System Cart

User Manual and
Assembly Instructions

Includes Instructions
for Adding cryoICE &
Cryo Cart Kit to the
ASC2 Cart

AtriCure®

Table of Contents

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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August, 2011 Printed in the USA.

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1. System Overview

1.1 Basic Cart

1.1.1 AtriCure developed a ‘modular’ approach to the cart. The System Cart consists of the Basic Cart (ASCB) and two upgrade kits: (1) the Cryo Cart Kit (ASCC); and (2) the ORLab Cart Kit (ASCO). The following pages describe the Basic Cart, the upgrade kits, components, and assembly instructions – Figure 1.

1.1.2 Basic Cart provides:

1.1.2.1 450 mm Cart

1.1.2.2 Isolation Transformer

1.1.2.3 125 mm (5") Casters

1.1.2.4 Pre-wired Cables and Mains Power Cord (Isolation Transformer to Wall)

Figure 1: (1) Power Column; (2) Power Column; (3) PC and Stimulus Connection Box Shelf; (4) ASU, ASB and cryoICE BOX Shelf; (5) Printer Shelf; (6) Stimulus Generator Shelf; (7) Isolation Transformer; (8) Mains Power Cord (Isolation Transformer to Wall); and (9) Cable Winders.

1.2 Customer Options

1.2.1 The modular approach allows customization to support all AtriCure components and accessories – Figure 2.

Figure 2: (1) Basic Cart; (2) Basic Cart, ASU, and ASB; (3) Basic Cart, Cryo Cart Kit and cryoICE BOX; (4) Basic Cart, ASU, and ASB, Cryo Cart Kit and cryoICE BOX; (5) Basic Cart, ASU and ASB, ORLab Cart Kit and ORLab components; and (6) Basic Cart, ASU and ASB, ORLab Cart Kit, ORLab components, Cryo Cart Kit and cryoICE BOX.

1.3 How to Use this Manual

1.3.1 This manual is designed to help you get the most from your AtriCure System Cart. Illustrations complement the text to explain how to assemble the cart kits, components, and accessories.

1.3.2 The following information is essential for safe, easy, and efficient operation of the AtriCure System Cart.

1.4 Table of symbols used in this manual

Item #	Symbol	Description
1.		Consult operating instructions.
2.		Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.
3.		Manufactured by.

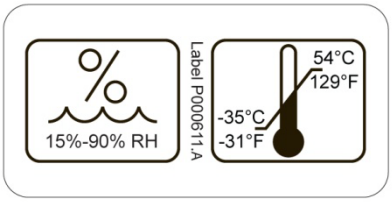
4.		Alternating Current.
5.		CE Mark.
6.		Temperature and Humidity Limits for Storage.
7.		Voltage.

Table 1: Symbols.

1.5 System Description

1.5.1 The System Cart supports medical equipment used in procedures for the treatment of arrhythmias in cardiothoracic theatres and hospital electrophysiological laboratories.
The complete system is comprised of five sub-systems:

1. **AtriCure® Ablation Sensing Unit (ASU)** produces and delivers RF energy, in a bipolar mode, at a frequency of approximately 460 kHz, with a maximum output power ranging from 12 Watts up to 30 Watts depending on the operating mode.

2. **AtriCure® Switch Matrix (ASB)** is a reusable accessory interface module that allows simultaneous connection of AtriCure® Isolator™ Transpolar™ ablative handpiece and pen devices to the ASU RF generator.

3. **AtriCure® cryoICE BOX (ACM)** is an electro-mechanical and pneumatic cryogenic surgical system that delivers a cryogenic energy source, namely Nitrous Oxide, to create lines of ablation through cardiac tissue.

4. **AtriCure® ORLab** is a programmable diagnostic cardiac stimulator with electrocardiogram display tailored for use as a diagnostic tool during surgical and RF ablation procedures.

    a. **NOTE:** Lexmark E260D printer is used in conjunction with the ORLab to produce paper copies of diagnostic read outs.

    b. **NOTE:** The handpiece and pen devices are separate components and are not a part of the AtriCure® Basic Cart.

5. **AtriCure® System Cart** is a 450 mm wide cart with an onboard Isolation Transformer. The Isolation Transformer supplies power to the other subsystems of AtriCure® System Cart.

    a. **NOTE**: The cart has omni-directional, lockable casters which allow for quick and easy transport of the system within hospitals and operating theatres.

1.5.2 No part of the AtriCure® System Cart or its accessories is intended to make contact the patient, instead, pacing stimuli are delivered, and ECG signal recorded, via AtriCure® Handpieces and approved third party products, which may include transvenous endocardial electrode catheters or epicardial mapping.

1.5.3 Indications for Use: The AtriCure System Cart is intended to be used as an accessory to the AtriCure Bipolar System, AtriCure Cryo Module System, and ORLab.

1.6 Equipment Classification

1.6.1 The AtriCure® System Cart consisting of the Basic Cart, the Cryo Cart Kit, and the ORLab Cart Kit are categorized as: Class 1 Equipment; Type CF Applied Part; IPX0; rated for 115-230 VAC 50-60 Hz; and 1800 VA.

1.7 Proper Use

1.7.1 **NOTE:** The AtriCure® System Cart consisting of the Basic Cart, the Cryo Cart Kit, and the ORLab Cart Kit is ONLY intended for use with the equipment listed in Table 2.

1.7.2 **NOTE:** The cart should never be used to carry equipment other than what is specified in this manual. The cart should not be operated on an incline exceeding 10°. During operation and storage the casters should be locked securely.

1.7.3 **NOTE:** This manual does not address specific instructions related to the equipment listed in Table 2. The user should refer to product specific manuals provided with individual components and systems for information pertaining to: (1) explanation of the function of controls, displays, and signals; (2) the sequence of operation; (3) the connection and disconnection of detachable parts and accessories; (4) indications of recognized accessories, detachable parts, and consumable materials; and (5) signal output or signal input parts intended only for connection to specified equipment described.

1.7.4 **NOTE:** Unplug cart before transport.

Manufacturer	Equipment Description	Product Code
MicroPace	ORLab EP Cardiac Stimulator / Recorder System	ORLab
AtriCure	AtriCure Ablation and Sensing Unit	ASU2 / ASU3
AtriCure	AtriCure Source Switch Accessory	ASB1 / ASB3
Lexmark	Laser Printer	E260d
AtriCure	cryoICE BOX	ACM1 / ACM2

Table 2: Compatible Equipment List.

1.8 Cleaning Instructions

1.8.1 **NOTE:** The Basic Cart Cleaning and Disinfection Instructions: (1) use a mild detergent (prepared to its specifications) and a damp cloth; and (2) do not use caustic, corrosive, or abrasive cleaning materials.

