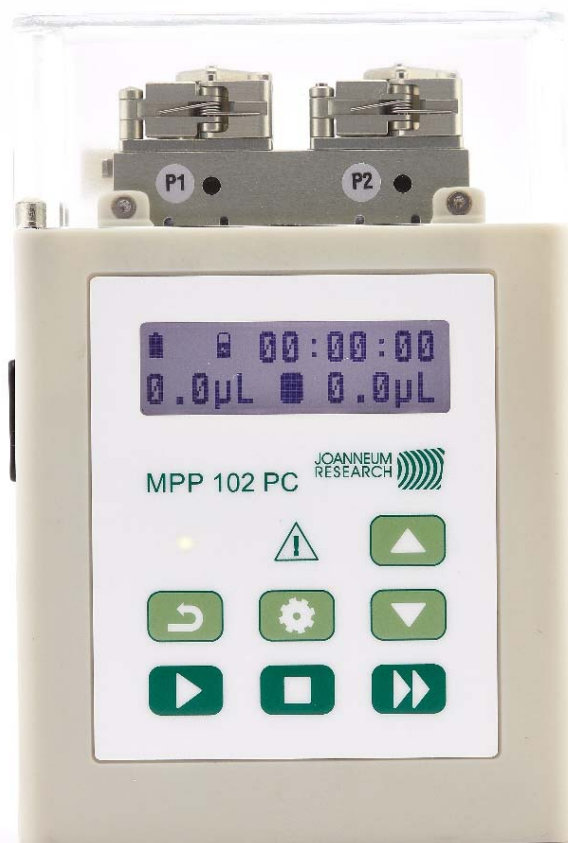


INSTRUCTIONS FOR USE



MICROPERFUSION-PUMP FOR LABORATORY USE MPP102 PC / MPP102-II PC

FOR FIRMWARE 1.X — STARTING WITH VERSION 1.3



Accuracy when going to press.

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READ Instructions for use before using the product! **ALWAYS** follow the warnings, cautions, and notes throughout this document. If you have questions regarding the safe or correct use of the product, please contact **your distributor**.

1 Intended Use

The Microperfusion-Pump (Type: MPP102 PC / MPP102-II PC; further MPP10x PC) is used to operate Microperfusion catheter during preclinical studies / laboratory use.

WARNING



DO NOT use pump and accessories in humans!

USE pump and accessories for laboratory research in animals or ex-vivo setups **ONLY**.

DO NOT use pump and accessories in household pets and other non-laboratory animals.

THE INVESTIGATOR IS RESPONSIBLE FOR THE SPECIFIC USE OF THE PRODUCTS AND COMPLIANCE WITH ALL NATIONAL REGULATIONS REGARDING THE USE OF LABORATORY ANIMALS.

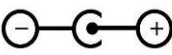
The pump enables easy access to the target tissue together with minimally invasive OFM Catheter and delivers liquid samples as basis for analysis of the local biochemical conditions.

The pump can operate as follows:

- PUSH / PULL operation with up to 3 (MPP102 PC) or 4 (MPP102-II PC) OFM Catheter (active introduction of perfusate with simultaneous aspiration of the dialysate).
- Only PUSH operation with up to 6 (MPP102 PC) or 8 (MPP102-II PC) OFM Catheter simultaneously.

2 Safety Information

2.1 Explanation of Symbols

Symbol	Meaning
	Temperature limitation from X°C to Y°C, Refer to Chapter 11 and Chapter 12 for further details
	Humidity limitation from X% to Y%, Refer to Chapter 11 and Chapter 12 for further details
	Air pressure limit from XkPa to YkPa, Refer to Chapter 11 and Chapter 12 for further details
	Caution, see Instructions for use
IP20	Device is protected against ingress of solid foreign objects $\varnothing \geq 2.5\text{mm}$ and larger Device is not protected against splash water
	Do not dispose pump in household waste
	Direct current
	Polarity of the power supply (positive pole inside). ONLY use the power supply provided from the manufacturer
	Identifies a warning statement that warns about the possibility of injury, death, or other serious adverse reaction associated with the use or misuse of the device
	Identifies a caution statement that warns failure to follow the instructions may lead to device misuse, malfunction, or damage
	Identifies additional information from the manufacturer
	Refer to Instructions for use / booklet

2.2 General Warnings and Safety Information



GENERAL WARNINGS

READ Instructions for use prior to use.

DO NOT use pump and accessories in humans! The pump and accessories have **NOT** been approved for use in humans.

DO NOT use pump and accessories in household pets or other animals that are not laboratory animals. Products are designed for use in laboratory animals or ex-vivo setups **ONLY!**

ALWAYS wear disposable protective gloves when operating pump and accessories to avoid any contamination or risk of infection.

ALWAYS disinfect pump before and after each use, after any contamination, and after any contact with unclean environment or biological material (refer to Chapter 8.1 Cleaning and Disinfection).

ONLY use proper pumps and accessories. **DO NOT** use damaged pumps or damaged accessories.

PROTECT pump and power supply from moisture, splashing water, excessive exposure to heat and direct sunlight.

DO NOT operate near explosives.

DO NOT operate the pump in the presence of inflammable gasses or fumes. Operation of the pump in such an environment will cause a safety hazard.

DO NOT use the pump with inflammable fluids or any other dangerous liquid (e.g. acids, alkaline solutions, solvents, detergents, etc.) or hot fluids (>45°C) as perfusate!

DO NOT operate pump in oxygen-enriched environment.

DO NOT operate pump in pressure chambers or inside/near MRI-devices.

DO NOT open the pump housing (exception: battery compartment). Tampering with the pump housing may introduce moisture in pump housing and cause electrical malfunction or failure.

DO NOT touch moving parts of the pump head if operating pump without cover.

DO NOT insert foreign bodies (fibres, fabrics, tools etc.) into rotating parts of the pump, pump head might be damaged.

DO NOT use the pump if labels or symbols on the keypad are **NOT** legible anymore.

DO NOT use pumps that have been dropped or are malfunctioning. The pump must be serviced by the manufacturer before being reused. See chapter 10 "Servicing / Maintenance" and chapter 14.1 "Return Material Authorization Policy" for more information on returning malfunctioning pumps.

DO NOT dispose the pump in household waste. Return the pump to your distributor or the manufacturer or dispose pump at municipal waste collection points or recycling centres.

ONLY use pump at a maximum of 2000m (6500ft) above sea level.

DO NOT use the pump in vertical orientation without the OFM Pump Base. The pump can easily tip over and cause a risk for the user or might be damaged.



WARNINGS WHEN USING OTHER PUMPS AND ACCESSORIES

USE manufacturer-approved pump combinations, accessories and disposables **ONLY!**

Using other than manufacturers' accessories causes risks to the user and equipment hazards, and impairs the pump's performance!



WARNINGS WHEN REUSING DISPOSABLES

ALWAYS read Instructions for use of accessories.

IMMEDIATELY discard disposable accessories (such as OFM Tubing Set, OFM Catheter, OFM Perfusate Bag) after every single use to prevent any contamination!

DO NOT reuse disposables after experiments! Reuse of the components causes contamination and risk of infection, and impairs the systems' performance by clotting the fluidic pathway.



WARNINGS REGARDING MODIFICATIONS, MAINTENANCE, REPAIRS, AND DAMAGES

IMMEDIATELY STOP operating the pump and **DISCONNECT** the power supply if you notice any of the following unusual conditions:

- Pump operates abnormally (NOTE: A small pulsation in the OFM-Tubing-Set is normal due to the peristaltic principal of the pump).
- Pump emits abnormal noise, smell, smoke, or sparks during operation.
- Pump generates high temperatures or electrical shocks during operation.
- Power cable, plug or housing of pump is damaged.

