

Instruction protocol

: 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 data

Date of instruction

Operator (name, address/stamp)

Careclave serial number

Date of installation

The following persons were present during the instruction session:

	Name, first name (print in block letters)	Signature
From practice/clinic:	<input type="text"/>
	<input type="text"/>
	<input type="text"/>
	<input type="text"/>
	<input type="text"/>
	<input type="text"/>

	Name, first name (print in block letters)	Signature
Authorised specialist instructor:	<input type="text"/>

From the company:

User instruction



PLEASE NOTE

Inform the users that the instruction does not replace the reading of the user manual and knowledge of the safety instructions.

X Checkmark the following points after execution.

1. Safety

- Risk of burns, contamination, risk of injury from instruments, personal protective equipment (PPE)

2. Description of the device and scope of functions

- Presentation of the functional scope of the Careclave
- Intended use
 - Cleaning, disinfection and sterilization
 - Care
 - Requirements for the location and ambient conditions
- Explanation of the device
- Power switch
 - Feed water tank
 - Accessories compartment
- Explanation of the elements behind the service flap
- Emptying the feed water tank
 - Key emergency door opening
 - Manometer double jacket steam generator
 - Overheat protection
 - USB connections
 - Dust filter
 - Sterile filter
- Explanation of the interfaces on the back of the device
- USB connection
 - Ethernet
- Explanation of the graphical user interface and menu navigation
- Favourites menu
 - Opening the door
 - LED status bar
 - Main menu
- User manual and hygiene plan
- Structure and contents

3. Feed water supply

- Explanation of the water supply
- Explanation of the existing water treatment unit
 - Warning values, limit values and maximum temperature
 - Water stop (leakage water detector)
 - Note on turning off the external water supply at the end of operation

4. Wastewater

- Explanation of the wastewater disposal
 - Overflow funnel
 - Double drainage with double-chamber siphon

5. Opening and closing the door

- Explanation of door functions
 - Opening, closing, emergency door opening, latching point
 - Oil can must be inserted

6. Carebox

- Explanation of the Carebox
 - Opening and closing
 - Adapter configuration, sieve, filters, media seals, housing seal and adapter O-rings
 - Carebox Blue and Carebox Green (optional)
 - Cleaning (do not use a washer-disinfector)

7. Loading the Carebox

- Preparation and execution of loading, safe handling, hygiene and hygiene plan, clean/unclean side
 - Prompt reprocessing after treatment
 - Removal of the tools from the chuck before reprocessing
 - Only reprocess dental instruments that can be connected to the adapters provided

8. Loading in Careclave mode

- The outside of the Carebox must be cold and dry, the sterilization chamber must be dry.
 - Start the program immediately after inserting the Carebox.

9. Program selection & options in Careclave mode

- Care programs and options
 - Care-Therm, Care-S, Care-B
 - Care, additional drying

10. Removing the Carebox

- Procedure and safe handling
 - Heat protection glove, residual condensate

11. Batch approval in Careclave mode

- Assessment, exclusion criteria, approval

12. Chuck care with ADDcare

- Weekly care, replacement of care oil, replacement of filters, venting

13. Handling of transfer instruments

- Preparation, manufacturer's instructions, inspection, drying, value retention
 - **Previously unnoticed damage to the bearing of rotating instruments may become visible through cleaning and reprocessing with Careclave.**

14. Cooling box (optional)

- Programs, operation and handling, cleaning

15. Loading in Vacuclave mode

- Preparation, correct handling and loading, wrapped and unwrapped, trays and holders
 - Drying instructions for wrapped loads

16. Program selection in Vacuclave mode

- Vacuclave programs and (drying) options
 - Universal-B, Quick-S, Gentle-B, Prion-B

17. Removal and storage

- Instructions for removal and storage
 - Correct handling during removal
 - Storage of sterile material

18. Batch approval in Vacuclave mode

- Assessment, exclusion criteria, approval

19. Documentation

- Documentation obligation of the operator (in Germany e.g. according to §8 para. 1 MPBetreibV)
 - Documentation media, logs, label printing, labelling

20. Routine checks

- Daily, weekly, batch-related

21. Maintenance / repair

- Activities and intervals
 - Checks and cleaning
 - Validation
 - Inspections going beyond device-specific maintenance

22. Administrative settings

- Setting options
 - User roles, settings, date and time, user administration, authentication, batch approval

23. Malfunctions

- Notifications, warnings, malfunction messages, troubleshooting

Operator instruction

Note on new users

- The operator has been advised that new users must be instructed. The responsibility for the execution of the follow-up instruction lies with the operator. The follow-up instruction should again be carried out by an authorised person.

Explanation

The operator declares with their signature that the Careclave and the associated accessories meet the necessary requirements. The Careclave can be used for cleaning, disinfection, care and sterilisation of dental instruments and hollow bodies in accordance with the intended use defined in the user manual. The installation and instruction of the Careclave and the accessories have been carried out successfully.

	Name, first name (please print in block letters)	Signature
Operator	