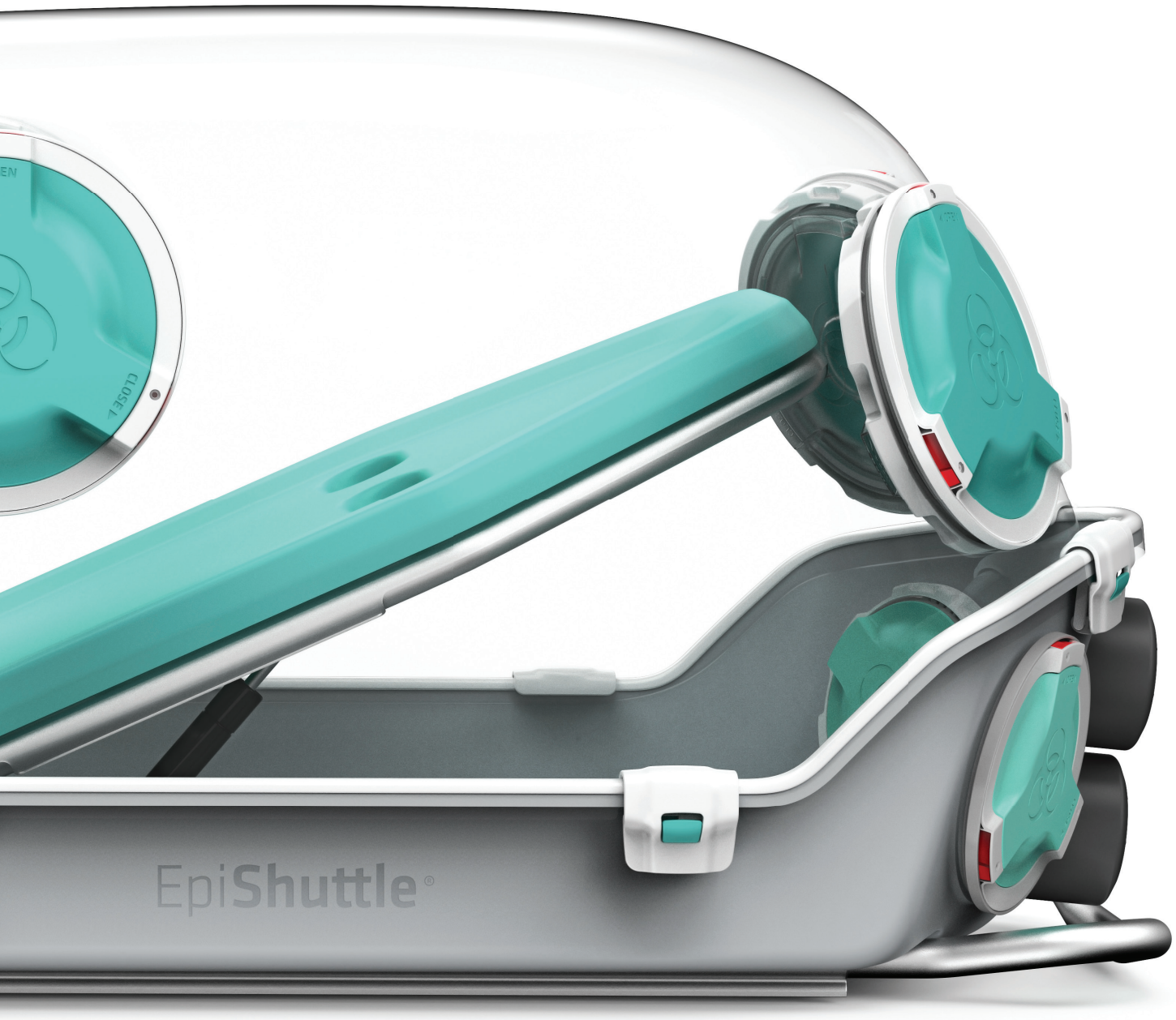

EpiShuttle®

Treatment without compromise

Product Information

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EpiShuttle®

Treatment without compromise

Introduction

EpiGuard AS is a Norwegian innovative company established in 2015. EpiGuard specializes in high end medical equipment for safe transport of contagious patients. The equipment is developed byclinical experts with first-hand experience in intensive care, treatment and transportation of patients with infectious diseases.

The company holds top level expertise in industrial design, product development and manufacturing.

The aim of the company is to provide medical equipment for patient transport that meets all requirements for full environmental protection from cross-contamination. The equipment is intended for use in both high risk scenarios and in every-day practice dealing with multi-resistant infections.

Easy access to the patient enables care and treatment without any compromise.

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Facts

Transmission of infectious diseases:

Air-borne infection can be transmitted by droplet nuclei over long distances. These particles are typically produced by desiccation of larger droplets from the patient. Examples of disease that may be transmitted by air include tuberculosis (also multi-drug resistant TB) and new strains of highly pathogenic influenza. Droplet transmission is also caused by generation of larger particles, such as when a patient coughs, vomits, sneezes or talks. These larger particles usually drop to the ground within a distance of one meter from the patient. Diseases known to be transmitted by droplets include SARS, smallpox, viral haemorrhagic fevers, and influenza. Contact transmission implies that a disease can be transmitted by direct or indirect contact with infectious material from a patient when contagion comes in contact with skin or mucous membranes.

The EpiShuttle

The EpiShuttle is a single-patient isolation system, specially designed for transport of patients. The unit protects the environment from an infected patient, but can also be used to protect the patient from a contaminated environment.

Intended purpose

EpiShuttle is intended for safe transportation of patients with high-risk contagious diseases, or for the transportation of patients requiring protection from the environment. When it is used for contagious patients, the aim is to avoid cross contamination from the patient to the environment outside the isolator. When it is used for protecting the patient from the environment, the aim is to avoid any hazardous material to enter the isolator.

EpiShuttle is intended to be used in a pre-hospital or hospital setting, transporting patients with contagious diseases to a treatment facility in a health care institution, or in a military setting.

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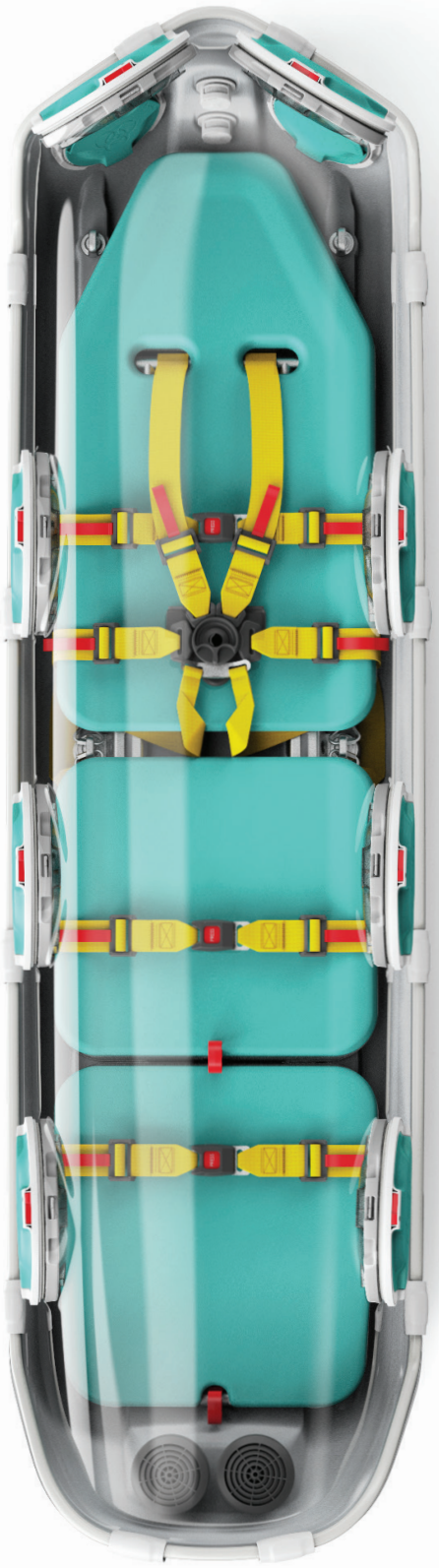

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EPi GUARD | Medical isolation and transportation systems

EpiShuttle key features

THE NEW STANDARD OF ISOLATOR TRANSPORTATION

The EpiShuttle has been created by clinicians with many years of experience within the field. This has resulted in a device uniquely designed to meet the needs of the patient, yet specifically the healthcare providers ability to give the absolute best patient care without the risk of contamination. In fact, the EpiShuttle has been designed by users for users.