IMMEDIATELY STOP operating the pump if you notice any ERROR message on the LCD display.

Contact your distributor for repairs of the pump. If you continue to operate without repairing the pump, there is a potential for hazards and/or damages to both the equipment and the operator. See chapter 10 "Servicing / Maintenance" and 14.1 "Return Material Authorization Policy" for more information on returning malfunctioning pumps.

DO NOT substitute parts or modify the pump. To avoid the danger of introducing additional hazards, **DO NOT** install substitute parts or perform unauthorized modifications to the pump.

DO NOT use the USB-port (**USED** by the manufacturer for maintenance purposes **ONLY**).

ONLY the manufacturer performs maintenance. There are **NO** user-serviceable parts inside the pump.

To avoid malfunctions, maintenance of the pump is required annually or when the maintenance symbol is displayed. Maintenance contracts can be entered into with your distributor.

MANUFACTURER IS NOT LIABLE FOR DIRECT OR INDIRECT DAMAGES OF THE PUMP OR PERSONS IF THE PUMP IS MISUSED OR IN CASE THESE INSTRUCTIONS ARE NOT FOLLOWED PROPERLY.

2.3 Electrical Warnings and Safety Information



WARNING

ONLY use indoors.

DO NOT exceed the operating input power, voltage, current level and signal type appropriate for the pump.

CONSIDER the general electrical safety regulations when operating electrical equipment and using the pump.

ONLY USE lithium batteries compliant with IEC 60084-4, such as manufactured by EVE, type ER26500M, by SAFT, type LSH 14, or by Dynamis, type LI-250 to avoid malfunction.

PAY ATTENTION to correct polarity when inserting batteries.

DO NOT use rechargeable or other batteries than specified in these instructions.

USE manufacturer-approved batteries (see also label in the battery compartment) **ONLY**. Non-manufacturer-approved batteries may supply incorrect voltage levels, which can reduce the pump's operational lifespan.

USE power supply of class II manufactured by Egston, type E2CFMW3 12 with 5V **ONLY**, when using the power grid network.

ONLY USE power supply on a socket with a fuse of maximum 2.5A.

DO NOT use powerbanks or similar power sources instead of the specified power supply, the pump might be damaged.

DO NOT use damaged power supplies (e.g. broken housing). Risk of electric shock.

To separate the pump from the power grid network, pull out the power supply. **DO NOT** operate the pump in a way that impedes with the separation.

Using other accessories than specified herein may result in increased emissions or decreased immunity to interferences of the pump.

Portable and mobile HF-communication equipment may affect the pump.

DO NOT place the pump directly next to or stacked with other electrical devices. In this case, the pump and its proper function must be observed.

DO NOT use the USB-port (**USED** for maintenance purposes **ONLY**).

3 Microperfusion-Pump MPP102 PC / MPP102-II PC at a Glance

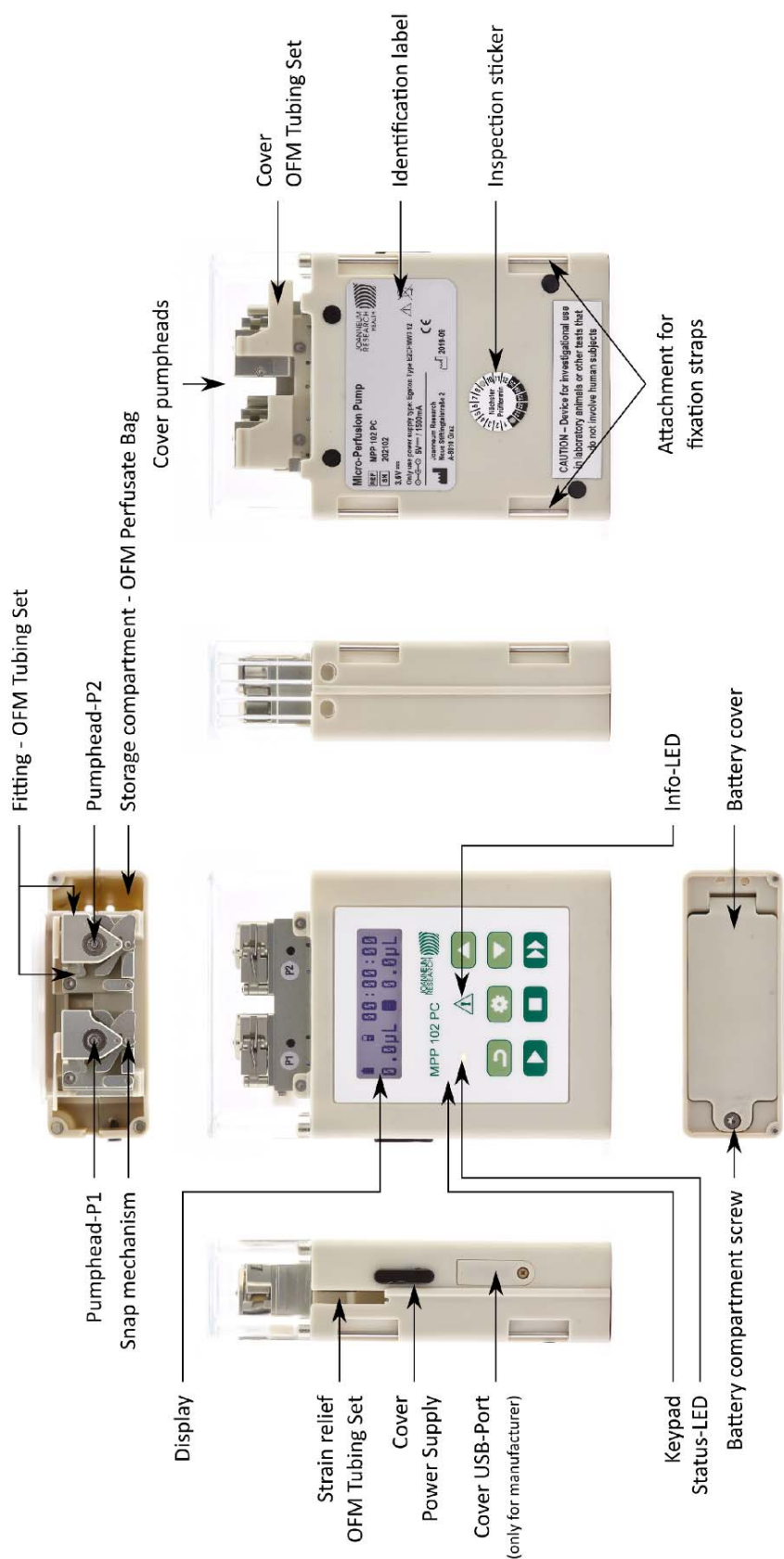


Figure 1: Overview of the Microperfusion-Pump MPP10x PC

4 Included Parts and Accessories

The delivered product includes the following:

- Microperfusion-Pump MPP102 PC or MPP102-II PC
- Instructions for Use
- Power Supply; type Egston E2CFMW3 12 with 5V
- T10 Key to open battery compartment
- Storage case
- OFM Pump Base
- OFM Bag Holder



Figure 2: Pump and accessories as delivered (battery not included)

To fulfil its intended use, the pump must be operated with manufacturer-approved accessories like OFM Catheter, OFM Tubing Set and OFM Perfusate Bag. Using non-manufacturer-approved tubing sets may cause pump malfunction or damage to the pump and loss of warranty!