1.9 Serviceable Parts

1.9.1 **NOTE:** The System Cart consisting of: the Basic Cart; the Cryo Cart Kit; and ORLab Cart Kit does not have any serviceable parts. For servicing issues, contact AtriCure, Inc.

1.10 Environmental

1.10.1 **NOTE:** Environmental Conditions: (1) operational temperature +10° C to +40° C; (2) storage temperature -35° C to +54° C; and (3) humidity 15% to 90% relative humidity.

1.10.2 Follow local governing ordinances and recycling plans regarding disposal or recycling of system components.

1.11 Preventative Maintenance

1.11.1 **NOTE:** Perform annual preventative maintenance procedures to ensure all Cart components are functioning properly, including but not limited to: (1) electrical power cords for fraying, damage, and proper grounding; (2) AC power switch; and (3) caster damage.

1.12 Safety Information

1.12.1 **PRECAUTION:** To avoid electrical hazards, all parts of the ORLab, including the computer, monitor, Stimulus Generator Unit, and Lexmark laser printer must be connected to the Isolation Transformer and never directly to a mains outlet.

1.12.2 **PRECAUTION:** To avoid electrical hazards and prevent overloading the transformer, do not connect any non-AtriCure approved equipment to the supplied Mains Isolation Transformer.

1.12.3 **PRECAUTION:** Use AtriCure® System Cart only in ventilated areas and away from flammable gasses. To avoid risk of explosion, the Basic Cart should only be used in a ventilated area as gasses may be released during charging of backup battery, and should not be used in rooms with flammable anesthesia.

1.12.4 **PRECAUTION:** AtriCure® System Cart is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous.

1.12.5 **PRECAUTION:** Secure tank with chain and ONLY use N_2O Tanks ≤ 20 cm (8") in diameter that weigh ≤ 29.5 kg (65 pounds).

1.12.6 **PRECAUTION:** If the cryoICE Box is connected to a grounded hospital AC power receptacle, it must be connected into the same grounded hospital AC power receptacle as Isolation Transformer.

1.13 Tool Kit

1.13.1 **NOTE**: The same Tool Kit is supplied with all cart kits – Figure 3.

Figure 3: Photo of the Tool Kit (A000810) supplied. The Tool Kit contains the following items: (1) User and Assembly Manual; (2) Velcro; (3) Flat Washers; (4) Lock Washers; (5) Socket Head Cap Screw for VESA Mount: (6) Socket Head Cap Screw for Tank Holder(s); (7) 10 mm Combination Wrench; (8) 3 mm Hex Key; (9) 5 mm Hex Key; (10) 10 mm Hex Key; (11) Straight Blade Screwdriver; and (12) Loctite brand Threadlocker.

1.14 EMC Guidance and Manufacturer's Declaration

1.14.1 Electromagnetic Requirements

1.14.1.1 The AtriCure System Cart (ASC2), along with its associated equipment (ASU2 / ASU3, ASB3, ACM1 / ACM2, and ORLab), from here on referred to as the AtriCure RF, Cryo, and EP Mapping System (ARC-EPMS) have been tested and found to comply with the limits for medical devices in IEC 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

1.14.1.2 The ARC-EPMS can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity.

1.14.1.3 Portable and mobile RF communications equipment can also affect the ARC-EPMS performance and care should be taken to minimize such interference. However, there is no guarantee that interference will not occur in a particular installation.

1.14.1.4 If the ARC-EPMS does cause harmful interference to other devices, which can be determined by turning the ARC-EPMS equipment off and on individually or in combination; the user is encouraged to try to correct the interference by one or more of the following measures:

1.14.1.4.1 Reorient or relocate the receiving device.

1.14.1.4.2 Increase the separation between the ARC-EPMS and the other device(s).

1.14.1.4.3 Connect the ARC-EPMS into an outlet on a circuit different from that to which the other device(s) are connected.

1.14.1.4.4 Contact an AtriCure service representative for help.

1.14.2 Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The AtriCure RF, Cryo, and EP Mapping System (ARC-EPMS) is intended for use in the electromagnetic environment specified below. The customer or the user of the ARC-EPMS unit should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>The ARC-EPMS unit, with the exception of the ASU2 / ASU3 RF Generator only during RF energy delivery, uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class A</td><td rowspan="3">The ARC-EPMS unit is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

1.14.3 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The AtriCure RF, Cryo, and EP Mapping System (ARC-EPMS) is intended for use in the electromagnetic environment specified below. The customer or the user of the ARC-EPMS unit should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply Lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in UT) for 0.5 cycle 40 % U_T (60 % dip in UT) for 5 cycles 70 % U_T (30 % dip in UT) for 25 cycles <5 % U_T (>95 % dip in UT) for 5 s	<5 % U_T (>95 % dip in UT) for 0.5 cycle 40 % U_T (60 % dip in UT) for 5 cycles 70 % U_T (30 % dip in UT) for 25 cycles <5 % U_T (>95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ARC-EPMS unit requires continued operation during power mains interruptions, it is recommended that the ARC-EPMS unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*			

1.14.4 EMC Guidance and Manufacturer's Declaration

Guidance and manufacturer's declaration – electromagnetic immunity			
The AtriCure RF, Cryo, and EP Mapping System (ARC-EPMS) is intended for use in the electromagnetic environment specified below. The customer or the user of the ARC-EPMS should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ARC-EPMS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ARC-EPMS is used exceeds the applicable RF compliance level above, the ARC-EPMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ARC-EPMS. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

1.14.5 Recommended Separation Distance

Recommended separation distances between portable and mobile RF communications equipment and the AtriCure RF, Cryo, and EP Mapping System

The AtriCure RF, Cryo, and EP Mapping System (ARC-EPMS) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ARC-EPMS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ARC-EPMS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz $d = 1.2 \sqrt{P}$**	**800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