EMS SYSTEM COMPATIBLE

EpiShuttle has an L-Track attachment system that allows for quick and secure attachment to stretchers, ambulances, aircrafts and helicopters.

ON-SITE MEDICAL CARE

For optimal treatment during transport, the EpiShuttle has eight entry ports. These ports have sealed gloves or other options like sluice port and waste bag that can be changed during use.

REUSABLE

The device is simple to clean and disinfect for multiple use. The device is easily disassembled and assembled without the use of any tools.

QUICK PATIENT LOADING

Short patient loading time possible due to easy operations and intuitive functions. The hard top is easily secured with EpiShuttle´s unique locking system to obtain airtight connection.

BATTERY POWERED

EpiShuttle allows for uninterrupted power for a minimum of 6 hours. The batteries can be replaced during transport, keeping the patient and environment safe from contamination up to 24 hours.

DUAL PROTECTION SYSTEM

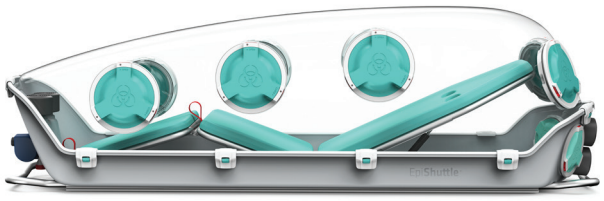
The pressure modes can be set to either protect the environment from the infected patient, or protect the patient from contaminants in the environmental air. It complies with all levels of transmission based precautions; standard, contact, droplet and/or airborne.

INTENSIVE CARE

EpiShuttle is equipped with medical ports for connecting IV lines, oxygen lines and monitoring cables, as well as providing mechanical ventilation to the patient. The intensive care system allows the health personnel to monitor, medicate, and give treatment to the patient without direct exposure.

OPTIMAL PATIENT COMFORT

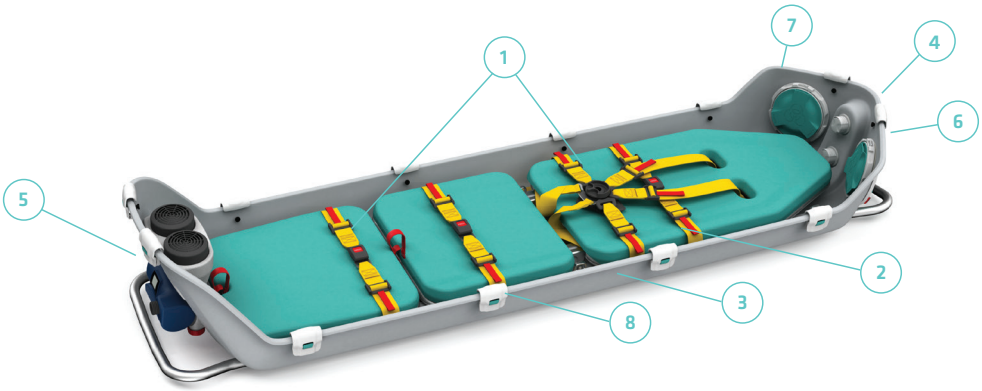
EpiShuttle has been uniquely designed for optimal patient comfort. The integrated bed is adjustable both for knee angle and backrest, allowing for increased comfort for the patient and better conditions for clinical procedures. The visibility through the transparent hardtop allows for better communication between the patient and surroundings.



EpiShuttle®

Treatment without compromise

Description of the device



Base

The base is made of impact modified grey colored Polycarbonate/ABS blend.
The base is sealed and will prevent air and fluid leakage to and from the device.

The bases has several functions integrated:

1. Integrated stretcher and mattress with adjustable backrest and knee angle
2. Safety belts; Quick release 6-point torso/hip restraint, chest strap, and upper / lower leg strap
3. Aluminum support frame, L-tracks and carrying handles
4. Air inlet filters
5. Air ventilation and air outlet filter system
6. Wire port: Membrane inlet for IV lines, monitoring cables and similar equipment.
7. Ventilator port: Generic port for all types of mechanical ventilator circuits
8. Quick-locks securing the hardtop to the base

Hardtop

The hardtop is made of impact modified transparent Polycarbonate. The hardtop has air-sealed connection to the base, and will prevent air and fluid leakage to and from the device.

The hardtop has 8 operator ports for gloves, waste bag or sluice bag configurations.

- Gloves (for safe patient access and treatment)
- Sluice bag (safe system for transferring equipment from outside and in to the isolator)
- Waste bag (for safe removal of waste or equipment from inside the isolator

The visibility through the transparent hardtop allows for better communication between the patient and surroundings.

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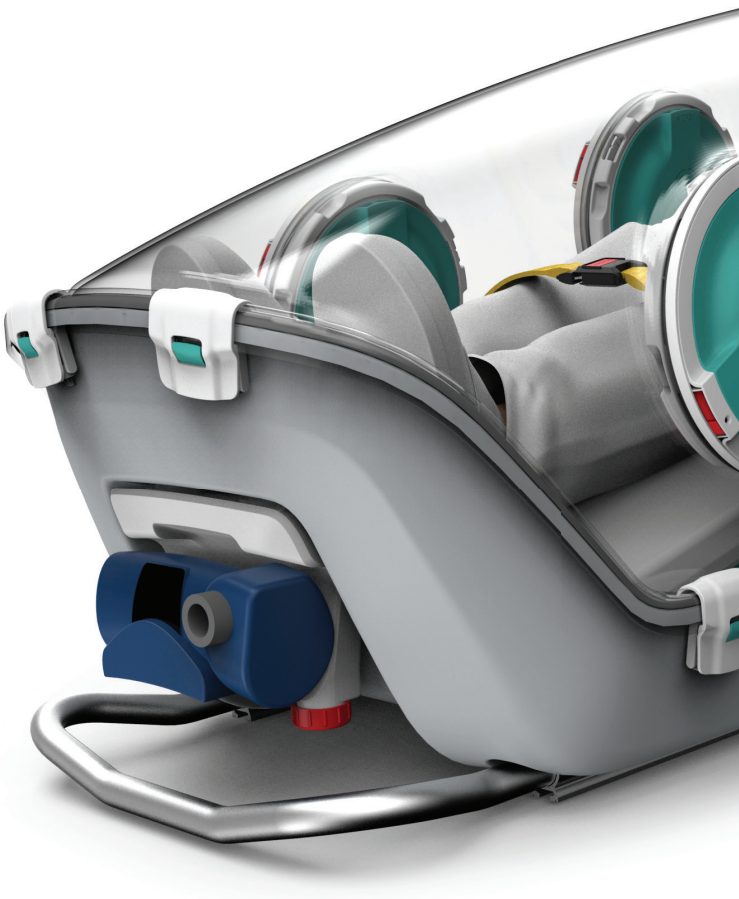
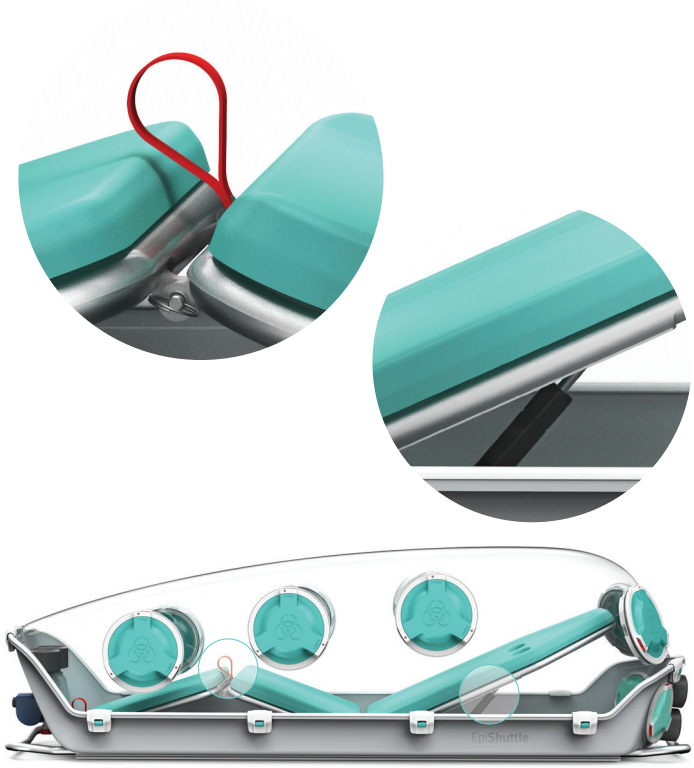
Glove ports

For optimal treatment during transport, the EpiShuttle has eight entry ports. These ports have sealed gloves or other options like sluice port and waste bag that can be changed during use.



