World Health Organization

Anexă

Digitally signed by Ceaicovschi Tudor
Date: 2023.12.28 00:16:10 EET
Reason: MoldSign Signature
Location: Moldova

Anexa 3

Achiziție sterilizator cu abur 90l

Lista cerințelor și specificațiilor

Sterilizator cu abur 90l					
NUME, CATEGORIA ȘI CODIFICARE					
	Parametrii		**Specificație minimă așteptată**	**Caietul de sarcini propus (de completat de ofertant)**	**Documentul de referință / broșura / pagina în care informațiile furnizate pot fi verificate de către comisia de evaluare**
1	Nume generic	Sterilizator cu abur 90l, clasa B		**MODEL: Cliniclave 45 single door Producător: MELAG Țara: Germania**	
CARACTERISTICI TEHNICE și CARACTERISTICI FIZICE					
2	CAPACITATE	Volumul camerei, orizontal, cu încărcare frontală	min. 85l	DA 105 Litri	user manual, pagina 79
3	CADRU, CORP	Se acceptă ușa cu balamale cu închidere automată / cu închidere verticală glisantă / ușă manuală	da	da	user manual, pagina 19
		Cameră din oțel inoxidabil AISI 316L	da	da	user manual pagina 79
		Designul poate fi ca versiune independentă sau de masă (desktop).	da	da, versiune independentă	user manual pagina 67
		Combinație de capac din oțel de calitate vopsit și plastic pentru panoul frontal sau din oțel inoxidabil AISI 304L față, capace laterale	da	da	conform standart-ului EN 285 si IEC 61010
		Țevile, mecanismul de pompare de apă și fitingurile sunt fabricate din oțel inoxidabil 316L	da	da	conform standart-ului EN 285 si IEC 61010
		Etanșarea ușii trebuie asigurată de garnitură din silicon	da	da	user manual pagina 63
		Ușa trebuie proiectată cu un sistem de siguranță pentru a preveni rănirea utilizatorului	da	da	user manual, pagina 19,20
		Tipul camerei de sterilizare - dreptunghiulară sau rotundă	da	da, rotundă	user manual pagina 79
		Egalizarea presiunii in camera de sterilizare asigurată de filtru HEPA	da	da	user manual, pagina 9
		Generator electric de abur incorporat. Sterilizatorul are un generator de abur incorporat complet automat, cu elemente electrice ca sursă de caldură.	da	da	brosura, pagina 5
		Încălzitoare interioare cu control separat și siguranță la scurtcircuit	da	da	brosura, pagina 5

4	GENERATOR DE ABURI	Protecție la supraîncălzire. Această protecție previne supraîncălzirea generatorului de abur dacă protecția împotriva fierberii uscate nu funcționează.	da	da	brosura, pagina 5
		Cameră generatoare din oțel inoxidabil AISI 316L	da	da	conform standart-ului EN 285 si IEC 61010
5	CICLU	Regimuri prestabilite de sterilizare	≥5 programe	da	user manual, pagina 27
		Regimuri de sterilizare care pot fi programate de utilizator	≥5 programe	da	user manual, pagina 28
		Setarea de către utilizator a regimului de sterilizare dorit	da	da	user manual, pagina 27-28
		Teste acceptate: test de vacuum (scurgere) și test Bowie-Dick	da	da	user manual, pagina 43
		Control electronic: microprocesor	da	da	
		Monitorizare digitală: temperatura camerei, presiunea camerei, timp, starea sterilizării	da	da	user manual, pagina 29
		Echipat cu pompă de vacuum pe baza de apă, integrată	da	da	user manual pagina 79
		Afișarea graficului de sterilizare pe ecran	da	da	user manual, pagina 29
		Gama de temperatură: 121 -134 grade C	da	da	user manual, pagina 27
		La sfârșitul ciclului de sterilizare trebuie să imprime un raport pe hârtie (stocarea paralelă a datelor în memorie).	da	da	user manual, pagina 34,36
6	SIGURANȚĂ	Protecție împotriva temperaturii excesive	da	da	user manual pagina 12
		Alarme: temperatură scăzută, eșec ciclu de sterilizare	da	da	user manual pagina 68
		Camera va menține o presiune de încercare ≥3 bar, echipată cu supapă de siguranță	da	da	user manual pagina 79
		Ușile trebuie să fie izolate termic pentru a preveni ca temperatura suprafeței să prezinte un potențial pericol pentru operatori	da	da	user manual pagina 12
		Sistemele de filtrare asigură decontaminarea aerului la intrarea în camera de sterilizare	da	da	user manual, pagina 9
		Sistem de protecție la deschiderea ușii în caz de presiune în camera de sterilizare	da	da	user manual pagina 19
CARACTERISTICI ELECTRICE					
7	CARACTERISTICI ELECTRICE	380V, 50 Hz, faza III-principală, sau 220V monofazat, 50Hz	da	da	user manual pagina 79
Caracteristici electronice					
8	Caracteristici electronice	Panou cu ecran multicolor de minim 4 inchi	da	da, 5.5 inch	user manual, pagina 15
		Memorie internă pentru stocarea a minim 500 de cicluri	da	da	user manual, pagina 37
ACCESORII, CONSUMABILE, PIESE DE SCHIMB, ALTE COMPONENTE					
9	Accesorii/ piese de schimb	Lubrificator pentru garnitura ușii minim 100gr.	da	da	
		Kit de întreținere pentru doi ani (trebuie să includă tot ce este da, dar nu numai, garnituri de uși, filtre HEPA)	da, 2 ani	da, 2 ani	
		Imprimantă de date integrată (hârtia utilizată pe imprimantă trebuie să aibă dimensiuni universale utilizate în alte unități)	da	da, imprimantă separat	user manual, pagina 60
		Suport de încărcare, în varianta 2 nivele sau rafturi în 2 nivele	da	da	
		Hârtie de imprimantă 10 buc	10 buc	da	
		Compresor de aer (fără ulei), în cazul în care sterilizatorul folosește aer comprimat	da		brosura, pagina 5
INSTRUIRE, INSTALARE SI UTILIZARE					
10	Transport	Furnizorul trebuie să includă transportul până la unitatea medicală finală	da	da	

11	Instalare	Furnizorul trebuie să efectueze complet verificările de instalare, siguranță și funcționare înainte de predare. Toate operațiunile trebuie să aibă un raport de conformitate. Trebuie asigurată instruire pentru utilizatori și tehnicieni.	da	da	
		Supape de presiune pentru apă și pompe de evacuare a apei în canalizare, dacă este cazul	da	da	
		Traseul de electricitate și canalizare a punctelor de racordare la sterilizatoare, va fi asigurat de beneficiar (confom recomandărilor producătorului)	va fi asigurat de beneficiar	da	
GARANȚIE ȘI ÎNTREȚINERE					
12	Garanție și deservire completă (inclusiv piese de schimb)	minim 24 de luni	da	da	
DOCUMENTAȚIE					
13	Cerințe de documentare	Toate documentele justificative, manualele de operare, de service trebuie prezentate în limba de stat sau în limba engleză. Manualul de utilizare/Instructiunile de utilizare trebuie prezentate în limba engleză și în limba de stat.	da	da	da
SIGURANȚĂ ȘI STANDARDE					
14	Standarde pentru producător	toate certificatele valabile enumerate mai jos: 1. Certificat de conofmritate CE conform directivei 93/42 EEC sau a Regulamentului 745 2. Declarația de conformitate CE conform directivei 93/42 EEC sau a Regulamentului 745 3. ISO 13485 și sau 9001 4. EN 285 5. IEC 61010- Cerințe de siguranță pentru sterilizatoarele utilizate pentru tratarea materialelor medicale	toate certificatele trebuie prezentate în copii cu ștampila de confirmare	DA	ISO 13485, 9001, precum si EN 285 si IEC 61010 sunt specificate in declaratia de conformitate. Restul documentelor se atașează

MELAG
competence in hygiene

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25.05.2022

Certificate

We hereby confirm, that

Legun Alexei from the company

"GBG-MLD" Chisinau, Republic of Moldova

has successfully joined the technical training in Berlin in MELAG Academy concerning the following MELAG appliances

Euroklav; MELAquick; Vacuklav;
Cliniklav 25; Cliniclave 45, MELAseal,

MELAclean, MELAprint, MELAtherm

Topics:

- introduction, accessories
- process cycle and functions of components
- installation, setting up
- operation, maintenance, trouble shooting

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Installation plan

1 Installation location

WARNING

Failure to comply with the set-up conditions can result in injuries and/or damage to the steam sterilizer.

- The steam sterilizer should only be setup, installed and commissioned by persons authorized by MELAG.
- The steam sterilizer is not suitable for operation in explosive atmospheres.
- The steam sterilizer is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.

1.1 General requirements

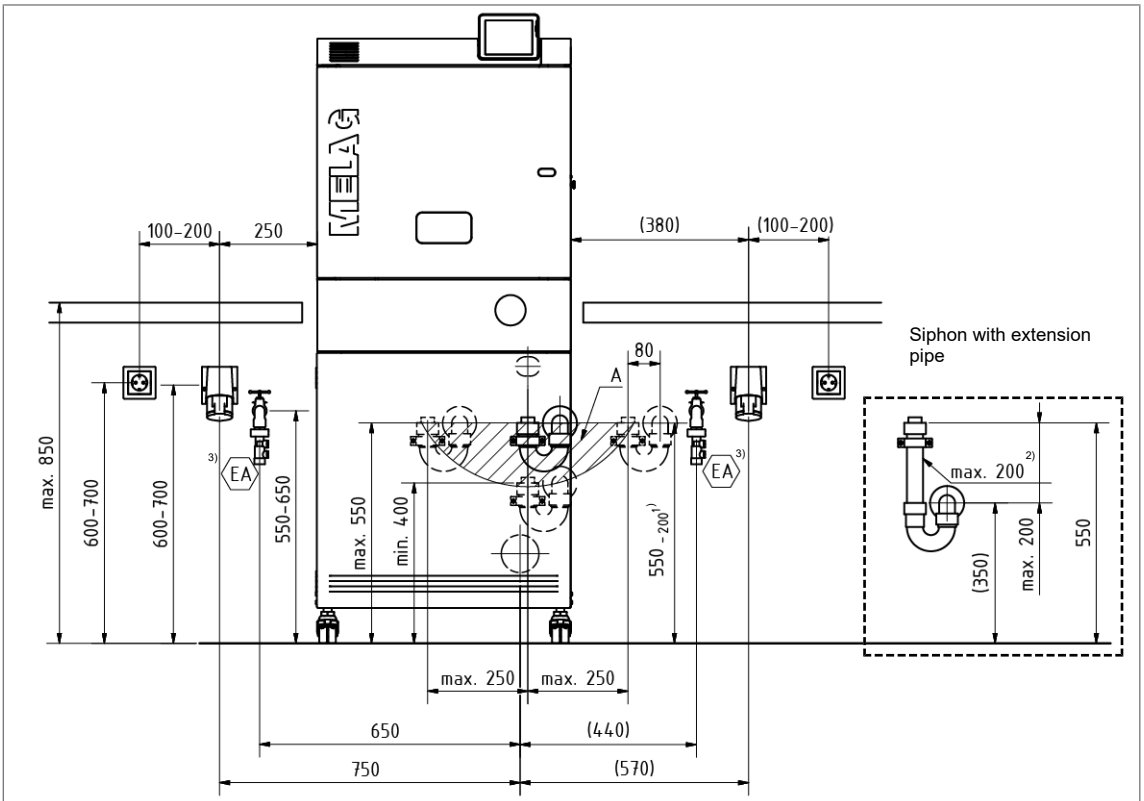
Property	Requirements of the installation location	
	Cliniclave 45	**Cliniclave 45 M**
Clear width from the entrance of the practice to the installation location	min. 70 cm	
Installation surface	level and horizontal in accordance with EN 285: waterproof, collects or deflects water running out of the steam sterilizer	
Installation location	interior of a building (dry and protected from dust)	
Max. floor loading (hydraulic pressure test)	400 kg | 100 kg per caster[1)]	610 kg | 152.5 kg per caster[2)]
Heat emission (with max. load)[3)]	1.4 kW	2.0 kW
Ambient temperature	5-40 °C (ideal range 16-26 °C) Sufficient ventilation of the room must be guaranteed.	
Relative humidity	max. 80 % at 31 °C, decreases in a linear fashion up to max. 50 % relative humidity at 40 °C	
Max. altitude	star connection: 3000 m | delta connection: 4000 m	
Illumination	in accordance with EN ISO 12100 and EN 1837	

Steam egress can occur during operation. Do not set up the device in the immediate proximity of a smoke detector. Maintain clearance from materials which could suffer damage from steam.

[1)] When using a MELAdem 56, an additional weight of 38 kg (9.5 kg per caster) must be taken into account.
[2)] When using a MELAdem 56 M, an additional weight of 53 kg (13.25 kg per caster) must be taken into account.
[3)] This applies to a max. (solid) load and with an opened door.

2 On-side connections for installation

Necessary installation requirements for the connections (all dimensions in mm)



A - Connection area for the cold water inflow hose on the siphon
1) This specification applies to the use of an extension pipe (siphon and extension pipe included in the installation package).
2) The extension pipe can be cut to the desired length.
3) The type EA back-flow preventer (included in the kiwa connection set art. no. ME86902) is only required in the Netherlands.

2.1 Mains supply

WARNING

Improper installation may lead to a short-circuit, fire, water damage or electrical shock.

This could result in serious injury.

- Only have the device set up, installed and commissioned by people authorized by MELAG.

Implement the following safety measures when dealing with the cable and power plug:

- Never damage or alter the power plug or cable.
- Never bend or twist the power cable.
- Never remove the plug by pulling on the power cable. Always take a grip on the plug.
- Never place any heavy objects on the power cable.
- Never run the power cable over areas in which it could become trapped (e.g. doors or windows).
- Never lead the cable along a source of heat.
- Never use any nails, paper fasteners or similar objects to fix the cable.
- Should the power plug or cable suffer damage, switch off the device. The power cable or plug should only be replaced by authorized technicians.

On-site requirements of the mains connection

Properties	On-site requirements	
	Cliniclave 45	**Cliniclave 45 M**
Local requirements	The electrical equipment must accord with DIN VDE 0100. A main switch (all-pole) should be fitted outside the installation room. This must be marked as a separator for the device and be easily accessible for the operator. The feed line to the electrical connection must be laid separately from the distribution to the device. Observe the clockwise rotating field!	
Electrical power	10.5 kW	13.5 kW
Electricity supply **(star connection):**	CEE socket (red) with 3x380-415 V + N + PE, 16 A, 50/60 Hz, position PE: 6 h	CEE socket (red) with 3x380-415 V + N + PE, 32 A, 50/60 Hz, position PE: 6 h
Building fuses **(star connection):**	A separate circuit with fuse (to guarantee continued practice operation during steam sterilizer malfunction): 3x16 A, RCD 30 mA	A separate circuit with fuse (to guarantee continued practice operation during steam sterilizer malfunction): 3x32 A, RCD 30 mA
Electricity supply **(delta connection)**	CEE socket (blue) with 3x220-240 V + PE, 32 A, 50/60 Hz, position PE: 9 h	CEE socket (blue) with 3x220-240 V + PE, 63 A, 50/60 Hz, position PE: 9 h
Building fuses **(delta connection)**	A separate circuit with fuse (to guarantee continued practice operation during steam sterilizer malfunction): 3x32 A, RCD 30 mA	A separate circuit with fuse (to guarantee continued practice operation during steam sterilizer malfunction): 3x63 A, RCD 30 mA
Length of the power cable	1.8 m from floor unit	1.8 m from floor unit
Other	Additional socket 230 V 50 Hz for leakage water detector (water stop), MELAprint 60 label printer or MELAprint 42/44 log printer	

2.2 Connection to a network socket / MELAprint 60 label printer

The installation in the floor unit requires a network cable of sufficient length.

The planned length of the network cable in the floor unit amounts to 60 cm with Cliniclave 45 and 112 cm with Cliniclave 45 M.

When selecting the length of a suitable network cable, take into account the additional length from the floor unit to the peripheral device or network socket.

2.3 Water connection

Requirements for the water connection

	Cold water	Feed water	Wastewater
Connection in the practice	To the cold water cut-off valve (water inflow tap) G 3/4“	To a water treatment unit	To a surface-mounted siphon (included in the installation package)
Length of the hose from the floor unit	1.3 m	--	1 m
Installation height	55-65 cm	--	max. 55 cm (upper siphon edge)
Min. flow pressure	1.5 bar at 8 l/min	0.5 bar at 5 l/min	--
Recommended flow pressure	2.5-6 bar at 8 l/min	2-4 bar at 5 l/min	--
Min. water pressure (static)	--	2 bar	--
Max. water pressure (static)	10 bar	5 bar	--
Max. throughflow volume	--	--	short-term max. 9 l/min
Max. water temperature	20 °C (ideal 15 °C)[4)]	--	short-term max. 90 °C
Water quality	drinking water, water hardness 4-12 °dH (in accordance with EN 285)[5)]	EN 285, Appendix B, table B.1, max. conductivity 5 µS/cm	--
Measures for protecting the drinking water supply	None (internally secured against backflow into the drinking water supply by an air gap in accordance with EN 1717, fluid category class 5)	**With MELAdem 56/ MELAdem 56 M** None (internally secured against backflow into the drinking water supply by an air gap in accordance with EN 1717, fluid category class 5) **Other water treatment unit** Additional protection required in accordance with EN 1717, fluid category Class 5	--
Leakage water detector	We recommend the installation of a leakage water detector with a cut-off valve (e.g. MELAG water stop).		

PLEASE NOTE

The outlet hose must be fitted at a constant decline without kinks or sagging. Deviations to the installation arrangements require consultation with MELAG.

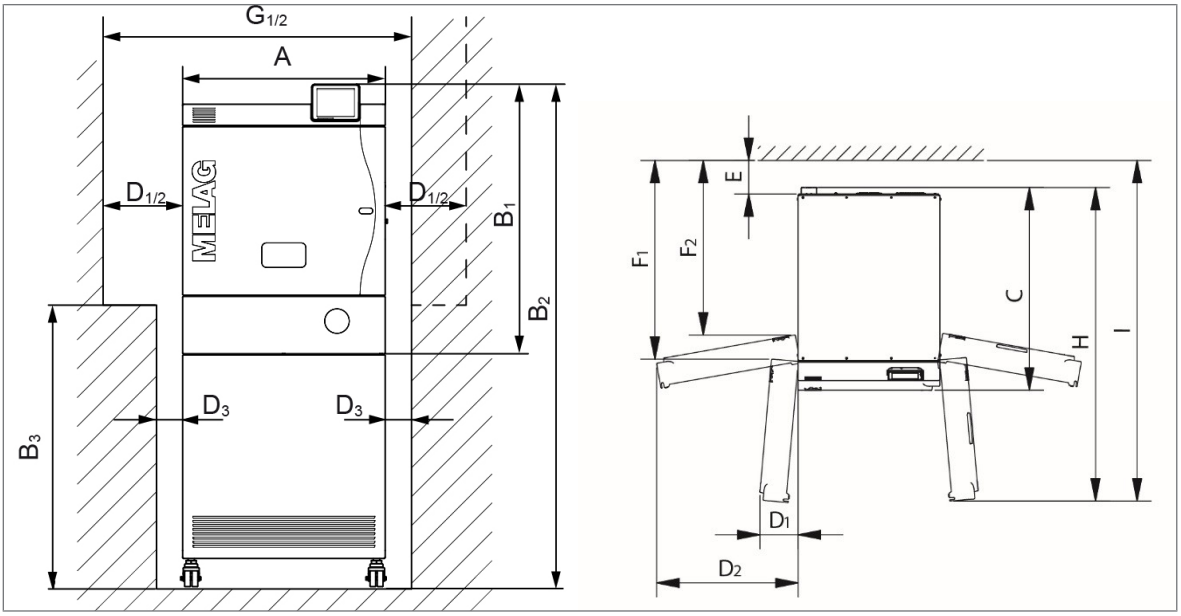
Failure to do so can result in malfunctions of the steam sterilizer.

