MOBYBOX
by hemovent

Instructions for Use

REF: IFU-104-01D | EU 2025-03

MOBYBOX™ System, digital

HVEU-009 + HVCEU-005

RHEOPAX
SURFACE TECHNOLOGY

Use only after reading these Instructions for Use.
Observe safety precautions!

EN

MOBYBOX™ System – Overview

Before you start

The MOBYBOX™ System is intended to provide extracorporeal circulation and gas exchange in patients with cardiac and or lung impairments in accordance with the intended purpose of the device. **Important: Make yourself familiar with the intended purpose of the device on page 6 before you consider device usage!** The device consists of three components 1.) the MOBYBOX™ , a disposable patient module and a gas exchanger, 2.) a de-airing set to pre-fill the MOBYBOX™ before usage and 3.) the MOBYBOX™ Runner, a pneumatic controller for the MOBYBOX™ .

The device has the following interfaces:

MOBYBOX™ Interfaces: The blood carrying tubes are compatible to 3/8" bloodline connectors, which are not supplied as part of the system.

MOBYBOX™ Runner Interfaces: The MOBYBOX™ Runner is connected to flask or wall sources of oxygen (3-5 bar). The MOBYBOX™ Runner communicates with the MOBYBOX™ through pneumatic lines that deliver O_2.

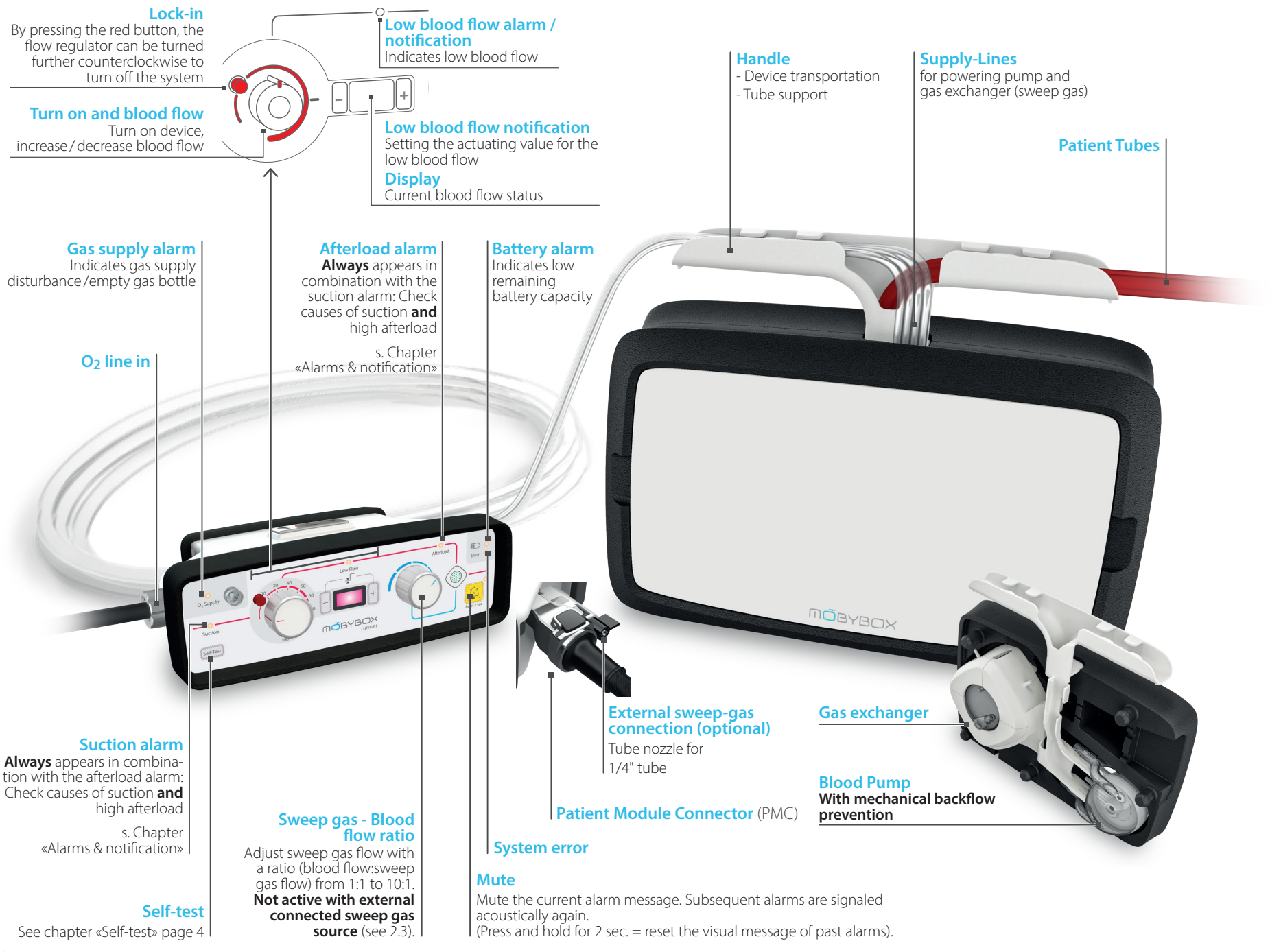
Use of the MOBYBOX™ System must be supplemented by an external vital-signs monitoring device (pulse oximeter (SpO_2) vital-signs monitor, etc.). A second independent gas source (e.g. oxygen bottle) can be connected via a changeover valve for uninterrupted operation.