5 Pump Keypad and User Interface

5.1 Display and Keypad – Overview

The pump is keypad-operated. Operation-relevant parameters are graphically shown on the display.

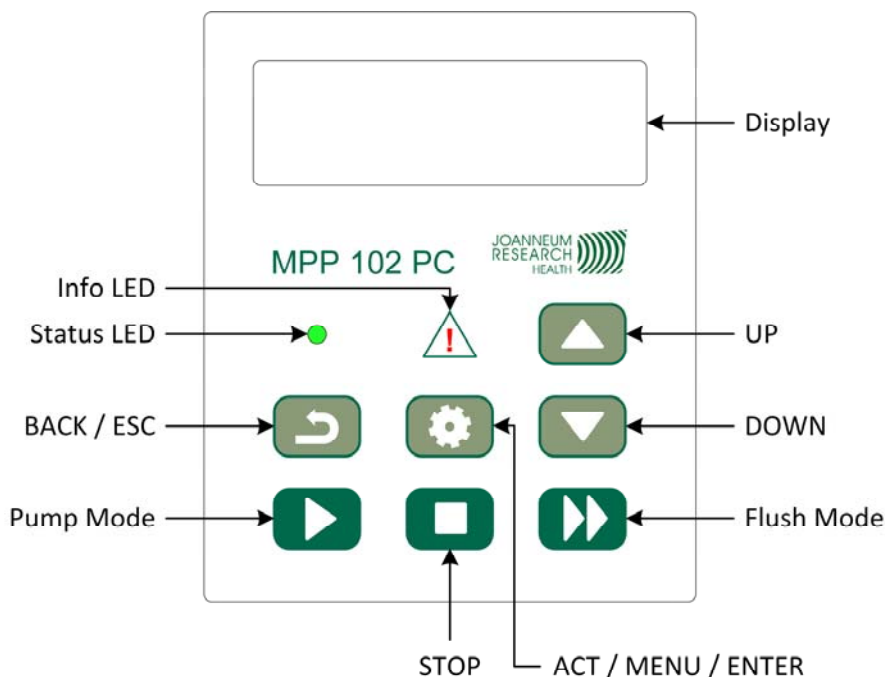


Figure 3: Overview of the display and keypad of the pump

The pumps display is the primary source of information for the user. The presentation of information is double-lined in stop / pump / flush mode (Figure 4) or four-lined during the parameterization via menu (Figure 5).

The home screen displays the actual flow rates of the two pump modules P1 and P2, the operating mode and time, the battery status and the keylock status.

Using the following symbols, the operating mode is displayed: Stop (■), pump mode (▶) or flush mode (▶▶ or ▶▶).

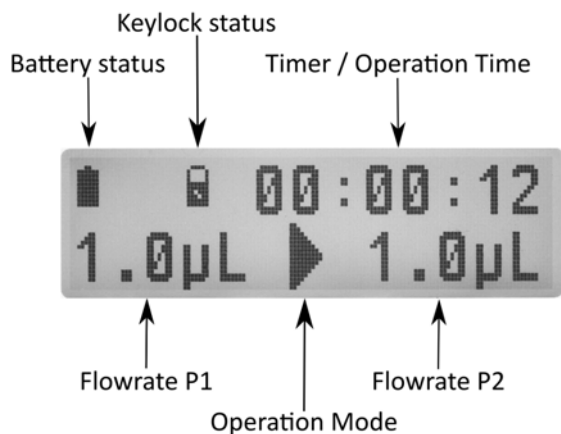


Figure 4: Double-lined display in home screen during stop / pump / flush mode

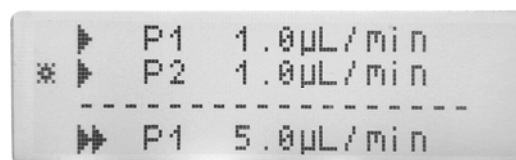


Figure 5: Four-lined display during parameterization via menu

5.2 Keypad and Functions

Element	Name	Function
	Status LED	Describes the status during operation
	Info LED	Indicates notification for the operator
	ACT/ SET/ ENTER	Long pressing (> 3s) in standby activates the pump Long pressing (> 3s) in home screen enters the menu Short pressing confirms the selected input or selection
	UP	Increases the numerical value or navigates through the menu By sequentially pressing  and  the keypad lock can be activated / deactivated By long pressing  all active notifications are shown
	DOWN	Decreases the numerical value or navigates through the menu
	BACK/ ESC	Returns to the previous menu without saving any changes At home screen: enters the parameter overview
	START	Short pressing starts the pump mode, when being confirmed with  afterwards
	FLUSH	Short pressing starts the flush mode, when being confirmed with  afterwards Long pressing (> 3s) starts the second flush mode, when being confirmed with  afterwards.
	STOP	Stops the pump and flush mode, when being confirmed with  afterwards

5.3 Display Symbols and Functions

Symbol	Name	Function
	Keypad lock	Keypad lock active The keypad lock can be activated / deactivated by sequentially pressing the buttons  and 
	Operated on power grid	Pump is operated by power grid supply
	Battery full	Sufficient battery capacity available Only visible in battery mode
	Battery nearly empty	Battery nearly empty, change the battery soon
	Battery empty	Insufficient battery capacity, change the battery immediately, the remaining runtime is less than 10min. In addition, the message "Battery low Confirm" is displayed and an acoustic signal is emitted
	ACT	Displays the current selection of the menu In addition, the symbol is requesting to confirm the selected parameters with 
	Choice	Displays the current choice of the menu before the new selection is made
	Maintenance pending	Maintenance interval exceeded or critical operating condition. Contact manufacturer for further information if symbol is shown permanently
	Pump Mode	Pump operates in pump mode
	Flush Mode	Pump operates in flush mode
	Second Flush Mode	Pump operates in second flush mode
	Stop	Pump is stopped

5.4 Messages and Meaning

The pump interacts with the user in three ways to indicate informational and/or error messages:

1. Status and Info LED - permanent or flashing visual signal
2. Acoustic beeper - acoustic signal
3. Messages on the display - words or symbols

By long pressing  all confirmed but still active notifications are shown. This includes restart messages.

Info on display	Function / Meaning	Status LED / Info LED	Acoustic signal
Selfcheck FW: X.X	Initialization / Self check	Flashing green	-
-	Ready to use / Operating / pump function ok	Steady green light or flashing light during operation	-
-	Key press	-	Single tone
Pump 1 Error Confirm	Motor or gear of pump head P1 without function	Flashing orange until error is fixed	10s interval until error is fixed
Pump 2 Error Confirm	Motor or gear of pump head P2 without function	Flashing orange until error is fixed	10s interval until error is fixed
Battery low Confirm	Battery is empty	Flashing orange until error is fixed	10s interval until error is fixed
Undervoltage Confirm	Rated voltage for operation with power supply was undershot	Flashing orange until error is fixed	10s interval until error is fixed
Overvoltage Confirm	Rated voltage for operation with power supply was overshot	Flashing orange until error is fixed	10s interval until error is fixed
Reboot Confirm	Info after power failure and restart (e.g. low battery)	Flashing orange until confirmed by user	10s interval until confirmed by user
Timer Reset Confirm	Pump-Timer was reset to 0 due to reboot in pump mode	Flashing orange until confirmed by user	10s interval until confirmed by user
Flush Stopped Confirm	Info after power failure and restart in flush mode if the flush is stopped due to menu setting	Flashing orange until confirmed by user	10s interval until confirmed by user
Flush Restart Confirm	Info after power failure and restart in flush mode if the flush is restarted due to menu setting	Flashing orange until confirmed by user	10s interval until confirmed by user
Power Error Confirm	Power supply without voltage Pump operates on battery supply	Flashing orange until error is fixed	10s interval until error is fixed