[4)] The higher the temperature, the longer the operating times and the higher the water consumption.
[5)] Higher levels of water hardness necessitate the upstream installation of a water-softening unit.

3 Space requirements

Space requirement for Cliniclave 45:

Left: fore view, door hinge left | right: view from above, door hinge left (D_1, D_2) and door hinge right

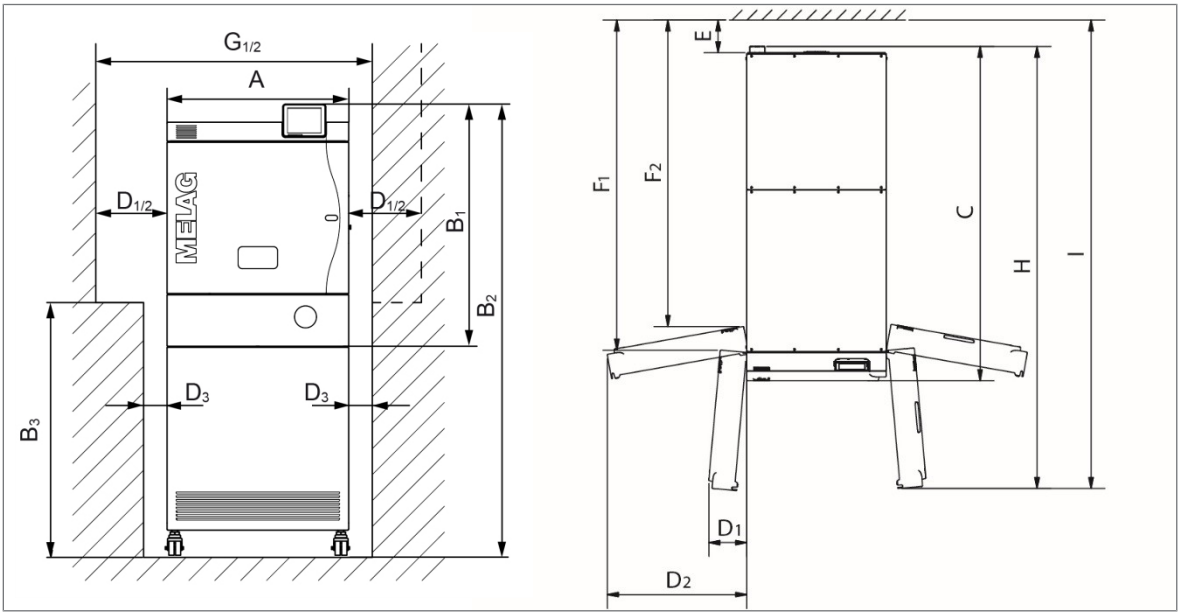


Dimensions		Cliniclave 45
Width	A	65 cm
Height	B_1	91 cm
Height with floor unit	B_2	158 cm
Height to door of steam sterilizer when using a floor unit	B_3	85 cm
Depth	C	91 cm
Min. clearance to the side of the door hinge*)	D_1	25 cm (opening angle 95°)
	D_2	75 cm (opening angle 170°)
Min. clearance to the side wall of the floor unit	D_3	8 cm
Min. clearance to the rear	E	15 cm
Free area with a fully-opened door	F_1	80 cm (opening angle 95°)
	F_2	70 cm (opening opening 170°)
Niche width required	G_1	min. 98 cm (opening angle 90°)
	G_2	min. 148 cm (opening angle 170°)
Clearance of door to device rear panel	H	140 cm (opening angle 95°)
Clearance of door to the wall	I	152 cm (opening angle 95°)
*) With door hinge right, the clearances are to be inverted (dotted line).		

A free area of 60 cm must be given each side of the steam sterilizer/must be achievable by moving the steam sterilizer to facilitate maintenance.

Space requirement Cliniclave 45 M

Left: fore view, door hinge left | right: view from above, door hinge left (D_1, D_2) and door hinge right



Dimensions		Cliniclave 45 M
Width	A	65 cm
Height	B_1	91 cm
Height with floor unit	B_2	158 cm
Height to door of steam sterilizer	B_3	85 cm
Depth	C	153 cm
Min. clearance to the side of the door hinge*)	D_1	25 cm (opening angle 95°)
	D_2	75 cm (opening angle 170°)
Min. clearance to the side wall of the floor unit	D_3	8 cm
Min. clearance to the rear	E	15 cm
Free area with a fully-opened door	F_1	145 cm
	F_2	135 cm
Niche width required	G_1	98 cm (with opening angle 90°)
	G_2	148 cm (angle of opening 170°)
Clearance of door to device rear panel	H	202 cm (angle of opening 95°)
Clearance of door to the wall	I	214 cm (angle of opening 95°)
Corridor width required		With a 90°curve, the sum of the door width and corridor width must amount to a minimum of 230 cm
*) With door hinge right, the clearances are to be inverted (dotted line).		

A free area of 60 cm must be given each side of the steam sterilizer/must be achievable by moving the steam sterilizer to facilitate maintenance.

EC Certificate

TÜVRheinland®

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 1082891-1

Manufacturer: MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany

Products: Active devices for disinfection and sterilization

Product groups included:

- Careclave
- Cliniclave
- MELAtronic
- MELAquick
- MELAtherm 10
- Premium-Plus-Class
- Pro-Class
- S-Class

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3327953-90

Effective date: 2021-01-28

Expiry date: 2024-05-26

Issue date: 2021-01-28

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dipl.-Ing. A. Fechner
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 1082891-1

Manufacturer: MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Scope
/01	MELAG Medizintechnik GmbH & Co. KG Geneststr. 6-10 10829 Berlin Germany	Design/development and manufacture
/02	MELAG Medizintechnik GmbH & Co. KG Geneststr. 2 10829 Berlin Germany	Design/development and manufacture

Report No.: 3327953-90

Effective date: 2021-01-28

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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TÜV Rheinland LGA Products GmbH
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EU-Konformitätserklärung
EU declaration of conformity

Hersteller / *Manufacturer:*	MELAG Medizintechnik GmbH & Co. KG	
Adresse / *Address:*	Geneststraße 6-10 10829 Berlin	
Land / *Country:*	Deutschland / *Germany*	
Produkt / *Product:*	Dampfsterilisator / *Steam sterilizer*	
Produktname / *Product name:*	Cliniclave® 45	
Angewandte Hauptnormen / *Applied main standards:*	EN ISO 13485 EN ISO 14971 EN 285 EN IEC 63000	EN 61010-1/-2-040 EN 61326-1 EN 1717 (incl. KIWA & SVGW) EN 13445-1/-2/-3/-4/-5

Hiermit erklären wir in alleiniger Verantwortung, dass das oben aufgeführte Produkt den Anforderungen der nachfolgenden Richtlinien und Verordnung sowie deren Umsetzungen in nationale Gesetze entspricht. Diese Erklärung gilt in Verbindung mit dem zum Produkt zugehörigen MELAG Dokument „Konformitäten und Werksprüfungsnachweise“.

Herewith, we declare under our sole responsibility that the product mentioned above meets the requirements of the following directives and regulation as well as their relevant transpositions in national laws. This declaration is valid in connection with the MELAG document “Conformities and works tests certificates”.

93/42/EWG (Medizinprodukterichtlinie) / *93/42/EEC (Medical device directive)*

Konformitätsbewertungsverfahren / *Conformity assessment procedure*:	Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4 *Directive 93/42/EEC Annex II, excluding section 4*
Klassifizierung / *Classification:*	Klasse IIb / *Class IIb*
GMDN Code / *GMDN code:*	38671
Benannte Stelle bezüglich 93/42/EWG / *Notified Body regarding to 93/42/EEC:*	TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431 Nürnberg, Germany
Zertifikatsnummer / *Certificate number:*	HD 1082891-1
CE-Kennzeichen / *CE mark*:	CE 0197
Gültig bis / *Valid until*:	26.05.2024

2014/68/EU (Druckgeräterichtlinie / *Pressure equipment directive)*

Konformitätsbewertungsverfahren / *Conformity assessment procedure:*	Richtlinie 2014/68/EU Modul D1 *Directive 2014/68/EU Module D1*
Kesseltyp / *Chamber type:*	Typ C45
Beschreibung der Komponenten / *Description of the components:*	Kessel, Dampferzeuger, Federsicherheitsventil und Rohrleitungen *Chamber, steam generator, safety valve and pressure tubes*
Benannte Stelle bezüglich 2014/68/EU / *Notified body regarding to 2014/68/EU:*	TÜV Rheinland Industrie Service GmbH, Am Grauen Stein, 51105 Köln, Germany
Zertifikatsnummern / *Certificate numbers:*	01 202 644/Q-18 B008
CE-Kennzeichen / *CE mark:*	CE 0035

Die Konformitätsbewertung für folgende EU-Richtlinien und -Verordnungen wurde allein durch den Hersteller durchgeführt:
2006/42/EG (Maschinenrichtlinie), 2014/30/EU (EMV-Richtlinie), 2014/35/EU (Niederspannungsrichtlinie), 1907/2006 (REACH-Verordnung) und 2011/65/EU (RoHS-Richtlinie)
The assessment of conformity for the following EU directives and EU regulations has been done by the manufacturer only:
2006/42/EC (Machinery directive), 2014/30/EU (EMC directive), 2014/35/EU (Low voltage directive), 1907/2006 (REACH regulation) and 2011/65/EU (RoHS directive)

Berlin, 17.11.2021

Sebastian Gebauer
(Geschäftsführer / *Managing director*)

Quality - made in Germany

Certificate

Quality Assurance System acc. to Directive 2014/68/EU

Certificate no.: 01 202 644/Q-18 B008

Name and address of the certificate holder:

MELAG Medizintechnik GmbH & Co. KG
Geneststr. 6-10
10829 Berlin
Germany

Herewith we certify that the above -mentioned manufacturer operates a quality system according to the European Directive 2014/68/EU.
The manufacturer has the permission to affix the following CE marking to pressure equipment described and manufactured in accordance to the scope covered by this Quality-Assurance System:

CE 0035

Test basis: **Directive 2014/68/EU: QA-System (Module D)**
(the QS-Modules E1, E, D1 are covered by Module D)

Audit report no.: 01 202 644/Q-18 B008

Scope: **Production of sterilizers for medical purposes and safety valves, see annex (Rev.:6, 2022-05-12) to certificate**

Manufacturing plant: see certificate holder

Validity: ***This certificate is valid until 2024-05-31.***

Cologne, 2022-12-12

Dipl.-Ing. (FH) Vera Ruff

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Precisely Right.

MELAG
competence in hygiene

The Cliniclave® series

Large steam sterilizers for practices and clinics

Quality – made in Germany

The Cliniclave® series

Four models for the greatest-possible flexibility

Our experience from developing and manufacturing steam sterilizers since decades, paired with the innovation power of our 165 specialist engineers has resulted in an especially innovative and energy-efficient steam sterilizers: the Cliniclave® series. In addition to the typical MELAG features of record operating times, an intuitive operating concept and integrated documentation and approval, the four large steam sterilizers of this new range present a series of further unique innovations which only we as the specialists for instrument decontamination could deliver to our customers. The focus of the new Cliniclave® series lies on the combination of even shorter operating times and even faster instrument availability, whilst achieving considerable levels of energy efficiency.
The Cliniclave® series consists of large steam sterilizers with a capacity of one or two sterilization units (StU), available as single-door or double-door (pass-through) models.

Cliniclave® 45 single-door version

Chamber: Ø 44 cm x 72 cm deep
Volume: 105 litres
Load: 35 kg
Capacity: 1 sterilization unit (1 StU)
Dimensions: W 65 x H 160 x D 91 cm

Cliniclave® 45 D double-door version

Chamber: Ø 44 cm x 74 cm deep
Volume: 110 litres
Load: 35 kg
Capacity: 1 sterilization unit (1 StU)
Dimensions: W 65 x H 160 x D 101 cm

Cliniclave® 45 M single-door version

Chamber: Ø 44 cm x 134 cm deep
Volume: 200 litres
Load: 70 kg
Capacity: 2 sterilization units (2 StU)
Dimensions: W 65 x H 160 x D 153 cm

Cliniclave® 45 MD double-door version

Chamber: Ø 44 cm x 136 cm deep
Volume: 205 litres
Load: 70 kg
Capacity: 2 sterilization units (2 StU)
Dimensions: W 65 x H 160 x D 163 cm

The three most important advantages of the Cliniclave® series at a glance

1. Save time

With a load quantity of up to 70 kg, the steam sterilizers of the Cliniclave® series can sterilize significantly more instruments than other devices of their class, and achieve record operating times with low levels of water and energy consumption.

2. Work ergonomically

A wide range of batch configurations can be inserted and removed from the steam sterilizer using the loading system (including loading trolley), thereby allowing ergonomic, quick and secure operation.

3. Document securely

The XXL colour-touch display enables intuitive operation. The integrated documentation and approval software permits com- plete reproducibility. Via the Ethernet interface the Cliniclave® series can be integrated in the practice or clinic network.

1. Save time

Sterilizing large quantities in short operating times.

The sterilization of large instrument quantities and textiles and their quick availability is one of the most important requirements in clinics, practices and outpatient centres. With a load quantity of up to 70 kg of wrapped instruments or 14 kg of textiles, the steam sterilizers of the Cliniclave® series provide far greater performance than almost all other large steam sterilizers. Used in connection with specially-designed mounts, the sterilization chamber provides the best solution for all medical fields.

Ideal solutions for sterilization containers, individually-wrapped instruments and textiles.

Loading example: 12 x MELA*store*®-Boxes 200
(Cliniclave® 45)

Dimensions of the MELA*store*®-Box 200: 19 cm (W) x 31.2 cm (L) x 6.5 cm (H).

„The large load quantities and short operating times make an important contribution to improving the energy-efficiency of our practice."

Kirsten, Dres. Frey, Oral Surgeons

2. Work ergonomically

With a loading system for secure and ergonomic loading and unloading.

The loading system of the Cliniclave® series enables the loading and unloading of a wide range of configurations without much effort.

Loading trolley for the steam sterilizers of the Cliniclave® series

The lower level of the loading trolley provides sufficient space to load the Cliniclave® series steam sterilizers with further sterilization containers or other load elements. The loading system includes a loading trolley and a batch slider with Teflon runners. The sterilization containers or the tray mount are placed on the batch slider and moved securely with the loading hook.

„The loading and unloading of the large steam sterilizer using the loading system and the loading trolley guarantees ergonomic and secure working practices."

Sabine, SPREEDOCS Outpatient Surgical Centre

3. Document securely

With an integrated software for the approval and traceability of instruments.

The XXL colour-touch display enables an intuitive operation and helps the personnel to avoid errors and to find all the important information quickly. The documentation and approval software integrated in all devices of the Cliniclave® series permits complete reproducibility and total security.

An individual PIN can be issued to every user to enable secure traceability in the approval procedure. Authentication of the batch approval can be performed quickly and securely on the display.

The Cliniclave® series provides a variety of documentation methods: network connection via Ethernet; the printout of barcode labels for marking wrapped instruments; and log output to a CF card.

Printing barcode labels with MELA*print*® 60

„The user-friendly batch approval provided by the Cliniclave® 45 facilitates documentation of the sterilization process, thereby simplifying instrument reprocessing. The logs are easy to save and are available at any time. This represents an important contribution to maintaining the high quality of practice processes."

Petra, Day clinic Krahl, Dr. Beltz, Dr. Poppelbaum

Documenting the complete workflow with MELA*trace*®:

Further device functions making your day that little bit easier

It is often the small things that make our working lives more pleasant. A range of features in the Cliniclave® series help to make your working procedures more simple and secure. These functions are integrated in all of the models of the Cliniclave® series and can be activated directly via the XXL colour-touch display.

DRYtelligence®

The procedure of the sensor-controlled and load-specific vacuum drying procedure saves time, cooling water and energy and guarantees optimal drying results.

Energy-saving mode

If the Cliniclave® 45 is not to be switched off during longer operating pauses, the energy-saving mode can be set. This shortens the pre-heating time before the next start.

Automatic shutdown

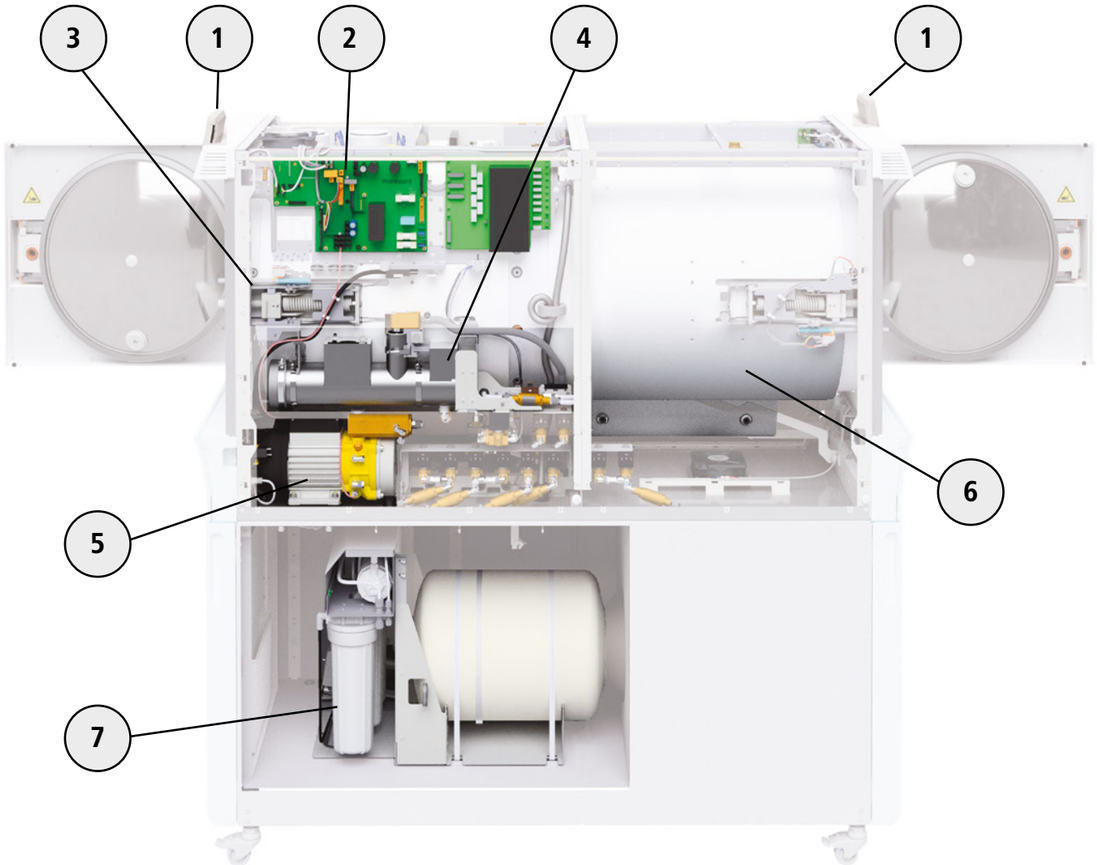
Activating this function before starting the last batch of the day means that the Cliniclave® switches-off automatically immediately after the end of the program. Batch approvel can then be performed the next day, immediately after activating the device.

Start time pre-selection

The start time pre-selection function enables the user to select any program and then start it at a specific time, e.g. in order to perform a routine test program.

Innovative and convincing technology

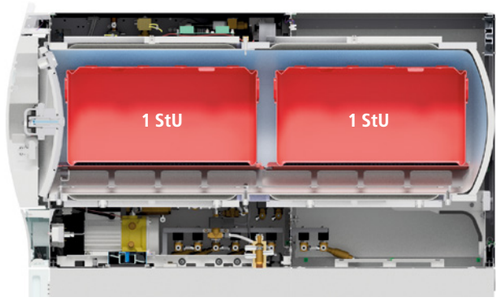
The innovative functions and durable components of the high-end Cliniclave® series produce consistently convincing results. The unique device concept satisfies the highest requirements. In addition to the central device components shown below, the steam sterilizers of the Cliniclave® series contain a range of further highlights, including the unique concept of multipoint steam intake and discharge technology for record operating times and excellent drying results.