MOBYBOX™ Runner HVCEU-005

Blood flow and gas exchange is regulated by the MOBYBOX™ Runner. Optionally, the connection of a blood flow-independent sweep gas source (flowmeter or gas blender possible) is possible. In this case, the internal sweep gas control is **deactivated**!

MOBYBOX™ (Part of MOBYBOX™ Set, HVEU-007)

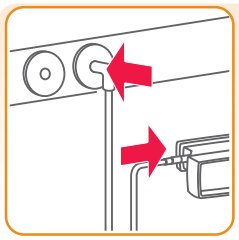
After usage the MOBYBOX™ patient module has to be appropriately disposed. Do not reuse.



1 Setup System (Patient <–> MOBYBOX™ <–> MOBYBOX™ Runner)

⚠ Ensure aseptic handling at all times. Avoid kinking the tubes att all times.

1.1 Preparation and de-airing procedure

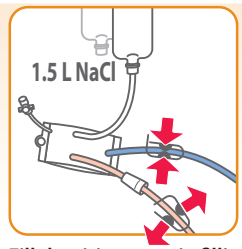


Connect MOBYBOX™ Runner to gas source

including sweep gas as shown in 2.3 (external gas blender).

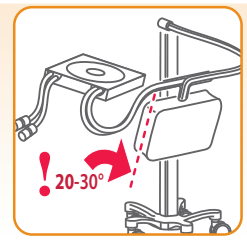
Unpack all material

Handle tray content in sterile way.



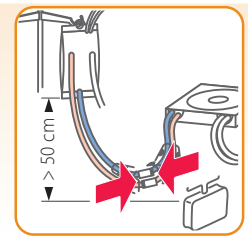
Fill de-airing set via filling line

Firmly close clamp on **blue** venous line, leave clamp open on **red** arterial line. Tighten stopcocks.
Fill with 1.5 L isotonic infusion solution, e.g. Ringer's lactate.



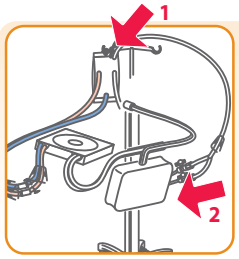
Unwrap MOBYBOX™

Hang the MOBYBOX™ on the lower rail of the docker.
The MOBYBOX™ then automatically hangs at an angle of 20°-30°.



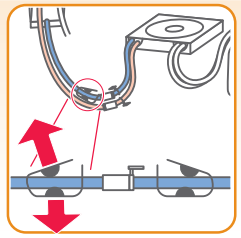
Connect tubes

Connect de-airing set with MOBY-BOX™ via quick connector. The de-airing set must be at least 50 cm over tube-tray.



Connect Purge-Line

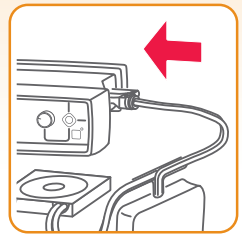
Connect the purge line to the stopcocks of the MOBYBOX™ and the filling bag, open the stopcocks and tighten the screw connections.



Passive deairing

Ensure that arterial clamp (**red** tube) is already open.
Let infusion passively run in. Open the clamp on the **blue** marked tube and wait until no more air bubbles rise in the de airing set.

Wait for approx. 30 seconds

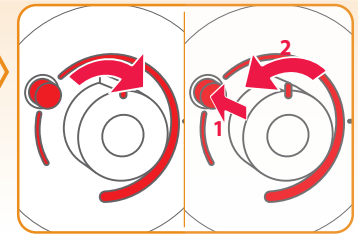


Connect MOBYBOX™ to MOBYBOX™ Runner

Connect the black hose of the MOBYBOX™ to the PMC of the Runner.

Active de-airing Part 1

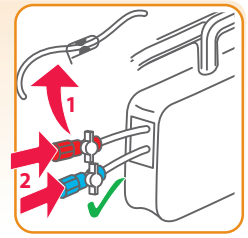
1. Turn on Runner and set approx. 1 liter of blood flow.
2. Clamp Roberts clamp on red marked blood tube.
3. Wait until no bubbles in Purge-Line.
4. Open clamp.



Active de-airing part 2

Start and stop the pump three times as shown below, to remove any residual air.

I. 15 sec. 2 L/min > Pause 5 sec.
II. 15 sec. 3 L/min > Pause 5 sec.
III. 15 sec. 4 L/min

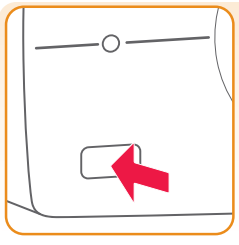


Remove Purge-Line

Check for proper closed stopcocks. Remove Purge-Line (1) and close with luer port caps (2).

