

MOBILE EQUIPMENT CART INSTRUCTIONS FOR USE

Table of Contents

- I. Intended Use
- II. Device Description
- III. General Warnings and Precautions
- IV. Qualified Equipment
- V. System Overview
- VI. System Set-Up
 - A. Physical Location
 - B. Electrical Connections
 - C. Operating and Storage Conditions
 - D. Assembly and Installation
 - E. System Accessories
- VII. Transportation of the Cart
- VIII. System Maintenance
- IX. Cleaning
- X. Disposal

I. Intended Use

The ClearPoint Mobile Equipment Cart enables ClearPoint qualified equipment to be stored and operated on one mobile platform.

II. Device Description

CP-MEC-01 Mobile Equipment Cart

Cart with 3 locking drawers, Monitor, Monitor Arm, Keyboard,

Mouse, Multiple Socket-Outlet Power Strip

III. General Warnings and Precautions

Warning: Do not perform any assembly of the Cart. All assembly is to be done by

ClearPoint Neuro, Inc.

Warning: To avoid the risk of electric shock, this equipment must only be

connected to a supply mains with protective earth.

Warning: The Cart should not be used with an extension cord or with another

multiple socket-outlet.

Warning: Do not connect items to the Cart which are not specified as part of the

System.

Warning: Do not connect the Monitor to other equipment that is not specified as

part of the System or is not approved for use with the System.

Warning: The multiple socket-outlet strip provided with the Cart is only to be used

for components supplied with the Cart. Do not connect other electrical

devices to the multiple socket-outlet strip.

Warning: Connection of any equipment which has not been supplied as part the

System to the multiple socket-outlet supplied with the System effectively creates an unverified System and may result in a reduced level of safety.

Refer to IEC 60601-1 for additional information.

Warning: Use the System only in an appropriate, dry area with proper power and

grounding connections.

Warning: Do not bring the Cart into the MR environment.

Warning: Do not stand or sit on the Cart.

Warning: Do not step into or onto drawers of the Cart.

Warning: Do not lean on the keyboard tray or treat it as a resting surface.

Warning: Do not have more than one drawer open on the Cart at any given time.

Warning: Do not attempt to lift or tilt the Cart. Damage to the Cart and its

equipment or harm to the operator may occur.

Warning: Do not modify this equipment without authorization of the manufacturer.

Warning: The Cart should only be pushed using the cart handles. Do not push the

Cart using side-mounted or top-mounted accessories as this may cause

the Cart to become unstable and tip over.

Caution: Prior to use, examine components for damage, deterioration,

deformation, and abuse. Do not attempt to use any components that

appear to be bent or otherwise damaged.

Caution: Engage the caster brakes when the Cart is in a stationary position to

prevent the Cart from moving.

Caution: Close and lock all drawers before transporting the Cart to avoid risk of

user injury or damage to the Cart.

Caution: Safety of the Cart has only been evaluated as a System as pre-

configured. Connection of the monitor directly to the wall outlet rather than the supplied multiple socket-outlet may result in compromised

electrical safety or performance.

Note: Always inform hospital personnel of any changes made to the hospital

capital equipment, including the IT infrastructure.

IV. Qualified Equipment

The following ClearPoint Neuro equipment / accessories are qualified for use with the Cart. The listed equipment / accessories have been determined by ClearPoint Neuro to be compliant with the safety, emissions, and immunity requirements of IEC 60601-1, Edition 3.2.

Caution: Prior to use, examine equipment / accessories for damage, deterioration,

deformation, and abuse. Do not attempt to use any equipment / accessories that appears to be bent or otherwise damaged.

Table 1. Qualified Equipment / Accessories

Part No.	Description	
1100-N1	Thermoguide Workstation	
CP-WRK-** or	ClearPoint Workstations	
CPA-WRK-**	Clear Point Workstations	

Caution: Only one piece of qualified equipment may be plugged into the on-board

power strip at any given time. Refer to each device's IFU for any

additional electrical requirements.

The following ClearPoint removable equipment / accessories may be stored on the cart at the user's discretion. The listed equipment may not be plugged into the on-board power strip.

Table 2. Removable Equipment / Accessories

Part No.	Description
1001-N2	ClearPoint Prism Mobile Laser Unit

V. System Overview

The ClearPoint Mobile Equipment Cart consists of the following components: Base Cart with Drawers (1), 27" Monitor (1), Single Arm Monitor Mount (1), Multiple Socket-Outlet with Outlet Covers (1). Each of these components may or may not be designed to be utilized according to its own individual labeling and instructions for use. The following information is provided to facilitate efficient and safe use of the Cart. This manual cannot be used as a substitute for the instructions included with each component device.

