ROSE Mobile™

USER MANUAL

GENERAL INFORMATION

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A: BECOMING FAMILIAR WITH THE MOBILE CART

1. SAFETY INSTRUCTIONS

It is the sole responsibility of the user to ensure that they have read and understood this user manual and have the appropriate training.

1.1. CONVENTIONS USED IN THIS USER MANUAL

General Warning! Text preceded by this icon alerts the user to the possibility of injury or other serious adverse reactions associated with the use or misuse of the device.

General Mandatory Action! Text preceded by this icon alerts the user to the possibility of a problem associated with the use or misuse of the device. Such problems can include device malfunction or failure, and damage to the equipment. The caution statement includes a precaution that should be taken to avoid such issues.

Note: Text preceded by this icon contains useful information to assist the user in the effective operation of the System.

1.2. GENERAL CAUTIONS

- Read the entire User Manual prior to initial usage to avoid issues, accidents, and misuse.
- The device is only for use by appropriately trained professionals in a clinic or laboratory environment.
- Do not use the system if the housing or electrical components appear damaged.
- The system must be placed on a stable, level surface away from direct sunlight.
- The system should be turned off when not in use to ensure optimal lifetime performance.
- It is the responsibility of the user/clinical site to provide an appropriate connected computer and maintain all necessary cybersecurity mitigations for private information. Consult your institution for any necessary cybersecurity precautions.
- The Mobile Cart is intended solely as a mobile support and storage surface for holding equipment and supplies during ROSE or other procedures. The cart does not contact the patient, perform a diagnostic or therapeutic function, control, or alter the performance of any medical device, or affect the structure or function of the body. Based on its intended use, the cart does not meet the definition of a medical device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act / 21 U.S.C. § 321(h), and is considered general clinical furniture/equipment. Therefore, FDA clearance, establishment registration and device listing are not required for the Mobile Cart.

1.3. ELECTRICAL SAFETY

General Warning! The User is responsible for ensuring that the mobile cart system, as installed and used at the user/clinical site, meets applicable workplace electrical safety requirements. If workplace policy or the facility's safety office requires a field safety evaluation/approval for the intended use environment (for example, by an OSHA-recognized Nationally Recognized Testing Laboratory (NRTL), such as evaluation to UL/CSA 61010-1), the user/clinical site is responsible for obtaining and documenting the required evaluation/approval before placing the mobile cart system into use.

WARNING

To reduce the risk of electrical shock:

- Do not attempt to disassemble the cart. The mobile cart contains no user serviceable parts.
- Only clean the surfaces of the device using the recommended cleaning agents (see "Cleaning the Device").
- Use only the supplied 120V power strip and region-specific outlet plug.

- Switch off the power and unplug the device when not in use.
- Do not handle the power strip or other electrical components with wet hands.
- Do not yank or twist the power cord. Remove the cord by gently pulling on the plug to remove it from outlet.

Note: Passive Cart: A power strip may be provided as an optional accessory in markets where permitted, subject to applicable regional regulatory and certification requirements.

1.4. PERSONAL SAFETY

WARNING

To reduce the risk of injury:

- Take care when going over bumps or uneven surfaces.
- Take care not to drop the devices or equipment while moving.
- Heed all warnings for maximum load weights for work surfaces, drawers, and shelves.
- Do not stand on, lean on, sit on, or otherwise use this cart for purposes other than intended by the workflow of ASP Health devices.
- All doors, trays, shelves, or work surfaces shall be closed/put away before moving the cart.
- Only approved and trained service technicians should use the system. Customers should not try to disassemble the system or replace/modify parts.

1.5. Weight Limits

WARNING

- The weight limit of the front pull-out drawer is 10 lbs.
- The weight limit of the left pull-out work surface is 10 lbs.
- The weight limit of the upper shelf in the cabinet is 10 lbs.
- The weight limit of the monitor mount is 26 lbs., or 22 lbs. for a curved monitor.
- No weight limit risks exist for the lower shelf in the cabinet, the computer storage area, or the main, top work surface.