Info on display	Function / Meaning	Status LED / Info LED	Acoustic signal
Temperature Confirm	Internal temperature is above 41°C	Flashing orange until temperature below threshold	10s interval until temperature below threshold
Service Confirm	Service due to operating hours or serious pump malfunction	Flashing orange until service is performed	10s interval until confirmed by user
Parameter Reset Confirm	One or more parameter was set to the default value	Flashing orange until confirmed by user	10s interval until confirmed by user

5.5 Menu Structure and Settings

5.5.1 Menu for Setting the Parameters

Parameterization of the pump is performed from the home screen by long (> 3s) pressing the  button. Afterwards, the following overview is displayed and can be navigated using buttons  and .

```

❖ ▶ P1 1.0µl
  ▶ P2 1.0µl
-----
▶▶ P1 5.0µl
▶▶ P2 5.0µl
▶▶ 00:05:00
▶▶ Auto Stop
▶▶ Reboot Stop
-----
┌┐ P1 5.0µl
┌┐ P2 5.0µl
┌┐ 00:05:00
┌┐ Auto Stop
┌┐ Reboot Stop
-----
Tubing Adj P1 0%
Tubing Adj P2 0%
Keylock Auto
Lock Timeout 60s
Light Energy Saving
Brightness 70%
Contrast 0
Buzzer Volume 3
Parameter Reset
Manual Standby
Serial No xyz

```

Figure 6: Menu items for setting the parameters (factory-default values shown in green)

Symbol ❖ indicates the current selection in the menu. The individual menu items can be accessed by pressing the  button again and can then be parameterized. The following settings of the pump can be parameterized and saved by pressing the  button:

Display	Function
▶ P1 1.0µl	Adjusts the flow rate in pump mode of pump head P1 from 0.1 to 10µl/min
▶ P2 1.0µl	Adjusts the flow rate in pump mode of pump head P2 from 0.1 to 10µl/min
▶▶ P1 5.0µl	Adjusts the flow rate in flush mode of pump head P1 from 0.1 to 10µl/min
▶▶ P2 5.0µl	Adjusts the flow rate in flush mode of pump head P2 from 0.1 to 10µl/min
▶▶ 00:05:00	Sets the duration of the flush mode in hh:mm:ss
▶▶ Auto Stop	Sets the next step of the pump after the flush mode is finished: "Auto Pump" - Automatic change from flush to pump mode "Confirm Pump" - After pressing , change from flush to pump mode "Auto Stop" - Pump stops automatically "Confirm Stop" - After pressing , the pump stops
▶▶ Reboot Stop	Sets the behaviour of the pump if a reboot during flush mode occurred: "Stop" - Pump stops automatically after reboot "Restart" - Flush mode is restarted from the beginning after reboot
┌ P1 5.0µl	Adjusts the flow rate in second flush mode of pump head P1 from 0.1 to 10µl/min
┌ P2 5.0µl	Adjusts the flow rate in second flush mode of pump head P2 from 0.1 to 10µl/min
┌ 00:05:00	Sets the duration of the second flush mode in hh:mm:ss
┌ Auto Stop	Sets the next step of the pump after the second flush mode is finished: "Auto Pump" - Automatic change from flush to pump mode "Confirm Pump" - After pressing , change from flush to pump mode "Auto Stop" - Pump will stop automatically "Confirm Stop" - After pressing , the pump stops
┌ Reboot Stop	Sets the behaviour of the pump if there was a reboot during second flush mode: "Stop" - Pump stops automatically after reboot "Restart" - The flush mode is restarted from the beginning
Tubing Adj P1 0%	Sets a correction factor for pump and flush mode for pump head P1 Is used to adapt to alternative OFM Tubing Set. In this case, the correction factor is visible on the packaging of the OFM Tubing Set under "Tubing Adj XX%"
Tubing Adj P2 0%	Sets a correction factor for pump and flush mode for pump head P2 Is used to adapt to alternative OFM Tubing Set. In this case, the correction factor is visible on the packaging of the OFM Tubing Set under "Tubing Adj XX%"

Display	Function
Keylock Auto	Sets the keypad lock: • "Auto" - Automatic keypad lock after timeout • "Manual" - Manual keypad lock
Lock Timeout 60s	Time (15 to 600s) that elapses until keypad lock is active
Light Energy Saving	Sets the display illumination: • "Permanent On" - Constantly turned on • "Permanent Off" - Constantly turned off • "Energy Saving" - Turns off automatically 10 seconds after last keypress
Brightness 70%	Adjusts brightness from 20 to 100%
Contrast 0	Adjusts contrast from -10 to 10
Buzzer Volume 3	Adjusts volume of the button signals from 0 (off) to 3 (loud) Informational and/or error messages are always set to volume 3
Parameter Reset	Resets all parameters to default values (only available if pump is stopped)
Manual Standby	Sends the pump directly to standby (only available if pump is stopped)
Serial No xyz	Displays serial number

5.5.2 Parameter Overview

To prevent unintended changes of parameters, all parameters can be displayed even without deactivating the keypad lock. For this, the button  must be pressed briefly on the home screen. Afterwards the following overview is displayed and can be navigated using the keys  and .

```

▶ P1 1.0µl
▶ P2 1.0µl
-----
▶▶ P1 5.0µl
▶▶ P2 5.0µl
▶▶ 00:05:00
▶▶ Auto Stop
▶▶ Reboot Stop
-----
┌ P1 5.0µl
┌ P2 5.0µl
┌ 00:05:00
┌ Auto Stop
┌ Reboot Stop
-----
Tubing Adj P1 0%
Tubing Adj P2 0%
Keylock Auto
Lock Timeout 60s
Light Energy Saving
Brightness 70%
Contrast 0
Buzzer Volume 3
P1  in 6000h
P2  in 6000h
Serial No xyz

```

Figure 7: Overview of parameters (factory-default parameters)

6 Preparing for Operation

Prior to using the pump read chapter 2 Safety Information.

6.1 Preparing the Pump

Check Contents upon Delivery:

Despite careful packaging, transport damage can occur. After unpacking, the pump should be checked for any damages and completeness according to these instructions. **DO NOT** operate a damaged pump!



CAUTION

Acclimatize pump and all accessories for at least 2 hours to room temperature and humidity level before use. Avoid the formation of condensation caused by sudden changes in temperature or high humidity.

Unpacking:

Remove the pump from its packaging over a secure base (e.g. table).

6.1.1 Disinfection of the Pump

Disinfect the pump prior to use according to chapter 8.1 Cleaning and Disinfection.

6.1.2 Insert Battery / Connect Power Supply / Start Pump

Insert battery (refer to Figure 8 to Figure 10): Open the battery compartment cover with the enclosed tool, check for correct polarity and insert new batteries. Then close the battery compartment cover.

USE Lithium batteries **compliant with IEC 60084-4**, size C with 3.6V **ONLY**; for example EVE ER26500M, Saft LSH 14 or Dynamis LI-250.



CAUTION

Using other types or rechargeable batteries than specified herein may lead to malfunctions or in worst case, may cause damage to the pump and thus endanger the user.



Figure 8: Open the battery compartment with the provided tool.



Figure 9: Insert a new battery according to the polarity. The battery removal strip underneath the battery facilitates easier removal.



Figure 10: Close the battery compartment cover with the tool by securing the battery compartment screw. Do not jam the battery removal strip.