VI. System Set-Up

A. Physical Location

It is important to note that the Cart is **NOT** MRI-compatible. The Cart components contain significant amounts of ferro-magnetic material which are not compatible with the MRI environment. These non-MRI-compatible components must be located outside of the high-field region of the MRI system.

The Cart should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, component devices should be observed to verify normal operation in the configuration in which it will be used. Do not position the Cart such that access to the power supply plug is difficult or cannot be disconnected in case of emergency.

B. Electrical Connections

Electrical service for the installed Cart equipment is provided by a single cord. The single cord services a multiple socket-outlet power strip into which various cart components will be connected during assembly. The multiple socket-outlet power strip is rated for 12A at 120VAC 50/60Hz for a maximum supported total load of 1440W.

The power cord should be connected to an appropriately connected electrical supply outlet that is properly grounded. No "grounded-to-ungrounded" or "ground-lift" adapter should be used with the Cart.

To prevent the potential for ground loops, all installed Cart Equipment should only be plugged into the multiple socket-outlet power strip provided on the Cart. No other electrical devices should be connected to the multiple socket-outlet power strip. Disconnect the power cord from the mains power supply

when the Cart is not in use or during system service. Unplugging of the power cord will isolate the Cart from the Supply Mains.

C. Operating and Storage Conditions

The Mobile Equipment Cart should only be stored and operated within the limits listed below in Table 3. Using or storing the product outside of these conditions may result in deterioration of the product which may subsequently result in user harm.

Table 3. Operating and Storage Conditions

Description	Operating	Storage (including Transport)	
Temperature Range	0°C to 40°C (32°F to 104°F)	-20°C to 60°C (-4°F to 140°F)	
Relative Humidity (maximum)	10% to 80% (non-condensing)	10% to 90% (non- condensing)	

Note: Operating and storage temperature ranges may differ among equipment or parts authorized to be used with or stored on the Mobile Equipment Cart. Operating or storing outside of these ranges may impact the performance.

D. Assembly and Installation

The ClearPoint Mobile Equipment Cart should only be assembled and installed by a ClearPoint Neuro, Inc. Service Representative.

E. Cart

A fully assembled, representative Mobile Equipment Cart is shown in Figure 1 with qualified, optional equipment included.

The Cart is mounted on four rubber-wheeled swivel casters. The casters have foot-operated brakes, which will prevent them from rolling. When the cart is stationed, the brakes should be set ON. The brakes should be set OFF for transport. Brakes should be operated only by foot as they pose a potential pinching risk if operated by hand. Do not move the cart during a procedure unless it has been verified that it is safe to do so. If it is necessary to move the cart during a procedure, verify that the pathway is free and clear from any obstructions prior to moving the cart, that there are no connections between equipment on the cart and the patient, and that no unnecessary hazards are created during or after the cart has been moved.

Included on the cart are three locking Drawers, which may be used by the operator for storage. Item(s) may be placed on the top surface of the cart (see Figure 1). Potential interference with the installed monitor should be considered. Table 4 lists the maximum supported loads. During storage and transportation, drawers should remain locked.

An LCD Monitor is provided with the Cart with VESA interface support, and is mounted to the Monitor Arm. It has built-in 1920 x 1080-pixel resolution. The monitor may only be connected to qualified equipment listed in Section IV.

An adjustable Monitor Arm is provided with the Cart. The Monitor Arm provides up to 33.5 cm (13.2 in) of vertical adjustment, 60 cm (23.7 in) of functional focal length and tilt adjustability.

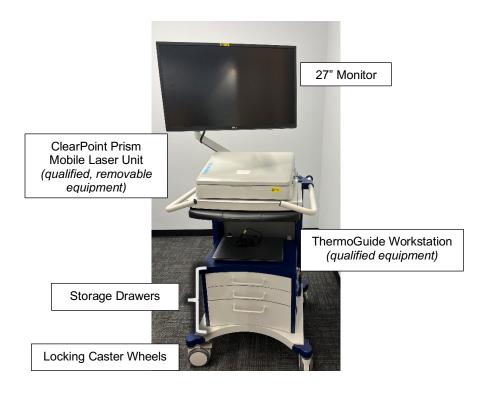


Figure 1. Representation of the Mobile Equipment Cart fully assembled with qualified, optional equipment shown.

A multi-device keyboard and mouse are provided with the Cart. For connection of the keyboard and mouse to a computer, refer to its respective manual. The keyboard and mouse are powered by AAA batteries, which will need to be replaced occasionally by the operator. The keyboard and mouse may be stored on the Keyboard Tray. The Keyboard Tray has a dedicated mouse pad that swivels out for use and may be stowed away when not in use. Table 4 lists the maximum load for the Keyboard Tray.

