1. Reprocessing instructions for thermostable components	645 2102 (Sec.1)
# A2. Reprocessing instructions for thermolabile components	645 2102 (Sec.2)
# A3. Reprocessing instructions for 1:1 contra-angle	645 2103

CE 0482

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