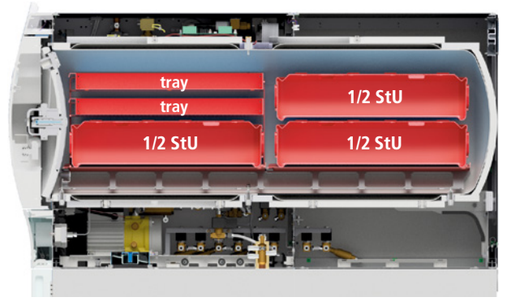
1. XXL colour-touch display
2. Microprocessor control and monitoring electronics for secure and valid processes
3. Electrical door lock for security and ease of use
4. Air gap in accordance with DIN EN 1717 for protection of the drinking water
5. High-performance vacuum pump for the best process results
6. Patented double jacket technology for the highest-quality saturated steam
7. Reverse osmosis unit for independent and automatic aqua dem subsequent feeding

Even more space in the Magnum steam sterilizers of the Cliniclave® series

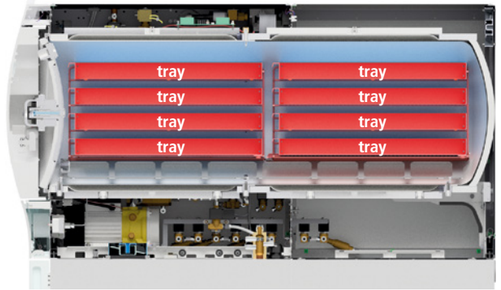
The Cliniclave® 45 M and Cliniclave® 45 MD accommodate 2 sterilization units and can sterilize up to 70 kg of instruments in record time. Four example loads:



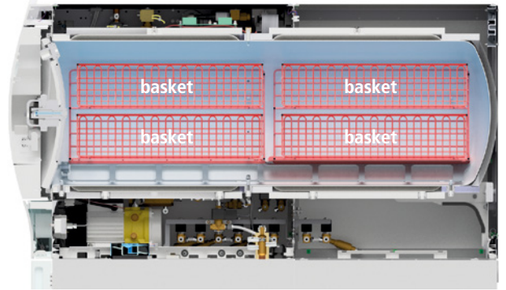
Cliniclave® 45 M with 2 sterilization containers 30 x 30 x 60 cm



Cliniclave® 45 M with 3 sterilization containers 30 x 15 x 60 cm and 2 trays 30 x 5 x 59 cm



Cliniclave® 45 M with 8 trays 30 x 5 x 59 cm



Cliniclave® 45 M with 4 instrument baskets

The Cliniclave® 45 M shown above is also available as the double-door pass-through steam sterilizer Cliniclave® 45 MD.

Discover the product highlights of Cliniclave® 45 MD in our video:

The Cliniclave® series provides the suitable model for every requirement

The compact dimensions of the four large steam sterilizers of the Cliniclave® series are ideally-suited to the needs of clinics, practices and outpatient centres. The position of the door hinge (left or right-hand side) can be chosen for each Cliniclave® model - including the doors of the pass-through steam sterilizers.

Programm	Cliniclave® 45	Cliniclave® 45 D	Cliniclave® 45 M	Cliniclave® 45 MD
Device version	single-door version	double-door version	single-door version	double-door version
Chamber volume	105 litres	110 litres	200 litres	205 litres
Capacity	1 StU		2 StU	
Door hinge	Selectable: left or right			
Chamber diameter	Ø 44 cm			
Chamber depth	72 cm	74 cm	134 cm	136 cm
Dimensions (W x H x D)	65 x 160 x 91 cm	65 x 160 x 101 cm	65 x 160 x 153 cm	65 x 160 x 163 cm
Empty weight	255 kg	298 kg	315 kg	384 kg
Operation weight	275 kg	335 kg	370 kg	435 kg
Power supply	3x380-415 V, 50/60 Hz, 10.500 W, 16 A	3x380-415 V, 50/60 Hz, 10.500 W, 16 A	3x380-415 V, 50/60 Hz 13.500 W, 32 A	3x380-415 V, 50/60 Hz, 13.500 W, 32 A

Cliniclave® 45

Cliniclave® 45 M

Supply with feed water is best performed via a MELA*dem*® 56 reverse osmosis unit. The MELA*dem*® 56 was developed especially for the Cliniclave® series and complies with the requirements of EN 1717 for the protection of the drinking water.

The MELA*dem*® 56 is installed in the floor unit to save space.

The devices of the Cliniclave® series can also be connected to a central water treatment unit or an existing ion exchanger.

Faster instrument decontamination and lower energy consumption

Fast operating times and secure sterilization are amongst the most important requirements of a large steam sterilizer. The devices of the Cliniclave® series always fulfil these requirements. The large load quantities and the low water and energy consumption make the steam sterilizers of the Cliniclave® series the most efficient and compact large steam sterilizers of their class.

Program	Operating time (with minimum to maximum load)				Drying		Loading
	Cliniclave® 45	Cliniclave® 45 M	Cliniclave® 45 D	Cliniclave® 45 MD	DRYtelligence® *	Time-controlled	
Universal-Program	19 - 35 min	24 - 48 min	18 - 40 min	23 - 50 min	> 4 min	20 min	Single and multiple wrapping
Quick-Program B	17 - 22 min	18 - 27 min	17 - 21 min	20 - 28 min	> 4 min	10 min	Single and unwrapped instruments (no textiles)
Quick-Program S	13 - 17 min	15 - 22 min	11 - 17 min	14 - 22 min	> 4 min	6 min	unwrapped (no textiles)
Gentle-Program	35 - 36 min	41 - 45 min	34 - 36 min	41 - 45 min	> 4 min	20 min	Single and multiple wrapping
Prion-Program	34 - 50 min	38 - 63 min	32 - 55 min	27 - 65 min	> 4 min	20 min	Single and multiple wrapping

* DRYtelligence® automatically adapts the drying process to your load. Thanks to intelligent drying, optimal drying results are achieved at all times.

Our priority is your satisfaction

"The high loading capacities in conjunction with quick sterilization times of Cliniclave® 45 ensures maximum efficiency in instrument decontamination.

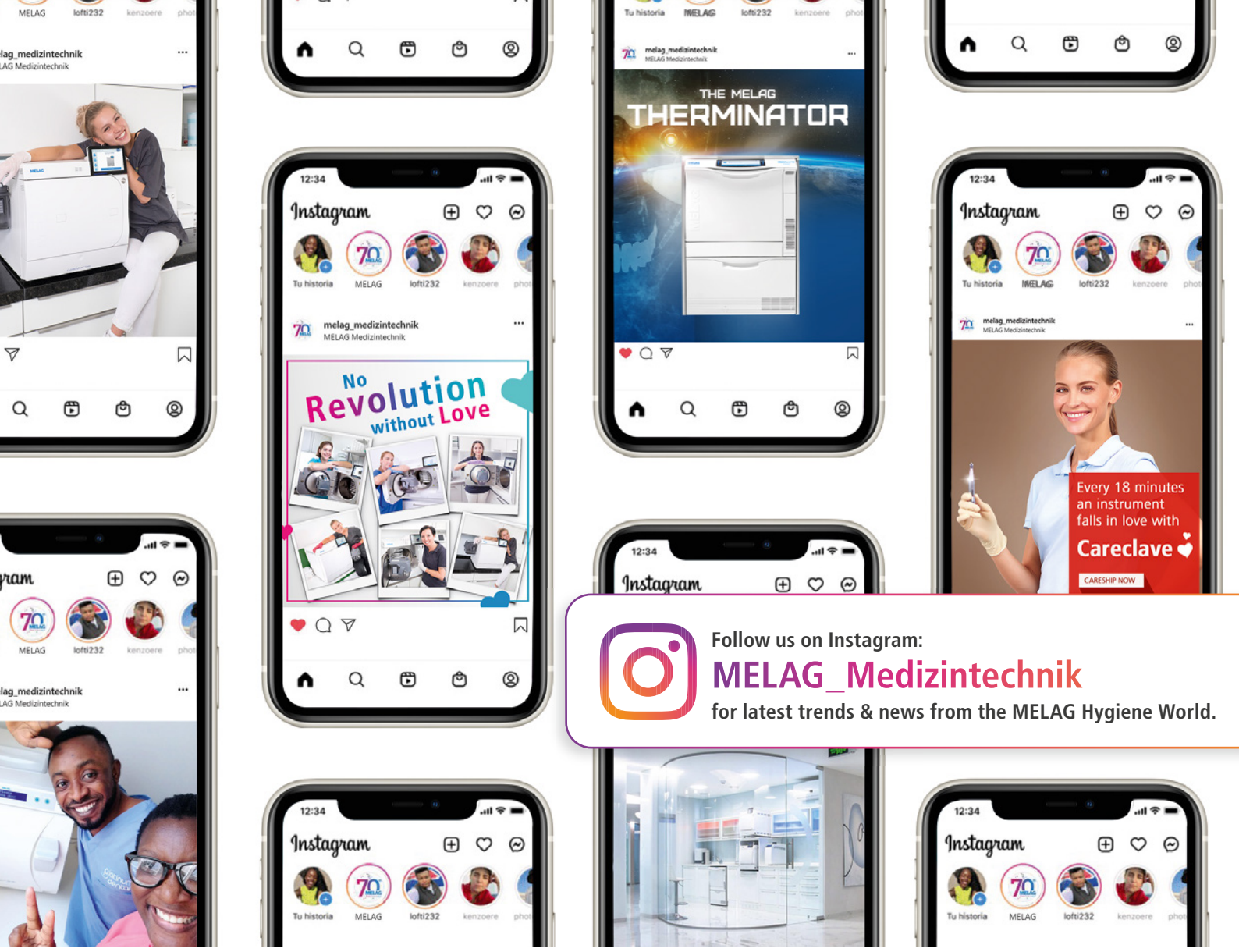
Clinica Veterinaria CMV
Varese, Italy

"Reliability and perfection – Cliniclave® provides us with time-saving processes and ensures the highest level of protection against infections for our patients."

Clinique Bellevue
Stavanger, Norway

„We rely on the MELAG system with Cliniclave® 45 D in a two-room concept: Easy loading on the unsterile side and safe unloading on the sterile side."

Thonburi Dental Clinic
Bangkok, Thailand



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System solutions, innovation and quality

MELAG was founded in 1951 and is an owner-operated family company, that specializes in products aiming at optimized practice hygiene. The manufacturing and production sites are exclusively located in Germany on a 22.000 m² premises with 450 employees working diligently to maintain MELAG´s world leading role in instrument decontamination.

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Save paper and protect the environment:
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Technical Manual

Cliniclave® 45
Cliniclave® 45 M

Large steam sterilizer

from software version 3.218

EN

Read this manual carefully and in the correct order before setting up and commissioning the device. The instructions include important safety information. You also receive a user manual with the device. Please store this manual and the user manual carefully and in close proximity to the device. They represent a component of the product.

CE 0197

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1 General guidelines

Read this manual carefully and in the correct order before setting up and commissioning the device. The instructions include important safety information. You also receive a user manual with the device. Please store this manual and the user manual carefully and in close proximity to the device. They represent a component of the product.

Should the manual no longer be legible, is damaged or has been lost, you can download a new copy from MELAG download centre at www.melag.com.

Symbols used

Symbol	Explanation
	Indicates a dangerous situation, which if not avoided, could entail slight to life-threatening injuries.
	Draws your attention to a situation, which if not avoided, could result in damage to the instruments, the practice fittings or the device.
	Draws your attention to important information.

Formatting rules

Example	Explanation
see **Chapter 2**	Reference to another text section within this document.
`Universal-Program`	Words or phrases appearing on the display of the device are marked as display text.

2 Installation requirements

Installation material

The installation set (art. no. ME09027) for the water connection includes:

Qty.	Article	Art. no.
1	Siphon for Cliniclave series (incl. extension pipe)	ME72420
1	Rubber seal 3/4" for external water supply	ME56950
1	Hose clamp	---
1	Hanger bolt M8x60	---

Included in the scope of delivery of the steam sterilizer (and required for installation):

Qty.	Article	Art. no.
1	Water outlet hose (1.5 m) inc. 2 flat seals for Cliniclave 45	ME86610
1	Water outlet hose (2.1 m) inc. 2 flat seals for Cliniclave 45 M	ME86620

The following additional material can be ordered as required:

Qty.	Article	Art. no.
1	Water tap 3/4” with safety combination	ME37310
1	Water stop	ME01056

The connection set*) for installation of the MELAdem 56 reverse osmosis unit contains:

Qty.	Article	Art. no.
1	Feed water hose (PE hose, 1.3 m, Ø 10/8 mm)	---
1	Outlet hose (PE hose, 0.7 m, Ø 6/4 mm)	---
1	Permeate line (PE hose, 1 m, Ø 6/4 mm)	---
1	Inlet hose (PE hose, 0.7 m, Ø 8/6 mm)	---
1	Manometer for measuring the primary pressure in the pressure tank	---

The connection set*) for installation of the MELAdem 56 M reverse osmosis unit contains:

Qty.	Article	Art. no.
1	Feed water hose (PE hose, 2 m, Ø 10/8 mm)	---
1	Outlet hose (PE hose, 2 m, Ø 6/4 mm)	---
1	Inlet hose (PE hose, 2 m, Ø 8/6 mm)	---
1	Manometer for measuring the primary pressure in the pressure tank	---

*) Only included in the scope of delivery of the steam sterilizer if a corresponding reverse osmosis unit is included in the scope of delivery.

The required volume of feed water for immediate commissioning:

13 l (Cliniclave 45), 20 l (Cliniclave 45 M) in accordance with EN 285, Appendix B

Installation location

WARNING

Failure to comply with the setup conditions can result in injuries and/or damage to the steam sterilizer.

- The steam sterilizer should only be setup, installed and commissioned by persons authorised by MELAG.
- The steam sterilizer is not suitable for operation in explosive atmospheres.
- The steam sterilizer is conceived for use outside the patient area. The device should be located a minimum of 1.5 m radius away from the treatment area.

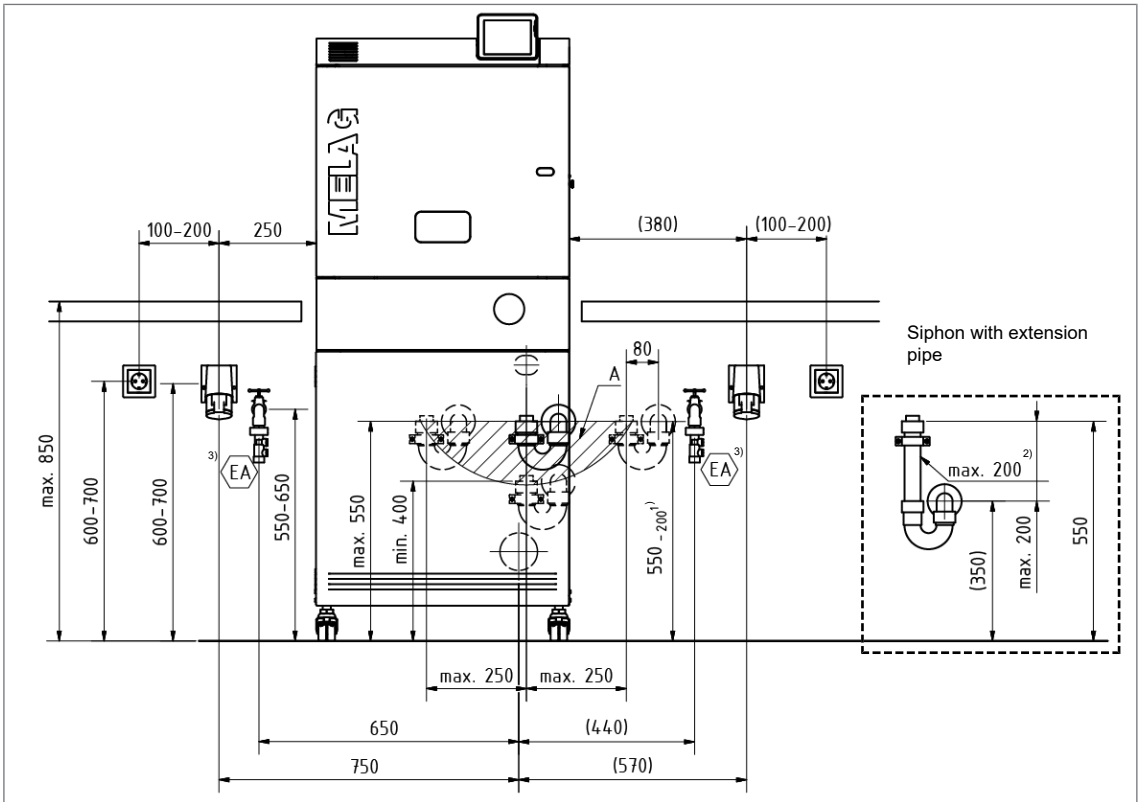
General requirements

Property	Requirements of the installation location	
	Cliniclave 45	**Cliniclave 45 M**
Clear width from the entrance of the practice to the installation location	min. 70 cm	
Installation surface	level and horizontal, in accordance with EN 285: waterproof, collects or deflects water running out of the steam sterilizer	
Installation location	interior of a building (dry and protected from dust)	
Floor loading (normal operation)	332 kg | 83 kg per caster*)	503 kg | 125.8 kg per caster**)
Floor loading (hydraulic pressure test)	400 kg | 100 kg per caster*)	610 kg | 152.5 kg per caster**)
Heat emission (at maximum solid load and with an opened door)	1.4 kW	2.0 kW
Ambient temperature	5-40 °C (ideal range 16-26 °C) Sufficient ventilation of the room must be guaranteed.	
Relative humidity	max. 80 % at temperatures of up to 31 °C, max. 50 % at 40 °C (decreasing in linear fashion in-between)	
Altitude (star connection)	max. 3000 m	
Altitude (delta connection)	max. 4000 m	
Illumination	in accordance with EN ISO 12100 and EN 1837	
*) incl. MELAdem 56 **) incl. MELAdem 56 M		

Steam egress can occur during operation. Do not set up the device in the immediate proximity of a smoke detector. Maintain clearance from materials which could suffer damage from steam.

On-side connections for installation

Necessary installation requirements for the connections (all dimensions in mm)



A - Connection area for the inlet hose on the siphon
1) This specification applies to the use of an extension pipe (siphon and extension pipe included in the installation set).
2) The extension pipe can be cut to the desired length.
3) The type EA back-flow preventer (included in the kiwa connection set, art. no. ME86902) is only required in the Netherlands.

Mains supply

WARNING

Improper installation may lead to a short-circuit, fire, water damage or electrical shock.

This could result in serious injury.

- Only have the device set up, installed and commissioned by people authorised by MELAG.

Implement the following safety measures when dealing with the cable and power plug:

- Never damage or alter the power plug or cable.
- Never bend or twist the power cable.
- Never remove the plug by pulling on the power cable. Always take a grip on the plug.
- Never place any heavy objects on the power cable.
- Never run the power cable over areas in which it could become trapped (e.g. doors or windows).
- Never lead the cable along a source of heat.
- Never use any nails, paper fasteners or similar objects to fix the cable.
- Should the power plug or cable suffer damage, switch off the device. The power cable or plug should only be replaced by authorised technicians.