CAUTION



Upon being turned on, the battery level may temporarily display incorrect information for a few minutes before resetting to the correct level. This is a characteristic of Lithium batteries. After a few minutes of operation, the shown battery level is correct.

If the pump is powered with battery, the display shows the symbol for battery operation (■).

Alternatively, the pump can be operated via power supply from the manufacturer Egston, type E2CFMW3 12 with 5V. For this purpose, remove the moisture protection jack and connect the power supply. If the pump is supplied with power, the display shows the power grid operation symbol ⚡. When the power supply is no longer needed and disconnected, insert the moisture protection jack again so that moisture penetration is prevented.

If the power supply is connected while there is a battery inside the pump, the supply is switched to the power supply automatically. In this case, the battery serves as a backup.

If the power supply is connected but the symbol for battery operation is shown or the “Battery low Confirm” message is shown the pump has to be checked by the manufacturer.

CAUTION



The use of other power supplies than specified herein, may lead to malfunctions and in the worst case, cause damage to the pump and thus endanger the users.



Figure 11: Alternative operation of the pump via power supply.

6.1.3 Switch on Pump

After inserting the battery or connecting the power supply, the pump switches on automatically. If the pump is on standby, long (> 3s) pressing of the button  will turn on the pump. When starting, the firmware version is shown.

“Selfcheck”: In the boot sequence the stored user parameter are checked for plausibility. If this check fails, the appropriate value is set to the default value and a message is displayed (refer to chapter 9).

6.1.4 Maintenance Check

Prior to use, the pump must be checked if the maintenance is overdue, refer to chapter 10.

6.1.5 Keypad Lock

To avoid unauthorized access, the pump features a keypad lock. An active keypad lock is displayed by the  symbol.

By sequentially pressing  and  the keypad lock can be manually activated / deactivated.

As default setting, the pump activates the keypad lock 60 seconds after the last button press. This period could be changed via the menu item **Lock Timeout 60s**.

6.1.6 Serial Number

The menu item “Serial Number xyz” in the parameter overview displays the serial number.

6.1.7 Buzzer Volume

The menu item “**Buzzer Volume 3**” adjusts volume of the button signal from 0 (off) to 3 (loud). By pressing the buttons  and , the volume can be changed if afterwards confirmed by pressing .

Informational and/or error messages always resound with volume 3.

6.1.8 Parameter Reset

With the menu item “**Parameter Reset**” all user-parameters are set to default values.

6.1.9 Pump Standby

With the menu item “**Manual Standby**” the pump could be sent to standby mode. This is only available if the pump is stopped.

In battery mode, the stopped pump is automatically sent to standby 10 minutes after the last keypress. If the pump is in pump or flush mode, the standby is disabled.

If the pump is operated on power supply, the automatic standby is disabled.

6.2 Configuration of Trial Parameter

6.2.1 Pump Flowrate

The pump flow rate can be adjusted via menu item **► P1 1.0µl** for pump head P1 or **► P2 1.0µl** for pump head P2. Flow rates can be adjusted from 0.1 to 10µl/min, using the buttons  and , and confirmed using .

Short pressing of  starts the pump mode when being confirmed with . The elapsed time since start / reboot is shown on the display.

Short pressing of  stops the pump mode when being confirmed with .

6.2.2 Flush Mode

The flush rate can be adjusted via menu item **►► P1 5.0µl** for pump head P1 or **►► P2 5.0µl** for pump head P2. Flush rates can be adjusted from 0.1 to 10µl/min using the buttons  and , and confirmed, using .

The duration of the flush mode is sequentially set via menu item **▶▶ 00:05:00** in hh:mm:ss using the buttons **▲** and **▼**, and confirmed using **⚙**. The duration could be any time between 00:00:01 and 23:59:59.

The menu item **▶▶ Auto Stop** sets the next step of the pump after the timer has expired:

- "Auto Pump" - Automatic change from flush to pump mode.
- "Confirm Pump" - After pressing **⚙**, change from flush to pump mode.
- "Auto Stop" - Pump will stop automatically.
- "Confirm Stop" - After pressing **⚙**, the pump stops.

The menu item **▶▶ Reboot Stop** sets the behaviour of the pump if a reboot occurs during flush mode. This could be caused by insufficient power supply. The following two options are available:

- "Stop" - The pump is stopped after reboot
- "Restart" - The flush mode is restarted from the beginning after reboot

The second flush mode can be parameterized analogue to the first flush mode using the menu items **P1 ▶ 5.0µl**, **P2 ▶ 5.0µl**, **▶▶ 00:05:00**, **▶▶ AUTO STOP** and **▶▶ Reboot STOP**.

Short pressing of **▶▶** starts the flush operation when being confirmed with **⚙**. The remaining time is shown on the display.

Long pressing (> 3s) of **▶▶** starts the second flush mode, when being confirmed with **⚙**. The remaining time is shown on the display.

6.2.3 Tubing Adjustment

The menu item **Tubing Adj P1 0%** and **Tubing Adj P2 0%** sets a correction factor for pump and flush mode for the corresponding pump head from -99 to 100%. This is used to adapt the pump to different OFM Tubing Set. The according value is shown on the label of the OFM Tubing Set with "Tubing Adj XX%".

The maximum possible value depends on manufacturer settings.

6.3 Preparing and Connecting Accessories

Only manufacturer-approved accessories may be used. Refer to chapter 4 for further information.



CAUTION

Read instructions for use of available OFM Tubing Set, OFM Catheter, OFM Perfusate Bag and further accessories to avoid contamination.



The assortment of OFM Tubing Set, OFM Catheter, and accessories is continuously expanded. Please contact your distributor or the manufacturer for detailed information and newest components.

6.3.1 Installing OFM Tubing Set and OFM Perfusate Bag



WARNING

The pump **MUST NOT** be used with inflammable fluids or any other dangerous liquid (e.g. acids, alkaline solutions, solvents, detergents, etc.) or hot fluids (>45°C) as perfusate! These liquids could damage the OFM Tubing Set and the OFM Pump.

This is a general instruction suitable for most OFM Tubing Set, for further details refer to the corresponding instructions for use:

1. Unpack OFM Tubing Set and OFM Perfusate Bag.
2. Connect Push-Part of OFM Tubing Set with OFM Perfusate Bag according to the instructions for use.
3. Fill OFM Perfusate Bag via injection port according to the instructions for use.
4. Remove the cover of the pump head.
5. Insert Tubing into the pump head according to the specific instructions for use:
 - a. Open pump head by pulling the snap mechanism.
 - b. The rotation of the pumphead is clockwise; fluid is pumped from the right to the left side.
 - c. Insert OFM Tubing Set, the part connected to the OFM Perfusate Bag has to be on the right side of the pump head. Therefore insert the OFM Tubing Set into the left (seen from the front), spring-loaded fitting of the pump head, pull it slightly forward and insert the OFM Tubing Set into the right fitting of the pump head.
 - d. Close the pump head.
 - e. Insert the OFM Tubing Set into the retaining spring on the back of the pump.
 - f. Put OFM Perfusate Bag into the right storage compartment or attach it to the OFM Bag Holder.
6. Insert OFM Tubing Set analogue into second pump head.
7. Reattach cover of the pump heads. Do not jam the OFM Tubing Set between pump and cover.



Figure 12: Opening of pump head using the snap mechanism.



Figure 13: Inserting the OFM Tubing Set into the left fitting.