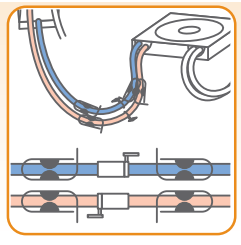
1.2 Prepare MOBYBOX™ for patient connection

⚠ The pre-filled MOBYBOX™ has to be attached to the patient within approx. 3 hours!
The pump does not need to run during stand-by! Do not perform self-test during patient treatment!



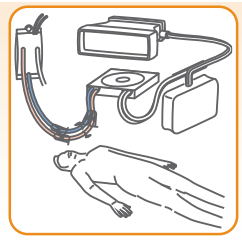
Start self-test when system is running

Press button to start test and check all alarms and display.



Clamp tubes

Clamp tubes close to the connector.

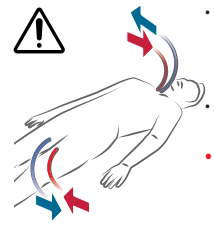


Bring MOBYBOX™ to patient

System remains completely connected to the filling bag until you go to the patient. Disconnecting and plugging together increases the risk of air entrapment.

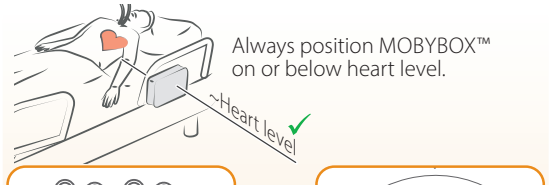
ℹ Perform a self-test with connected de-airing set with blood flow 1-3 L **before connecting the patient**. See chapter 4 for detailed descriptions.

Determine position of cannulae and cannulate patient



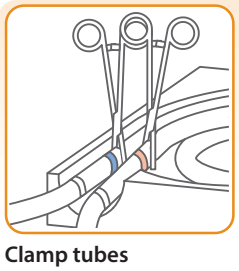
- Size, configuration and depth of insertion depends on procedure and estimated blood flow (oxygenation and perfusion requirements).
- Deploy cannula according to manufacturer's instruction.
- **Connect the blood tubes quickly after inserting and rinsing the cannulas and start the MOBYBOX™.**

⚠ Anticoagulation: If possible, apply the initial dose via the rinsing solution of the cannulas. Rinse cannulas immediately after application. Start long-term medication.



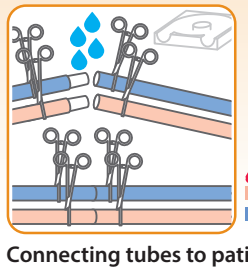
Always position MOBYBOX™ on or below heart level.

1.3 Connect MOBYBOX™ to Patient | Sterility must always be guaranteed!



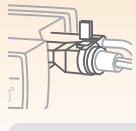
Clamp tubes

Remove tray cover. Clamp the tubes outside, next to the colour markings and cut between the colour markings and the white markings.

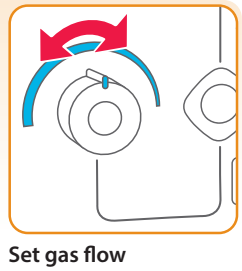


Connecting tubes to patient

Connect under falling drop to avoid air ingress. Hold tubes firmly in the clamp area.

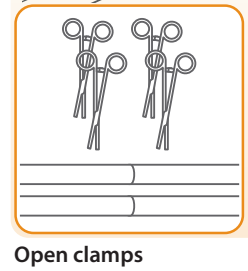


ℹ When available, use external gas blender, as shown in 2.3.



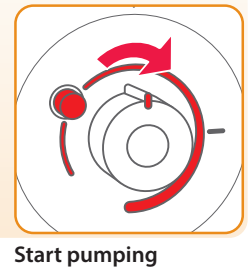
Set gas flow

With high $PaCO_2$ levels:
Start with approx. 1L sweep gas flow and slowly reduce CO_2 to target value over several hours (cerebral perfusion).



Open clamps

Fully open / remove all clamps (integrated backflow prevention)!



Start pumping

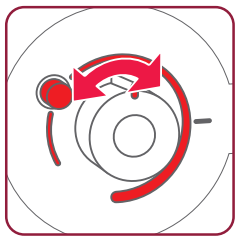
Slowly start system: with 1 L blood flow for approx. 45 sec.

2 Treat Patient

⚠ Do not operate the system without appropriate anticoagulation. Do not restart after it has been stopped for more than 1 minute. Avoid tube kinking! Secure strain-free tube positioning!

2.1 Start Treatment

⚠ Set blood flow to target value. Always connect backup gas source (gas bottle) with sufficient filling volume and in an open state. Lower blood flow increases risk of clotting. Consider anticoagulant status. Do not leave the system unattended.

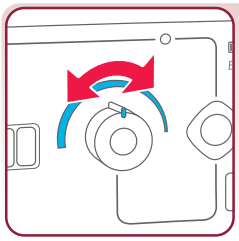


Adjust blood flow (left knob)

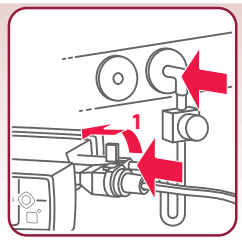
2.2 Adjust Sweep-Gas Flow | According to CO_2 removal needs of the patient.

