



INSTRUCTION FOR USE



INSTRUCTION FOR USE

for mobile equipment cart elo-cart

English

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This is a Class I medical device within the meaning of the European Medical Device Regulation (MDR) 2017/745, Annex VIII.

The manufacturer declares that this product is in compliance with the basic requirements as per MDR 2017/745, Annex IX, and documents this with the CE marking.

This IFU is used by iTD GmbH as well as by TouchPoint Medical Inc. On the product label specific documentation concerning Legal Manufacturer per product is documented.



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More information regarding sales and service /support can be found on our website (www.itd-cart.com).

We are continuously further developing our products. Please accept that we must reserve the right to make changes to the scope of delivery at any time in terms of form, equipment and technology.

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These instructions for use are valid for the following products:

Type designation	Description
MR.6000.xxx-MR.9999.xxx	elo-cart equipment cart
MR.0000.xxx-MR.5999.xxx	elo-cart system components and accessories
ZV.9000.xxx-ZV.9999.xxx	General system components and accessories
CN.0xxx.xxx-CN.9xxx.xxx	Customer-specific, mobile equipment carriers
Kx.0xxx.xxx-Kx.9xxx.xxx	
MS.0xxx.xxx-MS.9xxx.xxx	
0x.0xxx.xxx-0x.9xxx.xxx	
TP.0xxx.xxx - TP.9xxx.xxx	

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1 Important information

These instructions for use are valid for the mobile equipment carts in the elo-cart product line.

All iTD GmbH products are manufactured with a long and uninterrupted service life in mind. Their development, construction, sales and production are certified by iTD GmbH in accordance with DIN EN ISO 13485.

The products meet the requirements of the European Medical Device Regulation (MDR) and feature the CE marking.

- Read the instructions for use carefully from the beginning in order to gradually familiarise yourself with the functions.
- In case of queries or doubts, be sure to contact the manufacturer.
- The mobile equipment carriers are only intended for use as described.
- These instructions are to be retained for the duration of the product's service life.

These instructions for use are addressed at professional users in the field of medical technology. They provide information for the system configurator, which adopts the information relevant to a system for the corresponding instructions for use.

1.1 Intended use

iTD GmbH's mobile equipment carriers serve:

- To accommodate medical and IEC-certified devices in accordance with the permissible loads and in compliance with the requirements of IEC 60601-1 as amended.

The mobile device carrier can be used to move medical devices around a building before and after use and to position them within a room, making flexible, economical use of all the devices possible. This also facilitates floor cleaning.

1.2 General symbol explanation

In addition to the symbols listed, other symbols in accordance with Regulation (EU) 2017/745 or ISO15223 may be used if needed.



Medical Device



Unique Device Identification



Electrically conductive castors:

Electrically conductive castors are labelled with a lightning symbol or a yellow dot.



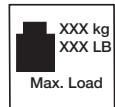
Only move with the arm folded in



Use the handle to push



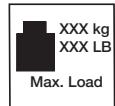
Follow the instructions for use



Total additional load, basic frame:

Maximum total additional load (= sum of actual loads).

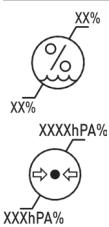
Please observe the sticker denoting the permissible load.



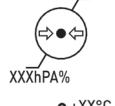
Load information (system components):

Please observe the sticker denoting the permissible load.

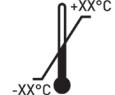
Humidity limit



Barometric pressure limit



Temperature limit



Suitable for indoor use only



Heavy object:

The mobile equipment carrier must be lifted by at least two people in order to prevent injuries.



Distributed by



Distributed by





Manufacturer



Date of manufacture



Use by date



Item number



Batch code



Serial number



Do not push:

Pushing the equipment cart above the handle is not permitted due to the risk of tipping.



Caution: "Tipping hazard"

1.3 Safety information

General:

- Staff (hospital and service staff) who work indirectly or directly with a mobile equipment carrier must be trained!
- Configuration work may only be performed by qualified staff.
- Repairs and maintenance work may only be performed by qualified staff.

Work in on an equipment cart safely:

- Disconnection from the power supply is only guaranteed if the mains plug is pulled from the socket.

Operation:

- Whenever the equipment carrier is relocated, it must be ensured that no one is injured and no objects are damaged!

Load:

- The total weight of the equipment and the accessories on the mobile equipment carrier must

- not exceed the permissible total additional load (see load sticker on the basic frame).
- The surface area loads printed on the system components must not be exceeded!
- The loads stipulated on the add-on modules must not be exceeded!



Please note: The applicable standard stipulates that the total mass of the equipment cart including all the equipment and systems must feature on the equipment cart as a sticker. We would be more than happy to assist you with creating this sticker!

Protection against infection:

- The hygiene regulations must be observed when performing cleaning work!
- Only hand cleaned and disinfected equipment and apparatus over to a service technician or maintenance and repairs!

Environmental protection:

- Dispose of all cleaning agent and disinfectant traces or residues without them causing harm and in an eco-friendly manner!
- Observe the regulations applicable in your region when disposing of the equipment cart.