Bed adjustment for patient comfort

The integrated bed is adjustable both for knee angle and backrest, allowing for increased comfort for the patient and better conditions for clinical procedures. Adjusting the position improves breathing and communication, and hence contributes in reducing anxiety.



Air ventilation and filter system

The air ventilation system filter the air in and out from the device and will ensure optimal patient comfort with more than 15 air exchanges per hour. EpiShuttle allows for uninterrupted power for a minimum of 6 hours. The batteries can be replaced during transport, keeping the patient and environment safe from contamination up to 24 hours.

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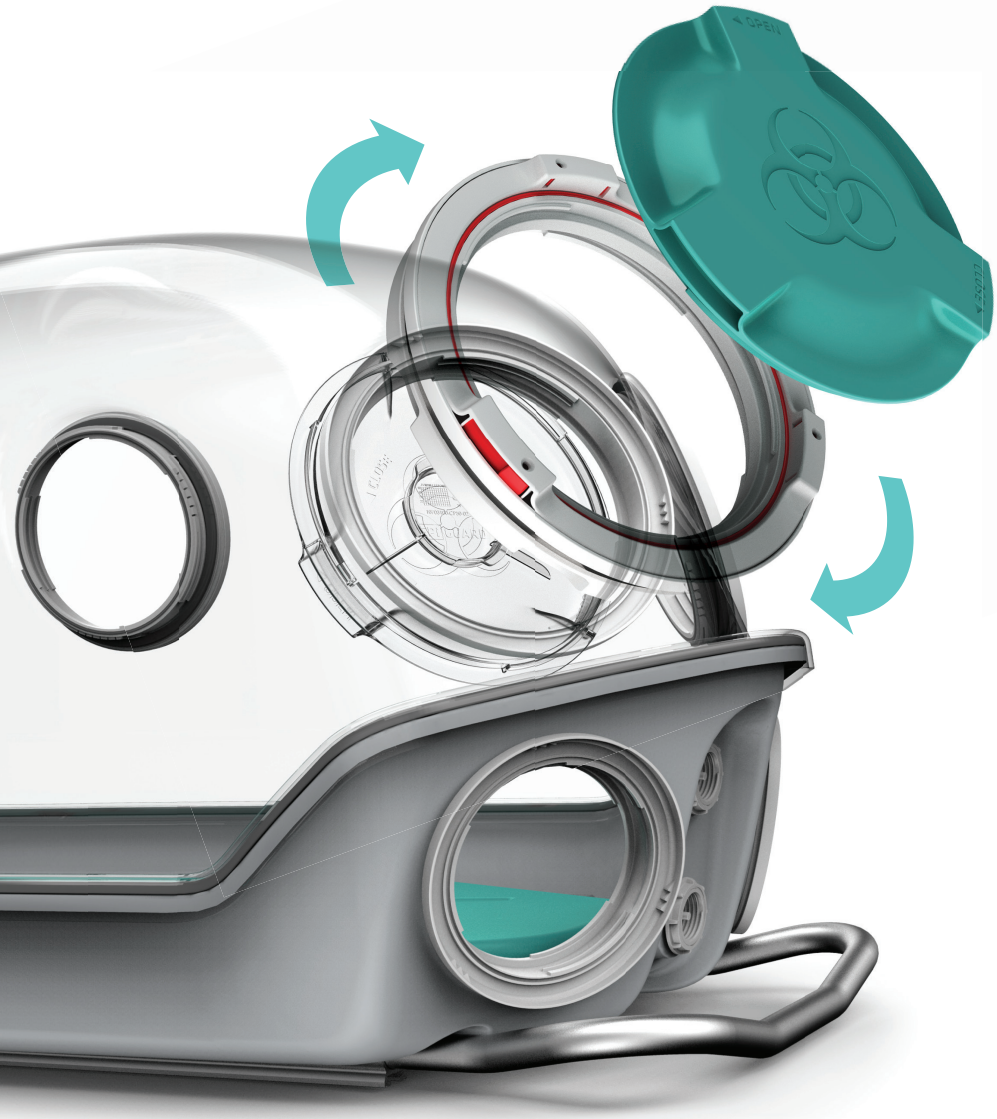
Installation without any tools

The device is designed to be easily disassembled without the use of any tools. No tools are needed for any installation or replacement of any of the device components.

The following sections describe, in brief, how to install or replace the main components:



Installation of operator ports and medical ports
The operator ports outer and inner rings are connected by a threaded connection which are easily attached and secured. The port configurations, operatorports , wireport and ventilationport are attached to the outer rings by a threaded connection, and securly locked with triple operating securitylocks.

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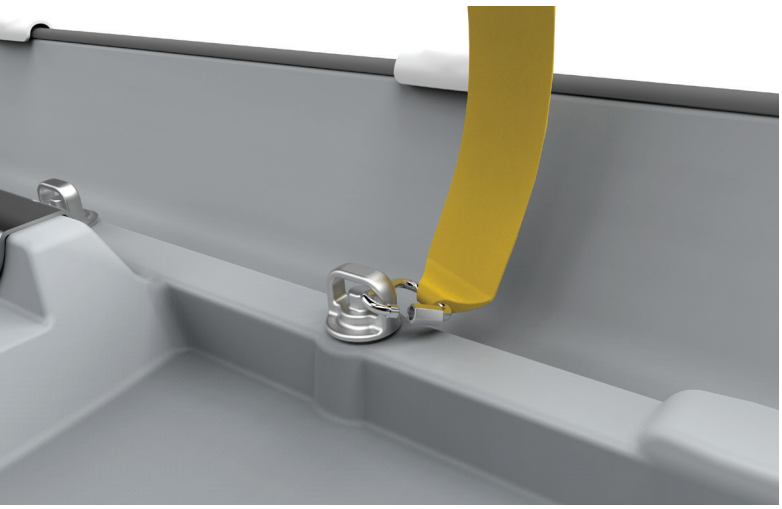
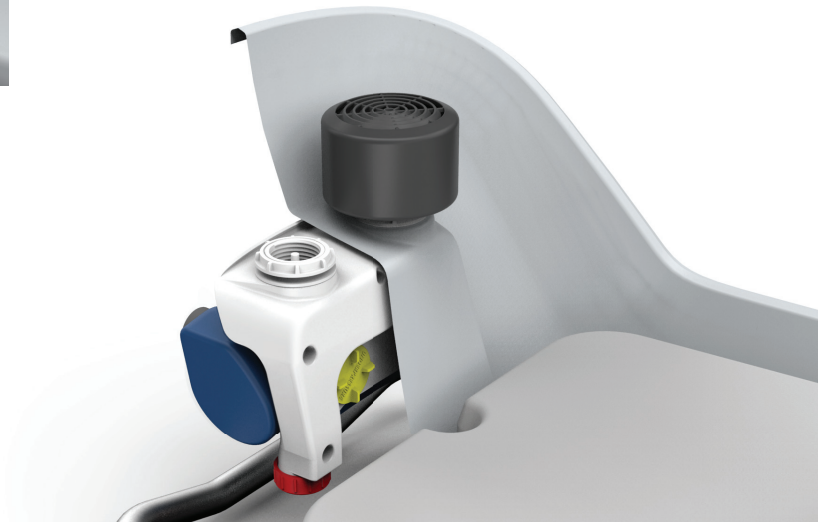


Installation of safety belts
The safety belts are easily connected to the belt nuts which are mounted to the base and secured to the rigid underlying aluminium frame.



Installation of the air ventilation system
The air ventilation system and air filters are mounted with threaded connections directly to the base foot-end. The battery connects by snap-connection to the front of the CleanAir Chemical blower.

The air filters are mounted with threaded connections in the foot end and head end.