Building-side requirements of the mains connection

Property	On-site requirements	
	Cliniclave 45	Cliniclave 45 M
Local requirements	The electrical equipment must accord with DIN VDE 0100. A main switch (all-pole) should be fitted outside the installation room. This must be marked as a separator for the device and be easily accessible for the operator. The feed line to the electrical connection must be laid separately from the distribution to the device. Observe the clockwise rotating field!	
Electrical power	10.5 kW	13.5 kW
Power supply (star connection)	CEE socket (red) with 3x380-415 V + N + PE, 16 A, 50/60 Hz, position PE: 6 h	CEE socket (red) with 3x380-415 V + N + PE, 32 A, 50/60 Hz, position PE: 6 h
Building-side fuse protection (star connection)	A separate circuit with fuse (to guarantee continued practice operation during device sterilizer malfunction): 3x16 A, RCD 30 mA	A separate circuit with fuse (to guarantee continued practice operation during device sterilizer malfunction): 3x32 A, RCD 30 mA
Power supply (delta connection)	CEE socket (blue) with 3x220-240 V + PE, 32 A, 50/60 Hz, position PE: 9 h	CEE socket (blue) with 3x220-240 V + PE, 63 A, 50/60 Hz, position PE: 9 h
Building fuses (delta connection)	A separate circuit with fuse (to guarantee continued practice operation during steam sterilizer malfunction): 3x32 A, RCD 30 mA	A separate circuit with fuse (to guarantee continued practice operation during steam sterilizer malfunction): 3x63 A, RCD 30 mA
Length of the power cable from the floor unit	1.8 m	
Other	Additional socket 230 V 50 Hz for leakage water detector (water stop), MELAprint 60 label printer or MELAprint 42/44 log printer	

Connection to a network socket / MELAprint 60 label printer

The installation in the floor unit requires a network cable of sufficient length.

The planned length of the network cable in the floor unit amounts to 60 cm with Cliniclave 45 and 112 cm with Cliniclave 45 M.

When selecting the length of a suitable network cable, take into account the additional length from the floor unit to the peripheral device or network socket.

Water connection

Requirements for the water connection

	Cold water	Feed water	Wastewater
Connection in the practice	To the cold water cut-off valve (water inflow tap) G 3/4“	To a water treatment unit	To a surface-mounted siphon (included in the installation set)
Length of the hose from the floor unit	1.30 m	--	1 m
Installation height	55-65 cm	--	max. 55 cm (upper edge of the siphon)
Min. flow pressure	1.5 bar at 8 l/min	0.5 bar at 5 l/min	--
Recommended flow pressure	2.5-6 bar at 8 l/min	2-4 bar at 5 l/min	--
Min. static water pressure	--	2 bar	--
Max. static water pressure	10 bar	5 bar	--
Max. throughflow volume	--	--	short-term max. 9 l/min
Max. water temperature	20 °C (ideal 15 °C)[1)]	--	short-term max. 90 °C
Water quality	drinking water, water hardness 4-12°dH (in accordance with EN 285)[2)]	EN 285, Appendix B, table B.1, max. conductivity 5 µS/cm	--
Measures for protecting the drinking water supply	None (internally secured against backflow into the drinking water supply by an air gap in accordance with EN 1717, fluid category class 5)	**With MELAdem 56/ MELAdem 56 M** none (internally secured against backflow into the drinking water supply by an air gap in accordance with EN 1717, fluid category class 5) **Other water treatment treatment unit for** Additional protection required in accordance with EN 1717, fluid category class 5	--
Leakage water detector	MELAG recommends the installation of a leakage water detector with a cut-off valve (e.g. MELAG water stop).		

PLEASE NOTE

Fit the outlet hose at a constant decline without kinks or sagging. In case of deviations to the installation arrangements, consult with MELAG.

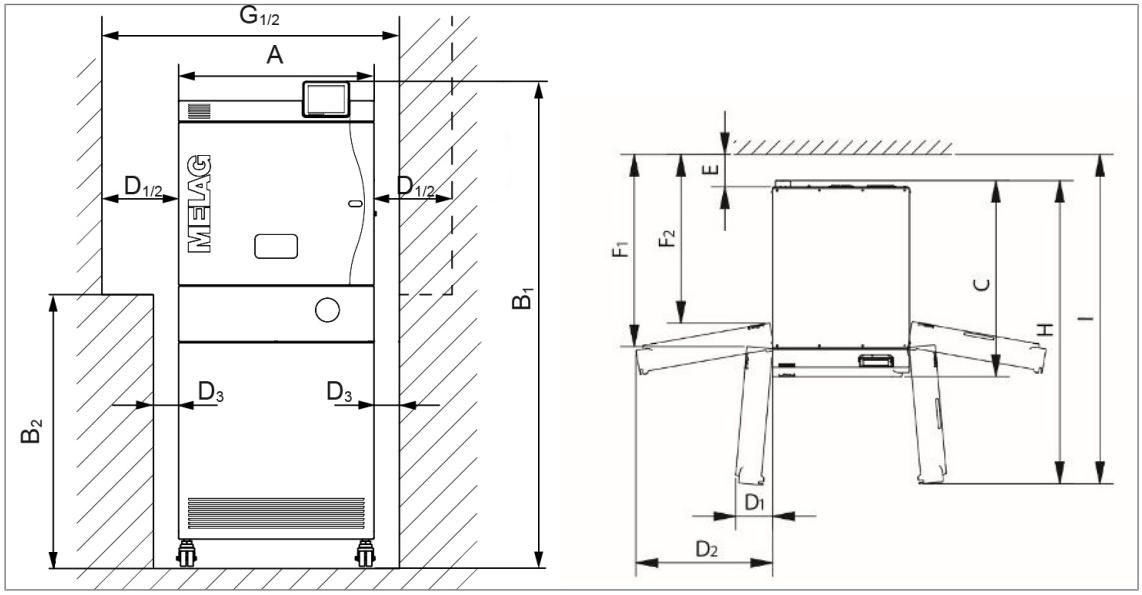
Failure to do so can result in malfunctions of the device.

[1)] The higher the temperature, the longer the operating times and the higher the water consumption.
[2)] Higher levels of water hardness necessitate the upstream installation of a water-softening unit.

Space requirements

Space requirement for Cliniclave 45:

left: fore view, door hinge left
right: view from above, door hinge left (D_1, D_2) and door hinge right

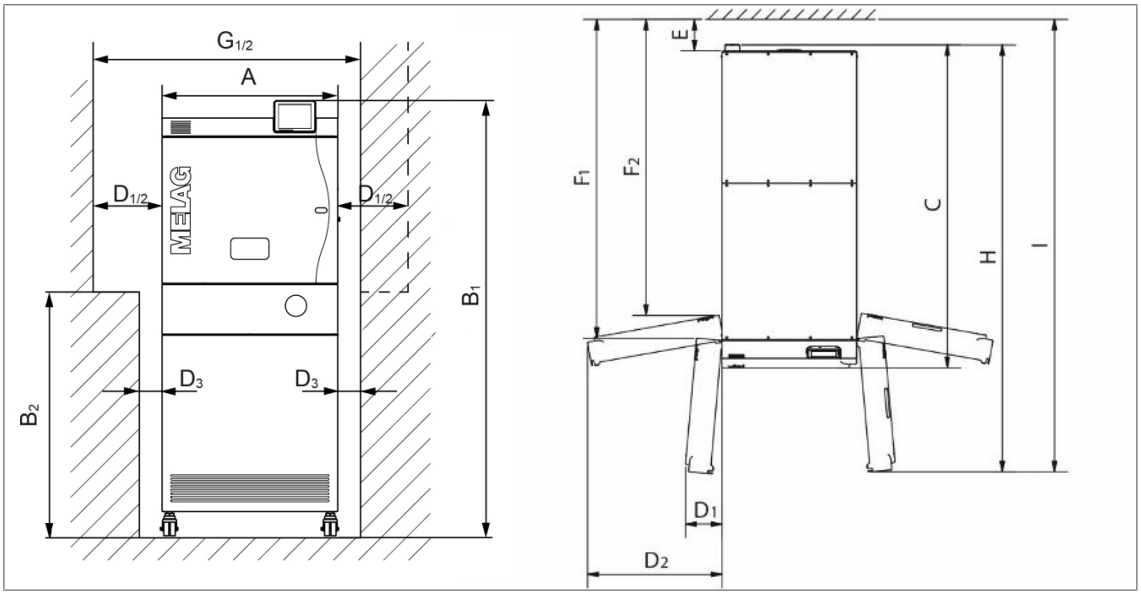


Device dimensions		Cliniclave 45
Width	A	64 cm
Height device with floor unit	B_1	158 cm
Height to door of steam sterilizer (free area below the swivel range of the door)	B_2	85 cm
Depth	C	91 cm
Min. clearance to the side of the door hinge*)	D_1	25 cm (opening angle 95°)
	D_2	75 cm (opening angle 170°)
Min. clearance to the side wall of the floor unit	D_3	8 cm
Min. clearance to the rear	E	15 cm
Free space when door open fully	F_1	80 cm (opening angle 95°)
	F_2	70 cm (opening angle 170°)
Niche width required	G_1	97 cm (opening angle 95°)
	G_2	147 cm (opening angle 170°)
Clearance of door to device rear panel	H	140 cm (opening angle 95°)
Clearance of door to the wall	I	152 cm (opening angle 95°)
*) With door hinge right, keep the clearances mirror-inverted (dotted line).		

A free area of 60 cm must be given each side of the steam sterilizer or must be achievable by moving the steam sterilizer to facilitate maintenance.

Space requirement Cliniclave 45 M

left: fore view, door hinge left
right: view from above, door hinge left (D_1, D_2) and door hinge right



Device dimensions		Cliniclave 45 M
Width	A	64 cm
Height device with floor unit	B_1	158 cm
Height to door of steam sterilizer (free area below the swivel range of the door)	B_2	85 cm
Depth	C	153 cm
Min. clearance to the side of the door hinge*)	D_1	25 cm (opening angle 95°)
	D_2	75 cm (opening angle 170°)
Min. clearance to the side wall of the floor unit	D_3	8 cm
Min. clearance to the rear	E	15 cm
Free space when door open fully	F_1	145 cm (opening angle 95°)
	F_2	135 cm (opening angle 170°)
Niche width required	G_1	97 cm (opening angle 95°)
	G_2	147 cm (opening angle 170°)
Clearance of door to device rear panel	H	202 cm (opening angle 95°)
Clearance of door to the wall	I	214 cm (opening angle 95°)
Sum of door width and floor width		With a 90°curve at least 230 cm
*) With door hinge right, keep the clearances mirror-inverted (dotted line).		

A free area of 60 cm must be given each side of the steam sterilizer or must be achievable by moving the steam sterilizer to facilitate maintenance.

Safeguarding in accordance with EN 1717

The connection of the device to the water line is comparable with the connection of a washing machine in a domestic context. In general, the connection of consumers to the drinking water supply should be performed in accordance with EN 1717, so that the drinking water supply is protected against contamination through the possible flow back of the water. The device has been developed in accordance with all the requirements of EN 1717 and is equipped with an air gap in accordance with fluid category 5. This obviates the need for additional protection from a safety combination consisting of a back-flow preventer and a pipe aerator. If a safety combination is already present, the drinking water supply is subject to double protection; this need not be removed. If the device is supplied with feed water via the MELAdem 56/ MELAdem 56 M reverse osmosis unit, EN 1717 has been fulfilled, even in the absence of a building safety system. The drinking water supply is protected, as the water treatment unit is supplied with water via the air gap integrated in the device. If the device is supplied with feed water via a domestic network, the water treatment unit requires protection via a protection unit in accordance with EN 1717, fluid category 5. Comply with your national regulations.

Checking the rotating field direction of the CEE socket

NOTICE

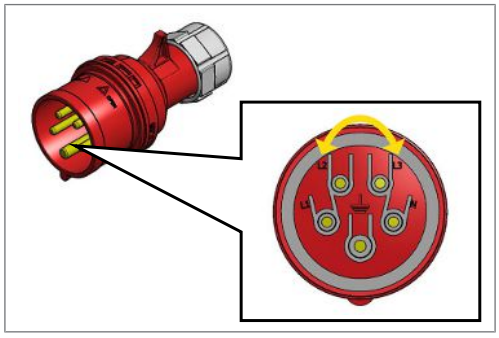
An incorrect rotating field can result in preservatives entering the device from the pump.

An opposite rotating field can cause malfunctions and damage to the device and practice fittings.

- Never connect the device to the power supply without first having checked the rotating field direction of the power supply. The device has been conceived exclusively for a clockwise rotating field.

1. Check the direction of rotation of the high-voltage current socket using a rotating field tester. The mains socket must have a clockwise rotating field. If this is not the case, commission a qualified electrician to change the rotating field on the high-voltage current socket.

2. If it is not possible to adapt it to the electric socket, commission a qualified electrician to switch phases L2 and L3 in the high-voltage current plug (figure: example Cliniclave 45 star connection 16 A).



System and network safety

The device is fitted with multiple external interfaces. Comply with the following information pertaining to the use of these interfaces to ensure safe operation of the device, especially to ensure incorporation in the local network (LAN).

Interfaces and connections

NOTICE

Only connect the hardware to the device which is listed in the following table. Only use the software which has been intended for the purpose and approved by the manufacturer.

Interface	Type	Hardware	Purpose/software
CF card slot	CF type I	MELAflash CF card up to 4 GB with an FAT16 or FAT32 file system	Writing log data on a MELAflash CF card
		MELAflash CF card up to 4 GB with a FAT16 file system	Device software update
Ethernet	Ethernet IEEE 802.3	Switch port (via CAT-5 patch cable)	MELAview saving log data, querying device data
			MELAtrace saving log data
			FTP server saving log data
			MELAconnect (mobile app) querying device data
			Connection to the local network (LAN)
		MELAprint 60 (via CAT-5 patch cable)	Label print
		MELAprint 42/44 (via CAT-5 patch cable with network adapter)	Log printing

NOTICE

When performing a device software update, use only the update data authorized by MELAG for the corresponding device type.

Operating the device with memory media

To prevent data loss, only use memory media to save the log data with the following characteristics:

- Functional capability (without malware etc.)
- Writeable
- Formatted with a correct file system

Perform regular data backup. Restrict access to the device and systems with access authorization to the necessary circle of persons.

Operating the device in the local network (LAN)

NOTICE

Do not connect the device to a public network (e.g. the internet).

An Ethernet/IP-based network connection (LAN) is required to operate the device in a local network. In its delivery state, the device is configured to obtain the IP address automatically from a DHCP server operated in a LAN.

NOTICE

Check the IP address carefully during the conversion for a manual configuration before connecting the device to the LAN.

An incorrectly-entered IP address can cause IP conflicts in the network and thus disturb another device in your network.

In the LAN with a firewall, only permit connections to and from the device which correspond to the intended use of the device. All ports not used are blocked on the device side.

The device is able to make the following connections as standard:

Log	Port source	Port destination	Direction	Purpose
TCP	≥ 1025	21	Outgoing	FTP control
TCP	Any	≥ 1025	Listening / incoming	FTP (active) data transfer (device set to FTP logging)
UDP	68	67	Outgoing	Communication to DHCP server - requests to the DHCP server
UDP	67	68	Listening / incoming	Answers from DHCP server(s)
TCP	Any	80	Listening	Data transfer to the MELAconnect app or web browser
TCP	Any	65001	Listening / incoming	Data transfer log data (device set to TCP logging)
UDP	17784	17784	Outgoing	Broadcast search log printer
TCP	50001	50000	Outgoing	Data transfer to log printer
UDP	42380	3000	Outgoing	Broadcast search label printer
TCP	52382 - 53382	9100	Outgoing	Data transfer to label printer

Network bandwidth / Quality of Service (QoS)

The device does not place any requirements on the LAN bandwidth for data transfer, that exceed the standard time-out times of the respective logs.

Process	Volume max.	Volume normal
Transfer status, legend, program, malfunction log	10 kB	2-6 kB
System log	64 kB	--
Graphic log	800 kB	580 kB
Data transfer MELAconnect	240 bit/s per device	c. 200 bit/s per device
Data transfer, web interface (browser)	12 kbits/s per connection	--

3 Setup and installation

WARNING

Improper installation may lead to a short-circuit, fire, water damage or electrical shock.

This could result in serious injury.

- Only have the device set up, installed and commissioned by people authorised by MELAG.

Dispatch / delivery

CAUTION

Danger of back injury and crushing from lifting excess loads.

- MELAG recommends carrying the device with at least six people.

Depending on the transport route and method, the device and the floor unit will be delivered either screwed together or separately.

Method 1: Complete dispatch

The device is delivered on the floor unit as a single package. Comply with the separate instructions when removing the transport packaging “Unpacking the complete dispatch package” (doc. AS_015-17).

Method 2: Separate delivery of device and floor unit

NOTICE

After having removed the packing hull, do not to contribute the device directly on the floor; this could damage the hose connections and components on the underside of device.

Transport the device and floor unit on the shipping pallet as close as possible to the installation location. Only then place the two components on top of each other using the transport bars provided.

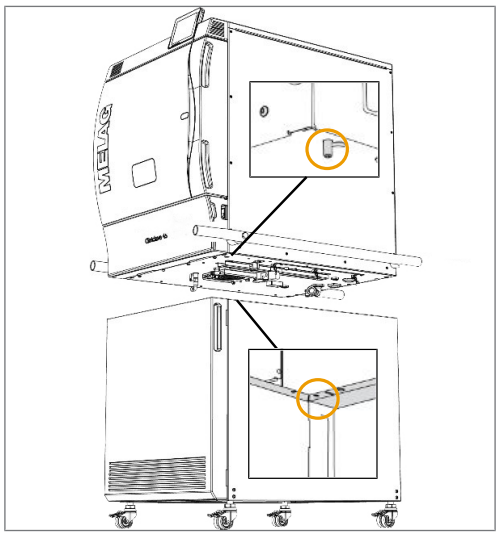
Removal from the packaging

This section indicates how to proceed when the floor unit and steam sterilizer have been dispatched separately. If the steam sterilizer is delivered screwed to the floor unit, begin with step 8.

Cliniclave 45

1. Remove the packaging from the steam sterilizer and floor unit. Leave the steam sterilizer to stand on the shipping pallet.
2. If possible, set up the floor unit directly at the installation location.
3. Unscrew the four plastic screws from the front and back of the side walls of the steam sterilizer.
4. Fit the two transport bars on the left and right-hand side of the steam sterilizer each with 4 hexagonal screws and 4 spacers. Tighten the screws fully.
5. Lift the steam sterilizer from the shipping pallet onto the floor unit so that the device door and the floor unit door face to the same side.

6. Ensure that the four pins on the underside of the steam sterilizer (marking) are guided into slots on the floor unit. The power cable and the inlet hose must be led into the floor unit and may not become jammed. Align the steam sterilizer with the floor unit so that the housing parts are flush along the side (use the transport bars). The plastic fronts of the floor unit and the steam sterilizer must also be aligned.



7. Working from below in the floor unit, tighten the nuts with toothed lock washers (included in the scope of delivery) to the pins, in order to screw the floor unit and steam sterilizer together.

8. **With separate delivery of steam sterilizer and floor unit:**
   Remove the transport bars and retain them for later use.
   With a complete dispatch:
   Unpack the device in accordance with the separate set of instructions “Unpacking the complete dispatch package” (doc. AS_015-17).
   Remove the carrying handles and retain them for later use.

9. Screw the four plastic screws in the location on which the transport bars or carrying handless were previously screwed in.

10. Connect the display, see Connecting the display [▸ page 18].

NOTICE

The housing screws can loose while transporting.

Tighten all housing screws.

Cliniclave 45 M

1. Remove the packaging from the steam sterilizer and floor unit.

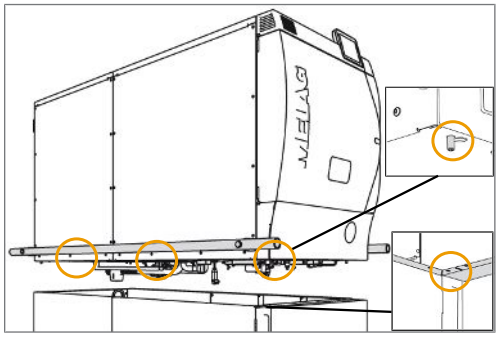
2. If possible, set up the floor unit directly at the installation location.

3. Unscrew the four plastic screws from the front and back of the side walls of the steam sterilizer. Do not remove the plastic screws in the centre of the device.