2. Basic Cart

Components and Accessories

2.1 Features: Basic Cart

2.1.1 No assembly required; ready to add components and accessories

2.1.2 450 mm Cart

2.1.3 Isolation Transformer

2.1.4 125 mm (5") Casters

2.1.5 Pre-wired for ASU, ASB, cryoICE BOX, and ORLab – Figure 4

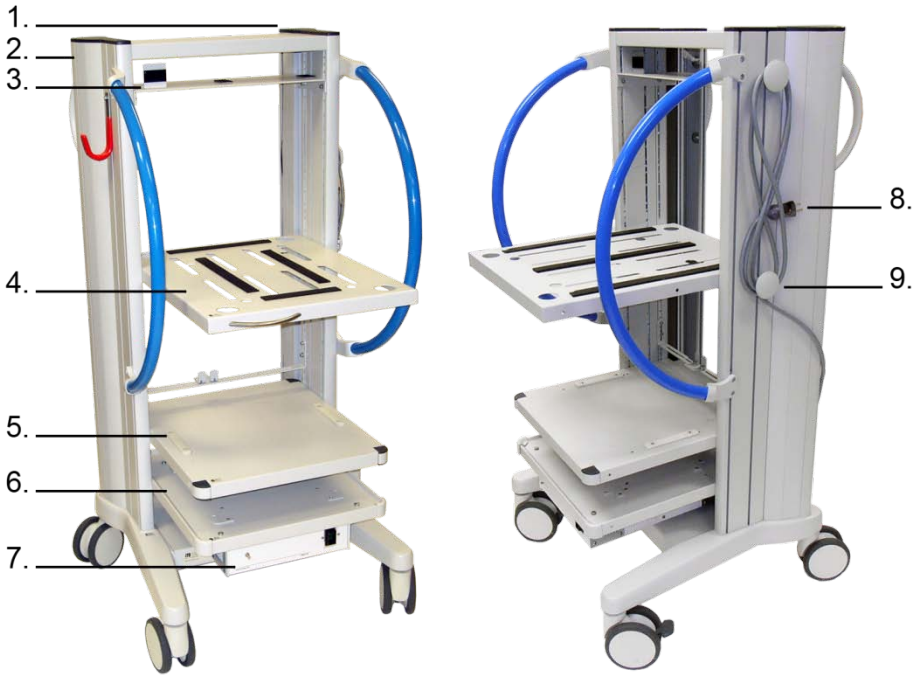


Figure 4: (1) Power Column; (2) Power Column; (3) PC and Stimulus Connection Box Shelf; (4) ASU, ASB and cryoICE BOX Shelf; (5) Printer Shelf; (6) Stimulus Generator Shelf; (7) Isolation Transformer; (8) Mains Power Cord (Isolation Transformer to Wall); and (9) Cable Winders.

2.2 Unpacking: Basic Cart

2.2.1 The Basic Cart is shipped in one Shipping Carton – Figure 5.

2.2.2 Relocate the Shipping Carton to an open area that will provide sufficient space to assemble the unit.

2.2.3 **NOTE:** Do not throw away any tools or manuals.

2.2.4 **NOTE:** Unpacking the Basic Cart requires two people.

Figure 5: Basic Cart Shipping Carton (Height approximately 1524 mm (60")).

2.3 Assembly: Basic Cart

2.3.1 No assembly required; ready to add components and accessories.

2.3.2 Proceed to Checklist and perform checklist for the Basic Cart.

3. ASU and ASB

Components and Accessories

3.1 Unpacking: ASU and ASB

3.1.1 There are two Shipping Cartons required to assemble this cart configuration. The Shipping Cartons are pictured below.

3.1.2 Relocate the Shipping Cartons to an open area that will provide sufficient space to assemble the unit.

3.1.3 Unpack the Shipping Cartons and make sure that you have the components pictured – Figures 6 and 7.

3.1.4 **NOTE**: Do not throw away any tools or manuals.

Figure 6: Shipping Carton and ASU.

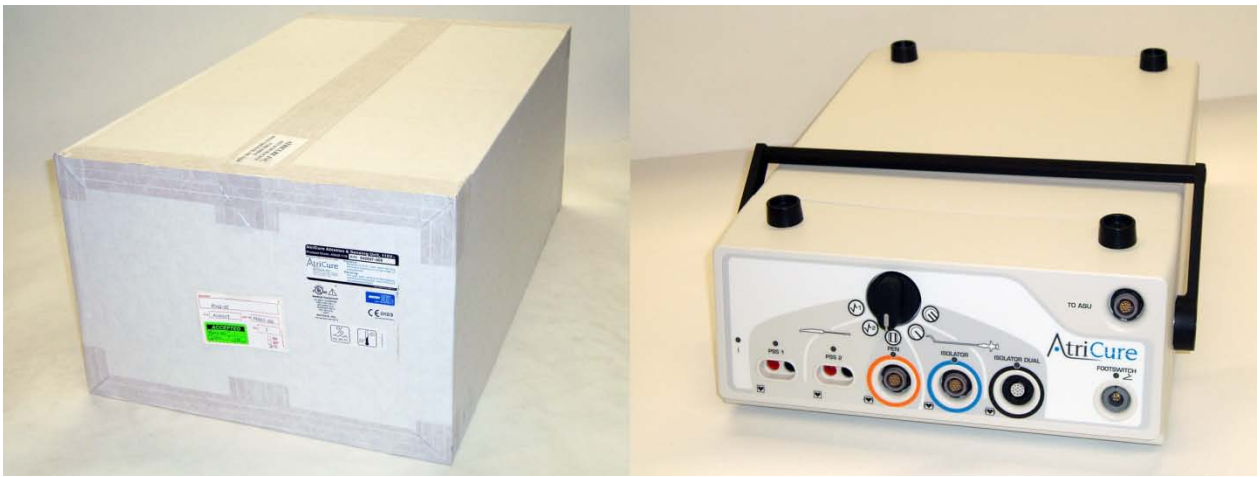


Figure 7: Shipping Carton and ASB.

3.2 Assembly: ASU and ASB

3.2.1 Place ASB on second shelf.

3.2.2 The feet of the ASB should be inserted into holes on the shelf – Figure 8.

3.2.3 Position the handle against the top of the ASB – Figure 8.

3.2.4 Place ASU on top of the ASB – Figure 9.

3.2.5 Be sure to nest the feet of the ASU into the holder cups on top of the ASB – Figure 9.

3.2.6 Position the handle against the top of the ASU – Figure 9.

3.2.7 **NOTE:** For some cart configurations, the cryoICE BOX may already reside on the second shelf. In this case, the ASB should be placed on top of the cryoICE BOX. Again, the feet of the ASB should be nested into holder cups on top of the cryoICE BOX.

3.2.8 **NOTE:** Start with Section 5: cryoICE BOX if installation includes the cryoICE BOX and the ASU / ASB.

Figure 8: ASU, ASB and cryoICE BOX Shelf with holes for feet indicated by red circles.

Figure 9: ASU stacked on top of the ASB. **NOTE:** Position of the handles.

3.2.9 Attach the Power Cables to the rear of the ASU and ASB – Figure 10.

3.2.10 **NOTE:** If cryoICE BOX is present, it will be necessary to locate the Power Cables stowed in the Left Power Column.