The filters are mounted to a self-closing valve, and can be replaced during use.

Ventilátor CleanAir

The battery can be replaced during use.

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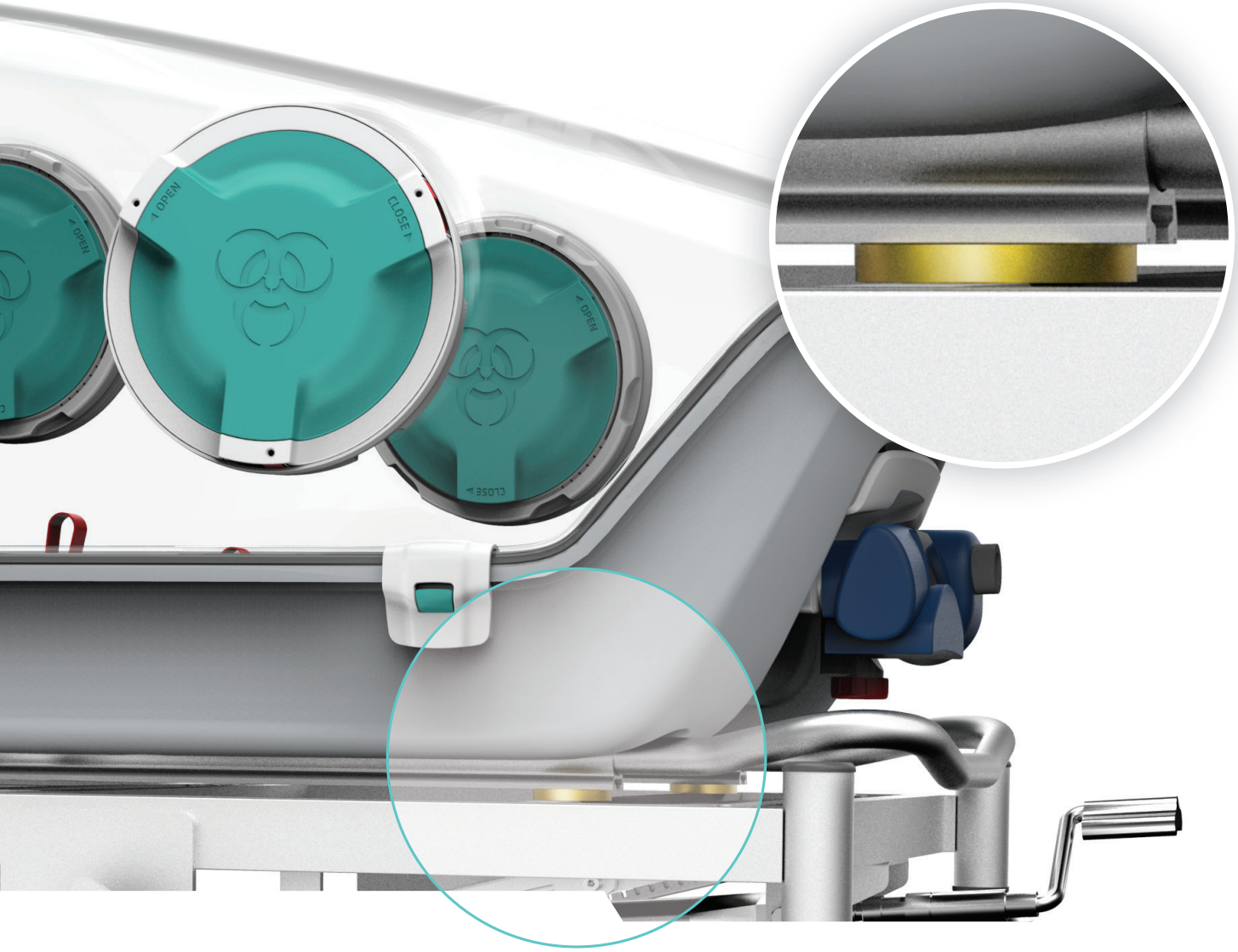

Mounting the EpiShuttle to transporting device
Position the EpiShuttle on the compatible stretcher undercarriage and secure it using the EpiShuttle mounting adapters.

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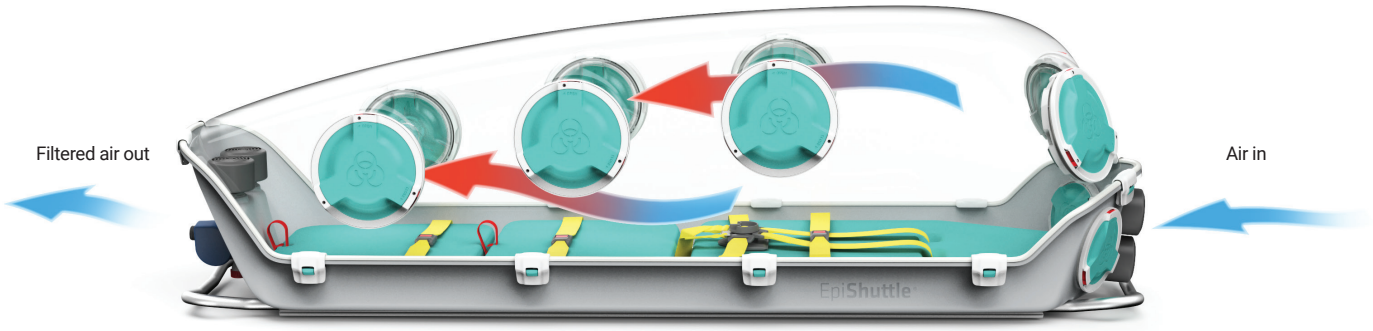
Air flow and pressure mode technology

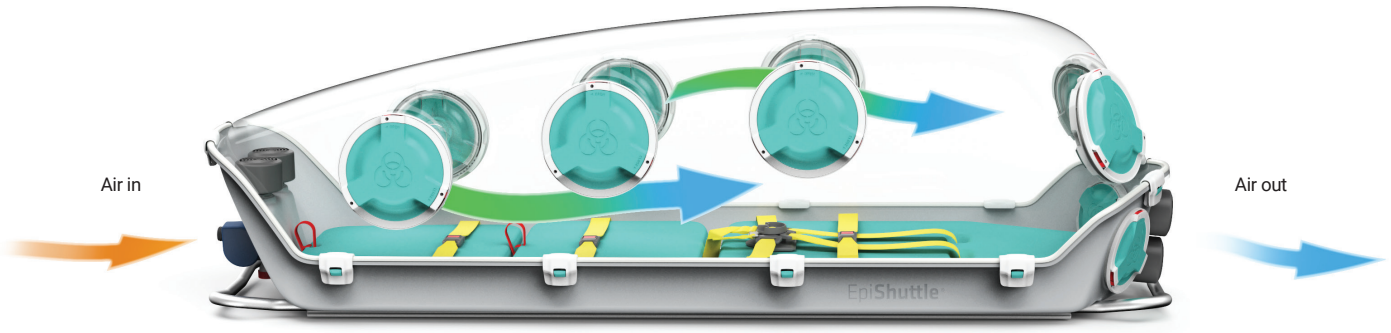
Negative pressure
protects the outside environment

In negative pressure mode, the air system generates negative pressure, relative to the environment, inside the device. The air flow is directed through the inlet filters at the head end, and through the outlet filters at the foot end. The negative pressure and the outlet filters prevents contaminated air to escape from the isolator.



Positive pressure
protects the patient inside

In positive pressure mode, the air system generates positive pressure, relative to the environment, inside the device. The air flow is directed through the inlet filters at the foot end, and through the outlet filters at the head end. The positive pressure and the inlet filters prevents the non-filtered environmental air to enter the isolator.



The air ventilation system generates more than 15 air exchanges per hour to ensure maximum patient comfort and safety.

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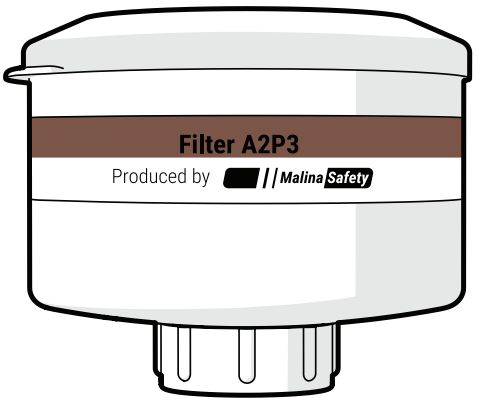
Blower and filters

The blower is CleanAir® Chemical 2F, with adjustable airflow between 120 and 235 litres/min. Tested according to EN 12941 TH2/TH3, EN12942 TM2/TM3 / IP65.