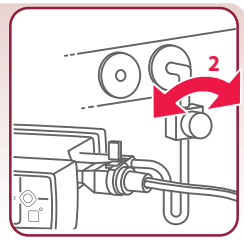
⚠ ATTENTION: the gas flow is adjusted by connected sweep-gas supply exclusively via the external source. If an external sweep gas line is connected, the gas flow is set exclusively via the external source!

Internal sweep-gas supply: **…via external sweep-gas supply:**

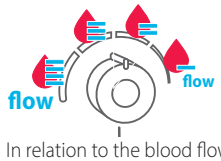


or





Adjust sweep-gas



In relation to the blood flow.

⚠ Adjustment/monitoring is carried out by measuring the Et-CO_2 or a blood gas analysis.

Connect gas source with flowmeter or blender to sweep-gas connection and adjust sweep-gas

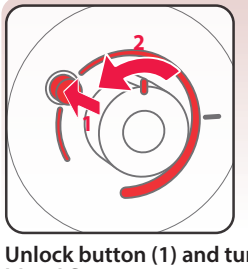
Turn the lever [1] on the sweep-gas connection and push it back. Attach 1/4" tube to the sweep-gas tube nozzle; make sure it fits securely. Set the sweep gas target value on the external gas source [2].

⚠ Internal sweep gas control inactive when external gas line is connected.

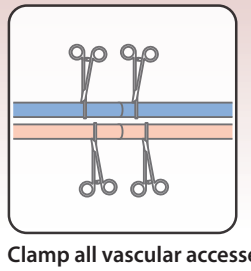
3 End Treatment

⚠ **Keep anticoagulation at therapy level during weaning procedure! Stop anticoagulation soonest 2 h prior to decannulation. Keep blood flow at flow rates above 2 L/min during time without anticoagulation!**

«continue at a good pace!»

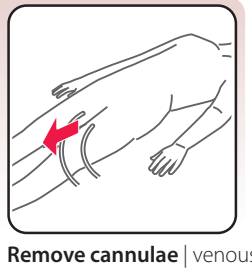


Unlock button (1) and turn blood flow to zero (2)



Clamp all vascular accesses

Clamp on both sides of the connector in any case.

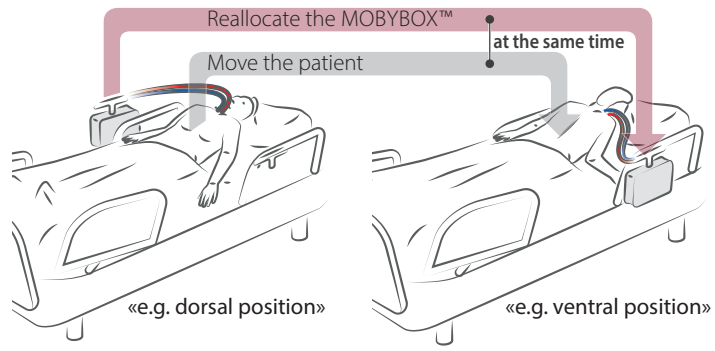


Remove cannulae | venous first

During Treatment

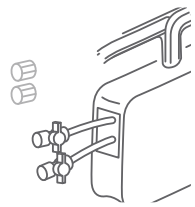
Moving the patient

⚠
- Always place the MOBYBOX™ close to the patient on the side of the cannula and on or below heart level.
- Avoid tube kinking! Secure strain-free tube positioning! Consider patient movements and nursery measures.
- Avoid contamination through aseptic handling.



Drawing blood samples

⚠ Flush the lines after sampling with approx. 10 mL sterile solution. Avoid contamination through aseptic handling.

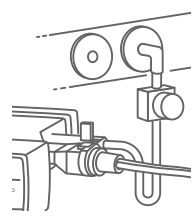


1 - Aspirate approx. 10 mL of blood before taking a blood sample. Consider returning blood after taking the blood sample.

2 - Blood sampling
Blue port for pre gas-exchanger.
Red port for post gas-exchanger blood.

3 - Rinse the sampling line with approx. 10 mL isotonic solution. Close luer cap.

Use of oxygen bottle (secondary gas source) and function of flow switch valve



In the event of a failure of the primary gas supply (long O_2 line), the switchover valve enables uninterrupted switchover to the backup supply via an O_2 gas bottle.

⚠ Backup gas source (O_2 gas bottle - connected to a short O_2 line) Always connect a gas bottle which is open and has a sufficient filling volume. Check the filling volume regularly. Only change gas bottles when the primary supply (long O_2 line) is connected.

Use external sweep gas (e.g. for use of a gas blender)

In this case, **no** gas flows via the internal sweep gas source. With secondary gas supply via oxygen cylinder, the sweep gas is set on the bottle's pressure reducer.

Set low flow notification

Press + or - button once: shows the current value of the notification limit for low blood flow. While the current value is displayed, it can be increased or decreased by pressing the + or - button. The setting does not need to be confirmed. The display automatically switches to the measured current blood flow.

