



This quick start guide is intended to provide a quick overview of your MEDIACLAVE's (MC) key features and to offer basic instructions for getting started. For detailed information, please refer to the operating instructions (OI) that can be found at www.integra-biosciences.com in different languages.

Intended use

This is a general-purpose laboratory instrument. Any use of this instrument in a medical or IVD setting is the sole responsibility of the user. MEDIACLAVE 10/30 is used for the preparation and sterilization of media and can easily be converted to a water bath (or for MC10 only to an autoclave for media sterilization in glassware).

Safety information

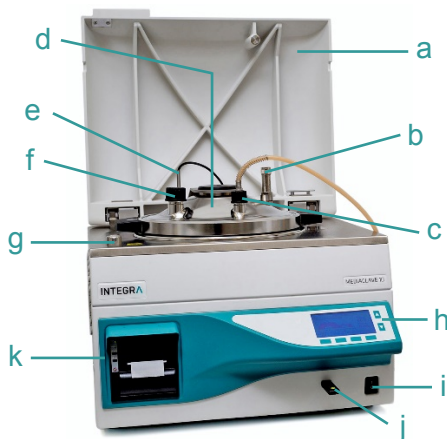
Regardless of the listed safety notes, all locally applicable regulations must be observed.

- 1) MEDIACLAVE may only be used by properly trained personnel in a manner specified by INTEGRA Biosciences.
- 2) In error case the instrument must not be used, e.g. if the pressure value is not displayed or above 1.7 bar or hot steam is released from the safety valve. There is the risk of burns or explosion. The instrument must be immediately switched off and separated from electricity supply. Stay away from the device.
- 3) Observe the hazard warnings on the device. Caution is required when opening ports or the vessel lid (potential risk of delay in boiling). Always wear safety goggles and oven gloves.
- 4) The hoses may get hot. Do not touch the hoses during operation.
- 5) Servicing work and repairs may only be performed by INTEGRA Biosciences or an authorized after-sales service member.
- 6) It is **mandatory** that a service is carried out at least once a year or after 1000 sterilization cycles (whatever is reached first).

Getting started



Install the instrument on a horizontal surface according to the IQ (PN 136951) and OQ (PN 136952) documents.



- a. Safety cover
- b. Safety valve
- c. Dispense port
- d. Vessel lid
- e. Temperature probe for media
- f. Adding port
- g. Safety cover lock
- h. Operating panel
- i. Main switch
- j. USB port
- k. Printer (optional)

Switch on/off:
Press the main switch.

Switch on the device. In the MAIN MENU, three options are accessible:

MAIN MENU			
INTEGRA		Temperature	21.8°C
		Pressure	0.00 bar
29.March.2010	10:42:45		
SELECT PROGRAM	MAIN-TENANCE	SYSTEM PARAMETER	

- **SELECT PROGRAM:** To define and execute a program.
- **MAINTENANCE:** To drain or fill the vessel, automatically clean the device and perform the safety valve tests.
- **SYSTEM PARAMETER:** To configure general device parameters, make a backup to USB, etc..

INTEGRA

Language selection

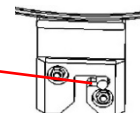
Navigate to **SYSTEM PARAMETER** and LANGUAGE SELECTION. Select a language and press SAVE. Set other system parameters to your requirements.

Preparing a media preparation program

- Check, if the white pivot pin disk inside the cuvette is pushed fully downwards and place the magnetic stirrer bar on the pivot pin inside at the cuvette bottom.



- Place the cuvette in the instrument vessel.
- Using both grips, turn the cuvette approx. 2 cm clockwise until the bolt locks into position as shown beside.
- To remove the cuvette, turn it counter clockwise and lift it up.



Fill coupling water



- Prepare softened coupling water: Add a cup of tap water or a pinch of salt to distilled water to make it conductive, which is required for the level sensors.
- Navigate to **MAINTENANCE**, select DRAINING/FILLING and press FILL COUP. WATER.
- Fill the vessel with coupling water until the upper level sensor is covered (approx. 2.7 l for MC10, 8.5 l for MC30).

Select a program

- Navigate to **SELECT PROGRAM**. The first programs are already pre-defined with default values:

Operation mode	Description
STANDARD	For preparation and sterilization of media
CHOCOLATE AGAR	Two step program for preparation of complex media.
AUTOCLAVE	For sterilization of media in glassware (MC10 only)
WATER BATH	For pre-swelling, warming up and thermostating media

- Select a program to be defined using the arrow keys and press SELECT PROGRAM and PROGRAM SETTINGS in order to adjust the program.
- Using the arrow keys, select a parameter you wish to change. Press CHANGE and follow the information on the screen.

Run a STANDARD or CHOCOLATE AGAR program



The nominal volume of the cuvette (10/30L) must not be exceeded. Consider vortex, foam or bubble formation and swelling.

- Navigate to **SELECT PROGRAM**. Select the previously defined STANDARD or CHOCOLATE AGAR program. Add water and ingredients according to your recipe into the cuvette. Press START and follow the instructions on the screen.