2 Assembly

2.1 Completeness and assembly

First, unpack the equipment cart and use the enclosed delivery note to check that all the ordered parts are there. Then assemble the equipment cart in accordance with the assembly instructions.

2.2 Loading

Stand the equipment cart on a level, horizontal surface and place the monitor/equipment on the designated mount/shelf. Assembly and loading may only be performed when the cart is not connected to the power supply. If there is insufficient stability, the cart must be visibly labelled in accordance with the 5° labelling obligation.

2.3 Hazard due to mechanical instability

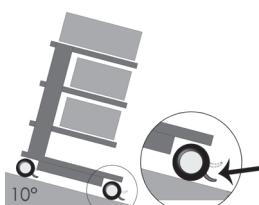
The entire system must meet the requirements as per IEC 60601-1. This is the responsibility of the system creator.

2.4 Castors

The equipment carts feature twin castors with brakes.

Before putting the equipment carts into operation, ensure that the castor locks work. All the castor brakes (castor locking mechanisms) are to be activated upon arriving at the parking position and to secure the cart during transportation.

Correspondingly, all the castor brakes are to be released when moving the cart. The castors must be inspected every twelve months for safety and to ensure that the castor securing bolts are snug and tight. If these are loose, please contact your supplier immediately.



2.5 Load

The equipment carts' load capacity may not be exceeded.

Please observe the equipment carts' maximum loads (see Section 10).

2.6 Subsequently adding system components

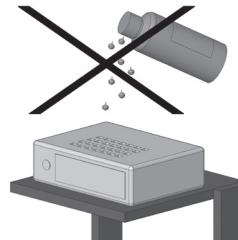
iTD system components may only be subsequently added by qualified staff in accordance with the assembly instructions provided. The modified system must be checked again for compliance with IEC 60601-1.

3 Electrical safety

3.1 Positioning of electrical equipment

Please note that electrical equipment on the equipment carts may not get wet.

Never place products which could leak liquids above electrical equipment into which the liquids could leak.



3.2 Gases

Electrical equipment must not be operated in the vicinity of gases, e.g. flammable narcotic gas or similar. The user is responsible for this as well as for compliance with IEC 60601-1-2.

3.3 Combining equipment

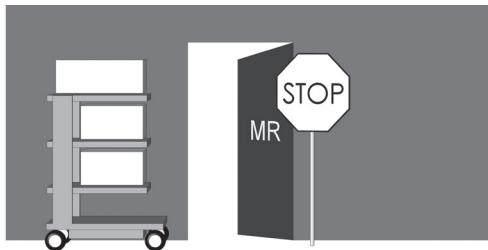
The following rules are to be observed when combining equipment on the equipment cart:

- Ancillary equipment which is attached to the equipment's analogue and digital interfaces must demonstrably comply with the relevant specifications (e.g. IEC 60950 for information technology equipment and IEC 60601-1 for medical electrical equipment).
- Additionally, all the configurations must comply with the valid version of the IEC 60601-1 standard. A person who connects additional equipment to the signal input or output part is a system configurer and is therefore responsible for compliance with the valid version of the IEC 60601-1 standard.

3.4 EMC

The electromagnetic compatibility of the pieces of medical electrical equipment on the cart is to be checked by the overall system configurer. Before an equipment combination is medically deployed, check the electromagnetic compatibility of the individual pieces of equipment.

Customer-specific equipment carts which are to be used in MR settings must be checked by the customer for usability due to proportions of ferromagnetic materials. iTD GmbH shall not accept any liability in this regard!



3.5 Minimum safety level

iTD GmbH is not aware of any equipment or accessories that reduce the system's minimum safety level. Only equipment which does not pose a hazard may be used. If necessary, this should be clarified by means of a risk analysis (ISO 14971).

4. Transportation

4.1 Safe transportation on castors

Before moving the equipment cart, ensure that:

- All the equipment/products on it are secured against falling off.
- All the articulated arms are folded in and secured.
- The power cable has been disconnected from the local power supply point.
- The castor brakes have been released.

The equipment cart may only be moved across a threshold at a maximum speed of 0.8 m/s +/- 0.1 m/s.

When moving on ramps with a maximum incline of 10°, it must be ensured that the equipment cart can be brought to a standstill at any time.

While all the precautionary measures have been taken to guarantee the product's maximum stability, attention should be paid to unevenness in the floor, lift door frames, cables, etc. in order to prevent accidents.

The requirements as per IEC 60601-1 generally apply.

4.2 Safe transportation by means of carrying

The handles are not designed for lifting the mobile device carrier and are purely for pushing purposes. The mobile device carrier may only be lifted and carried by two people, using the base stabilisers.

The requirements as per IEC 60601-1 generally apply.