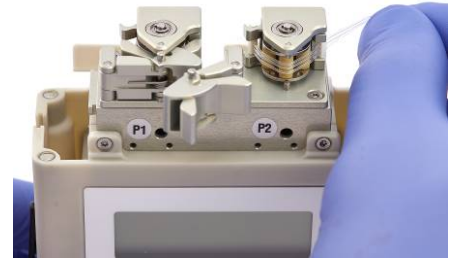


Figure 14: Inserting the OFM Tubing Set into the right fitting.



Figure 15: OFM Tubing Set is fixed with retaining springs in the pump.

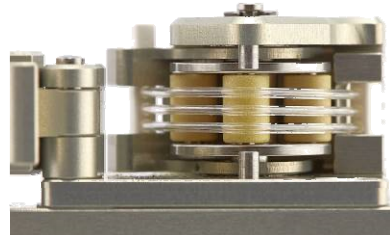


Figure 16: OFM Tubing Set inserted CORRECTLY.

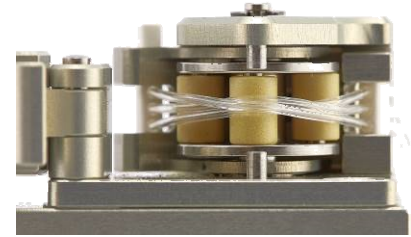


Figure 17: OFM Tubing Set inserted INCORRECTLY (twisted).

CAUTION



DO NOT use tools to insert the OFM Tubing Set into the pump.

When inserting the OFM Tubing Set, make sure that each of the individual tubings (if multichannel tubings are used) are parallel to the pump head and not twisted or crossed, because this can lead to incorrect flow rates or damage to the pump and OFM Tubing Set.

6.3.2 Implanting OFM Catheter

For implanting the OFM Catheter refer to the corresponding instructions for use for a/dOFM or cOFM catheters.

6.3.3 Pump fixation / OFM Pump Base

The pump could be used horizontal and vertical, for best durability use horizontal position. For fixation the four brackets on the backside could be used. Alternatively, the OFM Pump Base should be used to prevent the pump from tipping over.

6.3.4 OFM Bag Holder

The OFM Perfusate Bag could either be stored in the right storage compartment or hung up on the OFM Bag Holder, which is mounted in the right storage compartment. If the OFM Bag Holder is used the cover of the pumpheads can not be used.



Figure 18: Pump with OFM Pump Base



Figure 19: Pump with OFM Bag Holder

6.3.5 Flushing the System

Before starting with the actual sampling process, the OFM Tubing Set must be filled with perfusate. This can be performed by using an increased flow rate at a maximum of 10µl/min in the flush mode.

Take care to ensure that the entire OFM Tubing Set is completely filled with perfusate. Remove visible air bubbles using flush mode until the OFM Tubing Set is free of any air bubbles.



The OFM Tubing Set could face some kind of running-in behaviour (within the quoted tolerance of $\pm 20\%$) in the first few hours of operation. The flow rate could be slightly varying.

6.3.6 Connecting and Operating the System

Connect the used OFM Catheter with an appropriate connector to the push tubing (refer to the instructions for use of the OFM Catheter respectively the OFM Tubing Set for detailed information).

Connect the OFM Sampling Unit: Connect the inserted OFM Catheter with an appropriate connector to the pull tubing or sampling unit (refer to the instructions for use of the OFM Catheter, OFM Tubing Set or OFM Sampling Unit for detailed information).

Operation of the Overall System: Now, fluid samples from the tissue can be collected with the required flowrate.

7 Recurring Activities during Operation

7.1 Changing the Battery

During longer studies, it may be necessary to change the battery. If the battery runs out, it will be indicated on the display by the message “Battery low Confirm”. Additionally an acoustic signal and an orange flashing LED is activated. Change the battery immediately, the remaining operation time is less than 10min.

Refer to chapter 6.1.2 on how to change the battery.

If the battery is replaced, the pump is in operation mode and not supplied from a power supply unit, the message “Reboot Confirm” followed from the message “Timer Reset Confirm”/“Flush Stopped Confirm”/ “Flush Restart Confirm” appears after inserting a new battery. This messages has to be confirmed. The behaviour of the pump after changing the battery depends on the operating mode prior to the battery change:

- Pump mode: the pump starts again automatically, but the timer is set to zero.
- Flush mode: the behaviour depends on the setting “ Reboot” and “ Reboot” in the menu and is shown via the message “Flush Stopped Confirm” or “Flush Restart Confirm” after the “Reboot Confirm” message. If the flush mode is restarted, the timer starts again at the value defined in the menu.

7.2 Changing / Refilling the OFM Perfusate Bag

The OFM Perfusate Bag can be refilled easily during use. Refer to the specific instructions for use for detailed information.

The OFM Perfusate Bag can also be changed during use:

- When changing the OFM Perfusate Bag, a new, empty one should already be prepared.
- The pump heads have to remain closed.
- The OFM Tubing Set must remain in the pump! Only remove it after completion of the study.
- Stop the pump to avoid air bubbles from entering the system.
- Open the cover of the pump heads and remove the empty OFM Perfusate Bag.
- Loosen the connector from the empty OFM Perfusate Bag and screw it onto the new empty OFM Perfusate Bag. A few drops of perfusate could drop out of the (nearly) empty OFM Perfusate Bag.
- Fill the new OFM Perfusate Bag as described in the instructions for use.
- Insert the new OFM Perfusate Bag in the right storage compartment of the pump or on the OFM Bag Holder and close the cover.
- Start pump again.



CAUTION

Maintaining a sterile environment during the OFM Perfusate Bag-changing process is recommended.

7.3 Changing the Probe Container

The probe container must be changed periodically depending on the flowrate and study design.

In the case of long sampling intervals, actions have to be taken if there is any chance of liquids pouring out of the OFM Tubing Set. This is to prevent the pump from being contaminated.

8 Removing the Pump – End of Trial

After completion of the study, remove pump as follows:

- Deactivate keypad lock by sequentially pressing the buttons  and .
- Short pressing of  and sub sequential pressing of  stops the pump.
- To remove the pump, loosen the connector between OFM Tubing Set and OFM Catheter.
- Remove the OFM Tubing Set from the pump.
- Clean the pump according to chapter 8.1.

For explantation of the OFM Catheter, refer to the corresponding instructions for use.



WARNING

DISPOSE all single-use products (e.g. OFM Catheter, OFM Tubing Set and OFM Perfusate Bag) according to routine regulations to prevent reuse or contamination with biological material.

8.1 Cleaning and Disinfection

The pump and the power supply should be cleaned and disinfected before and after every trial using biological material.

Recommended procedure:

- Lint-free cotton cloth
- Alcoholic cleaner (> 70%), non-abrasive for wipe and spray disinfection

CAUTION

To avoid the risk of electric shock before and after cleaning and disinfection:



- Unplug power supply from mains and pump.
- Remove batteries from the pump and dispose properly.
- Let the pump and power supply dry completely before reuse.

DO NOT autoclave or immerse pump in liquids.



CAUTION

Other cleaners then listed above may affect the plastic housing of the pump.