2. ABOUT THE MOBILE CART

2.1. SUMMARY

The Mobile Cart provides a movable workspace and storage area for compatible equipment, accessories, and supplies, including separately supplied items such as ROSE Prep™ and ROSE View™, a computer, a monitor, and related equipment and supplies, as applicable. The Mobile Cart is intended for organization, storage, and transport only. It is non-medical equipment and does not perform clinical, diagnostic, therapeutic, analytical, or device-control functions. The Mobile Cart does not integrate, modify, control, or augment the performance of any equipment placed on or within it.

Features:

- Post for monitor attachment
- Placement areas for equipment and supplies
- Main work surface
- Extra pull-out and reversible work surface/drawer
- Extra drawer and shelving cabinet storage
- Four swiveling and locking wheels (one of the four is directional as well)

2.2. INTENDED USE

NOTE: The device is intended for the US market.

The Mobile Cart is intended for use in a clinic or laboratory environment by professionals who have been trained to work with specimens. The intended users perform evaluations of samples as part of their work and are aware of the hazards associated with handling biological samples. The users will have to read the user manual and be aware of the hazards associated with the use of the system.

Intended Use - Mobile Cart System:

The Mobile Cart is non-medical equipment intended only to provide a movable support surface and storage area for compatible equipment, accessories, and supplies, including separately supplied items such as ROSE Prep™, ROSE View™, a computer, and a monitor, as applicable. The Mobile Cart is intended for organization, storage, and transport only and does not perform clinical, diagnostic, therapeutic, analytical, or device-control functions.

Intended Operating Environment:

The Mobile Cart system is intended for use in a professional medical facility such as a hospital or clinic and is not intended for home use. The system is intended for indoor use only.

Intended Operational Setup:

The Mobile Cart is intended as a stationary system during operation that can be moved between usages. Typically, the instrument will be operated by a trained operator who works with a clinician who collects the samples to be evaluated. In some cases, the clinician may work alone and use the system to evaluate samples, and in other cases, the trained operator also collects and evaluates the samples.

The system is non-sterile. Do NOT place the system in the sterile field.

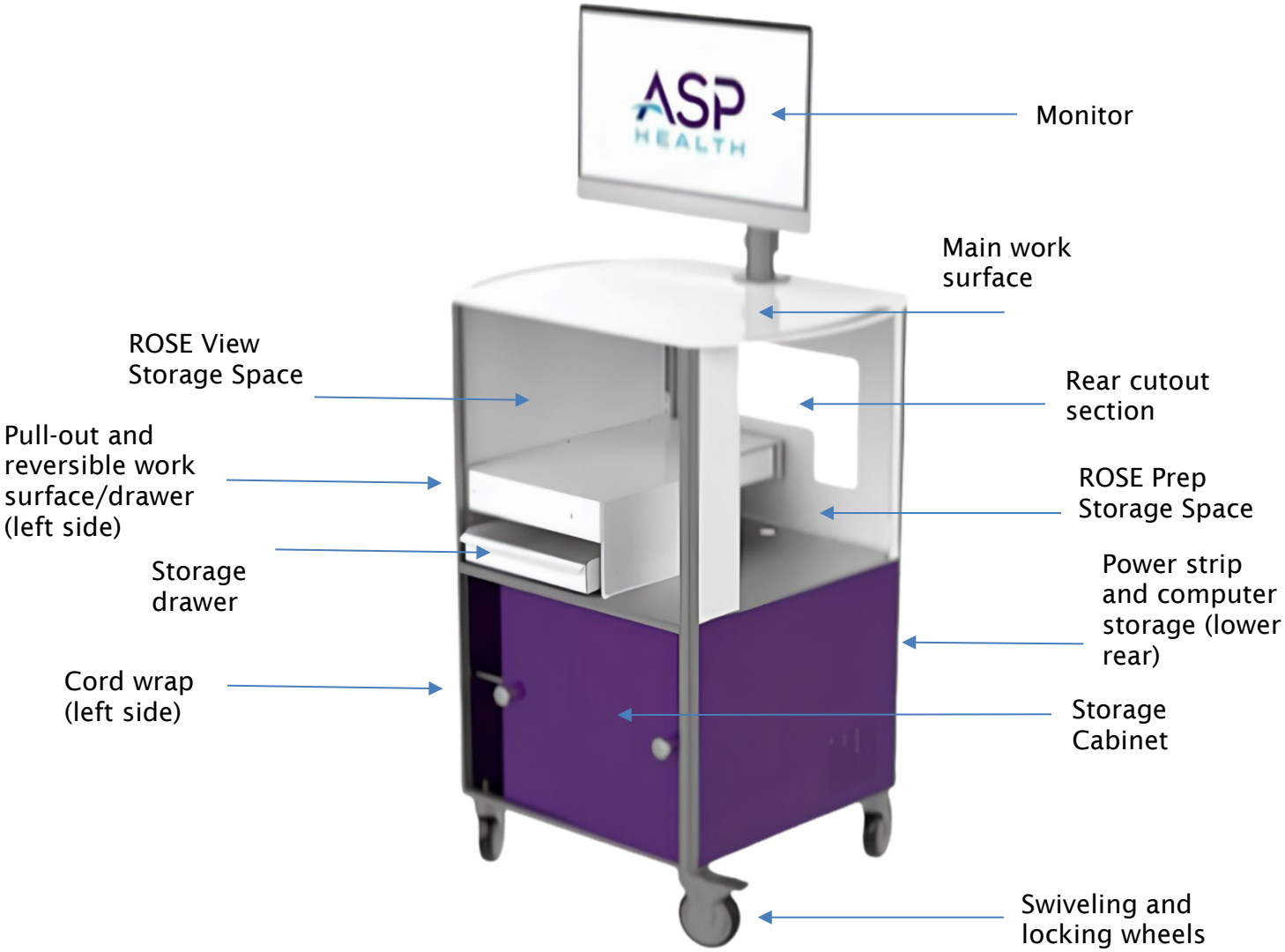
Intended Users:

The device is intended for use in a clinic or laboratory environment by professionals who have been trained to work with specimens.

The intended users of the system are usually clinical professionals who are trained to work with and evaluate specimens. These may be medical professionals such as Cytotechnologists, Cytopathologists, or other personnel who perform similar functions in different environments - such as a laboratory.

The intended users perform evaluations of samples as part of their work. The users are aware of the hazards associated with handling biological samples.

2.3. OVERVIEW



2.4. STORAGE

NOTE: The cart must be decontaminated if it will be out of use for more than one week (see “Maintenance”).

Please use the original packaging and protective inserts for storage and/or transport.

Refer to section 7. For ambient and operational conditions such as temperature and humidity.

B: PREPARING THE MOBILE CART

3. INSTALLATION & SETUP

- The Mobile Cart will be delivered fully assembled. The cart must be installed on a stable, level surface.
- Ensure clear access to the rear of the cart to allow the devices to be easily switched on or off, to allow for easy disconnection and connection of the device power cables, and to access the device labels and warnings.
- Ensure at least 6 inches in front and to the right of the system to allow space for operations.
- No initial nor routine calibration should be required for the Mobile Cart system.

Refer to section 7. For ambient and operational conditions such as temperature and humidity.

3.1. PACKAGE CONTENTS

- 1 x Mobile Cart System with monitor post and power strip

NOTE: Check all packaging and contents for any visible signs of damage.

3.2. SWITCHING THE POWER ON/OFF

1. Plug all device and computer equipment power cords into the power strip.
2. Unwrap the power strip cord from the cord wrap on the side of the cart and plug it into an appropriate outlet.
3. Turn the power switch on the power strip on.
4. Turn the power switches on the back of the devices on and power up computer equipment.