A multiple socket-outlet power strip is provided with the Cart and is located behind the Drawers. No other devices should be connected to available outlets. To prevent misuse, unused outlets are locked.

Table 4. Maximum load capacity of System.

System Item	Load Capacity	
3" Drawer	9.1 kg (20 lbs.), each	
6" Drawer	9.1 kg (20 lbs.)	
Keyboard Tray	0.9 kg (2 lbs.)	
Top Surface	14.5 kg (32 lbs)	

Caution:

Avoid placing items on the Top Surface that exceed 20 cm (8 inches) in height. Doing so may impede the usage of the monitor or may result in potential harm to the user or damage to the equipment.

VII. Transportation of the Cart

When moving the cart between storage and its usage position, prepare the Cart as follows:

- Disengage all caster wheels by using the foot-operated brakes.
- Gather the 15' power supply cable and place it on the cart to prevent the risk
 of tripping. This can be accomplished by wrapping the cable around the cord
 wrap posts on the backside of the Cart (extension from push handles). See
 Figure 2.
- As applicable, power down then disconnect any Qualified Equipment /
 Accessories from its power supply and from the monitor. Store the qualified
 equipment in one of the Cart drawers.
- As applicable, disconnect any Removable Equipment / Accessories from its power supply and stow any power cables on the cart to prevent the risk of tripping.
- If desired, the keyboard and mouse may be placed in a drawer for storage; otherwise, move the mouse from the dedicated mousepad and place it with the keyboard on the keyboard tray. Stow the dedicated Mouse Pad by rotating it inwards and underneath the Keyboard Tray. Push the keyboard tray fully in until it is in a closed position.
- Close all drawers, then lock all drawers with the key provided.
- Position the Monitor so that it is aligned and rotated above the cart as shown in Figure 2.

Take caution when transporting the cart and make sure there is reasonable clearance on all sides of the cart if moving through narrow spaces. Avoid bumping

the cart, mounted accessories, or stored equipment into other objects during transport. Doing so may damage property.



Figure 2. Left: Monitor position during transportation. Right: Power cable managed across Cart cord wrap posts.

VIII. System Maintenance

The only user-serviceable component of ClearPoint Cart is to replace the AAA batteries of the included keyboard and mouse. The Cart contains no material which is consumed during operation. Under normal operation, the Cart is not subject to deterioration. However, components included on the Cart during installation may require annual inspection and testing.

At a minimum, inspection should include:

- Inspecting cables for damage, cuts, or connector wear.
- Inspecting cart, casters, and monitor for damage or wear.

Testing should include:

Verifying full functionality of keyboard, mouse, monitor, and monitor arm

Additional inspection and testing may be required based on the labeling of the qualified equipment / accessories described in Section IV. Please contact ClearPoint Neuro to schedule a full maintenance and system check appointment.

IX. Cleaning

The Cart and its associated components require cleaning per the following recommendations as needed, or by following institutional cleaning policies.

Caution: Do not allow fluid to enter any system enclosure. Disconnect from power

and allow the system to dry if you suspect fluids may have entered any

part of the unit.

Caution: Do not spray any of the equipment directly with liquid cleaning products.

Always apply the cleaning product to a cloth before wiping the equipment

with the dampened cloth.

1. Power down and unplug the system before cleaning.

 Per power strip manufacturer's recommendation: Wipe the power cord with a clean cloth. The cloth may be dampened with an all-purpose cleaner (e.g. 70% Isopropyl Alcohol)

- 3. Per monitor manufacturer's recommendation: Unplug the monitor power cable prior to cleaning. To clean the screen, lightly dampen a soft, clean cloth with water. If possible, use a special screen-cleaning tissue wipe or solution suitable for anti-static coating. Do not use benzene, thinner, ammonia, abrasive cleaners, or compressed air. Use a lightly dampened cloth to clean the monitor. Avoid using detergent of any kind as some detergents leave a milky film on the monitor.
- 4. Clean the exterior of the Cart system (drawers, surfaces, handles, etc.) and the monitor arm using a soft, clean cloth, lightly dampened with water.
- 5. Inspect the device for cleanliness. If any soilage remains, repeat cleaning.

X. Disposal

Contact ClearPoint Neuro, Inc. to dispose of the Cart after the end of the system's service life.

Explanation of symbols on product or package labeling - Refer to the appropriate product for symbols that apply.

SYMBOL	DEFINITION	SYMBOL	DEFINITION
	Date of Manufacture		Manufacturer
i	Consult instructions for use		General Warning Sign
REF	Catalogue number		Keep dry
SN	Serial Number	**	Keep away from sunlight
	No pushing	R	Not MR Safe
∇	Temperature Limits	%	Humidity Limits
₹ U	Do not use if packaging is compromised		



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