9 Trouble Shooting

Error / Message	Cause of error	Trouble shooting
"Pump Error Pump 1"	Pump head 1 blocked Motor / gears broken	Open pump head - check for any blockages – close pump head and restart pump ¹ Contact distributor
"Pump Error Pump 2"	Pump head 2 blocked Motor / gears broken	Open pump head - check for any blockages – close pump head and restart pump ¹ Contact distributor
"Battery low Confirm"	Empty Battery	Insert new battery Normal behaviour for a new battery in the first minutes, especially in flush mode
"Temperature Confirm"	Internal temperature above 41°C	Remove pump and replace with a new one Do not place pump on any heat source Check room temperature Contact distributor
"Reboot Confirm"	Message after reboot of the pump in pump or flush mode (e.g. low battery)	Renew battery or confirm if just changed Check power supply
"Timer Reset Confirm"	Message after reboot of the pump in pump mode	Just information for the user that the timer is reset
"Flush Stopped Confirm"	Message after reboot of the pump in flush mode (e.g. low battery), depends on the menu settings	Just information for the user that the pump has stopped due to reboot
"Flush Restart Confirm"	Message after reboot of the pump in flush mode (e.g. low battery), depends on the menu settings	Just information for the user that the flush mode has restarted due to reboot

¹ In very rare cases, this warning could occur in the first 100 to 200 hours of a new pump or if the pump was stored for a long time without operation, especially when directly used with high flow rates. This is due to slightly hardened lubricant in the gearhead. Try starting the pump with 1µL/min and let it run for several hours in horizontal orientation. If the error persist, contact the distributor or manufacturer.

Error / Message	Cause of error	Trouble shooting
"Power Error Confirm" + maintenance symbol	Rated voltage for operation with power supply is insufficient Power grid failure Power supply is not connected to the power grid (only to pump)	Exchange power supply Check power grid Connect the power supply to the power grid
"Undervoltage Confirm" or "Overvoltage Confirm"+ maintenance symbol	Rated voltage for operation with power supply was undershot or overshot	Check for correct power supply Exchange power supply Contact distributor
Pump cannot be turned on	Wrong / empty battery Power supply unit broken Keypad broken	Exchange battery Exchange power supply Contact distributor
"Service Confirm"	Service interval reached	Contact distributor
No flow rate	OFM Tubing Set inserted incorrectly OFM Perfusate Bag empty OFM Tubing Set pinched off Pump head not closed	Check OFM Tubing Set Check level of OFM Perfusate Bag Check snap mechanism of the pump head Close pump head
Decreased flow rate	Incorrect OFM Tubing Set Tubing adjustment configured wrong Incorrect settings OFM Tubing Set pinched off Pump head not closed Air bubbles within the system	Check OFM Tubing Set Check settings Check snap mechanism of the pump head Close pump head Remove air bubbles
Increased flow rate	Incorrect OFM Tubing Set Tubing adjustment wrong or not determined Incorrect settings	Check OFM Tubing Set Check settings
Air bubble within the system	Air suction System not tight Air bubbles inside of OFM Perfusate Bag	Check connectors Remove air bubbles from the system / OFM Perfusate Bag
Pulsation of fluid inside OFM Tubing Set	No error, normal behaviour due to peristaltic pump	--

Error / Message	Cause of error	Trouble shooting
Leakage of liquids	System not sufficiently fastened	Check connectors
	OFM Tubing Set damaged	Check OFM Tubing Set
Parameters already set by the user are set repeatedly to default after rebooting or message "Parameter Reset"	Memory broken	Contact distributor

10 Servicing / Maintenance

DO NOT perform maintenance work or service on any part of the pump. In order to ensure optimum function the pump must be inspected at least every 12 months or when service is indicated on the display. Failure to carry out maintenance in accordance with the instructions will invalidate the warranty.

The menu item " **P1**  in 16h " and " **P2**  in 16h " displays the remaining operating hours. In this case, both pump modules would require maintenance within 16 hours. If, due to increased operating hours, maintenance activities are necessary to be performed before the end of 12 months, this is indicated by the  symbol. The message "Service Confirm" will also be displayed. The normal inspection interval is 6000 operating hours at 1µl/min. In case of other flowrates, the interval changes proportional to the flowrate.

In case the 12 months expired (refer to the inspection sticker on the backside of the pump) or when the  symbol is shown on the display send the pump to the distributor for service.



Figure 20: Inspection sticker



Always send the pump within the storage case and with the power supply.



CAUTION

DO NOT use dropped or malfunctioning pumps. The pump must be checked by the manufacturer before being reused.



To avoid data loss during servicing, parameters and settings must be recorded and stored by the user prior service or repair.



CAUTION

Maintenance and repairs must be performed by the manufacturer Joanneum Research or by authorized and qualified professionals only. For further information to Service or Maintenance, contact your distributor.

DAMAGE CAUSED TO THE PUMP BY USER OR ANY NON-AUTHORIZED THIRD PARTY MAY VOID MANUFACTURER'S WARRANTY.

BATTERIES OR ANY PROBLEM THAT IS CAUSED BY ABUSE OR MISUSE ARE NOT COVERED.

ALSO, CONSEQUENTIAL AND INCIDENTAL DAMAGES ARE NOT RECOVERABLE UNDER THIS WARRANTY. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

11 Storage and Transportation

The pump must be sufficiently stored before transportation. Transport the pump only in its original storage case to avoid damages to the pump while transporting. Always include the power supply when the pump is sent for service or maintenance.



Figure 21: Storage case

ALWAYS store the pump in the designated storage case. **REMOVE** the batteries from the battery compartment while storing the pump.

Store the pump in a suitable place, the following conditions are strictly recommended:

- **NO** storage on places with high dust concentrations (e.g. mechanical workshops)
- **NO** storage on places with high UV-Radiation
- Temperature: -30°C to +70°C
- Humidity: 10% to 95%, non-condensing
- Air Pressure: 70 to 106kPa

Unless stated otherwise on accessories' packaging, store accessories under the same conditions as the pump.

AVOID formation of condensation caused by sudden changes of temperature or high humidity. A slow adjustment to room temperature is recommended.

12 Technical Data

Microperfusion-Pump

Type: MPP102 PC or MPP102-II PC

Firmware: 1.x – starting with version 1.3

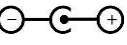
Field of application: Microperfusion and Microdialysis

Adjustable Flow Rates: 0.1 - 10µl/min flow rate (with an accuracy of $\pm 20\%$; depends on OFM Tubing Set used. Use precalibrated OFM Tubing Set to ensure best accuracy)

Resolution:

- 0.1µl/min at 0.1 – 2.0µl/min flow rate
- 0.2µl/min at 2.0 – 5.0µl/min flow rate
- 0.5µl/min at 5.0 – 10.0µl/min flow rate

Power Supply:

- Lithium Battery, Size C, 3.6V, conform to IEC 60086-4
 - E.g. EVE ER26500M, SAFT LSH 14 or Dynamis LI-250
 - Typical operating time (with a new battery): up to 48 hours at 1.0µl/min
- Power supply of manufacturer Egston, type E2CFMW3 12 with 5V, 1500mA
 - 3.75 / 1.35mm DC Plug with polarity: 

Rated Data of Pump:

- Nominal voltage: 3.6V
- Current Rating: 1500mA $\equiv$

Dimensions:

Pump 135 x 92 x 34.5mm

Total Weight:

MPP 102 PC: 320g excl. battery and accessories
 MPP 102-II PC: 325g excl. battery and accessories

Compatibility OFM Tubing Set:

MPP102 PC: up to 3-channel OFM Tubing Set
 MPP102-II PC: up to 4-channel OFM Tubing Set

Display: LCD with backlight

Ambient Operating Temperature: 5 to 40°C

Operating condition: indoor use only, up to 2000m / 6500ft above sea level

Permissible Relative Humidity during Operation: 20 to 80%, non-condensing

Delivery: Storage case with foam inserts, Microperfusion-Pump MPP102 PC or MPP102-II PC, instructions for use, power supply, T10 key to remove the battery, OFM Pump Base and OFM Bag Holder.