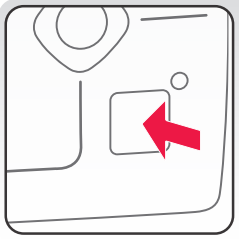
ℹ Low flow limit notification starts at 1,5 L/min and can be increased in steps of 0,5 L/min. If set below this limit, notification function will be deactivated.

Alarms & Notifications

A possible failure of the alarm system or the blood flow display does not lead to a pump stop. Ensure pump performance by checking SaO_2 (v-v) or arterial bloodpressure (v-a) and replace defective device promptly.

The unavailability of the alarm system does not affect the clinical performance of the device!

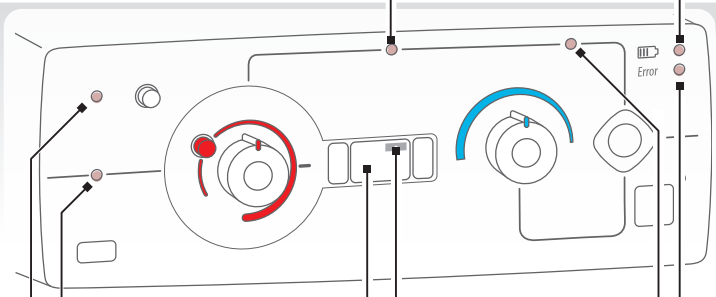
* **Suction and afterload alarms appear together. So you have to check the cause of suction and afterload increase if an alarm is running.** A higher preload or afterload always leads to a lower blood flow. It is therefore recommended that the low blood flow alarm limit is always set close to the current blood flow.



Mute alarm

Mutes the current alarm for 2 min.
(10 minutes for low battery alarm)

Check alarm cause

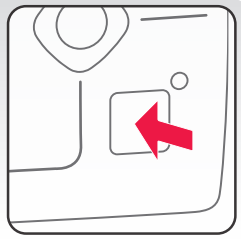


Low flow alarm
Blood flow below 1 L/min.

Low battery alarm

Exchange battery when the battery alarm appears and the patient is in a stable condition. Supply a new battery for each new treatment.

Eliminate cause



Reset alarms

Alarm status:

- Red and sound (high priority): **acute alarm**
  Red and sound (medium priority): **Notification**
- Red, no sound: **acute alarm, mute button being pushed within the last 2 minutes. Battery life < 5 hours.**
- Yellow, no sound: **past alarm, not yet reset.**
- No alarm

Suction alarm *
Feeding tube clogged or squeezed.

When adjusting blood flow, consider possible flow limitation due to cannula size. When aspirating the cannula, consider adding volume or reducing blood flow.

Supply gas alarm
Check gas connections. If necessary, replace gas source.

Error display
(see trouble shooting)
ERROR: fatal errors
Maintenance Backup: critical error

Immediatly switch to Backup System. Contact Technical Service.

Low / High flow
< 1.0 (display of current flow alternating with limit value when falling below the set limit value): low blood flow
> 6.0 (blinking): high blood flow

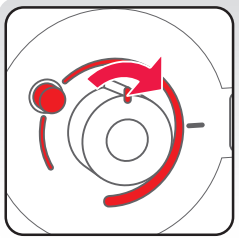
System error
See trouble shooting section.

Afterload alarm *
Stenosis in gas exchanger or returning blood line / cannula.

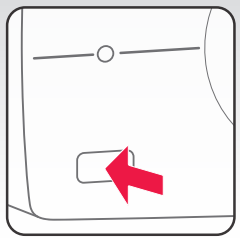
Check tubes and cannulae kinking, occlusion or inadequate cannulation! Exchange device after ruling out all other potential causes.

Self-test ...perform before treatment with the system connected to the de-airing set

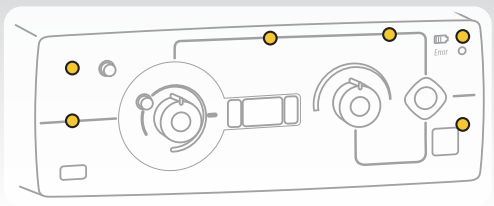
Self-test running – Duration appr. 10 sec.

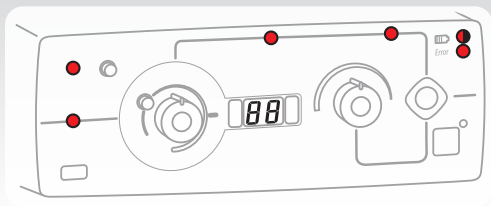


Switch on the device and set the blood flow to a value < 3 L/min



Start self-test
Display message dissapars after 2 seconds.





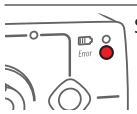
The following functions are checked after starting the self-test:
1. an alarm sounds?
2. LEDs are displayed alternately in yellow and red.
3. error codes are shown in the display. Note the code for the clinical support.

The system is equipped with an internal backup battery that will alert the user in case of battery failure. The self-test function of the system checks the status of the backup battery.