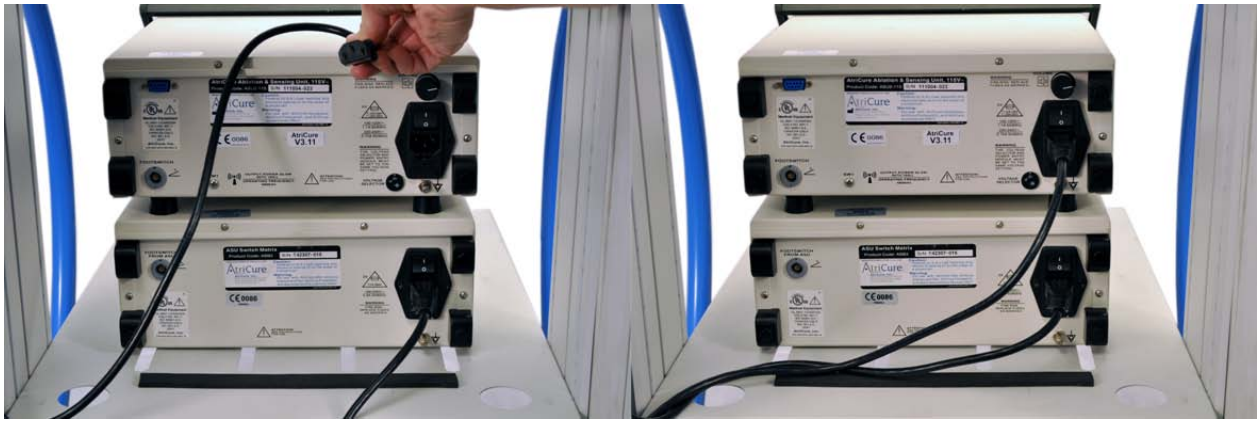


Figure 10: Power Cable attachment to the rear of the ASU and ASB.

3.2.11 Install Footswitch Jumper Cable between the ASU and ASB on the rear – Figure 11.

Figure 11: Installation of Footswitch Jumper cable between the ASU and ASB.

3.2.12 Install the Hand Piece Jumper Cable between the ASU and ASB – Figure 12.

Figure 12: Installation of the Hand Piece Jumper Cable between the ASU and ASB.

3.2.13 Connect Stimulus Connection Box to ASB with 609 mm (24") PSS Interface Cable – Figure 13.

3.2.14 Push Connectors into Plugs Firmly to ensure proper connection – Figure 13.

3.2.15 **NOTE:** Connect 'ATRIUM-CH1' to 'PSS 1' – Figure 13.

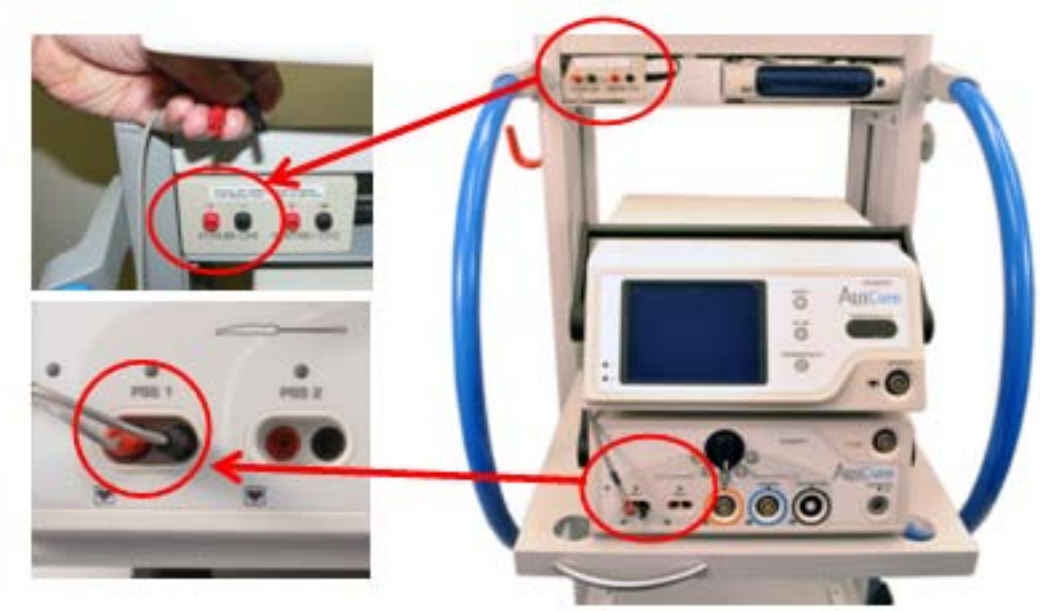


Figure 13: Connect Stimulus Connection Box to ASB with 609 mm (24") PSS Interface Cable.

3.2.16 Connect the Footswitch Cable to FOOTSWITCH Connector on the ASB – Figure 14.

Figure 14: Connect the Footswitch Cable to FOOTSWITCH connector on the ASB.

3.2.17 Store the Footswitch in the Footswitch Holster – Figure 15.

Figure 15: Footswitch Holster.

4. Cryo Cart Kit

Components and Accessories

4.1 Unpacking: Cryo Cart Kit

4.1.1 There is one Shipping Carton required to assemble this cart configuration – Figure 16.

4.1.2 Relocate the Shipping Carton to an open area that will provide sufficient space to assemble the unit. Unpack the Shipping Carton and make sure that you have the components pictured.

4.1.3 **NOTE:** Do not throw away any tools or manuals.

Figure 16: (1) Cryo Cart Kit Shipping Carton; (2) Tank Holder (QTY: 1); (3) Shorter Cable Covers (QTY: 2); (4) Tap Strips (QTY: 2); (5) Tool Kit; and (6) Chain to secure N_2O Tanks (not shown).

4.2 Assembly: Cryo Cart Kit

4.2.1 Remove the Power Column Caps and Covers on the right side – Figure 17.

Figure 17: Remove the Power Column Caps and Covers on the right side.

4.2.2 Use the 5 mm Hex Key to remove the Cable Guard – Figure 18.

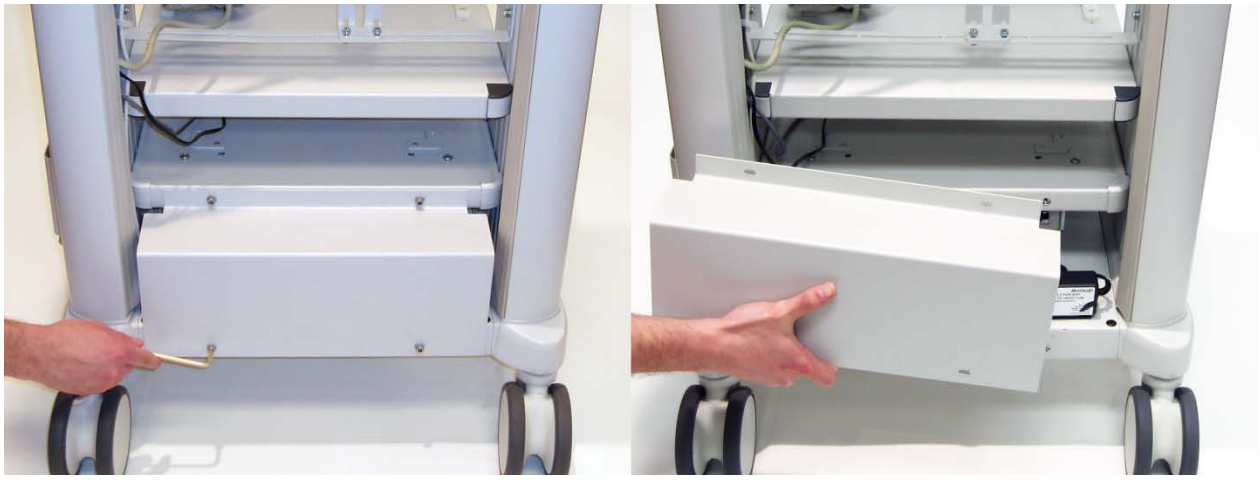


Figure 18: Use the 5 mm Hex Key to remove the Cable Guard.