Overvoltage category and pollution degree:

- Pump: I
- Power supply: II

13 Identification Label and Symbols

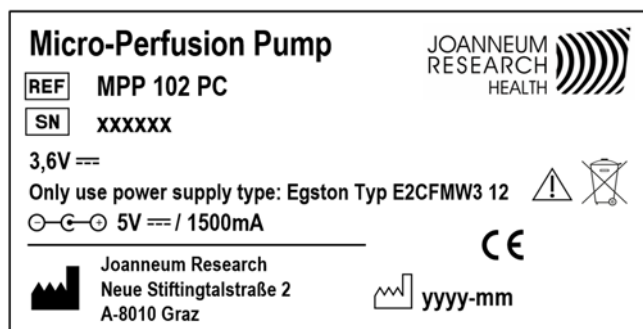


Figure 22: Identification label on the back of the MPP102 PC

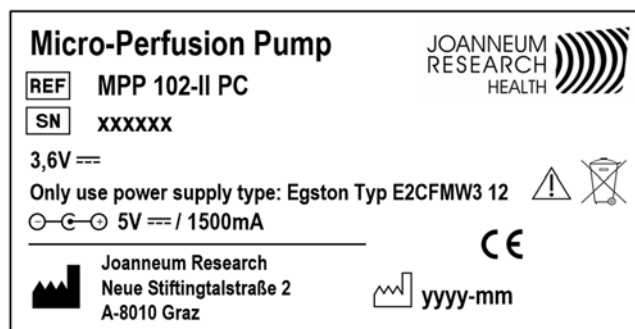


Figure 23: Identification label on the back of the MPP102-II PC

Symbol	Description
	Order number (type designation)
	Serial number
	Date of manufacture
	Name and address of manufacturer
	Identifies a caution statement that warns failure to follow the instructions may lead to device misuse, malfunction, or damage.
	Do not dispose pump as household waste
	Direct current
	Polarity of the power supply (positive pole inside)

14 Limited Warranty

All equipment sold by Joanneum Research (“Company”) is warranted to be free from defects in both materials and workmanship for a period of one (1) year unless otherwise specified. Parts and accessories (excluding batteries) are covered by a 90-day limited warranty unless otherwise specified. Batteries are not covered under this warranty. Any stated warranties are in effect from the date of sale. Joanneum Research reserves the right to repair, replace or refund (less cost of shipping) any item(s) requiring warranty service. The customer is responsible for return shipping costs and required to contact Joanneum Research prior to shipping the item(s) back.

To obtain the benefits of this warranty, proof of rebuild by Joanneum Research (such as a copy of repair record, invoice or cancelled check) must be submitted if requested by Joanneum Research.

This warranty is void if:

- (a) The equipment has been damaged by negligence, accident or mishandling, or has not been operated in accordance with the procedures described in the instructions for use; or
- (b) The equipment has been altered or repaired by any company or entity other than Joanneum Research or adaptations of accessories have been made or attached to the equipment which, in the determination of Joanneum Research shall have affected the performance, safety, or reliability of the equipment. **NO OTHER WARRANTY EXPRESSED OR IMPLIED, INCLUDING MERCHANTABILITY, APPLIES TO THE EQUIPMENT, NOR IS ANY PERSON OR COMPANY AUTHORIZED TO ASSUME ANY OTHER WARRANTY.** Joanneum Research does not assume any responsibility for any consequential damages occasioned by the equipment, or inconvenience or interruption in operation.

Exclusions

- Parts and accessories are covered for 90 days.
- Batteries are excluded from this warranty.
- International orders are excluded from this warranty.
- This Limited Warranty does not cover normal wear and tear of the product or costs related to the removal, installation, or troubleshooting of the customer’s electrical systems. This warranty does not apply to and Joanneum Research will not be responsible for any defect in or damage to:
 - o The product if it has been misused, neglected, improperly installed, physically damaged or altered, either internally or externally, or damaged from improper use or use in an unsuitable environment or the use of unauthorized accessories;
 - o The product if repairs have been done to it other than by Joanneum Research or its authorized service centres (hereinafter “ASCs”);
 - o The product if the annual or by the pump requested maintenance was not performed or was performed by other than by Joanneum Research or its authorized service centres;
 - o The product if it is used as a component part of a product expressly warranted by another manufacturer; or
 - o The product if its original identification (tamper tag, trademark, serial number) markings have been defaced, altered, or removed.

WARNING Limitations On Use

Please refer to your instructions for use for limitations on uses of the product.

14.1 Return Material Authorization Policy

Before returning a product, you must contact your distributor to obtain a Return Material Authorization (“RMA”) number and the correct factory “Ship To” address. Products must also be shipped prepaid. Product shipments will be refused and returned at your expense if they are unauthorized returned without an RMA number clearly marked on the outside of the shipping box, if they are shipped collect, or if they are shipped to the wrong location. When you contact your distributor to obtain service, please be prepared to supply the following information:

1. Your product serial number,
2. A copy of your dated proof of purchase,
3. Information about the installation and use of the unit, and
4. Information about the failure and/or reason for the return.

Return Procedure

1. Clean the pump and all accessories according to Chapter 8.1 Cleaning and Disinfection
2. Package the unit safely, preferably using the original box and packing materials. Ensure that the product is shipped fully insured in the original packaging or equivalent. This warranty will not apply where the product is damaged due to improper packaging.
3. Include the following:
 - a. The RMA number supplied by the distributor clearly marked on the outside of the box.
 - b. A return address where the unit can be shipped. Post office boxes are not acceptable.
 - c. A contact telephone number where you can be reached during work hours.
 - d. A brief description of the problem.
4. Ship the unit prepaid to the address provided by your customer service representative.
5. The customer must notify the distributor or service center of a return with seven days of receiving the item. The customer will be responsible for return shipping costs and a 15% restocking fee.

Customers are responsible for the freight cost of returning the equipment to the distributor. The distributor will pay for the return of the serviced equipment. Customers are responsible for expedited method of shipping.

Disclaimer

THIS LIMITED WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY PROVIDED BY COMPANY IN CONNECTION WITH YOUR COMPANY PRODUCT AND IS, WHERE PERMITTED BY LAW, IN LIEU OF ALL OTHER WARRANTIES, CONDITIONS, GUARANTEES, REPRESENTATIONS, OBLIGATIONS AND LIABILITIES, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE IN CONNECTION WITH THE PRODUCT, HOWEVER ARISING (WHETHER BY CONTRACT, TORT, NEGLIGENCE, PRINCIPLES OF MANUFACTURER’S LIABILITY, OPERATION OF LAW, CONDUCT, STATEMENT OR OTHERWISE), INCLUDING WITHOUT RESTRICTION ANY IMPLIED WARRANTY OR CONDITION OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE TO THE EXTENT REQUIRED UNDER APPLICABLE LAW TO APPLY TO THE PRODUCT SHALL BE LIMITED IN DURATION TO THE PERIOD STIPULATED UNDER THIS LIMITED WARRANTY. IN NO EVENT WILL COMPANY BE LIABLE FOR ANY SPECIAL, DIRECT, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, LOSSES, COSTS OR EXPENSES HOWEVER ARISING WHETHER IN CONTRACT OR TORT INCLUDING WITHOUT RESTRICTION ANY ECONOMIC LOSSES OF ANY KIND, ANY LOSS OR DAMAGE TO PROPERTY, ANY PERSONAL INJURY, ANY DAMAGE OR INJURY ARISING FROM OR AS A RESULT OF MISUSE OR ABUSE, OR THE INCORRECT INSTALLATION, INTEGRATION OR OPERATION OF THE PRODUCT.

15 Notes

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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Doc. No.: UM_MPP102_PC_6-0

Date: 16-Aug-2022