3.3. SETUP

1. Place the necessary equipment in the appropriate areas on the cart. The ROSE View microscope should sit in the recessed area on the left side of the cart. The ROSE Prep feet should sit into the mounted pucks on the right side of the cart.
2. Mount the monitor to the post. The keyboard and mouse can go on the top, main work surface.
3. Install the computer in the lower back compartment with the half wall.
   - In the case of larger computer towers, the half wall panel at the lower back of the cart can swing open to allow full access to the computer storage area.
   - To do this, start by loosening, but do not remove the screws inside at the bottom of the half-wall panel.
   - On the inside near the top of the half-wall panel, there will be two screws close to each other. Remove the top screw only from both sides.
   - You can now gently lift the half-wall a bit to avoid scratching and swing it open to place the computer tower.
   - Perform the reverse steps to secure the half wall back in place.
4. Place any needed consumables, supplies, stains, etc. in the storage drawer and cabinet.
5. Route all cords and plugs through the gromets and holes on the carts to the computer and power strip to minimize visibility.

C: OPERATING THE MOBILE CART

4. OPERATION

4.1. NORMAL USAGE AND FEATURES

Typical operation for the storage and transport of devices, equipment, and materials.

- There is a monitor post designed to hold any standard monitor via a standard VESA mount. The monitor mount can be articulated in different directions. We recommend at least a 27" HD monitor with a camera, microphone, and speakers.
- Next, there is the main, large work surface designed to hold the keyboard and mouse, be used for writing on slides, or holding supplies.
- Below this area are designated spaces that may be used to hold separately supplied equipment, such as ROSE Prep™ and ROSE View™, as applicable. These spaces are intended for organization and storage only and do not integrate, control, modify, or augment the performance of any device.
- There are specifically placed cutout areas at the back of the cart to be able to access the device cords, power switch, and labeling.
- All cords are designed to be routed with minimum visibility down through the cart. All plugs connect to a single, medical-grade power strip, with a single cord coming off the cart for easy usage.
- Next, there are handles on the side for maneuvering the cart, as well as an extra pull-out work surface for writing on slides or holding materials.
- Similarly, there is a single pull-out work surface/drawer that is designed to hold extra materials such as consumables. It can be fully removed from the cart and flipped upside down to allow customizable switching between the work surface and drawer orientations.
- The last storage space down below is a double sliding door cabinet with two separate levels. This is designed to hold even more materials and equipment such as extra reagent bottles.
- Behind this cabinet area is the space for holding the computer that operates the microscope and monitor. The space is big enough to hold small or mid-size tower computers and will be designed with half walls or gaps to allow for sufficient ventilation.
- Lastly, the base contains four swiveling castor wheels with locking capabilities. In addition, the single, differently colored wheel can be set to allow for directionally-locked pushing in a straight line.

4.2. SHUTDOWN PROCESS

1. Turn off the power switches at the back of all devices and power off computer equipment.
2. Turn off the power switch on the power strip.
3. Unplug the cord from the wall and wrap around the cord wraps on the side of the cart.

5. CLEANING THE DEVICE

Safe Cleaning:

- It is recommended that the power be switched off before cleaning the system to prevent any electrical hazards.
- The operator must wear gloves that are suitable for handling biological matter and cleaning agents.

5.1. MAINTENANCE

NOTE: The maintenance cleaning takes less than three minutes to complete. It is recommended that the system be cleaned between patients and as part of End-of-Day (Daily) Cleaning to avoid cross-contamination and maintain functionality. Cleaning may also be needed between patients if any spills or contamination occurs.

Daily maintenance must be performed:

- To ensure correct operation and cleanliness.
- To avoid cross-contamination between samples/patients.

Required Items:

- Soft 70% alcohol cleaning wipe or other germicidal wipe.
- Personal Protective Equipment (PPE).

Do not use bleach-based wipes or harsh disinfectants/solvents. Stop and consult appropriate cleaning materials if any scratching or wearing of surface coatings is observed.

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6. TROUBLESHOOTING

If errors persist, please contact support (see “Support”).