Troubleshooting

In case of errors which cannot be rectified immediately, the device must be replaced. If the electronics fail, switch to the backup system promptly and when the patient is stable. Do not leave the patient unattended and check the operation of the system via the monitoring monitor (SaO_2 at v-v; art. mean pressure at v-a)

MOBYBOX™ Runner problems

Problem	Solution
No display?	Battery ok?
 System error alarm?	Release mute button! Release self-test button!
	Persisting alarm: Do not leave patient unattended. Exchange MOBYBOX™ Runner immediatly with the backup device. Send the device to repair.
No pump function?	Enough gas supply? Pneumatic line kinked/right attached?

MOBYBOX™ problems

Problem	Solution
Low blood flow?	Blood or gas tubes kinked / Ports blocked?
Pump stopped? No blood flow or low blood flow and gas alarm?	Gas bottle open? Gas tubes connected to gas supply?
«… ERROR» Message	Fatal error. Switch to Backup System. Contact Technical Service.
«Maintenance Backup» Message	Critical error. The internal backup battery (not AA battery) needs maintenance. Switch to backup system. Contact Technical Service.
Pump stopped? «low blood flow» alarm, (possibly with delay) Scution/ Afterload alarm, **no gas alarm?**	Reduce blood flow. Disconnect the MOBYBOX™ from Controller via patient module connector shortly to relieve the pump from suction. Then slowly increase the blood flow to avoid renewed suction. Consider intravascular volume injection.

Device operation

- Read this Instructions for Use before using the MOBYBOX™ System. MOBYBOX™ System components are designed to be exclusively operated with corresponding MOBYBOX™ System components. Never operate the MOBYBOX™ with another controller. Never use the MOBYBOX™ Runner to operate any other components.
- Check the gas bottle's filling state before and during device operation. Always have a spare gas bottle at hand.
- Increase the blood pump flow slowly to minimize the risk of causing suction and cavitation. Lower blood flow increases risk of clotting. Consider anticoagulant status of the patient! Check blood flow regularly while considering therapeutic requirements, pressure ranges, cannula sizes and patient volume status.
- During patient treatment no maintenance work is allowed at the MOBYBOX™ Runner, at the MOBYBOX™ or at any other accessory equipment. Gas supply must never be interrupted.
- Safeguard sterility. Non-sterile material or material with faulty wrapping must NOT be used.
- New battery must be loaded before each new deployment of the MOBYBOX™ Runner. Always have a new battery (1 x Type AA, 1.5 V) ready at hand for gapless operation. Patient treatment is not dependent on batteries' charge condition.
- Check alarm system before device operation (Self-test).
- Monitor at least once a day gas exchange performance with BGA at the device (red marked extraction line of the MOBYBOX™. At 100% O_2).
- Avoid external mechanical strain on tubes and cannulae. Check cannulae and tube positions regularly. Do not re-position a dislodged cannulae by pushing it back into the vessel. Inspect cannulae access areas regularly, keep it disinfected and change dressings regularly.
- Do not use Heparin in HIT (heparin induced thrombocytopenia) patients. Immediate usage of a back-up MOBYBOX™ (disposable) may be necessary should patient develop a DIC (disseminated intravasal coagulopathy) or HIT syndrome.
- Always keep anti-coagulation at ACT-levels of 150-200 sec. Check anticoagulation status / ACT levels regularly. Follow the protocol of your clinic.
- When the external sweep-gas connection is used, there is NO inherent sweep-gas flow from the MOBYBOX™ Runner to the gas exchanger.
- Sufficient sweep-gas supply must be ensured at all times.

General

- Always have a back-up system (second controller, active device) at hand in case of failure of active device and ready for use and spare disposables.
- Flush the oxygeantor at least once a day with approx. 20 L/min O_2 for 10 sec. (Repeat if necessary), when connected to external gas blender/flowmeter, according to the clinical protocol, to remove condensate from the fibers.
- Displayed blood flow values are approximated values.
- This device and the available instructions for use may not be modified. Repairs and maintenance may only be done by authorized service personnel.
- Never install a passive infusion line in the same vessel as the drainage cannula.
- Cable ties are required for manufacturing processes but may become loose after sterilisation and do not have a fixing function. This does not affect the safety or integrity of the product.

Safety related check

- In case of commercial use, safety related checks (according to §12 MPBetreibV) are to be conducted for the device at an interval of 12 months. These checks have to be carried through by a specialist with device-related medical knowledge (according to §5 MPBetreibV). Detailed information can be obtained from the manufacturer.

Statement of rejection

- The manufacturer refuses any responsibility if the directions and safety precautions in this Instructions for Use are not observed.

Accessories

- Only use accessories / replacement parts recommended by the manufacturer.

Blood handling

- Do not operate the MOBYBOX™ without appropriate anticoagulation of the patient´s blood during system operation. Anticoagulation must be applied immediately after cannulation and until decannulation of the patient. RHEOPAX™ conditioning is NOT an anticoagulation measure!
- Before starting the MOBYBOX™, ensure that the system is purged according to the manufacturer's guidelines.
- Ensure that there is never any possibility of air entering the venous system, taking the negative pressure along the drainage cannula through the extracorporeal circuit into account. Do not connect any infusions with vented infusion sets without an infusion pump!
- DO NOT restart the MOBYBOX™ after it has been stopped for more than 1 minute. Risk of thromboembolism in the blood leading components!