4. Fit the two transport bars left and right of the steam sterilizer with four hexagonal screws and spacers. Tighten the screws fully.

5. Working with a minimum of six people, lift the steam sterilizer from the shipping pallet onto the floor unit so that the device door and the floor unit door face to the same side.

6. Ensure that the six pins on the underside of the steam sterilizer (marking) are guided into slots on the floor unit. The power cable and the inlet hose must be led into the floor unit and may not become jammed. Align the steam sterilizer with the floor unit so that the housing parts are flush along the side (use the transport bars). The plastic fronts of the floor unit and the steam sterilizer must also be aligned.



7. Working from below in the floor unit, tighten the nuts with toothed lock washers (included in the scope of delivery) to the pins, in order to screw the floor unit and steam sterilizer together.

8. **With separate delivery of steam sterilizer and floor unit:**
   Remove the transport bars and retain them for later use.
   With a complete dispatch:
   Unpack the device in accordance with the separate set of instructions “Unpacking the complete dispatch package” (doc. AS_015-17).
   Remove the carrying handles and retain them for later use.

9. Screw the four plastic screws in the location on which the transport bars or carrying handless were previously screwed in.

10. Connect the display, see Connecting the display [▸ page 18].

NOTICE

The housing screws can loose while transporting.

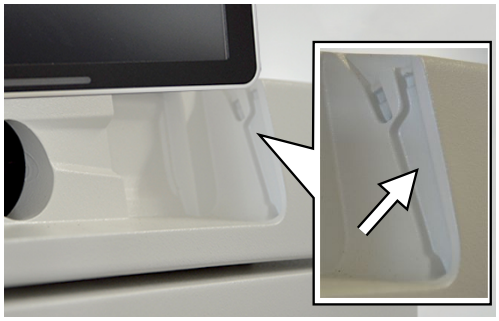
Tighten all housing screws.

Connecting the display

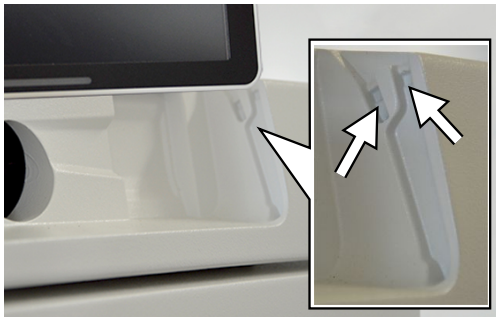
1. Remove the display from the service hatch and remove the packaging.

2. Connect the Ethernet cable of the device to the display.

3. Slide the display into the fore long groove at the device.



4. Guide both lateral display locking elements into the same guide groove on the steam sterilizer.



5. Press the display downwards until you feel it engaging. The display can be set at various positions to permit ergonomic working, see Setting the display position [▸ page 38].

Installing Cliniclave 45

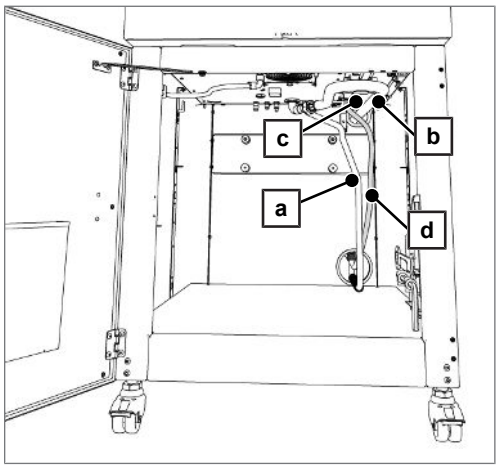
Installing the steam sterilizer

PLEASE NOTE

To prevent water damage, MELAG recommends the use of a leakage water detector e.g. the MELAG water stop.

1. Installing the leakage water detector (optional).

2. Lead the cold water inflow hose with Aqua-Stop (pos. a) through the lower opening in the rear panel of the floor unit to the outside and connect it to the building cold water inflow.



3. Connect the outlet hose (pos. b) to the wastewater fitting on the steam sterilizer using one of the seals included in the scope of delivery. Place it in the tensioning carriage (pos. c) and lead it through the upper opening in the rear panel of the floor unit.

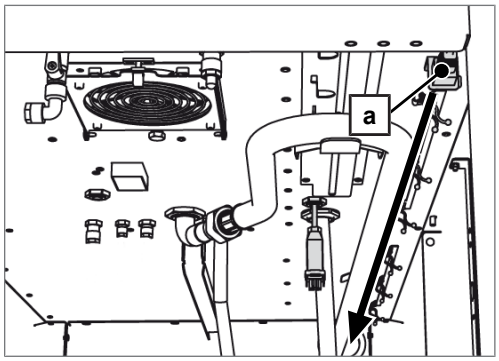
4. Connect the outlet hose to the siphon using the other seal.

5. Lead the power plug (pos. d) through the lower opening in the rear panel of the floor unit. Do not yet plug the power plug into the mains socket.

Connecting the network cable (optional)

The network cable can be connected to a computer (in the practice network) or to the label printer.

1. Connect the network cable on the underside of the device to the network socket (pos. a). Guide the network cable in the floor unit over the cable clips.



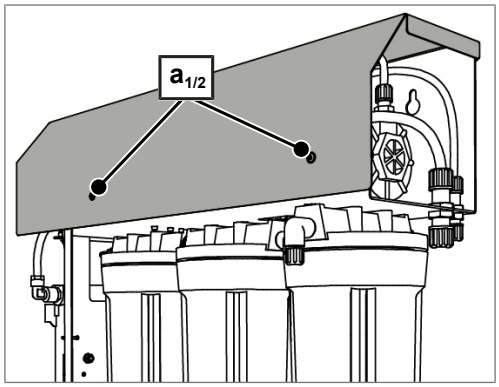
2. Lead the power cable through the upper opening in the rear panel of the floor unit to the outside.

3. Connect the network cable to the network socket/ the label printer (optional).

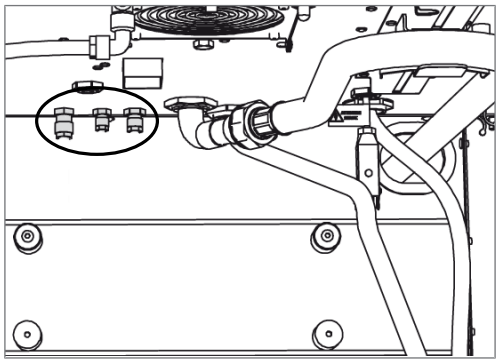
Installing the MELAdem 56 (optional)

Proceed as follows to connect the reverse osmosis unit and prepare flushing:

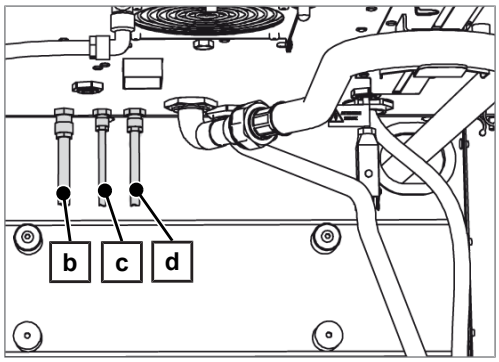
1. Loosen the screws (TX20) (pos. $a_{1/2}$) on the cover of the osmosis module and pull the cover upwards. Proceed with caution.



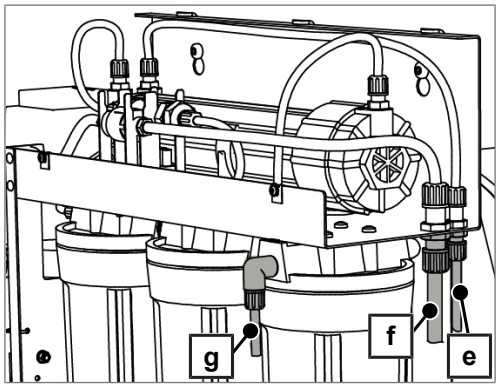
2. Work carefully to remove the closure caps from the hose connections on the underside of the steam sterilizer. To do so, disconnect the union nuts. Store the sealing caps carefully. They could be required for transport or decommissioning.



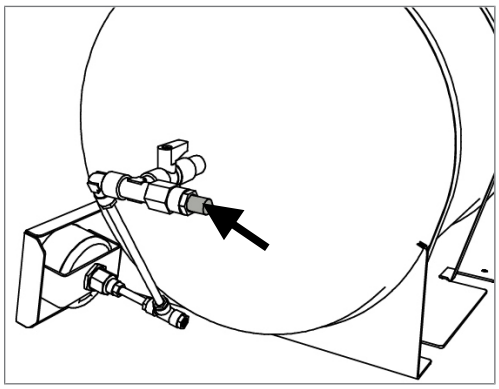
3. Connect the feed water hose (pos. b), the outlet hose (pos. c) and the inlet hose (pos. d) to the floor trough connections of the steam sterilizer; see Installation material [▸ page 5] for the hose diameter and lengths.



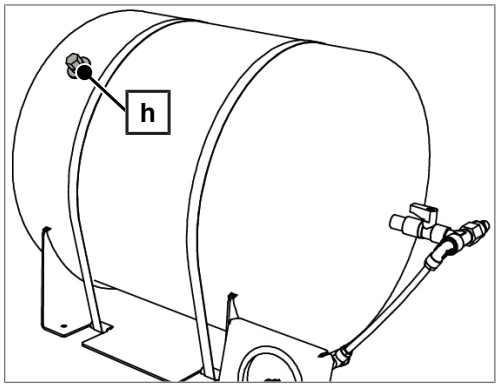
4. Remove the closure caps from the reverse osmosis unit connections. Connect the outlet hose (pos. e), the inflow hose (pos. f) and the permeate line (pos. g) with the corresponding connections of the reverse osmosis unit.



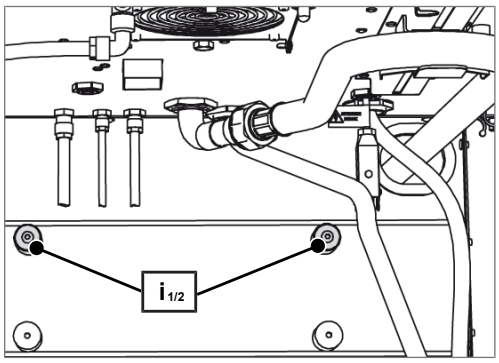
5. Do **not** yet remove the sealing cap on the feed water connection of the pressure tank (upper-most T-piece).



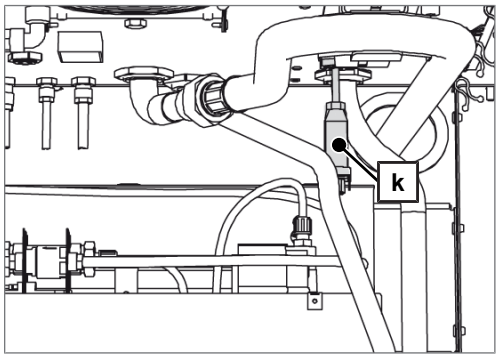
6. Open the valve (pos. h) on the pressure tank and measure the primary pressure using the manometer included in the scope of delivery. The target pressure is 0.6 bar. Should the primary pressure of an empty pressure tank exceed this value, reduce the pressure by pressing in the valve tappet. Given insufficient pressure, increase this pressure using e. g. a car foot pump.



7. Hang the reverse osmosis unit on the screws of the spacer (pos. $i_{1/2}$) on the rear wall in the floor unit. Ensure that the inflow hose and the power cable do not become jammed behind the reverse osmosis unit.



8. Connect the power plug of the reverse osmosis unit to the cable socket (pos. k) on the underside of the steam sterilizer.

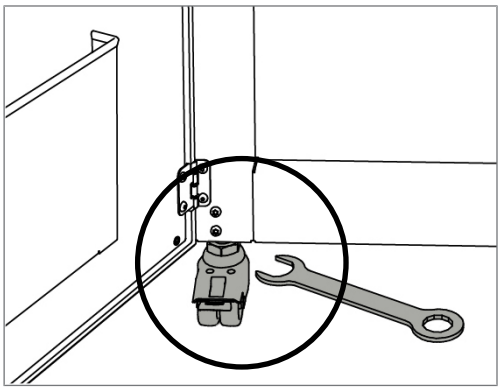


9. The reverse osmosis unit is flushed during the Test runs [▸ page 23].

Aligning the device

To align the device, it must be located in its final installation location. Align the device using a spirit level so that it is plumb on all sides. To this end, place the spirit level on the top of the unit cover (1x fore - 1x rear - 1x right and 1x left).

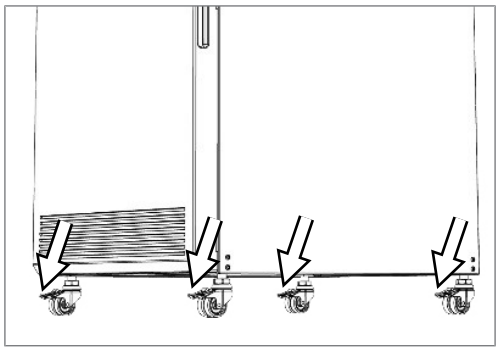
The casters can be screwed out up to 20 mm to compensate for an uneven floor, using the open-end wrench included in the scope of delivery. The casters are delivered completely screwed in. If the device is to be aligned before being slid into its final position, the alignment must be re-checked once in its final position. Then apply the brakes on the casters.



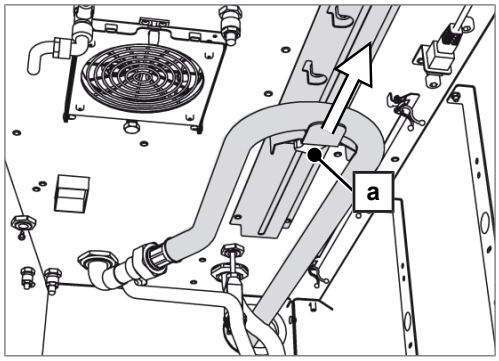
Tensioning the outlet hose

The outlet hose must be free of kinks and sagging to ensure malfunction-free operation of the device. To this end, a tensioning carriage is fitted on the underside of the device. Depending on the clearance between the outlet hose and the siphon, tension the hose as follows:

1. Check that the brakes on the casters have been applied.



2. Release the star knob (pos. a) on the tensioning carriage.



3. Place the outlet hose in the tensioning carriage if this has not already been performed.
4. Pull the tensioning carriage so far forward that the outlet hose is tensioned slightly.
5. Tighten the star knob (pos. a).

6. Check that the outlet hose is installed without sagging and for the stability of the siphon behind the device.

Test runs

In order to reduce the installation time and ensure quicker commissioning of the device, a separate container with feed water of sufficient quality (Cliniclave 45: min. 13 l; Cliniclave 45 M: min. 20 l) in accordance with EN 285, Appendix B, Table B.1 is required, see Feed water quality [▸ page 45].

If a container is not present, follow the installation instructions contained in the user manual MELAdem 56/56 M. The following section describes the time-saving version of commissioning the device with the reverse osmosis unit.

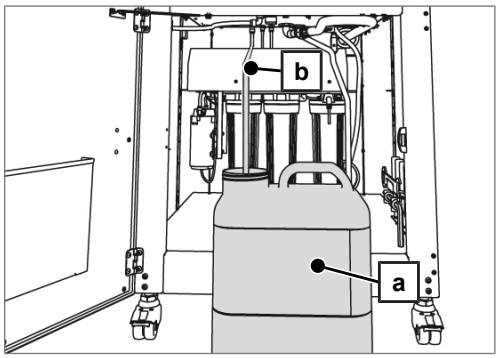
Vacuum test and rinsing the reverse osmosis unit

PLEASE NOTE

The reverse osmosis unit must not need to be removed from the rear panel in the floor unit for this procedure.

A) Preparations

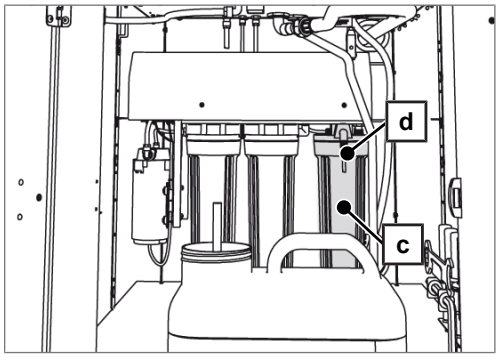
1. Fill fresh feed water of the corresponding quality into a container with a min. volume of 13 l (pos. a). Place the container in front of the floor unit. Lead the free end of the feed water hose (pos. b) into the container.



PLEASE NOTE

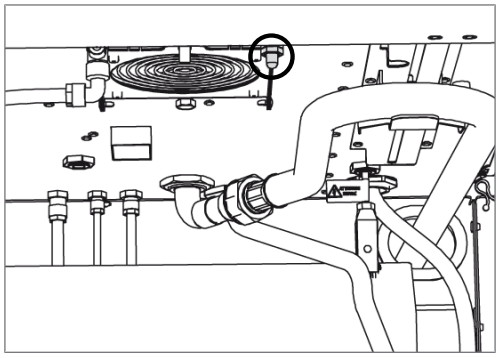
The feed water hose must reach to the floor of the container so that the water is pumped in even when the water level falls.

2. Unscrew the filter container of the ion exchanger (pos. c) using the container key (included in the scope of delivery of the reverse osmosis unit). Remove the mixed-bed resin cartridge. Screw the empty filter container into the housing of the water treatment unit. Hold the free end of the permeate line (pos. d) in a 5 l container or similar.



B) Checking the direction of rotation of the vacuum pump

1. Open the cold water inflow.
2. Connect the power plug and activate the device. The vacuum pump will run for a short while after activation.
3. Directly during activation, check whether the silicone cap (marking) on the de-calcification connection contracts, i.e. suction. This indicates a correct direction of rotation.



   ➥ If the silicone cap does not contract, switch off the device immediately and perform a repeated phase sequence check test, see Checking the rotating field direction of the CEE socket [▸ page 12].

C) Starting a vacuum test and flushing the reverse osmosis unit

1. After activation, working in menu **`Settings`** > **`Device settings`** > **`Water supply`**, select **`NO`** and save the setting. The steam generator will begin to fill. At the same time, check whether the feed hose in the container is immersed far enough in the water. **NOTICE! Do not permit it to suck in air.**
2. Start the vacuum test with empty, cold sterilization chamber.

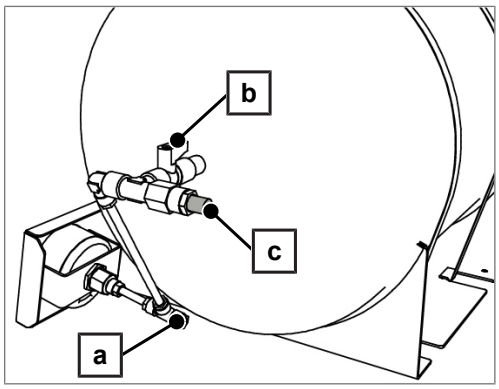
   ➥ At the same time, the reverse osmosis unit is flushed, freeing it of preservatives and dust residue. The process lasts approx. 20 minutes.
3. Use this time to begin with the instruction of the operators. The vacuum test must be successful (a leakage rate of 0-0.4 mbar/min).

D) Ending the rinsing process

1. Following a successful vacuum test, select menu **`Diagnosis & Service`**.

   ➥ The rinsing process is finished.
2. Remove the ion exchanger filter container. **PLEASE NOTE:** The filter container is full to the brim with water. Pour off the water in the filter container.
3. Reinsert the mixed-bed resin cartidge. Ensure that the flat seal of the mixed-bed resin cartridge points upwards, see user manual MELAdem 56/56 M.
4. Screw the ion exchanger filter container back on. Tighten the filter container lightly using the container key.

5. Connect the free end of the permeate line to the lower T-piece of the pressure tank (pos. a). Open the pressure tank shut-off valve (pos. b). The feed water connection (pos. c) on the upper T-piece of the pressure tank remains closed.