4.2.3 Install the two Tap Strips provided in the kit – Figure 19.

4.2.4 **NOTE:** Ensure that the embossed features (bumps) on the tap strips are oriented toward the outside of the cart – Figure 20.

4.2.5 **NOTE:** “Up and Down Orientation” of the tap strips is not required (they are symmetrical).

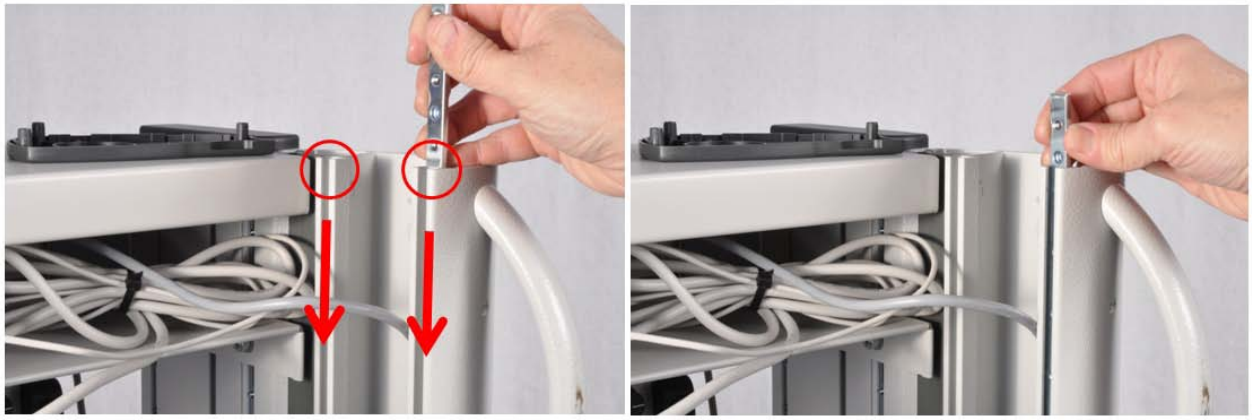


Figure 19: Install two tap strips in the Right power column.

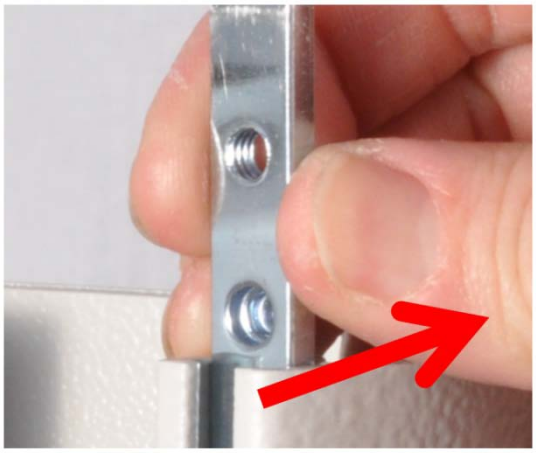


Figure 20: Orient the bumps on the Tap Strip toward the outside of the cart.

4.2.6 Place the Hinge Leaf of the Tank Holder against the Right Power Column.

4.2.7 **NOTE:** Ensure that it is resting at the bottom of the Power Column – Figure 21.

4.2.8 **NOTE:** The bolt assemblies consist of a Socket Head Cap Screw, Flat Washer and Lock Washer – Figure 21.

4.2.9 Using the 5 mm Hex Key snug down the four bolt assemblies.

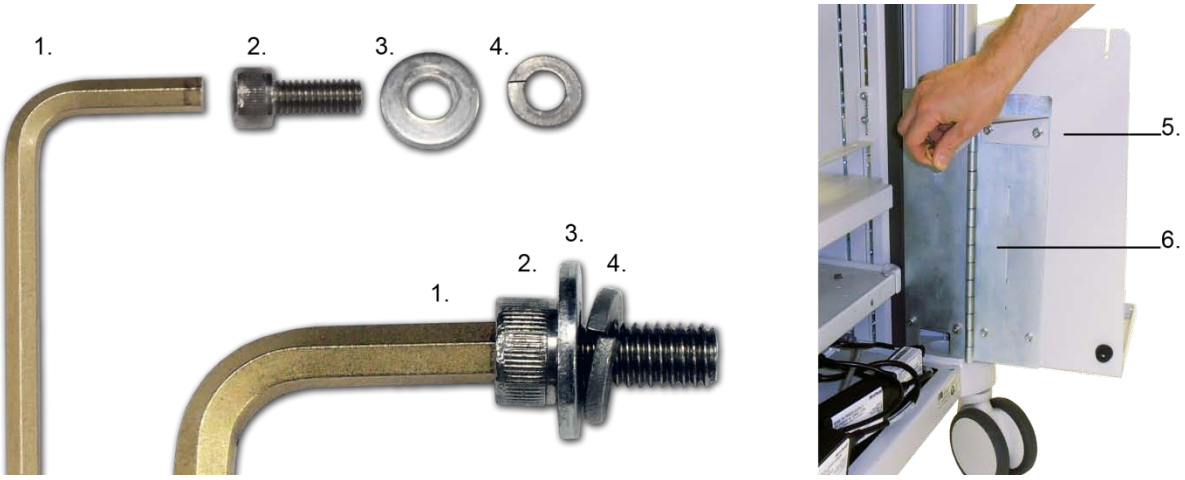


Figure 21: (1) 5 mm Hex Key; (2) Socket Head Cap Screw (3) Flat Washer; (4) Lock Washer; (5) Bracket; and (6) Hinge Leaf.