Cannulation

- Always use an additional antegrade cannula for limb perfusion during femoral arterial cannulation. Monitor limb perfusion.
- Select adequate cannulae sizes according to blood flow rate and treatment(v-v/v-a). Use cannulation according to manufacturers instructions. Select correct dilators size (max. 1Fr smaller than cannula). Make sure that dilators do not perforate vessel walls (Never push the wire jointly with dilator / cannula).

Warning for reuse of disposals

- Already used MOBYBOX™ devices, de-airing sets, tubes and other consumable supplies are to be disposed properly and may not be reused.

EMC

- Warning: False low flow, suction, afterload alarms may occur, or these alarms may be suppressed, due to EM interference. Use of the device stacked or adjacent to other equipment may result in improper operation of these systems. Usage near RF communication devices (< 30 cm), or in other than the prescribed environment may result in improper operation. The clinical performance is immune to EM interference.

Requirement:	Reference:	Compliance Level:
Radio Disturbance Electric Field < 1 GHz	CISPR 11 CISPR 16-2-3	30 MHz - 1 GHz (class B) SAC
Radio Disturbance Electric Field	CISPR 25	30 MHz - 1 GHz
Radio Disturbance Electric Field	DO160G, sect. 21	100 MHz - 6 GHz, Category M
Power Frequency Magnetic Field	IEC 61000-4-8	30 A/m 50 Hz and 60 Hz
Radio-frequency electromagnetic field. Amplitude modulated	IEC 61000-4-3	80 MHz – 2.7 GHz Home Healthcare 10 V/m
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	380 - 390 MHz: 27 V/m; PM 50 %; 18 Hz 430 - 470 MHz: 28 V/m; (FM ±5 kHz, 1 kHz sine) PM; 18 Hz 704 - 787 MHz: 9 V/m; PM 50 %; 217 Hz 800 - 960 MHz: 28 V/m; PM 50 %; 18 Hz 1700 - 1990 MHz: 28 V/m; PM 50 %; 217 Hz 2400 - 2570 MHz: 28 V/m; PM 50 %; 217 Hz 5100 - 5800 MHz: 9 V/m; PM 50 %; 217 Hz
Electrostatic discharge (ESD)	IEC 61000-4-2	Contact: ±8 kV Air: ±15 kV

Disposal

- The system must be disposed of in accordance with applicable regulations for the disposal of electronic scrap in compliance with local regulations.

Data available upon request:

- Blood pathway pressure drop (D1)
- Gas pathway pressure drops (D2)
- Data related to blood cell damage (D3)
- Data on particle release from MOBYBOX™ System according to Hemovent's GmbH's quality control management system (D4)
- Residual blood volume (D5)
- List of materials of blood pathway (D7)
- Data of in vivo, in vitro and clinical testing (D8)

Indications

- The MOBYBOX™ System is intended to provide extracorporeal cardiopulmonary support for patients in whom cardiac, respiratory, or cardiac and respiratory failure has or may occur.
- Use of the MOBYBOX™ System device must be supplemented by an external vital-signs monitoring device that includes an oxygen saturation alarm function (pulse oximeter, SpO_2, vital-signs monitor, etc.).

Contraindications

- Coagulation disorders (hemophilia or thrombosis)
- Vessel diseases (i.e. dissection, aneurysms)
- Need for long-term support for more than 30 days

Complications

Deployment of ECMO circuits may lead to the following clinical complications:

- Hemorrhages, Hemodilution, Hemolysis
- Cannulation related vessel damage, thrombosis or ischemia
- Thrombocytopenia and HIT syndrome (if Heparin is administered)
- Stroke / Strombembolic event

Intended Environment

- The system will be used in the Professional Healthcare Environment.

Intended users

- Medical doctors and medical staff who have been trained on general application of ECMO and the MOBYBOX™ System.

Intended patients

- The patient population includes male and female adults with cardiac and / or lung impairments who are 16 years or older and who meet the indications for use and have none of the contraindication for use.

Duration of use

- The device is intended to be used to provide cardiopulmonary support for up to 14 days.

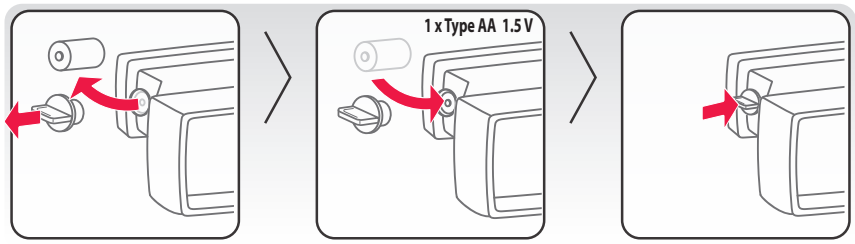
Labels, Symbols, Abbreviations

EN	Language
	Dispose according to electronic scrap regulations
	Expiry date
	Manufacturer with address
	Date of manufacture
CE	CE symbol in the number of the notified body
LPM	L/min
LST	Packing list
	Telephone number
REF	Order number
SN	Serial number
MD	Medicine device
PN	Part number
UDI	Unique Device Identification
STERILE EO	Device that has been sterilized using ethylene oxide