6. Place the pressure tank in the floor unit.
7. Leave menu Diagnosis & Service.

   ↪ The feed water supply will begin and the pressure in the pressure tank increases. The pressure increase can be followed on the pressure tank manometer.

Bowie & Dick test and instruction

1. Place the Bowie & Dick test package (included in the scope of delivery) in the device and start the program Bowie & Dick test.
2. Start with or continue the instruction of the user.

Documenting the test runs

1. Document the results of the vacuum test and the Bowie & Dick test on the record of installation and setup.
2. Print the sterilization logs if possible, and attach to the record of installation and setup.
3. Continue with the chapter Operational readiness [▸ page 34].

Installing Cliniclave 45 M

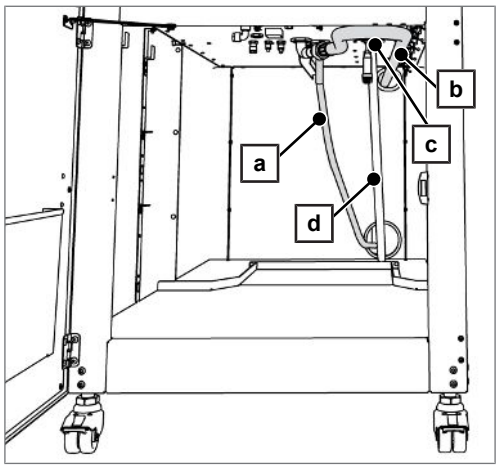
Installing the steam sterilizer

PLEASE NOTE

To prevent water damage, MELAG recommends the use of a leakage water detector e.g. the MELAG water stop.

1. Install the leakage water detector (optional).

2. Lead the cold water inflow hose with Aqua-Stop (pos. a) through the lower opening in the rear panel of the floor unit to the outside and connect it to the building-side cold water inflow.



3. Connect the outlet hose (pos. b) to the wastewater fitting on the steam sterilizer using one of the seals included in the scope of delivery. Place the outlet hose in the tensioning carriage (pos. c) and lead it through the upper opening in the rear panel of the floor unit.

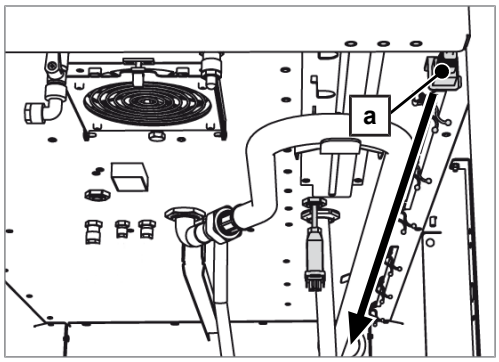
4. Connect the outlet hose to the siphon using the other seal.

5. Lead the power plug (pos. d) through the lower opening in the rear panel of the floor unit. Do not yet plug the power plug into the mains socket.

Connecting the network cable (optional)

The network cable can be connected to a computer (in the practice network) or to the label printer.

1. Connect the network cable on the underside of the device to the network socket (pos. a). Guide the network cable in the floor unit over the cable clips.



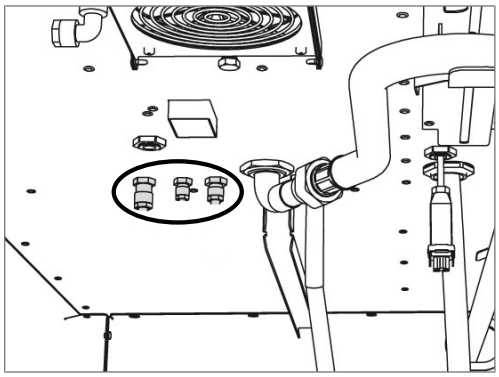
2. Lead the power cable through the upper opening in the rear panel of the floor unit to the outside.

3. Connect the network cable to the network socket/ the label printer (optional).

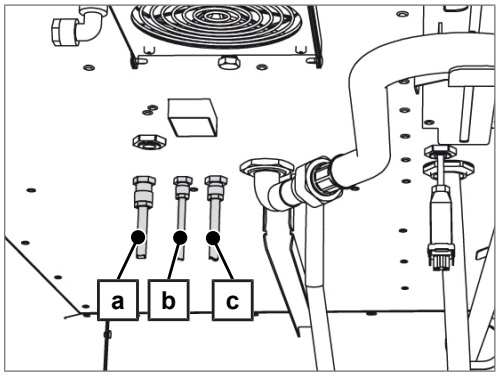
Installing the MELAdem 56 M (optional)

Proceed as follows to connect the reverse osmosis unit and prepare flushing:

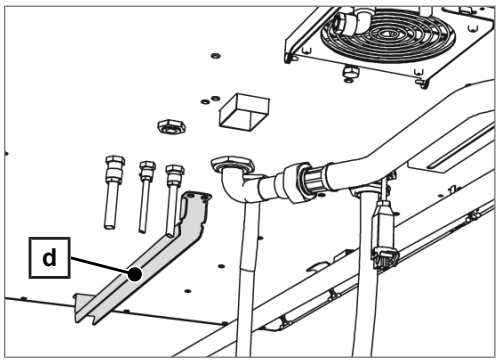
1. Remove the closure caps from the hose connections on the floor trough of the steam sterilizer. To do so, disconnect the union nuts. Store the sealing caps carefully. They could be required for transport or decommissioning.



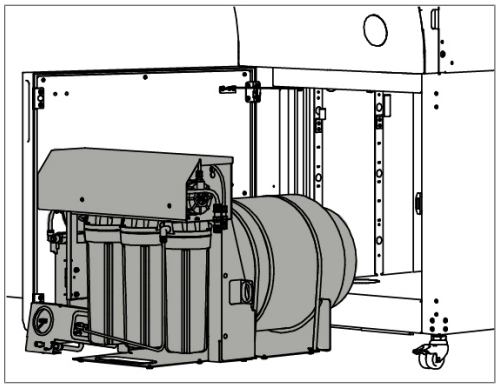
2. Connect the feed water hose (pos. a), the outlet hose (pos. b) and the inlet hose (pos. c) onto the floor trough connections of the steam sterilizer.



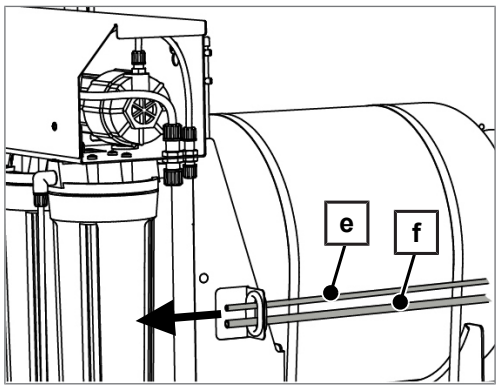
3. Place the outlet hose and inlet hose of the MELAdem 56 M from left to right over the bracket clip (pos. d) in the rear area of the floor unit.



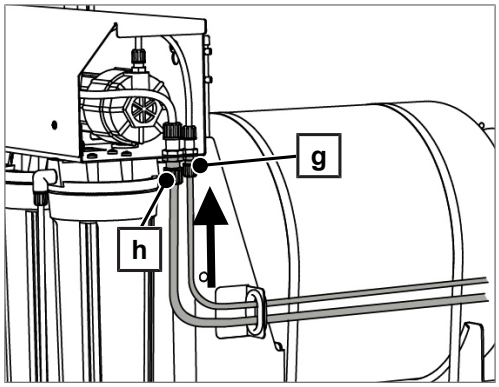
4. Place the reverse osmosis unit in front of the floor unit.



5. Lead the outlet hose (pos. e) and the inlet hose (pos. f) through the conduit on the right-hand side of the osmosis unit.



6. Remove the sealing caps on the hose connections of the reverse osmosis unit and connect the outlet hose (pos. g) and the inlet hose (pos. h) with the corresponding connections of the reverse osmosis unit.

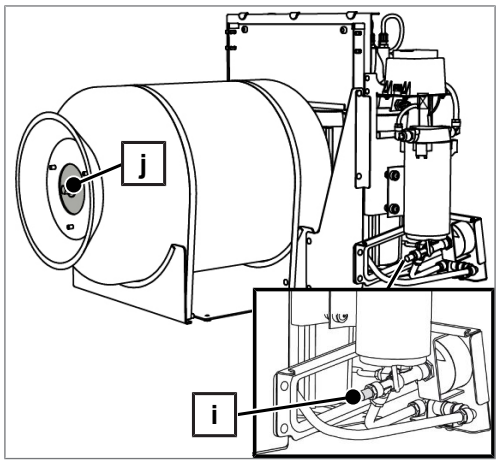


7. Lead the feed water hose out of the floor unit to the left.

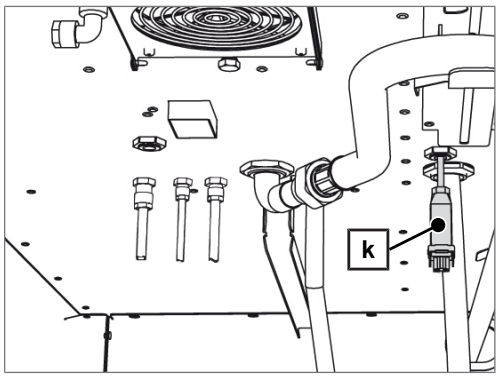
PLEASE NOTE

Do not yet remove the sealing cap on the feed water connection of the pressure tank (pos. i) on the rear panel of the manometer.

8. Open the valve (pos. j) on the pressure tank and measure the primary pressure with the manometer included in the scope of delivery. The target pressure is 0.6 bar. Should the primary pressure exceed these values when the pressure tank is empty, reduce the pressure by pressing in the valve tappet. Given insufficient pressure, increase this pressure using e. g. a car foot pump.



9. Connect the power plug of the reverse osmosis unit to the cable socket (pos. k) on the underside of the steam sterilizer.

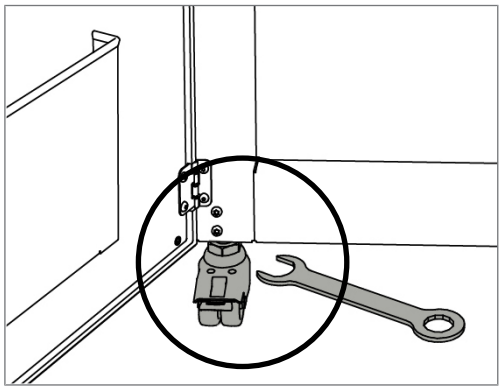


10. Slide the reverse osmosis unit into the floor unit.
11. The reverse osmosis unit is flushed during the Test runs [▸ page 30].

Aligning the device

To align the device, it must be located in its final installation location. Align the device using a spirit level so that it is plumb on all sides. To this end, place the spirit level on the top of the unit cover (1x fore - 1x rear - 1x right and 1x left).

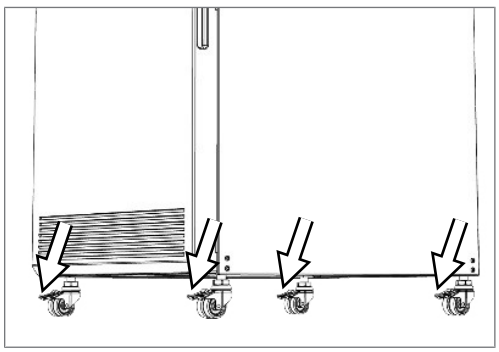
The casters can be screwed out up to 20 mm to compensate for an uneven floor, using the open-end wrench included in the scope of delivery. The casters are delivered completely screwed in. If the device is to be aligned before being slid into its final position, the alignment must be re-checked once in its final position. Then apply the brakes on the casters.



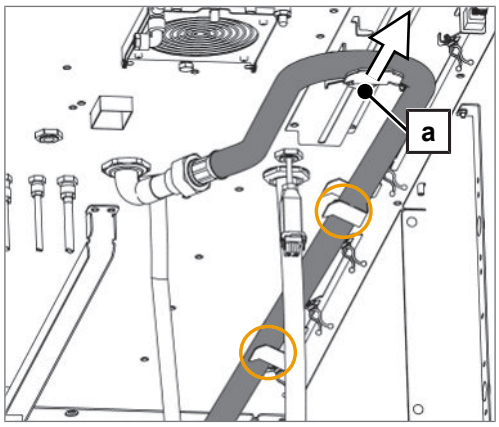
Tensioning the outlet hose

The outlet hose must be free of kinks and sagging to ensure malfunction-free operation of the device. To this end, a tensioning carriage is fitted on the underside of the device. Depending on the clearance between the outlet hose and the siphon, tighten the hose as follows:

1. Check that the brakes on the casters have been engaged.



2. Release the star knob (pos. a) on the tensioning carriage.



3. Install the outlet hose in the two holding plates (marking).
4. Place the outlet hose in the tensioning carriage if this has not already been performed.
5. Pull the tensioning carriage so far forward that the outlet hose is tensioned slightly.
6. Turn the star knob (pos. a) tight.
7. Check that the outlet hose is installed without sagging and for the stability of the siphon behind the device.

Test runs

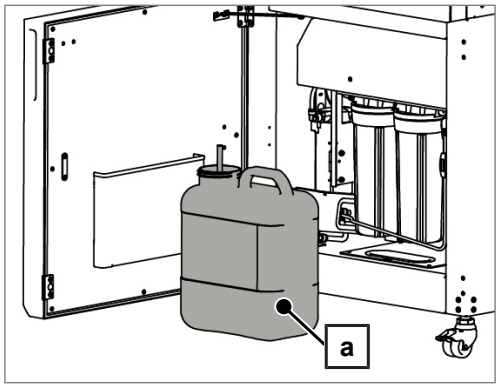
In order to reduce the installation time and ensure quicker commissioning of the device, a separate container with feed water of sufficient quality (Cliniclave 45: min. 13 l; Cliniclave 45 M: min. 20 l) in accordance with EN 285, Appendix B, Table B.1 is required, see Feed water quality [▸ page 45].

If a container is not present, follow the installation instructions contained in the user manual MELAdem 56/56 M. The following section describes the time-saving version of commissioning the device with the reverse osmosis unit.

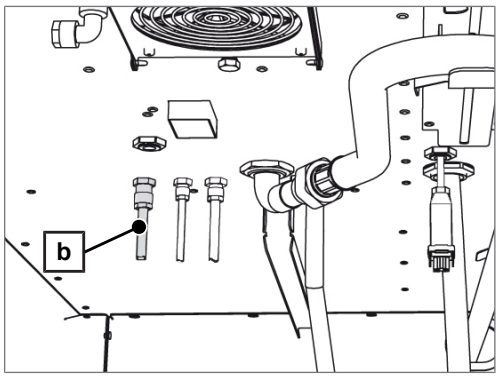
Vacuum test and rinsing the reverse osmosis unit

A) Preparations

1. Fill a container with a volume of min. 20 l (pos. a) with feed water of sufficient quality and place the container in front of the floor unit.



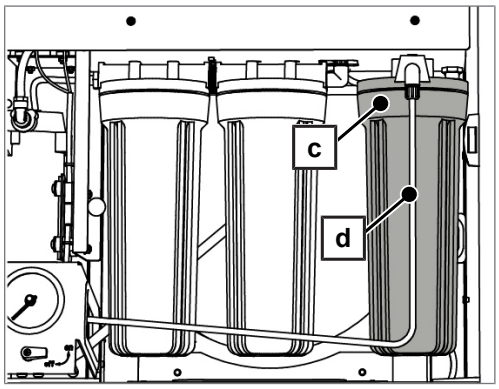
2. Lead the free end of the feed water hose (pos. b) into the container.



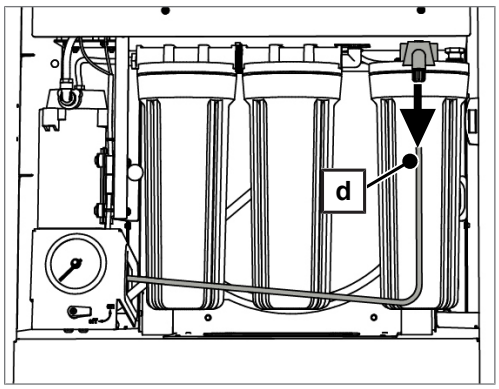
PLEASE NOTE

The feed water hose must reach to the floor of the container so that the water is pumped in even when the water level falls.

3. Unscrew the filter container of the ion exchanger (pos. c) using the container key (included in the scope of delivery of the reverse osmosis unit). Remove the mixed-bed resin cartridge. Screw the empty filter container into the housing of the water treatment unit.



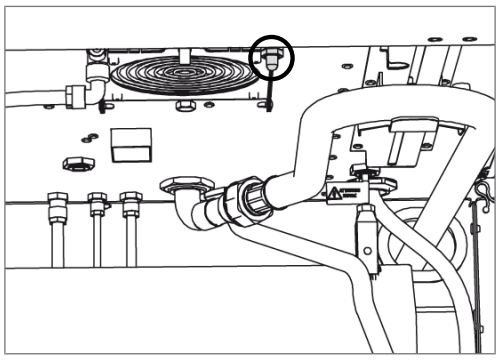
4. Remove the permeate line (pos. d) from the filter container and place a 5 l container or similar under the hose connection of filter container.



B) Checking the direction of rotation of the vacuum pump

1. Connect the power plug and activate the device. The vacuum pump will run for a short while after activation.

2. Directly during activation, check whether the silicone cap (marking) on the de-calcification connection contracts, i. e. suction. This indicates a correct direction of rotation.



➥ If the silicone cap does not contract, switch off the device immediately and check the rotating field of the practice socket or the wiring of the phases, see Checking the rotating field direction of the CEE socket [▸ page 12].

C) Starting a vacuum test and flushing the reverse osmosis unit

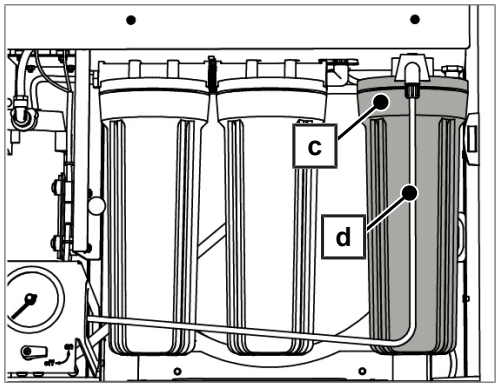
1. After activation, working in menu **`Settings`** > **`Device settings`** > **`Water supply`**, select NO and save the setting. The steam generator will begin to fill. At the same time, check whether the hose in the container is immersed far enough in the water. **NOTICE! Do not permit it to suck in air.**
2. Start the vacuum test with empty, cold sterilization chamber.

   ➥ At the same time, the osmosis unit is flushed, freeing it of preservatives and dust residue. The process lasts approx. 20 minutes.
3. Use this time to begin with the instruction of the operators. The vacuum test must be successful (a leakage rate of 0-0.4 mbar/min).

D) Ending the rinsing process

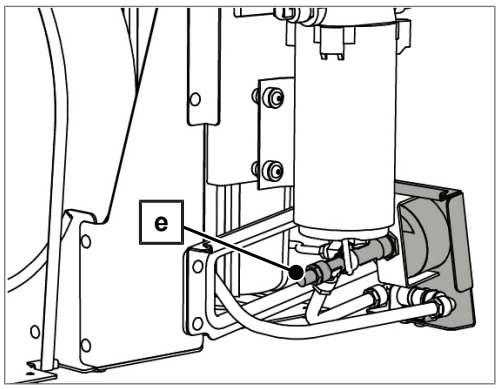
1. Following a successful vacuum test, select menu **`Diagnosis & Service`**.

   ➥ The rinsing process is finished.
2. Unscrew and remove the ion exchanger filter container (pos. c). **PLEASE NOTE:** The filter container is full to the brim with water. Pour off the water in the filter housing.



3. Reinsert the mixed-bed resin cartidge. Ensure that the flat seal of the mixed-bed resin cartridge points upwards, see user manual MELAdem 56/56 M.
4. Screw the ion exchanger filter container back on. Tighten the filter container lightly using the container key.