4.2.10 Rotate Tank Holder against the Right Power Column.

4.2.11 Using the 5 mm Hex Key, Socket Head Cap Screw, and Flat Washer; attach and snug down one bolt – Figure 22.

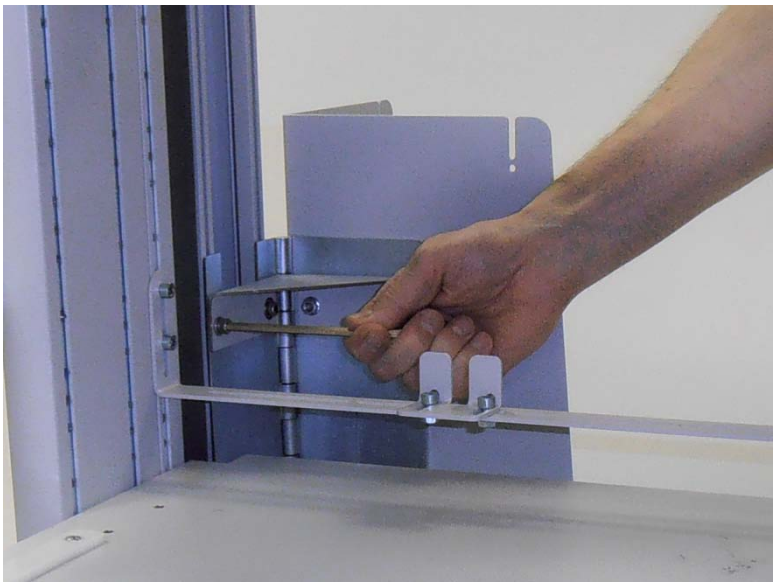


Figure 22: (1) 5 mm Hex Key; (2) Socket Head Cap Screw; and (3) Flat Washer.

4.2.12 The J-hook is factory installed. If not, install the J-hook by inserting the T-nut into the Left Power Column.

4.2.13 Use the 5 mm Hex Key provided in the Tool Kit.

4.2.14 Secure the J-hook to the Left Power column – Figure 23.

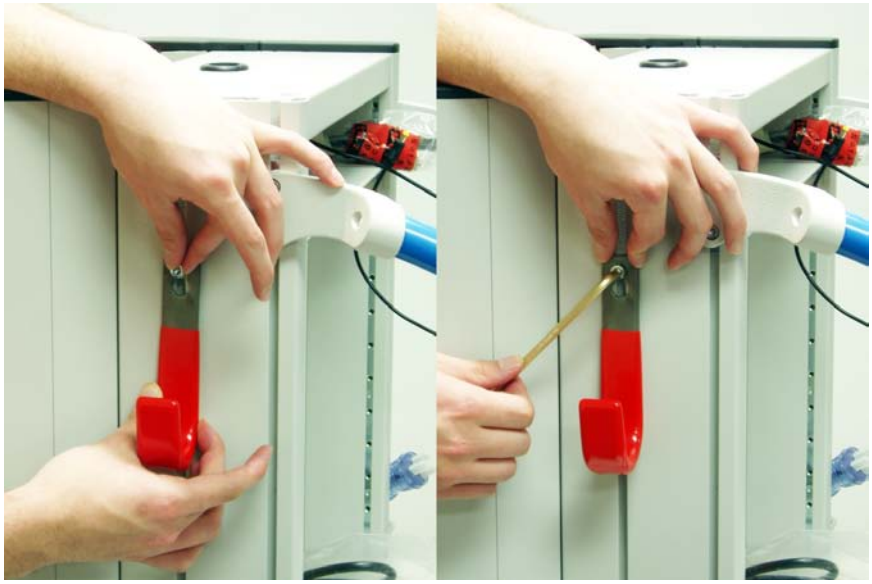


Figure 23: Use the 5 mm Hex Key to secure the J-hook to the Left Power Column.

4.2.15 Replace the cable guard – Figure 24.

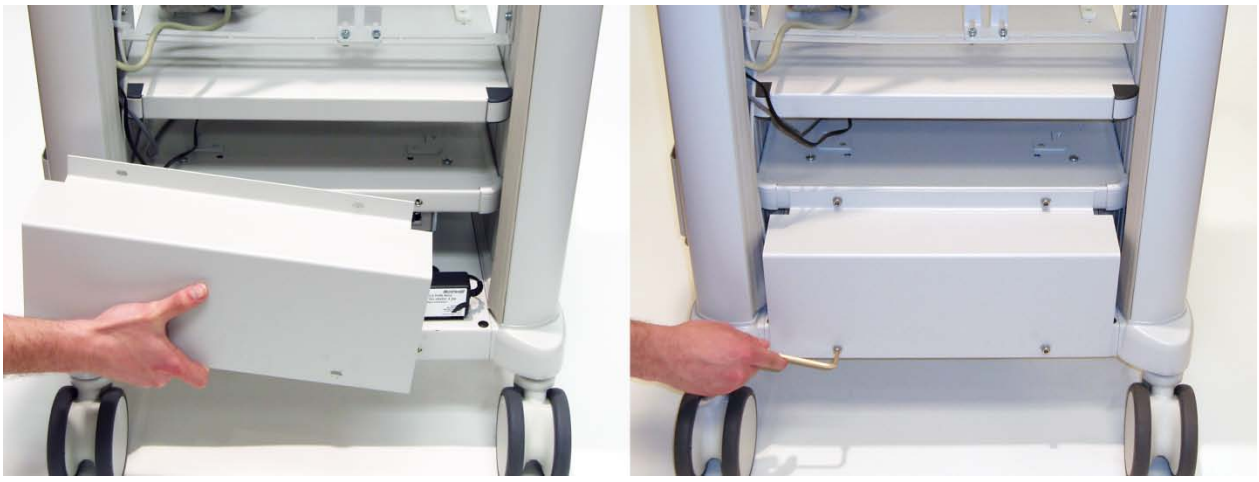


Figure 24: Replace the cable guard.

4.2.16 Install the shorter Power Column Covers provided with the Cryo Cart Kit – Figure 25.

4.2.17 Reinstall the Power Column Caps – Figure 25.

Figure 25: Install the shortened Power Column Covers and Power Column Caps.

4.2.18 Single Tank Holder assembly should look like this – Figure 26.

Figure 26: Basic Cart with Single Tank Holder installed.

4.2.19 **PRECAUTION:** Secure tank with chain and ONLY use N_2O Tanks ≤ 20 cm (8") in diameter that weigh ≤ 29.5 kg (65 pounds).

5. cryoICE BOX

Components and Accessories

5.1 Unpacking: cryoICE BOX

5.1.1 There are 2 Shipping Cartons required for the cryoICE BOX – Figures 27 and 28.

5.1.2 Ensure that you have the components pictured.

5.1.3 **NOTE:** Do not throw away any tools or manuals.