Error	*Possible Cause*	*Possible Solution*
Power Strip Does Not Power On	• Power cord is not properly connected. • Power switch is not on.	• Remove the power cord and reconnect it. • Turn off power switch and turn it back on again.
The wheels are not rolling smoothly or locking properly	• Debris caught in wheels • Damage to wheels	• Clean and remove any visible debris or blockage. • Contact support for troubleshooting and/or replacement parts.
The drawer, cabinet sliding doors, or pull-out work surface are not sliding smoothly.	• Debris caught in rail tracks • Damage to rail tracks or surfaces	• Clean and remove any visible debris or blockage. • Utilize WD-40 or other lubricating sprays to improve functionality. • Contact support for troubleshooting and/or replacement parts.
Parts are damaged, coming loose, or missing	• Manufacturing error • Damage to cart system	• Contact support for troubleshooting and/or replacement parts.

7. TECHNICAL SPECIFICATIONS

General Specifications	
Dimensions	L 609.6 (24") x W 609.6 (24") x H 1524 (60") mm
Approximate Weight	50kg (110lbs)
Power Strip Specifications	120V DC, 15A, 1875W
Electrical Rating	120-125 VAC, 60 Hz, 15A
Input Power Cable Requirements	Connector End 1: Compatible With Regional Specific Power Inlet Connector End 2: IEC C13 Minimum Conductor Gauge: AWG 14
Ambient Operating Temperature	0˚C to 40˚C (32˚F to 104˚F)
Ambient Storage Temperature	-10˚C to 50˚C (14˚F to 122˚F)
Operating and Storage Relative Humidity	10% to 90% (non-condensing)
Transportation Environmental Conditions	5% to 95% RH (non-condensing), -10˚C to 50˚C (14˚F to 122˚F)

D

8. TABLE OF SYMBOLS

	Manufacturer ISO 15223-1:2021 Reference no. 5.1.1 ISO 7000:2019 Reference no. 3082		Serial Number ISO 15223-1:2021 Reference no. 5.1.7 ISO 7000:2019 Reference no. 2498
	Catalogue (SKU) Number ISO 15223-1:2021 Reference no. 5.1.6 ISO 7000:2019 Reference no. 2493		Consult Accompanying Documents ISO 7010 Reference no. M002
	Paper Instructions for Use ISO 15223-1:2021 Reference no. 5.4.3 ISO 7000:2019 Reference no. 1641		General Warning Sign: General Warning Sign ISO 7010:2019 Reference no: W001
	Safety Markings: Caution Symbol ISO 15223-1:2021 Reference no. 5.4.4 ISO 7000:2019 Reference no. 0434A		User Manual informal convention rather than a regulated safety symbol: text preceded by this icon contains useful information to assist the user in effective operation of the System.
	Safety Markings: General mandatory action ISO 7010:2019 Reference no: M001		Do Not Use if Package is Damaged ISO 15223-1:2021 Reference no. 5.2.8 ISO 7000:2019 Reference no. 2606
	Warning, dangerous voltage ISO 3864 Reference: B.3.6 IEC /TR 60878 Ed. 3.0 b:2015		Humidity Limit, Storage ISO 15223-1:2021 Reference no. 5.3.8 ISO 7000:2019 Reference No. 2620
	Fragile, Handle with Care ISO 15223-1:2021 Reference no. 5.3.1 ISO 7000:2019 Reference no. 0621		Temperature Limit, Storage ISO 15223-1:2021 Reference no. 5.3.7 ISO 7000:2019 Reference No. 0632
	Humidity Limit, Operating ISO 15223-1:2021 Reference no. 5.3.8 ISO 7000:2019 Reference no. 2620		This Way up ISO 7000:2019 Reference no. 0623
	Temperature Limit, Operating ISO 15223-1:2021 Reference no. 5.3.7 ISO 7000:2019 Reference No. 0632		WEEE Directive EU 2012/19/EU
	Keep Dry ISO 15223-1:2021 Reference no. 5.3.4 ISO 7000:2019 Reference no. 0626		

9. SUPPORT

Email: info@asp-health.com
Web: https://asp-health.com and https://enhancingcancerdx.com
Phone: 877-527-7432

10. WARRANTY

Warranty information can be found by emailing ASP Health at info@asp-health.com, or on the ASP Health website Resources page: https://enhancingcancerdx.com/hcp/resources/

11. DISPOSAL

If you wish to dispose of used electrical and electronic products, please contact your local authority so as to comply with the correct disposal method.

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