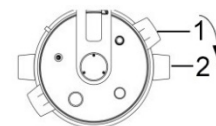


The semi-rigid temperature probe (MC10) must be handled with great care and must not be deflected more than 30 degrees from the vertical! Do not clamp the cable of the flexible temperature probe when closing the vessel lid.

INTEGRA



- Close the vessel lid by turning the grips clockwise around the attachment point. The grips of the vessel lid (1) must be aligned above the black stickers (2).



- Close the safety cover and keep it pressed down until it is locked by the bolt after pressing START.

Dispensing the media

When the dispensing phase is reached, you are informed by an acoustic sound (press \cancel{A} to switch off).

- Press START DISPENSE. The media can now be dispensed through the sterile dispensing port. For dispensing by an external pump, e.g. DOSE IT or MEDIAJET, press STANDARD DISPENSE. (For other dispense option please refer to the OI.)
- Unscrew the dispense port cap and insert the sterile fitting for dispensing tubing with silicone tubing (inner diameter of 6 mm) connected. Connect the tubing to the external pump.
- After dispensing press BACK and press twice END DISPENSE to finish the process. Open the vessel lid by turning the grips counterclockwise.

Run an AUTOCLAVE program (MC10 only)

When using the AUTOCLAVE mode, the autoclave cuvette and the flexible temperature probe must be installed, see OI for length adaption.



The MEDIACLAVE is not suitable for sterilization of instruments, glassware and medical devices. All containers must be opened throughout the whole process.

- Navigate to **SELECT PROGRAM**. Select the previously defined AUTOCLAVE program and press START.
- Insert the glassware filled with media into the cuvette and distribute it evenly.
- Fill the vessel with coupling water such that the water level is slightly under the medium surface inside the glass container for optimal heat transfer.
- Put the flexible temperature probe into a reference container.
- Press START and follow the instructions on the screen.
- Once the autoclave phase is finished press END to open the safety cover. Open the vessel lid.

Run a WATER BATH program

When using the WATER BATH mode, the vessel lid and safety cover must be left opened.

- Navigate to **SELECT PROGRAM**. Select the previously defined WATER BATH program and press START.
- For thermostating of media in glassware (MC10 only), install the autoclave cuvette and insert the glassware. Fill the vessel with coupling water as described for AUTOCLAVE.
- For prewarming and preswelling of media install the cuvette with stirrer and add the ingredients. Press START.
- Press END to terminate the thermostating phase.

Maintenance



The MEDIACLAVE requires periodical cleaning in order to ensure safe and reliable operation. Daily and monthly cleaning procedures according to the OI are mandatory. Before starting manual cleaning, ensure the device is switched off and disconnected from the electricity supply.

Daily:

- Unscrew the dispensing tubing, disconnect the decanting tubing on the underside of the vessel lid and rinse the tubings.
- At the end of a working day, navigate to **MAINTENANCE**, select DRAINING/FILLING and press DRAIN COUP. WATER to empty the vessel automatically.
- Clean the following instruments parts with a lint free cloth and washing detergent: cuvette; magnetic stirrer; pivot pin; temperature probe; vessel including the coupling water level sensors, deaeration opening and drain; vessel lid with dispense and adding ports, safety valve; lid seal; housing. Do not let solution drip inside the device.
- If you use media with salt concentrations above 3 %, causing corrossions of stainless steel, rinse all salt residues thoroughly with plenty of water. Apply a chrome steel cleaning agent to all affected surfaces according to the instructions by the manufacturer. Completely remove it with warm water and a sponge.
- Dry all areas with paper towels.

Monthly:

- Navigate to **MAINTENANCE**, select CLEANING and follow the instructions on the screen.
- Navigate to **MAINTENANCE**, select SAFETY VALVE. Insert the cuvette, fill the vessel with coupling water and follow the instructions on the screen.
- Perform Daily cleaning including check of steel surfaces.
- Check the white pivot pin disk below the stirrer. It must be replaced if its thickness is below 1 mm.

Equipment Disposal



MEDIACLAVE must not be disposed of with unsorted municipal waste. Dispose of MEDIACLAVE in accordance with the regulations in your area governing disposal of devices.

Manufacturer

INTEGRA Biosciences AG
CH-7205 Zizers, Switzerland
T +41 81 286 95 30
F +41 81 286 95 33
info@integra-biosciences.com
www.integra-biosciences.com

INTEGRA Biosciences Corp.
Hudson, NH 03051, USA
T +1 603 578 5800
F +1 603 577 5529



Declaration of Conformity MEDIACLAVE 10

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
MEDIACLAVE 10	136 000, 136 005, 136 010, 136 015, 136 020, 136 025

comply with:

EU Directives (DoW: Date of Withdrawal)	Before DoW	DoW	After DoW
Low Voltage Equipment	2006/95/EC	20.04.2016	2014/35/EU
Pressure Equipment	97/23/EC	19.07.2016	2014/68/EU
Electromagnetic Compatibility	2004/108/EC	20.04.2016	2014/30/EU
Restriction of Hazardous Substances	2011/65/EU		
Waste Electrical and Electronic Equipment	2012/19/EU		