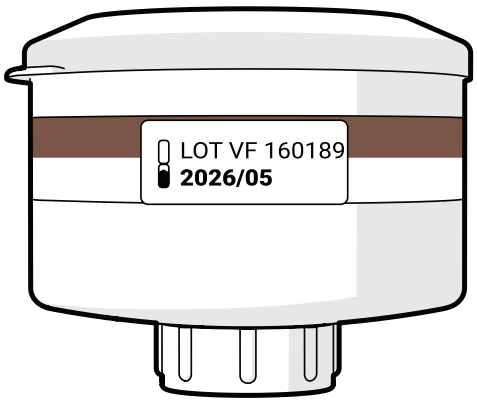
The blower has a full colour LCD that displays current operating information: flow, resistance and battery capacity.

Alarm sound are generated for critical events like:
High resistance
- Low output/flow
- Low battery level

- The blower is powered by a Li-ion 14.4 V 2.6 Ah chargeable battery. The battery charge time is <3hours



The P3 Particle filters can be changed during use. The unique automatic closing system prevents unwanted contamination of the unit by particles during the changing procedure.



The standard filters are canister filters A2P3, manufactured with thread RD40x1/7" in accordance with EN 148-1 and are fully EN approved according to the following standards:
EN 143, EN 12941, EN 12942, EN 14387.

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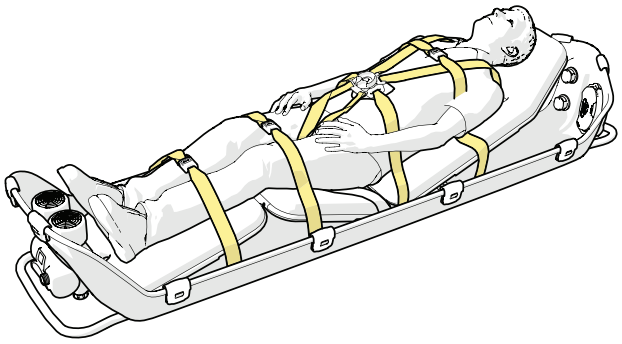
Patient loading and off-loading

Loading procedure

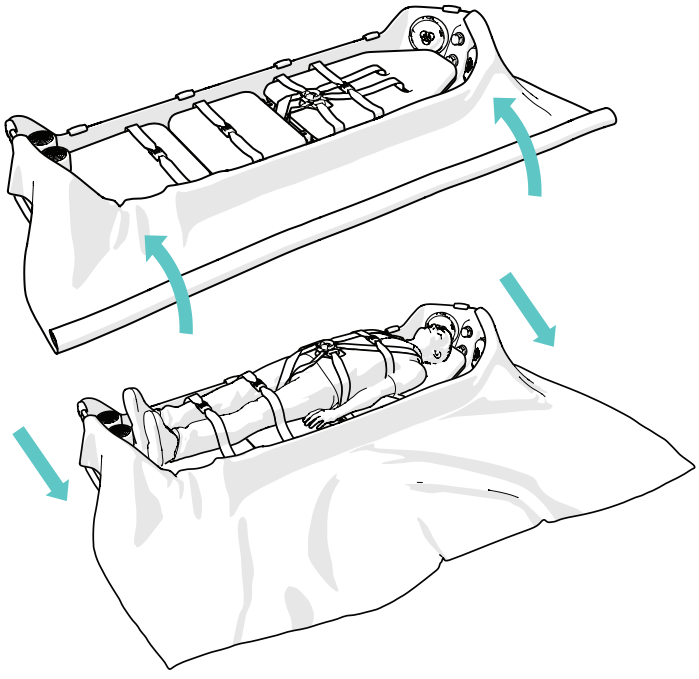
- Necessary medical equipment is wired through the medical port and the ventilation sleeve, according to the foreseen clinical needs of the patient.
- The isolator is placed in an uncontaminated clean environment, and a “clean” and a “non-clean” patient side is defined.
- Cover blanket with adhesive edge is attached to the internal stretcher to protect the entire outside of the isolator base. The patient can then be loaded into the base on the internal EpiShuttle stretcher bed.

Preparing and operating procedure



- Safety belts should be fastened, and medical arrangements (IV lines, ventilator tubes, monitoring cables) must be prepared.
- The air ventilation system must be turned on. (default setting: Negative pressure).
- When all arrangements are set, the cover blanket must be removed and the preconfigured hardtop can be placed onto the base and secured with the 12 quick-locks.
- After verifying negative pressure, all possible contaminated areas on the outside of the EpiShuttle must be disinfected with recommended disinfectant.
- All personnel exposed to the contamination must change PPE or decontaminate accordingly.
- The EpiShuttle with patient inside should now be ready for transportation.

Off-loading procedure



- The isolator should be placed on a cover blanket to avoid contamination of the wheels/structures of the undercarriage. A “clean” and a “non-clean” side must be defined.
- The hardtop can now be unlocked by unlocking the 12 quick-locks. The cover blanket should be attached to the EpiShuttle base to cover the entire outside of the unit.
- The hardtop can now be removed and placed on a smooth surface.
- Safety belts should be unlocked before medical equipment and monitoring cables are replaced by equipment from the institution.
- The patient can now be off-loaded.
  The cover blanket must be removed and disposed, and the hardtop must be reattached to the EpiShuttle. The outside of the unit must be disinfected with the recommended disinfectant or placed directly into a safe place for disassembly and decontamination.

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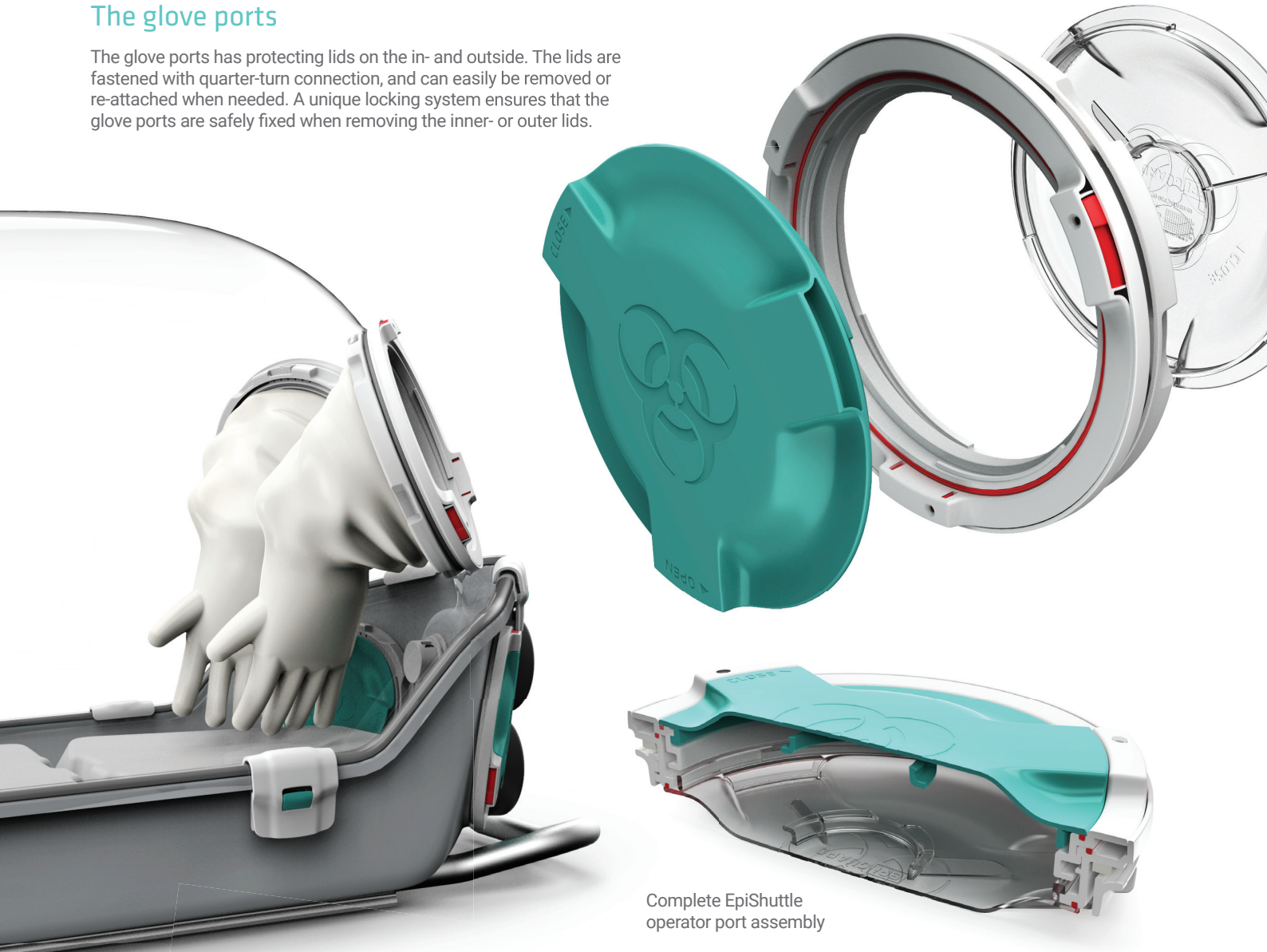
Operator ports