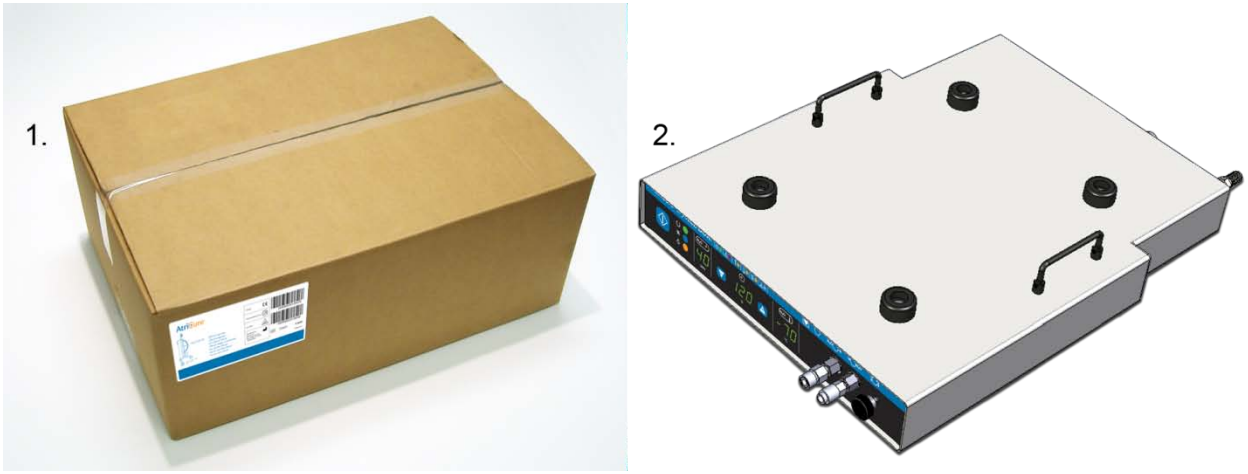


Figure 27: (1) cryoICE BOX Shipping Carton; and (2) cryoICE BOX.

Figure 28: (1) cryoICE BOX Accessories Shipping Carton; and (2) cryoICE BOX Footswitch; (3) Heater Band; (4) Exhaust Hose; and (5) cryoICE BOX N_2O Gas Line Hose.

5.2 Assembly: cryoICE BOX

5.2.1 **NOTE:** If the ASU, ASB and cryoICE BOX Shelf (second shelf) does not look like Figure 30, please refer to Section 8 Instructions for Adding cryoICE and Cryo Cart Kit to ASC2.

5.2.2 Carefully place the cryoICE BOX on its top to access the rubber feet.

5.2.3 Using the 3 mm Hex Key provided in your Tool Kit; unfasten and remove the two rear rubber feet in Position 1 and replace them in Position 2 – Figure 29.

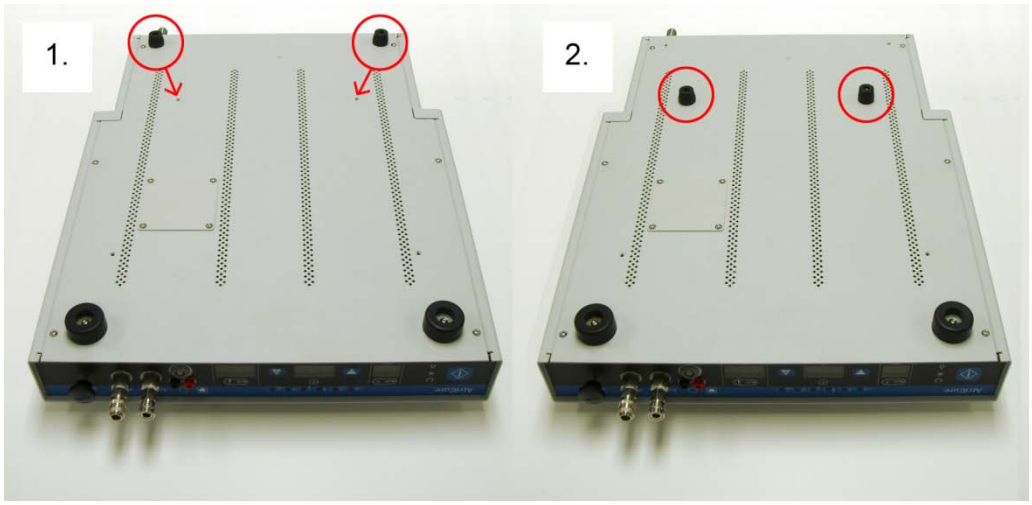


Figure 29**:** Unfasten and remove the two rear rubber feet in Position 1 and replace them in Position 2.

5.2.4 Place cryoICE BOX on second shelf.

5.2.5 Insert the feet of the cryoICE BOX into holes on the shelf – Figure 30.

5.2.6 Cart is prewired with approved hospital grade power cord for the cryoICE BOX.

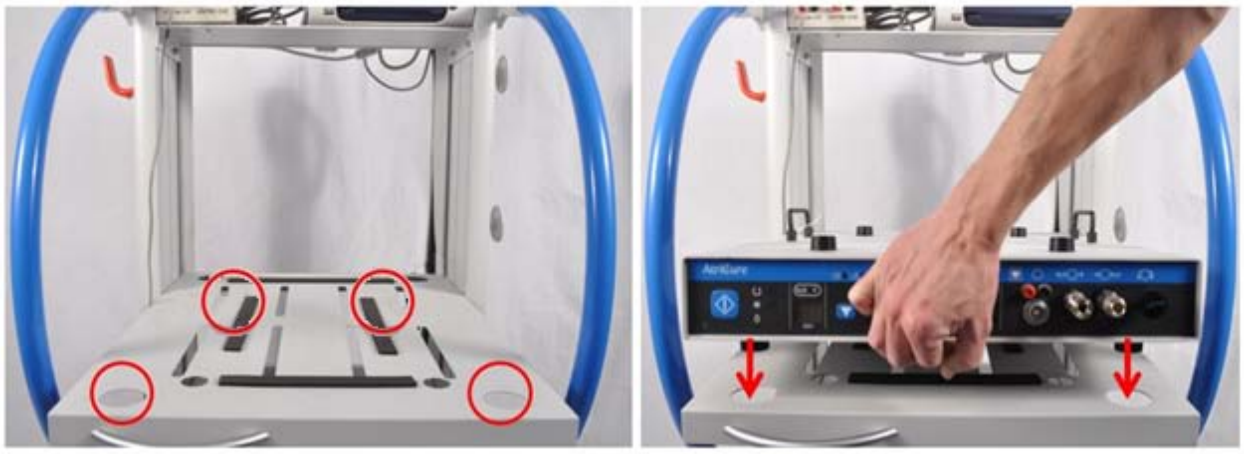


Figure 30: Place cryoICE BOX on second shelf with the feet inserted into the holes on shelf.