EU Regulation

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) **1907/2006**

Directive 97/23 EC and 2014/68/EU

Description of pressure vessel		Allowable temperature TS	0-126 °C
Operational fluid	liquids/gases	Volume	V 16.3 l
Fluid group	2	Test pressure	PT 2.5 bar
Category (97/23 EC)	I (Art. 9)	Pressure test medium	water
Category (2014/68/EU)	II (Art. 13)	Serial No.	0267-7999
Max operating pressure	1.4 bar	Marking	CE1253
Safety valve set pressure,	1.7 bar	Safety equipment	assembly
Max allowable pressure PS		Drawing No./Rev	136400/09

Description of assembly pressure vessel, circulation pump, safety valve, circulation heater, heat exchanger, piping

Conformity assessment procedure Module: A1 (97/23/EC) / A2 (2014/68/EU)

Certificate No. PED-Z-COS.EP.5507079

Notified body for inspection Swiss Safety Center AG, CH-8304 Wallisellen, CE1253

Certified Q-System ISO 9001:2000 SQS, CH-3052 Zollikofen, Reg. No. 15072

Standards for EU

Safety requirements for electrical equipment for laboratory use	EN 61010-1: 2010
Electrical equipment for laboratory use - EMC requirements	EN 61326-1: 2013
Pressure cookers	EN 12778: 2002
Qualification test of welders - Fusion welding - Part 1: Steels	EN 9606-1: 2013
Specification and qualification of welding procedures	EN 15614-1: 2004
Metallic products types of inspection documents, Type 3.1 certificate	EN 10204: 2004
Safety devices for protection against excessive pressure	EN 4126-1: 2013

Standards for Canada and USA:

Safety requirements for electrical equipment for measurement, control and laboratory use **UL 61010-1**


Requirements for laboratory equipment for the heating of materials **UL 61010-2-10**

Pressure cookers **UL 136**

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. **Part 15 of the FCC Rules Class A**

Zizers, December 3, 2018


Elmar Morscher
CEO


Thomas Neher
Quality Manager



Declaration of Conformity MEDIACLAVE 30

INTEGRA Biosciences AG – 7205 Zizers, Switzerland

declares on its own responsibility that the devices

Description	Models
MEDIACLAVE 30	136 050, 136 055

comply with:

EU Directives (DoW: Date of Withdrawal)	Before DoW	DoW	After DoW
Low Voltage Equipment	2006/95/EC	20.04.2016	2014/35/EU
Pressure Equipment	97/23/EC	19.07.2016	2014/68/EU
Electromagnetic Compatibility	2004/108/EC	20.04.2016	2014/30/EU
Restriction of Hazardous Substances	2011/65/EU		
Waste Electrical and Electronic Equipment	2012/19/EU		

EU Regulation

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) **1907/2006**

Directive 97/23 EC and 2014/68/EU

Description of pressure vessel		Allowable temperature TS	0-126 °C
Operational fluid	liquids/gases	Volume	V 43.2 l
Fluid group	2	Test pressure	PT 2.5 bar
Category (97/23/EC)	II (Art. 9)	Pressure test medium	water
Category (2014/68/EU)	I (Art. 13)	Serial No.	8000-18000
Max operating pressure	1.4 bar	Marking	CE1253
Safety valve set pressure,	1.7 bar	Safety equipment	assembly
Max allowable pressure PS		Drawing No./Rev	136450/09

Description of assembly pressure vessel, circulation pump, safety valve, circulation heater, heat exchanger, piping

Conformity assessment procedure Module: A1 (97/23/EC) / A2 (2014/68/EU)

Certificate No. PED-Z-COS.EP.5507079

Notified body for inspection Swiss Safety Center AG, CH-8304 Wallisellen, CE1253

Certified Q-System ISO 9001:2000 SQS, CH-3052 Zollikofen, Reg. No. 15072

Standards for EU

Safety requirements for electrical equipment for laboratory use	EN 61010-1: 2010
Electrical equipment for laboratory use - EMC requirements	EN 61326-1: 2013
Pressure cookers	EN 12778: 2002
Qualification test of welders - Fusion welding - Part 1: Steels	EN 9606-1: 2013
Specification and qualification of welding procedures	EN 15614-1: 2004
Metallic products types of inspection documents, Type 3.1 certificate	EN 10204: 2004
Safety devices for protection against excessive pressure	EN 4126-1: 2013

Standards for Canada and USA:

Safety requirements for electrical equipment for measurement, control and laboratory use	UL 61010-1
Requirements for laboratory equipment for the heating of materials	UL 61010-2-10
Pressure cookers	UL 136

Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. **Part 15 of the FCC Rules Class A**

Zizers, December 3, 2018


Elmar Morscher
CEO


Thomas Neher
Quality Manager