The functionality is based on uniquely designed 200mm operator ports in the isolator hardtop. The eight ports are positioned to ensure access to all parts of the patient's body, including the airways.

This enables intensive care treatment of the patient with possibility for procedures such as intubation, inserting of central venous lines, urinary catheter etc.

The glove ports

The glove ports has protecting lids on the in- and outside. The lids are fastened with quarter-turn connection, and can easily be removed or re-attached when needed. A unique locking system ensures that the glove ports are safely fixed when removing the inner- or outer lids.



Complete EpiShuttle operator port assembly

The gloves

The gloves have ambidextrous design, made from flame-resistant CSM/hypalon, compliant with European Directive PPE Category 3, and tested according to EN 374:2003, EN 421:2010, EN 388:2003.

- In case of damaged or ruptured gloves during use, the gloves can be replaced by using a EpiShuttle change bag.
- The gloves are reusable, and can be removed and reused if no damage or rupture are discovered.

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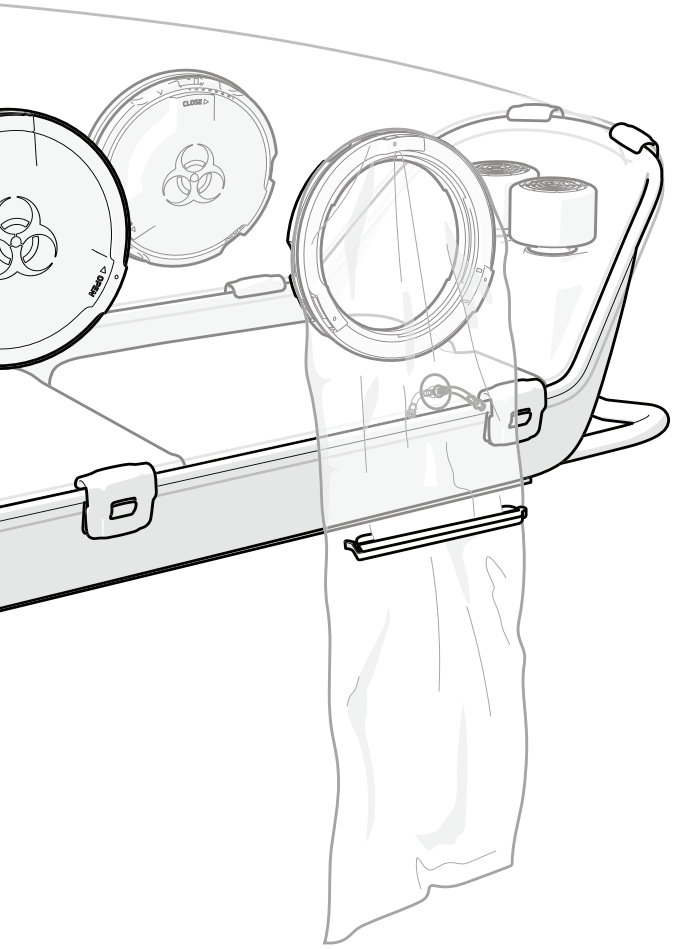
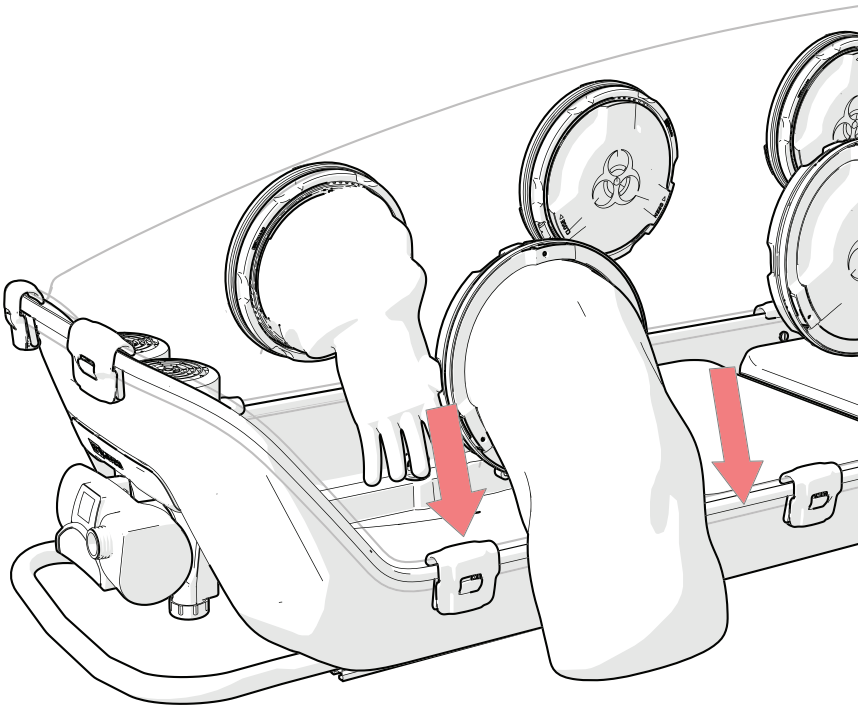
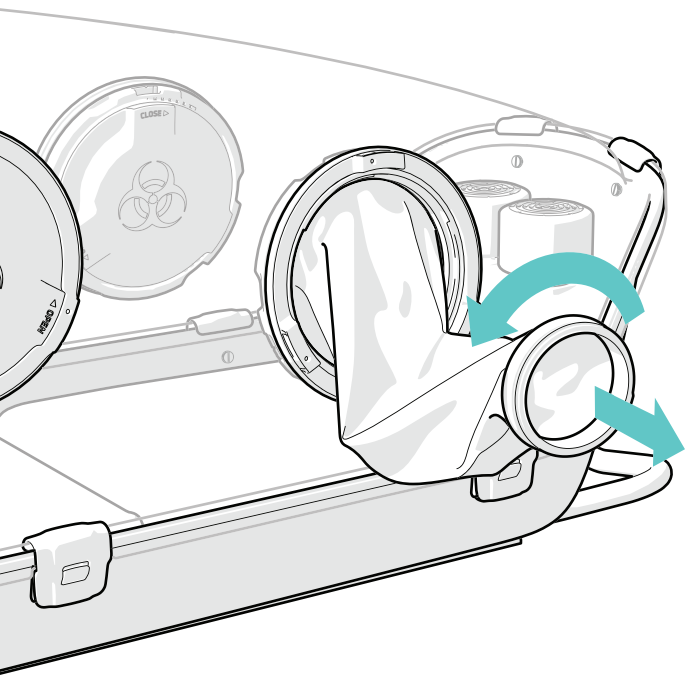


Change bag

A change bag can be connected to the outside of the Epiport200 operator port to do safe replacement of a damaged glove or to change the port-configuration.



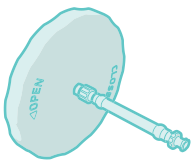


Waste bag

A waste bag can be connected to the Epiport200 operator port, providing a closed space for waste (used urine bag, wet tissues etc.).

