

Record of installation and setup

: ipcc@melag.de /Fax: +49 (0)30 75 79 11 1050 (Please return)

Careclave registration portal

Take advantage of the online device registration on the MELAG website at:
<https://www.melag.com/en/careclave-registration>



MELAG Medizintechnik
Geneststr. 6 – 10
10829 Berlin
Germany

Dear Madam/Sir,
in order to comply with the specifications of the MDR, to ensure a validated procedure (Installation Qualification / IQ) and for quality assurance, it is necessary to set up this MELAG device and conduct its demonstration at the place of use by trained personnel in accordance with the rules of technology.

Fill up this form after installing the device as a proof, sign it and preferably send it back to us by an email.

Its return is a pre-condition of the MELAG manufacturer's warranty.

Device and set-up data

The following device has been professionally set up and handed over ready for operation.

Stockist (name, address/stamp)

Operator (name, address/stamp)

Email address for software update

Email address for software update

Serial number Careclave

Serial number Cooling Box

Serial number corresponding to the water treatment unit

Serial number(s) Carebox

Other devices connected to the unit

Please checkmark where applicable

Initial setup

Subsequent setup

Date

The installation was handed over and taken over by the following persons:

Signature technician: Name, first name (print in block letters) Signature

From the company:

From practice/clinic: Name, first name (print in block letters) Signature

Work performed

X Checkmark the following points after execution.

Checking the electrical connection

- Socket and power plug at the device are freely accessible for disconnection from the mains in case of emergency
- Device has separate power circuit with 16 A fuses
- RCD (residual current device) with rated residual current = 30 mA is present

Ensuring the feed water supply

- It was pointed out that demineralized water with minimum quality according to EN 13060, appendix C must be used as feed water, and the sterilization material must be clean and free of cleanser and disinfectant residues.
- Water treatment unit installed according to the technical manual and associated water treatment unit user manual

For safety reasons, an electronic water stop (art. no. 01056) was:

- recommended installed

Wastewater connection

NOTICE! The device must be connected to an external wastewater disposal system.

- Wastewater and overflow funnel connected to double chamber siphon according to technical manual
NOTICE! The Careclave must be connected as defined in the technical manual, otherwise there is a risk of damaging wastewater fittings that are not resistant to dental oil.
- Both drain hoses were laid with a steady slope in the direction of the siphon in compliance with the specified maximum lengths.
- The non-return flap is mounted on the Y-piece in the wastewater connection of the overflow funnel. The flap must not be mounted in the normal wastewater connection (pressure drain)!

Preparing the side panels

- Carrying straps dismantled
- If necessary, holders for Carebox attached and unused openings closed with delivered cover caps

Ensuring the compressed air supply

- Compressed air supply has been checked or retrofitted and meets the requirements specified in the manuals
- Compressed air supply connected to device according to technical manual

Aligning the device

To enable malfunction-free operation, the device must be setup level using a spirit level placed on the chamber flange. Then the front feet of the unit must be unscrewed by about five rotations in order to give the device a slight backwards tilt.

- Front feet of device screwed out 3 rotations

Checking the software version

Check the software version in accordance with a separate set of instructions (doc. AS_023-20_SW).

- Up-to-date Not up-to-date Software update to the most recent version performed.

Connection test

- Unit and all connections checked for leakage

Checking the date and time setting

- Date and time are correct or set correctly

Perform vacuum test

Perform the service program **Vacuum test**, **Program variant: Default** with an empty, cold sterilization chamber and record it

Vacuum test performed. Leakage rate: mbar/min

Carebox commissioning

Carebox(es) has/have been configured as follows in accordance with the accessories user manual:

Service program **Carebox test** performed for each available Carebox

Please note: Due to air in the hoses, the water level may be too low during the first function test, then repeat the function test.

- Service program **Carebox test** performed for all Careboxes successfully
- Service program **Carebox test** performed but not successfully because:

Checking the chuck care

- Chuck care vented
- Chuck care checked for functionality

Performing and recording test runs

Perform and record the following programs

- Service program **Oil dosing venting without** instruments (with Options > Number of care cycles: 3)
Please note: Then remove the care oil from inside the Carebox before performing the following test runs.
- Program **Care-B** or **Universal-B** with approx. 1.5 kg load (instruments) and Helix test body (laid on the Carebox if necessary)
- **Care-Therm** (Carebox with at least two instruments)
 - Oil dosing venting** successfully performed
 - Care-B** or **Universal-B** successfully performed
 - Care-Therm** successfully performed

Preparing the device logbook

Device logbook filled out and placed in the document case in the accessories compartment

Entering the contact information

The following address (preferable of the attending stockist/customer service) was entered in the **Settings** > **Service** menu:

Company	<input type="text"/>	Street	<input type="text"/>
Post Code	<input type="text"/>	Location	<input type="text"/>
Telephone	<input type="text"/>	Contact person	<input type="text"/>
Email	<input type="text"/>	Fax	<input type="text"/>

Settings in user administration/logging

User created at the request of the operator (optional) YES NO

Batch approval YES NO

Indicator assessment YES NO

Authentication at:

Reprocessing program start YES NO

Reprocessing program end YES NO

Service program start YES NO

Service program end YES NO

Resetting the maintenance counter

Maintenance counter re-set in accordance with a separate set of instructions

Resetting user role

User role Service technician logged off

Instructing the user

Please note: A user must be instructed in the operation of the device before using it.

Users have been instructed with the instruction protocol.

Users will be instructed separately later with the instruction protocol

Technical documentation

User manual is available in digital or printed format

Technical manual is available in digital or printed format

The manufacturer's inspection report including the certificate of conformity was handed over

Declaration of warranty was handed over

Output logs and attach to the record of installation and setup

System log

Status log

Program log Vacuum test

Program log Carebox test

Program log Oil dosing venting

Program log Care-B or Universal-B

Program log Care-Therm

The device was properly installed by the above named technician

without complaint

with complaint