5. Connect the free end of the permeate line (pos. D) to the ion exchanger filter container. Open the pressure tank shut-off valve. The feed water connection (pos. E) at the rear of the manometer on the pressure tank remains closed.



6. Leave menu **`Diagnosis & Service`**.

➥ The feed water supply will begin and the pressure in the pressure tank increases. The pressure increase can be followed on the pressure tank manometer.

Bowie & Dick test and instruction

1. Place the Bowie & Dick test package (included in the scope of delivery) in the device and start the program Bowie & Dick test.
2. Start with or continue the instruction of the user.

Documenting the test runs

1. Document the results of the vacuum test and the Bowie & Dick test on the record of installation and setup.
2. Print the sterilization logs if possible, and attach to the record of installation and setup.
3. Continue with the chapter Operational readiness [▸ page 34].

4 Operational readiness

Determining the delivery capacity and the conductivity of the reverse osmosis unit

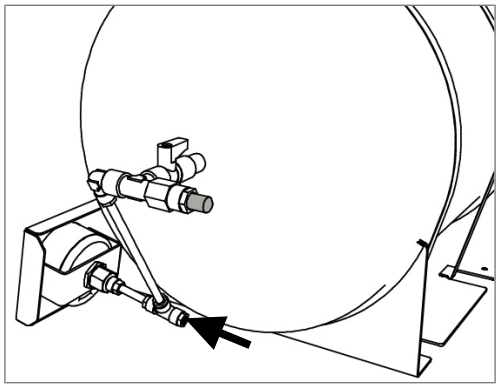
Proceed as follows to determine the delivery capacity of the reverse osmosis unit:

1. Select menu Diagnosis & Service.

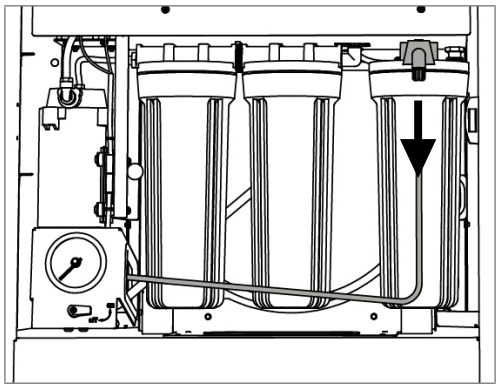
   ➥ The reverse osmosis unit does not function in this state.

2. Close the pressure tank shut-off valve.

3. **MELAdem 56**: Disconnect the permeate line from the lower T-piece of the pressure tank (arrow marking) and hold the hose in a measuring beaker with a minimum volume of 0.5 l.



4. **MELAdem 56 M**: Remove the permeate line from the filter housing of the ion exchanger (arrow marking) and place a measuring beaker with a minimum capacity of 0.5 l under the connection of the ion exchanger.



5. Leave menu Diagnosis & Service to start pumping the water into the measuring beaker.
6. Run water in the measuring cup for 2 min. Check the amount of feed water being pumped. This must amount to min. 260 ml.
7. Enter the value in the record of installation and setup.
8. **MELAdem 56**: Select menu **`Diagnosis & Service`** again, and connect the permeate line to the pressure tank.
9. **MELAdem 56 M**: Select menu **`Diagnosis & Service`** again, and connect the permeate line to the filter housing.
10. Open the pressure tank shut-off valve.

11. Leave menu **`Diagnosis & Service`**.

    ↪ The pump in the reverse osmosis unit starts and the pressure tank is refilled.

12. Check the conductivity of the water in the measuring cup with a conductivity meter (e.g. MELAG Conductivity meter). The conductivity should not exceed 5 µS/cm.

Operational readiness

When using the MELAG water treatment unit

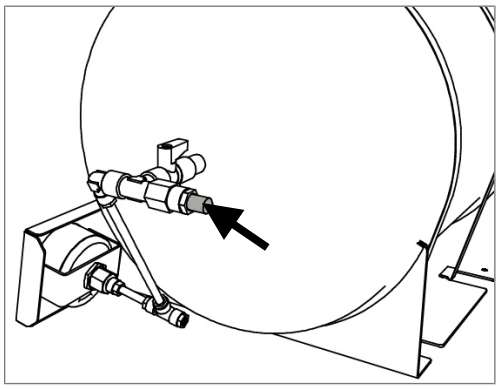
From a pressure of 1.5 bar in the pressure tank, you can convert the feed water supply to the reverse osmosis unit by proceeding as follows:

1. Select menu Diagnosis & Service.

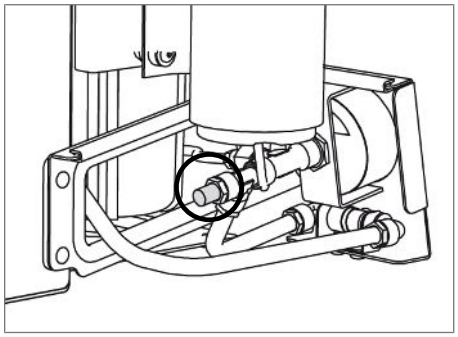
   ↪ The water supply in the reverse osmosis unit ends.

2. Close the pressure tank shut-off valve.

3. **MELAdem 56**: Remove the sealing cap from the feed water connection on the upper T-piece of the pressure tank. Store this cover cap carefully.



4. **MELAdem 56 M**: Remove the sealing cap of the feed water connection on the rear of the pressure tank manometer and connect the feed water hose. Store this cover cap carefully.



5. Open the pressure tank shut-off valve.

6. Working in menu **`Settings`** > **`Device settings`** > **`Water supply`** set the feed water supply to YES.

7. Save the settings and leave the menu.

8. **MELAdem 56**: Check all lines and connections of the reverse osmosis unit for leaks; then refit the cover of the osmosis unit and replace the reverse osmosis unit cover. Ensure that no hoses become jammed or kinked.

9. **MELAdem 56 M**: Check all lines and connections of the reverse osmosis unit for leaks; then slide the reverse osmosis unit into the floor unit. Ensure that no hoses become jammed or kinked.
10. Do not switch off the device, so that the pressure in the tank can rise to a minimum of 2 bar.

When using a central water treatment unit

For more information on connecting, see the separate set of instructions “Connecting an external feed water supply” (doc. IA_001-14). IA_001-14).

Checking the pressure of the reverse osmosis unit

Check the pressure in the pressure tank on the manometer. Record the pressure in the record of installation and setup.

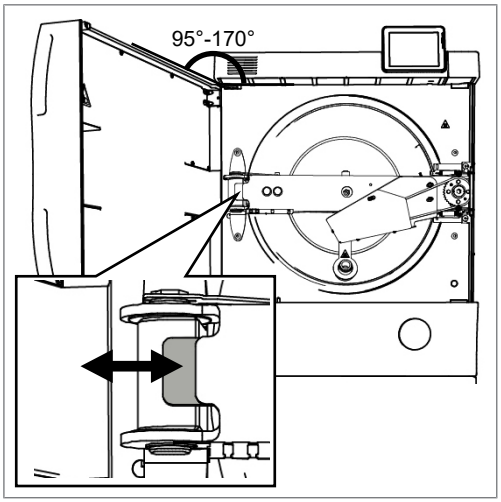
Instructing the user

- Explain all the user-typical features for the documentation and setting combinations for the operator after section Settings and adjustment [▸ page 37].
- Advise users to check the pressure on the manometer before switching off the device. In daily operation, the operating pressure should amount to a minimum of 2 bar. If the pressure is < 2 bar, MELAG recommends leaving the device switched on until 2.5 bar is reached. This avoids unnecessary waiting times, warnings and any program aborts.
- Hand over the user manual and technical manual, the manufacturer's inspection report and the warranty certificate. The declarations of conformity regarding the Pressure Equipment Directive and the Medical Devices Act are included in the manufacturer's inspection report.

5 Settings and adjustment

Setting the door hinge

The opening angle of the door in its delivery state is approx. 95°. This can be set to any angle up to 170°. Working with a separate set of instructions “Setting the door hinge” (doc. JA_005-13) set the opening angle of both doors to fit the space provision of the practice and the wishes of the operators.



Aligning the door panels

Device door panel

The clearances of the door panels have been set in advance. Nevertheless, the clearances can vary during setup, according to the levelness of the floor at the installation location. Check the clearance of the door panels after aligning the device and align them, if required, in accordance with the separate set of instructions “Setting the clearance - door panel” (doc. JA_009-13):

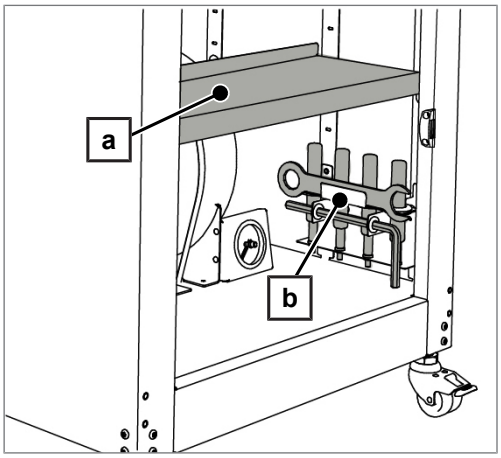
- When in the correct position, the two horizontal clearances above and below the door panel must be the same size and must run parallel.
- The door panel must be laterally flush with the plastic panel above and below the door panel.

Floor unit door panel

If the gap between the floor unit and lower device panel is not parallel, align the door panel in accordance with the separate set of instructions “Setting the clearance - door panel on the floor unit” (doc. JA_010-13).

Inserting the shelf

You can insert the shelf (pos. a) at the desired height. You can install the tool bracket (pos. b) in the mounting intended for this purpose. It can be used to store the carrying handles, the special key (hex for the casters) and the Allen key for opening the door in an emergency.

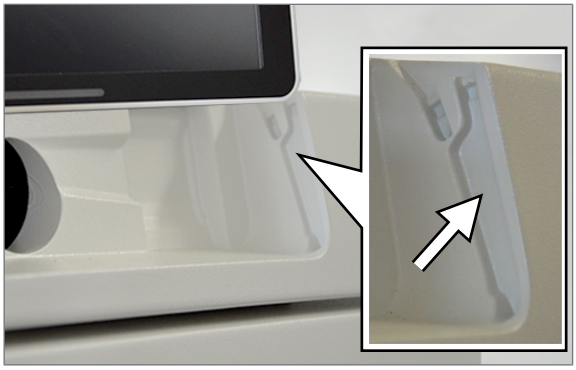


Setting the display position

The display can be set at various positions to permit ergonomic working on the steam sterilizer.

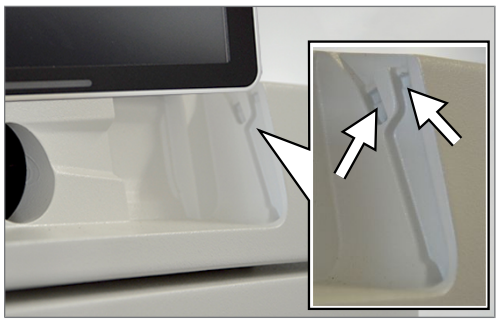
PLEASE NOTE

The lower guide bars remain in the fore long groove (see arrow).



1. Grasp the display left and right and pull it upwards until leaving its locking position.

2. Guide both lateral display locking elements into the same guide groove on the steam sterilizer.



3. Press the display downwards until you feel it engaging.

Settings on the device

Date and time

Check the date and time and set if necessary. Consult the user manual.

Display settings

If required, working in the **`Settings`** menu, adjust the brightness, key tone and the touch-sensitivity.

Contact data of the service partner

Working in the **`Settings`** > **`Service`** menu, enter the name and address of the responsible service partner.

Resetting the maintenance counter

Reset the maintenance counter in accordance with the instructions “Resetting the maintenance counter upon initial commissioning and maintenance” (doc. PW_common).

User administration and logging

Instruct the user in the user administration and possible logging: consult user manual. If you require an admin PIN, enter this and any further settings in the record of installation and setup.

IP addresses

NOTICE

The setting up in the (practice) network will require in-depth understanding of the network technology.

Handling errors of IP addresses can result in malfunctions and data loss in your user network.

- IP addresses may only be set by the (practice) network system administrator.

The device is equipped as standard with IP addresses which all belong to a common network with the subnet mask stated in the following table. These pre-set IP addresses listed in may not yet been assigned in the (practice) network.

Works pre-setting of the device IP addresses

Device	IP address	Remarks
Steam sterilizer	192.168.40.40	Pre-set ex works
computer	192.168.40.140	Pre-set ex works
Log printer	192.168.40.240	Pre-set ex works
Label printer	192.168.40.160	Pre-set ex works
Gateway	192.168.40.244	Not relevant within a network

Device	IP address	Remarks
Subnet mask	255.255.255.0	Possibly to be adopted by customer network

Additional drying and further program modifications

The stages of the steam sterilizer programs (fractionating, heating, sterilizing, pressure release, drying and aeration) and its parameters (pressure, temperature and time) are conform with the usual requirements placed by a practice environment. The **`Additional drying`** function in the **`Settings`** menu provides a standard possibility of influencing the course of the program run. Further alterations to the program run are possible in each individual case and will still ensure the effectiveness of the sterilization, but may only be performed by authorized technicians. Please consult your stockist or MELAG.

System and status log

Output a system and status log and document this on the record of installation and setup.

Counter stands

Working in menu **`Info & Status`**, you can access counter stands and other up-to-date technical data.

6 Frequently Asked Questions (FAQ)

What does the log name mean?

Complete encoding of both the serial number and the total batch number is performed in the 8 digit log name. Manually re-named files are always easy to identify but not to be recommended. A log name is never assigned twice. The log name achieves good log sortability.

Knowledge of the encoding within the name of the log file is not necessary, as a double-click on the file reveals the content and thus serial number and total batch number immediately. This requires assignment of a log file to a text editor.

Example	H	5	0 P 1	0 0 B	.	P R 0
Meaning	**Serial number**			**Total batches**		**File ending**
	Year of construction	Type	Production no.			
Explanation	H...2017 I...2018 J...2019 K...2020	5…45 5...45 M 5...45 D 5...45 MD				Example: .PRO = successfully ended program

Date and time of the log files

The date and time of the log files in Windows explorer are identical with the time of the program start, provided of course that the files were saved on the corresponding medium via immediate output. The information is lost upon subsequent collected issue on a medium or e-mail dispatch.

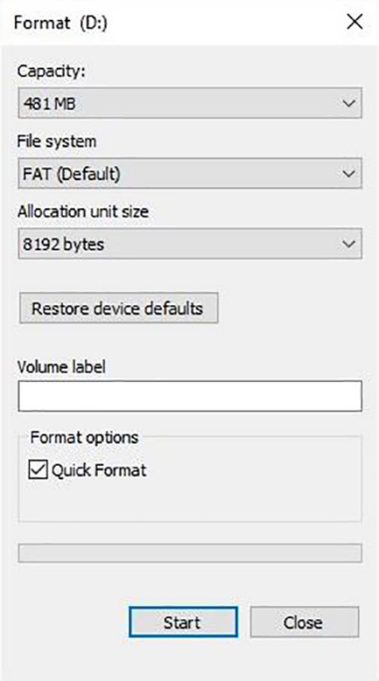
How to format a CF card on the computer correctly?

The CF card should be only formatted on the device. Formatting on the computer is permissible only under exceptional circumstances. The CF card to be used may have a max. memory capacity of 4 GB and must be formatted with the file system FAT16 or FAT32. CF cards from which a software update is to be performed may only be formatted in a FAT16 file system.

The device can only file or read data on CF cards formatted in this way. CF cards supplied by MELAG fulfil these requirements and have already been formatted.

Formatting on a computer is described in Windows 10:

1. Insert the CF card in the MELAflash card reader installed and connected to the computer.
2. Working in Windows Explorer, **`This PC > Devices and drives`** select the corresponding drive and open the menu window by right-click.
3. Working in the menu window, select **`Format...`**. The adjacent dialogue window opens.
4. Working under the file system, select format **`FAT (Default)`**.
5. Working under **`Allocation unit size`**, Windows automatically selects the appropriate allocation unit for the size of the CF card. The allocation unit is dependent of the size of the CF card.
6. Click on **`Start`**.



How to integrate the device in a (practice) network?

Arrange for the IT company that services your network to integrate your device in the network.

The following requirements must be fulfilled:

- The computer is fitted with a network card with RJ45 bushing (LAN).
- Log archive via FTP: an FTP server*) or an FTP service is installed on the computer that permits the creation of users with write permission independent of the operating system.
- Log output via TCP: a suitable program, e.g. MELAview/MELAtrace, is installed.

*) MELAG recommends using the MELAG FTP server to integrate network-compatible MELAG devices in a (practice) network.

1. Setting up the FTP server (only with log output via FTP)

A computer must be determined in the (practice) network on which the FTP server should run. This program receives the logs via data transfer. The steam sterilizer searches for the FTP server using the IP address set in the steam sterilizer and logs on. The logs of the completed program are saved on this computer later. When choosing the computer, be aware that it would be advantageous to integrate the logs thus saved in the practice automatic data saving system.

MELAG provides its own FTP program free of charge. Using the MELAG FTP server enables the registration of multiple devices as users simultaneously and the receipt of data from the steam sterilizer and other devices such as a washer-disinfector. The FTP server supports the so-called multithread capability. You can determine the folder in which the device directory and log files are to be stored in the FTP server program.

1. Working in the (practice) network, determine which computer should run on the FTP server.
2. If an FTP server has not yet been installed, install the MELAG FTP server for preference and set the steam sterilizer as user with a user name and password.
3. Working on the steam sterilizer, set the computer as the log output medium (log output via FTP). Further information regarding log output is set out in the user manual (chapter Settings, Logging).

2. Connecting the network cable

- Connect the network cable to any network data connection of the device and connect it to the (practice) network, see Connecting the network cable (optional) [▶ page 19].

3. Adjusting IP addresses in the steam sterilizer

NOTICE

The setting up in the (practice) network will require in-depth understanding of the network technology.

Handling errors of IP addresses can result in malfunctions and data loss in your user network.

- IP addresses may only be set by the (practice) network system administrator.

NOTICE

If you use a subnet mask other than that set in the steam sterilizer, an IT specialist should adapt all the IP addresses in the device.

As a matter of course: The selected computer must always have a fixed IP address, regardless of whether it is in an automatically or manually configured network. In an automatically configured network, it is necessary to inform the DHCP server of the area with the number or the number itself as a static IP address(es). The computer can also be assigned multiple IP addresses if those already present in the computer are not to be used.

1. Ask the IT administrator for the IP address of the computer first or find out yourself.
2. Check whether the computer has a dynamic or a fixed IP address.

   ↪ The computer must be issued with a fixed IP address. Change this if necessary.

With a manually-configured (practice) network:

1. Check whether the steam sterilizer and the computer belong to a subnetwork. In the majority of cases, this usually means that the first three numbers of the IP address of the sub network should correspond (e.g. **192.168.40**.xx). The IP addresses of the steam sterilizer and the computer must be different in the fourth number block (e.g. IP steam sterilizer: 192.168.40.**20** and IP computer: 192.168.40.**140**).

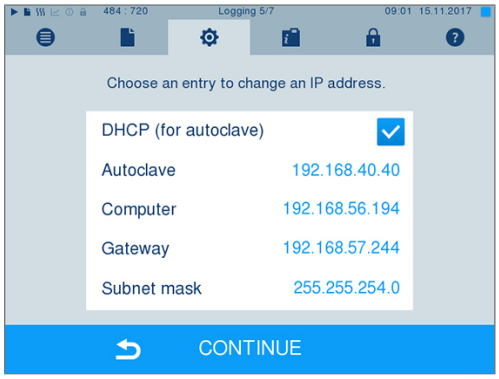
   ↪ If the IP addresses of both devices do not belong to a subnetwork, change the steam sterilizer IP address directly in the steam sterilizer.
2. Check whether the IP address of the computer set in the steam sterilizer is correct.

   ↪ If the IP address of the practice computer deviates from the IP address set in the steam sterilizer, adapt the IP address of the computer in the steam sterilizer.