Sluice bag

A sluice bag can be connected to the Epiport200 operator port and can be used for transferring equipment, food or medicine to the patient.



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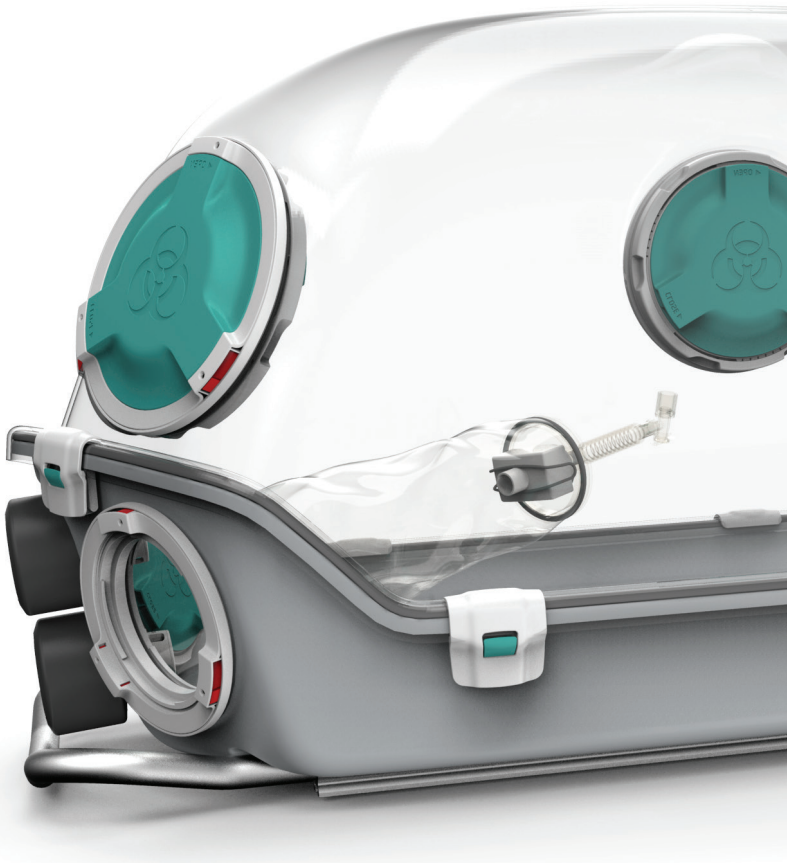
Medical ports

The two medical ports are located at the head end of the EpiShuttle base. These ports can be equipped with a medical wire membrane or a ventilation sleeve.

The wire port

The medical wire membrane is made of a highly flexible rubber material, permitting a secure passage of IV lines, monitoring cables, or oxygen lines.



The ventilator port

The ventilator sleeve is a flexible and transparent sleeve for the entry of mechanical ventilator hose. The sleeve seals the HEPA filter that connects the ventilation hose on the clean side and the oropharyngeal tube, mask or other patient respiratory device inside the EpiShuttle. This ensures that the entire mechanical ventilator and ventilator hose are on the clean side.

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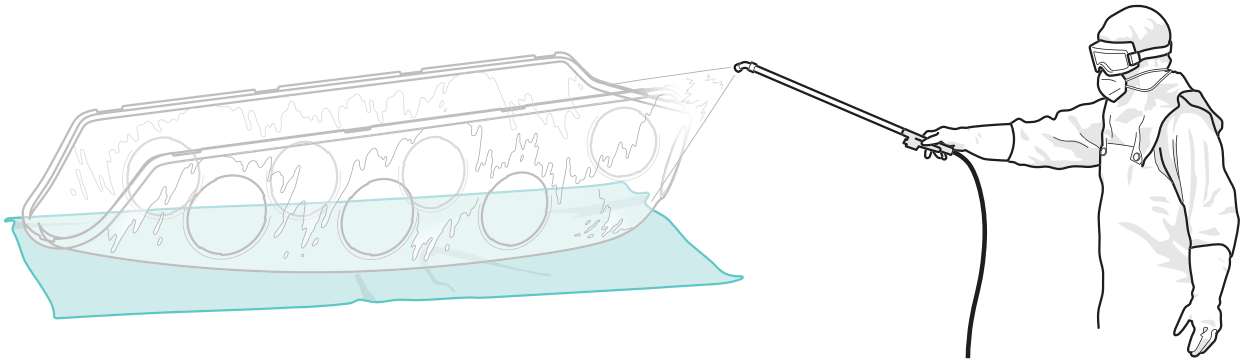
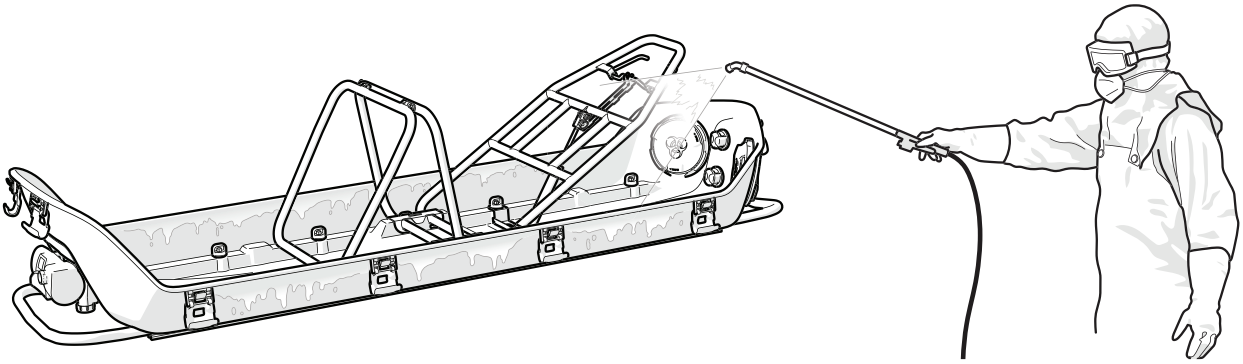
Decontamination

The EpiShuttle must be disassembled and decontamiated after each use. After decontamination the device can be reassembled by the assembly procedures described by EpiGuard. Some components are disposable and must be replaced after use. All components can be disassembled, and reassembled without the use of tools.

Disposable parts like filters, sealings, wire port membrane, ventilation sleeve, waste/sluice bag, mattress and sheet, damaged parts, must be replaced after each use by purchasing these items directly from EpiGuard AS or the local dealer. The components which are not disposable have chemical resistance to a number of different disinfectants.





Illustrations shows disinfection of
the EpiShuttle hardtop and EpiShuttle base.

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Emergency procedures

The EpiShuttle are designed to reduce reduce risk to personnel and the patient in the event of unexpected critical situation.

Critical situations can be:

Blower failure

The blower manifold is designed with a connection where an additional blower, or a manual pump, can be attached to maintain the negative pressure and air exchange in the case the blower fails.

Glove damage

The outer lid can easily and quickly seal the glove port. The design of the port allows personnel to replace the glove using a change bag connected to the outer ring.

Filter blockage

The inlet and outlet filters can easily be replaced during use by following the EpiGuard safety procedures.

Evacuation

The device has an unique locking system that are designed to be one-hand operated and easy to open, -even from the opposite side of the isolator. This is particularly relevant in events requiring rapid evacuation of the patient (vehicle fire, accidents etc).

User requirements

EpiShuttle is intended for use by qualified health care professionals (QHPs) only. QHPs are individuals qualified by education, training, and licensure/regulation who perform professional health care services within the standards of conduct set forth by the state's licensing authority.

Expected knowledge of the users:
Physicians / assistants:
- Training in infection control, patient care and use of personal protective equipment.

Emergency personell / paramedics / field workers:
- Training in infection control, patient care and use of personal protective equipment.

Users must have appropriate training in infection control, patient care, and use of personal protective equipment (PPE) as outlined in current WHO Practical Guidelines for Infection Control in Health Care Facilities (www.who.org) as well as in National Guidelines published by national health authorities.

Note!

Use of the EpiShuttle does not and cannot totally eliminate risk of infection.

All operators of EpiShuttle must use appropriate PPE and comply to routines for clean and contaminated areas.