5 Mechanical height adjustment

The special safety regulations as per IEC 60601-1 'Mechanical hazards associated with moving parts' are to be observed for mechanical height adjustment via gas pressure. The following rules apply:

- The permissible gaps between moving parts as per Table 20 of IEC 60601-1 (ISO 13857:2008) are to be considered and observed.
- Compliance with the required minimum gaps is the responsibility of the relevant system configurer.
- The total weight of the mounted equipment and accessories may not exceed the maximum total additional load for height adjustment. Overloading can lead to height adjustment damage and to loss of warranty.
- With mechanical height adjustment via gas pressure, stored energy is released. When a system is not loaded, abrupt, unbraked activation of the height adjustment can lead to injuries and damage.
 - To prevent injuries and damage, the height adjustment is to be placed in the highest ('energy-free') position prior to mounting and dismounting equipment.

6 Support arms/monitor mounts

6.1 Cabling

Please note the following information:

- There must be sufficient cabling in order to prevent cable damage or equipment outage when swivelling equipment.
- Under no circumstances should hanging cables be used as handles.
- Please ensure that the enclosed assembly materials are used correctly in accordance with the assembly instructions.
- Pay attention to any cable loops when swivelling the arms.

6.2 Horizontal swivelling

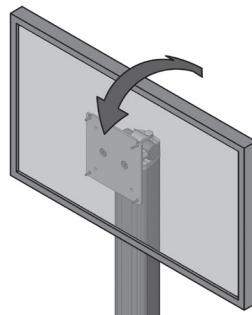
Ensure that the swivel range of system components is geared both to the equipment size and the space conditions.

When horizontally swivelling system components bearing attached equipment, the equipment may not collide with other equipment, other system components or the wall. A collision can result in damage to the equipment and personal injury.

6.3 Tilting/rotating equipment

In the case of tiltable/rotatable system components, verify that the clamping force is appropriate for the equipment being attached. If the clamping force is incorrect, there is a risk of the equipment tipping over. It must therefore be attached in such a way that the equipment can be easily tilted/

rotated while nevertheless remaining stable in the desired position.



6.4 Dismantling and repositioning system components and accessories

If system components and accessories need to be dismantled or repositioned, it is essential that the attached equipment be removed first.

6.5 Use as intended when manoeuvring mobile equipment carriers

When manoeuvring mobile equipment carriers, the attached support arms should ideally be folded in. The carrier's stability cannot otherwise be guaranteed (see Section 2.4).

7 Miscellanea

7.1 Cleaning and disinfection

Please note: Disconnect the entire system from the mains before cleaning and disinfection.

The equipment carts may be cleaned using commercially available all-purpose cleaners (neutral cleaning agents). Commercially available disinfectants which are approved for surface/wipe-down disinfection may be used for disinfection. The disinfectants are to be used purely for wipe-down disinfection purposes in accordance with the manufacturer's specifications.

For example, iTD has performed tests using the following disinfectants:

Product	Manufacturer
Bacillol plus	Bode
Cleanisept Wipes	Dr. Schumacher
Mikrobac Tissues	Bode
mikrozid sensitive wipes	Schülke
terralin protect	Schülke
Incidin Plus	Ecolab
Incidin Foam	Ecolab

If full disinfection is required, modules can be dismantled by an expert and wiped down with disin-

fectant while dismantled.

7.2 Maintenance/servicing

The equipment cart is to be cleaned and disinfected using suitable cleaning agents before every instance of maintenance, including if being returned for repair purposes! Maintenance work on the equipment cart may only be performed by qualified staff. We recommend you contact iTD GmbH regarding all servicing.

7.3 Environmental conditions

The equipment carts are designed with ordinary hospital and surgery operations in mind.

Operation:

Ambient temperature:	10°C to 40°C
Humidity:	30% to 75%
Air pressure:	700 hPa to 1,060 hPa
Protection rating:	IP20

Transportation/storage:

The Rollstand is suitable for customary transportation by lorry, airfreight and sea freight. The packaging has been designed accordingly.

Ambient temperature:	-25°C to 70°C
Humidity:	10% to 95%
Air pressure:	500 hPa to 1,200 hPa

7.4 Parts

Only parts approved by iTD GmbH may be used.

8 Accessories

An extensive array of accessories can be found in our catalogues or at www.itd-cart.com (information for retailers).

9 Servicing

The equipment carts have been developed and built for many years of trouble-free use. Check the functionality of the following parts every twelve months to guarantee safety:

Shelves:

- Check that the fastening screws are tight and that the shelf is stable and even.

Castors:

- Ensure that the castors are free-running and check that all the brakes work.
- Check that the four bolts used to attach the castors to the underside of the base and the castors themselves are firmly secured in their mounts.
- In the case of electrically conductive castors, the treads must be free of dirt in order guarantee functionality.

Support arms:

- Rotating and tilting them must be smooth, without too much effort.

Serial numbers:

- Compare the cart's serial/batch number with the information in the equipment logbook.

If you identify a problem when performing this check, please contact your supplier immediately.

10 Technical specifications

Rollstand 2.0 payload

Basic frame, total additional load	40 kg
Shelf	10 kg
Monitor mount	10 kg
Basket, high	3 kg
Basket, flat	3 kg

iTD GmbH is responsible for the correctness of this content.



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