With a dynamic (practice) network (DHCP):

The steam sterilizer can also be administered automatically in a dynamic network. If log output is made via FTP, the computer should be issued with a fixed IP address which is entered on the steam sterilizer.

1. Working in the **`Settings`** menu > **`Logging`**, set the IP address of the steam sterilizer to DHCP.



2. Check whether the IP address of the computer set in the steam sterilizer is correct.

   ➥ If the IP address of the practice computer deviates from the IP address set in the steam sterilizer, adapt the IP address of the computer in the steam sterilizer.

PLEASE NOTE

If a DHCP server cannot be located in the (practice) network, the steam sterilizer will automatically receive the pre-set static IP address.

How do I determine the IP address or network setting of a computer (Windows 7/10)?

1. Open “Network and Sharing Center” or the network and internet settings.
2. Open the Properties window under “Local Area Connection” > right-click on “Properties”.
3. Working in the Properties window, select “Internet Protocol Version 4 (TCP/IPv4)” and click on push-button “Properties”.

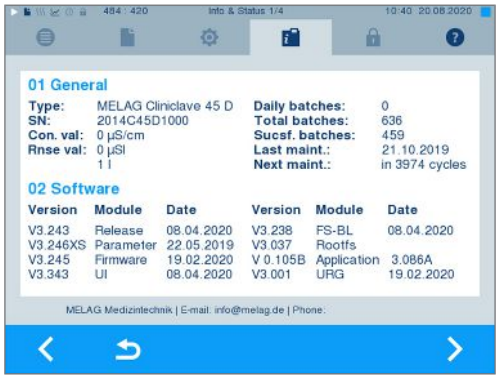
   ➥ If “Obtain the IP address automatically” is selected in the opening dialogue window, the computer is addressed dynamically in the (practice) network i.e. via DHCP.

What do the terms IP address, subnetwork and DHCP mean?

Term	Meaning
IP address	The IP address is a identifier of the computer or device expressed in numbers in a network. It serves to identify the computer or device with four number blocks (e.g. 192.168.88.8).
Subnetwork	Every IP address is divided into a network and a device (host) section. The division is performed via the subnetwork mask (also: subnet/sub-net mask). The network section of the IP addresses must be identical so that the devices can communicate with each other. With a network entry mask = 255.255.255.0 (the most often) the first three numbers (e.g. 192.168.88.x) must be the same. The device part of the IP address is assigned individually and only once. The first (network itself) and the highest (broadcast) device address may not be issued.
DHCP	The IP addresses are automatically issued in a computer network via DHCP (= Dynamic Host Configuration Protocol) i.e. the IP addresses need not be entered manually in every device in the network. The precondition is the presence of a DHCP server in a network.

How can I check the software version of the steam sterilizer?

- You can read off the software version of the activated steam sterilizer from the **`Info & Status`** menu.



7 Technical tables

Feed water quality

EN 285 Appendix B, Table B.1 – Impurities in the feed water for an assigned steam generator

Substance/property	Feed water
Evaporation residue	≤ 10 mg/l
Silicates	≤ 1 mg/l
Iron	≤ 0.2 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Residues of heavy metals apart from iron, cadmium, lead	≤ 0.1 mg/l
Chloride	≤ 0.5 mg/l
Phosphate	≤ 0.5 mg/l
Conductivity (at 25 °C)	≤ 5 µS/cm
pH Value	5-7.5
Appearance	without colour, without residue
Hardness	≤ 0.02 mmol/l

EN 285, section 13.3.4, table 4 - Suggested maximum values of impurities in the condensate from the steam supply for the sterilizer chamber

Substance/property	Condensate
Silicates	≤ 0.1 mg/l
Iron	≤ 0.1 mg/l
Cadmium	≤ 0.005 mg/l
Lead	≤ 0.05 mg/l
Residues of heavy metals apart from iron, cadmium, lead	≤ 0.1 mg/l
Chloride	≤ 0.1 mg/l
Phosphate	≤ 0.1 mg/l
Conductivity	≤ 4.3 µS/cm
pH Value	5-7
Appearance	without colour, no deposits
Hardness	≤ 0.02 mmol/l

Precision and drift behaviour

Sensors

Temperature sensors

Sensor type	PT 1000 Class A according to DIN EN 60751
Precision (at 135 °C)	± 0.42 K
Drift per year	± 0.05 K
Drift in 5 years	± 0.25 K

Pressure sensor

Sensor type	Piezoresistant absolute pressure sensor 0 to 4000 mbar
Precision	± 0.3 % corresponds to ± 12 mbar corresponds to approx. ± 0.13 K steam
Drift per year	± 0.2 % corresponds to ± 8 mbar corresponds to approx. ± 0.09 K steam
Drift in 5 years	± 1.0 % corresponds to ± 40 mbar corresponds to approx. ± 0.44 K steam

Measuring chains

Measuring chain for the temperature measurement on the electronics (without sensor)

Precision (at 135 °C)	± 0.2 K
Drift per year	± 0.005 K
Drift in 5 years	± 0.025 K

Measuring chain for the pressure measurement on the electronics (without sensor)

Precision	± 0.2 % corresponds to ± 8.0 mbar corresponds to approx. ± 0.09 K steam
Drift per year	± 0.004 % corresponds to ± 0.16 mbar corresponds to approx. ± 0.017 K steam
Drift in 5 years	± 0.02 % corresponds to ± 0.8 mbar corresponds to approx. ± 0.09 K steam

After 1 year

Entire measuring chain of the temperature measurement

Precision (at 135 °C)	at pure addition of individual errors approx. ± 0.70 K
Precision (at 135 °C)	according to Gauss' law of propagation approx. ± 0.47 K

Entire measuring chain of the pressure measurement

Precision	at pure addition of indiv. errors	± 0.70 % corresponds to ± 28.0 mbar corresponds to approx. ± 0.30 K steam temperature
Precision	per Gauss' law of propagation	± 0.41 % corresponds to ± 16.5 mbar corresponds to approx. ± 0.18 K steam temperature

After 5 year

Entire measuring chain of the temperature measurement

Precision (at 135 °C)	at pure addition of individual errors approx. ± 0.70 K
Precision (at 135 °C)	according to Gauss' law of propagation approx. ± 0.47 K

Entire measuring chain of the pressure measurement

Precision	at pure addition of individual errors	± 0.70 % corresponds to ± 28.0 mbar corresponds to approx. ± 0.30 K steam temperature
Precision	per Gauss' law of propagation	± 0.41 % corresponds to ± 16.5 mbar corresponds to approx. ± 0.18 K steam temperature

Nominal value tolerances

	Universal-Program		Quick-Program B		Prion-Program		Gentle-Program		Quick-Program S			
Step	Press. P	Tolerance	P	Tol.	P	Tol.	P	Tol.	P	Tol.	*All values in mbar*	
SK11	1700	+100/- 20	◄	◄	◄	◄	◄	◄	◄	◄	Steam intake	1
SK12	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	◄	◄	Pressure release	
SK11	1700	+100/- 20	◄	◄	◄	◄	◄	◄	---	---	Steam intake	
SK12	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	---	---	Pressure release	
SK21	1700	+100/- 20	◄	◄	◄	◄	◄	◄	◄	◄	Steam intake	
SK22	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	◄	◄	Pressure release	
SK21	1700	+100/- 20	◄	◄	◄	◄	◄	◄	---	---	Steam intake	
SK22	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	---	---	Pressure release	
SK21	1700	+100/- 20	◄	◄	◄	◄	◄	◄	---	---	Steam intake	
SK22	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	---	---	Pressure release	
SF12	500	+ 30/- 30	◄	◄	◄	◄	◄	◄	◄	◄	Evacuation	2
SF13	1600	+100/- 20	◄	◄	◄	◄	◄	◄	◄	◄	Steam intake	
SF21	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	◄	◄	Pressure release	
SF22	180	+ 30/- 30	◄	◄	◄	◄	◄	◄	◄	◄	Evacuation	
SF23	1800	+100/- 20	◄	◄	◄	◄	◄	◄	◄	◄	Steam intake	
SF31	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	◄	◄	Pressure release	
SF32	200	+ 30/- 30	◄	◄	◄	◄	◄	◄	◄	◄	Evacuation	
SF33	1900	+100/- 20	◄	◄	◄	◄	◄	◄	◄	◄	Steam intake	
SF41	1300	+ 20/- 50	◄	◄	◄	◄	◄	◄	---	---	Pressure release	
SF42	400	+ 30/- 30	◄	◄	◄	◄	◄	◄	---	---	Evacuation	
SF43	1700	+100/- 20	◄	◄	◄	◄	**1800**	◄	---	---	Steam intake	
SH01	2750	+ 60/- 60	◄	◄	◄	◄	**1850**	◄	◄	◄	Hold steam intake	
SH02	2880	+ 60/- 60	◄	◄	◄	◄	**1950**	◄	◄	◄	Hold control	
SS01	3080	+ 60/- 60	◄	◄	◄	◄	**2080**	◄	◄	◄	Sterilization entry	
SS02	3170	+ 60/- 60	◄	◄	◄	◄	**2150**	◄	◄	◄	Sterilization	
SA00	1300	+ 20/- 50	◄	◄	◄	◄	**1300**	◄	◄	◄	Pressure release	

Key:

◄ As in Universal-Program

1 - Conditioning

2 - Fractionation

Pressure-time charts

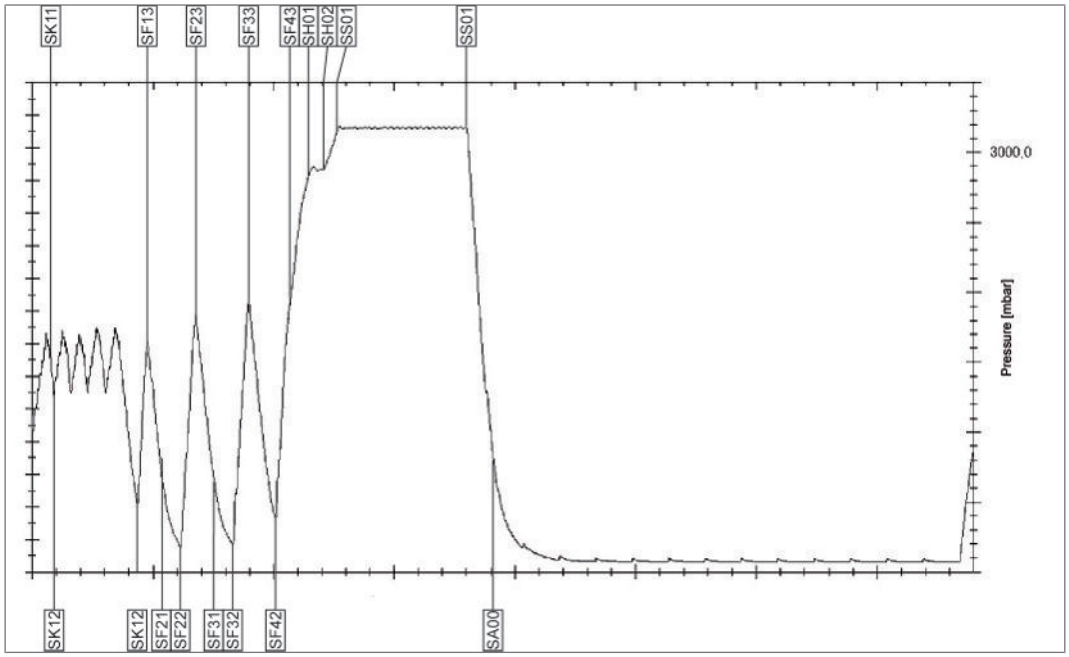


Fig. 1: Pressure-time chart for the Universal-Program, 134 °C and 2.1 bar

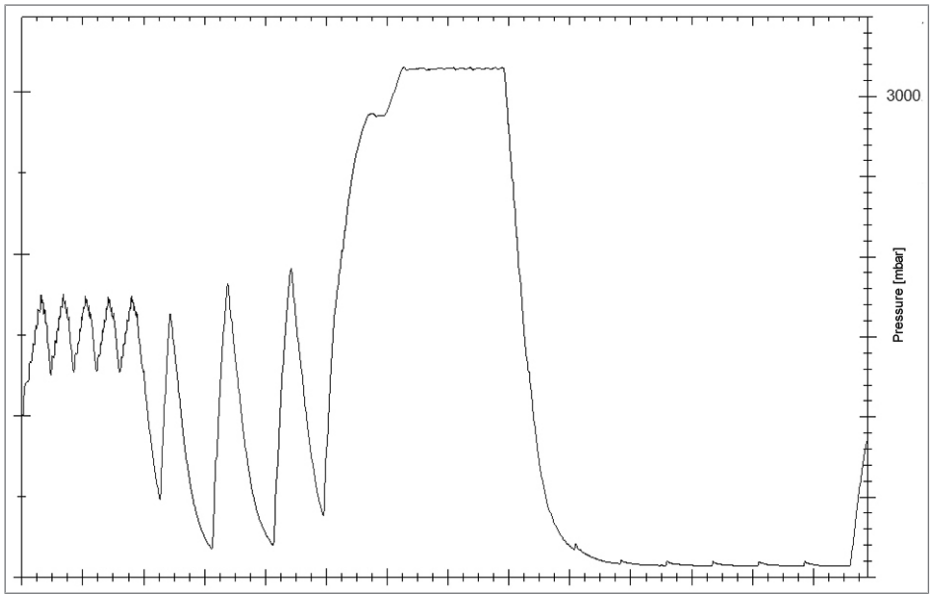


Fig. 2: Pressure-time chart for the Quick-Program B, 134 °C and 2.1 bar

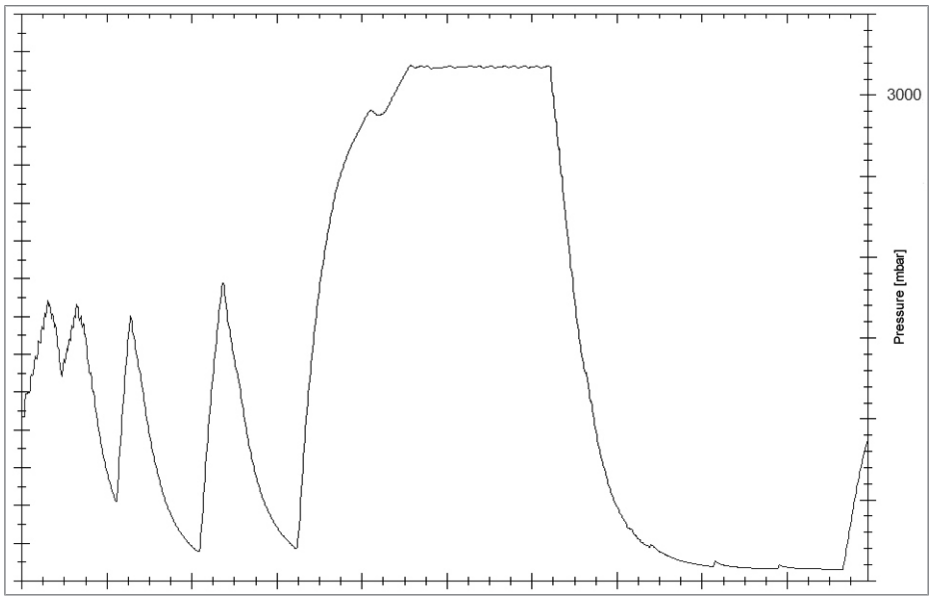


Fig. 3: Pressure-time chart for the Quick-Program S, 134 °C 2.1 bar

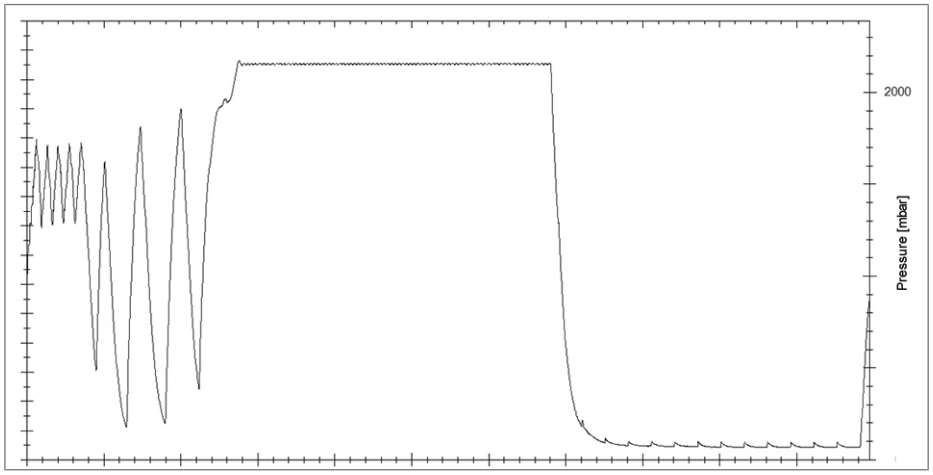


Fig. 4: Pressure-time chart for the Gentle-Program, 121 °C 1.1 bar

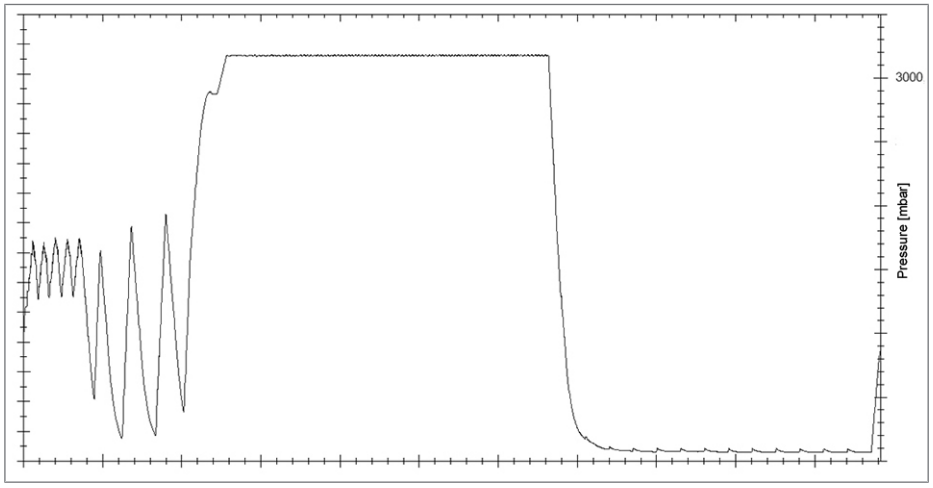


Fig. 5: Pressure-time chart for the Prion-Program, 134 °C 2.1 bar

MELAG
competence in hygiene

Certificate of Suitability

According to the recommendations of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute

Manufacturer:	MELAG Medizintechnik GmbH & Co. KG
Address:	Geneststraße 6-10 10829 Berlin
Country:	Germany
Product:	Cliniclave® 45 / Cliniclave® 45 M
Type of device:	Steam sterilizer
Classification:	Class IIb
Device type acc. to EN 285:	Large sterilizer

We herewith declare that the above designated product is suited for sterilization of

- **Solid instruments (wrapped and unwrapped)**
- **Porous goods (wrapped and unwrapped)**
- **Products with narrow lumen (wrapped and unwrapped)**
- **Simple hollow items (wrapped and unwrapped)**

Instructions on load quantities and loading variants are specified in the user manual and must be observed.

Be sure to observe the manufacturer's instructions for medical devices intended for sterilization according to EN ISO 17664.

We herewith declare that the following test system is suited for testing the above cited steam sterilizer.

- **Helix-Test body according to EN 867-5:**
  MELA*control*® Helix and MELA*control*® Pro

Berlin, 30/09/2021

Dr. Steffen Gebauer
(Management)

Quality - made in Germany

MELAG Medizintechnik GmbH & Co. KG

Geneststraße 6-10
10829 Berlin
Germany

Email: info@melag.com
Web: www.melag.com

Original instructions

Your stockist

TH_C45_45M_EN.pdf | Rev. 12 - 23/0507 | Modification date: 2023-02-14