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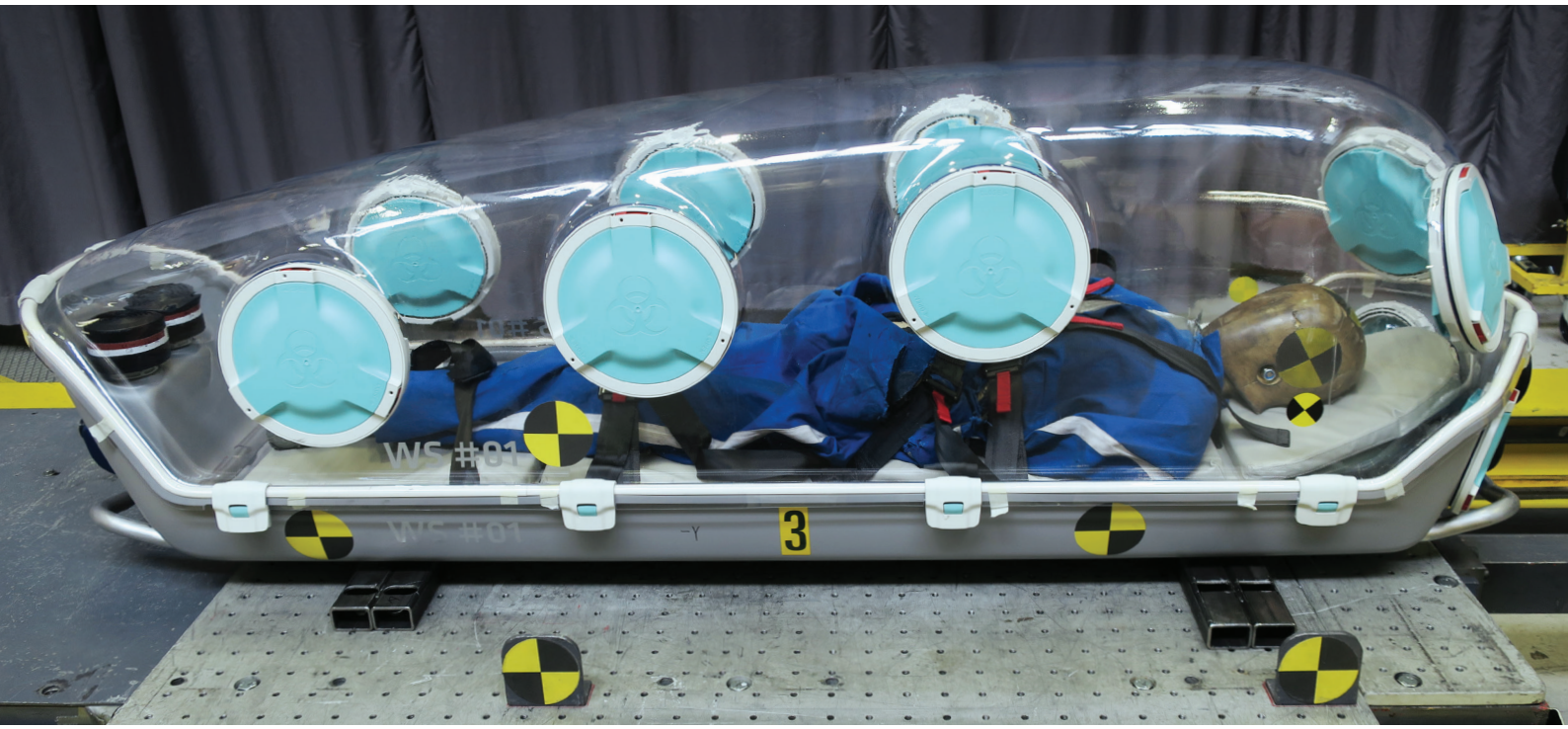
Testing according to land and air transportation standards



Test specification:

Test of the fixation : EN 1789 : 2007+A2:2014, AS/NZS 4535:1999, section 3.6 (a) (i).

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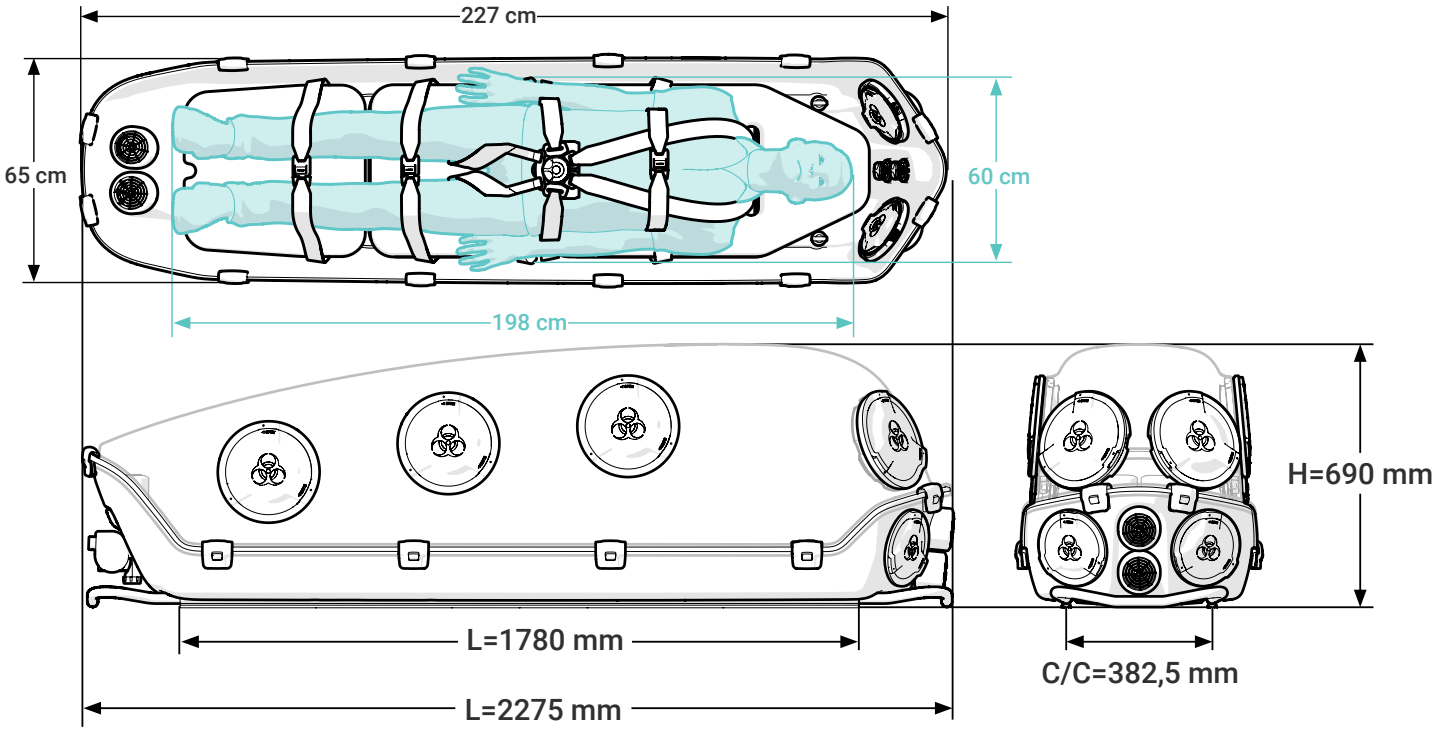
Specifications

Technical data:
Outer dimensions: L=2275mm W=650mm H=690mm.
Weight: 45-50 kg depending on configuration.
Patient weight: max 150 kg.
Patient Length: max 198 cm.
Operating temperature between: 0° and +40° C.

Patient retention/safety belts:
Quick release 6-point torso/hip restraint, chest strap, and upper / lower leg strap.

Access ports:
Operator ports : 8 ports for gloves, waste bag or sluice bag configurations.
Wire port: Membrane inlet for IV lines, monitoring cables and similar equipment.
Ventilator port: Generic port for all types of mechanical ventilator circuits.

Air system:
Blower unit: CleanAIR® Chemical 2F.
Power source : Rechargeable Li-ion battery 14,4V 2,6 Ah, CE1024.
Air exchange : More than 15 air exchanges per hour.
Operating Negative pressure: min 15 Pa relative to the environment.
Operating Positive pressure: min 15 Pa relative to the environment.



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Saving one – protecting everyone

EPi GUARD® Medical isolation and transportation systems

EpiShuttle®

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