Note	Safety Information
IP44	Protected against splash water all over
	Follow instructions for use and accompanying documents
	Biological risk. Dispose contaminated material properly
2 STERILIZE	Do not re-sterilize
	Do not re-use
	Do not use if package is damaged
	Keep away from sunlight
	Keep dry
PHT DEHP	Contains phthalate
	Fragile, handle with care
	Defibrillation-proof type CF applied part
	Temperature limits to which the device can be exposed during storage

Replace Battery

New battery must be loaded before new deployment of the MOBYBOX™ Runner. Ensure to have a spare battery available during treatment and exchange battery as soon as battery alarm appears. The pump's function is not impaired during the battery exchange.



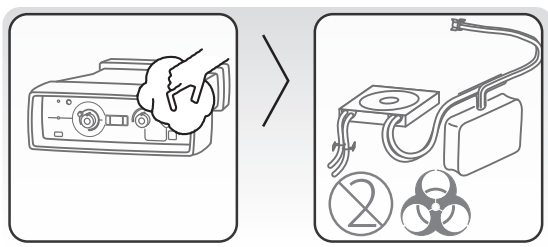
Open battery compartment, take out empty battery
Unscrew battery compartment and remove cover. Dispose old battery properly.

Insert new battery
Put in 1 x Type AA, 1.5 V with correct polarization.

Close battery compartment
Attach battery compartment cover and screw it on.

The system has an internal backup battery that alerts you to a battery failure. The status of the backup battery is checked by the system in the self-test.

Cleaning



Wipe-disinfect the MOBYBOX™ Runner
Water-alcohol based solutions with no more than the following solution: max. 70-30%.

Dispose MOBYBOX™ and consumable supplies
Follow local disposal rules.

Hemovent recommends Schülke mikrozid® universal wipes.

The use of other desinfectants lays in the responsibility of the user. Higher alcohol-concentrations may damage the product.

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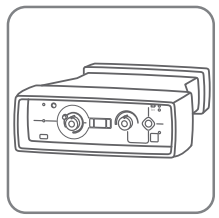
service@hemovent.com

MOBYBOX™ System | Part number HVEU-009 CE 0297

Components



MOBYBOX™ Runner, digital | Part number REF HVCEU-005

Ensure that a ready-to-use backup system of the active medical device is always available.

Other accessories for the MOBYBOX™ system:
- Holding system (e.g. trolley)
- Flow change-over valve
- Oxygen hoses (with country specific connectors)
- Gas blender, Pressure reducer, Tube heater

MOBYBOX™ Set | Part number REF HVEU-007

- 1× MOBYBOX™ (patient module)
- 1× De-airing set
- 4× Cable ties
- 1× Surg. scissors
- 4× Surg. clamps
- 1× Instructions for use

Technical data

Environmental conditions

	Operation	Shipping	Storage
Temperature	0 to 40 °C	0 to 55 °C	0 to 40 °C
Air humidity	10 to 95 %	10 to 95 % non condensing	10 to 95 % non condensing
Air pressure	0.56 to 1.5 bar (56 to 150 kPa)	0.4 to 1.2 bar (40 to 120 kPa)	0.7 to 1.06 bar (70 to 106 kPa)

Specifications

Duration of use	up to 14 days
Shelf Life MOBYBOX™	24 months
Service Interval MOBYBOX™ Runner	1 year
Guaranteed life time MOBYBOX™ Runner	5 years *
Gas interface MOBYBOX™ Runner	3-5 bar (wall supply)
Cannulae interface MOBYBOX™	3/8″
System filling volume	approx. 500 mL
Blood flow rate	1 to 5 L/min depending on cannula configuration
Sweep-gas flow	0.1 to 20.0 L/min ± 10 %
O_2 transfer rate (gas exchanger capacity)	100 % O_2 saturation at blood flow of 5 L/min, O_2: ≥60 mL O_2/min per L/min blood flow
CO_2 transfer rate (gas exchanger capacity)	≥50 mL CO_2/min per L/min blood flow
Δp gas exchanger blood path	45 mmHg at 5 L/min blood flow
Δp gas exchanger gas path	10 mmHg at 20 L/min gas flow
Audio alarm	> 55 dB at 1 m distance
Weight MOBYBOX™…	Runner 2.5 kg, Set 3 kg, Patient unit 2 kg

* After expiry of the guaranteed life time, life time can be extended to 8 years by annual maintenance.

Materials

Pump housing	Methylmethacrylat (MABS)
Pump membrane	Polyurethane (PU)
Gas exchanger housing	Methylmethacrylat (MABS)
Gas exchanger fibers	Polymethylpenten (PMP)
Gas exchanger potting	Polyurethane (PU)
Tubing	Polyvinylchloride (PVC), Silicone
Blood carrying surfaces (gas exchanger, pump)	RHEOPAX™ conditioning: Recombinant human serum albumin (rHSA), Polyethylene glycol (PEG)

hemovent
A MicroPort Innovation Lab

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