5.2.7 Insert the power cord into the power entry module of the cryoICE BOX – Figure 31.

Figure 31: Insert the power cord into the power entry module of the cryoICE BOX.

5.2.8 With the connector alignment arrow in the 12 o'clock position, push the Footswitch Connector into the Footswitch Receptacle on the rear panel of the cryoICE BOX – Figure 32.

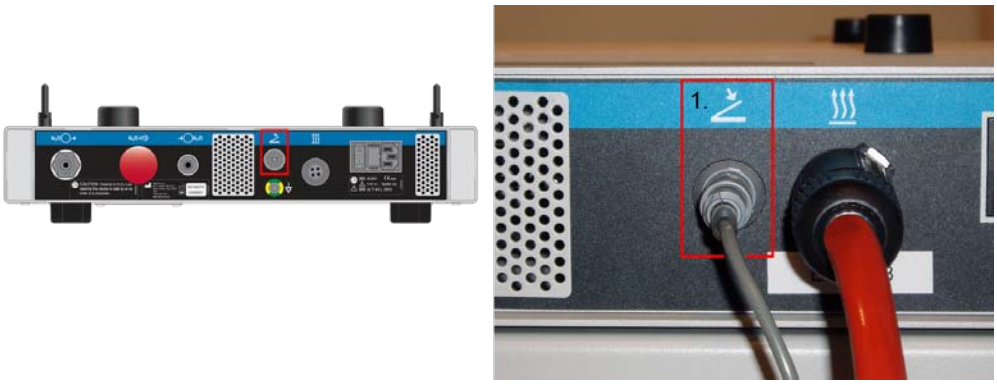


Figure 32: (1) Footswitch Cable installation.

5.2.9 Place the Foot Switch in the holster on the side of the cart – Figure 33.

Figure 33: Footswitch Holster.

5.3 Cylinder Heater Band Installation

5.3.1 Inspect Cylinder Heater Band for any signs of physical damage to the cable and connector.

5.3.2 Contact AtriCure for replacement if physical damage is found or the Cylinder Heater Band does not perform within specification.

5.3.3 Place the Cylinder Heater Band around the N_2O cylinder.

5.3.4 Secure all 6 tensioning spring retainers – Figure 34.

5.3.5 **NOTE:** It is easiest to start with the top and bottom spring retainers first, and then buckle then middle retainers last.

5.3.6 **NOTE:** Position Cylinder Heater Band 50 mm (2") from the bottom for optimal performance.

Figure 34: Secure all 6 tensioning spring retainers.

5.4 Cylinder Heater Band Connection

5.4.1 With the connector alignment arrow in the 10 o'clock position, push the Cylinder Heater Band Connector into the Cylinder Heater Band Receptacle on the rear panel of the cryoICE BOX – Figure 35.

Figure 35: Cylinder Heater Band connection.

5.5 Installing N_2O Gas Line Hose

5.5.1 Inspect the N_2O Gas Line Hose and pneumatic connectors for any signs of physical damage.

5.5.2 Contact AtriCure for replacement if physical damage is found or the N_2O Gas Line Hose does not perform within specification.

5.5.3 Connect the N_2O Gas Line Hose to the cryoICE BOX.

5.5.4 Align the quick-connect gas connector with the cryoICE BOX N_2O inlet port.

5.5.5 Insert and push in the connector until you hear it “click”. Ensure the connection is fully seated and secure – Figure 36.

Figure 36: Align the quick-connect gas connector with the cryoICE BOX N_2O inlet port. Insert and push in the connector until you hear it “click”.

5.5.6 Install N_2O Exhaust Hose.

5.5.7 Align the end of Exhaust Hose with the N_2O Exhaust port of the cryoICE BOX and push in place – Figure 37.

5.5.8 Coil and bundle the hose with a Hose Hanger.

Figure 37: Align the end of 50 ft Exhaust Hose with the N_2O Exhaust port of the cryoICE BOX and push in place.

5.5.9 Exhaust hose coiled and stored on the J-hook on the Left Power Column – Figure 38.

Figure 38: Exhaust hose coiled and stored on the J-hook.

6. ORLab Cart Kit

Components and Accessories

6.1 Unpacking: ORLab Cart Kit

6.1.1 There is one Shipping Carton required to assemble the ORLab Cart Kit – Figure 39.

6.1.2 Relocate the Shipping Carton to an open area that will provide sufficient space to assemble the unit.

6.1.3 Unpack the Shipping Carton and make sure that you have the components pictured – Figure 39.

6.1.4 Do not throw away any tools or manuals.

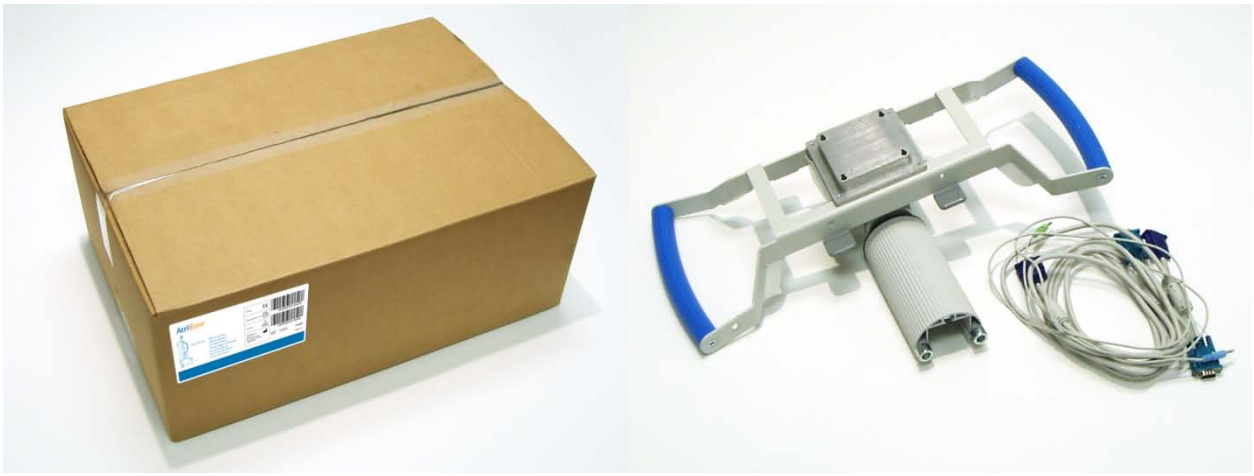


Figure 39: ORLab Cart Kit components and Shipping Carton.

6.2 Assembly: ORLab Cart Kit

6.2.1 Place the Monitor Holder on the Top Shelf.

6.2.2 **NOTE:** Use the 10 mm Hex Key to tighten the two socket head cap screws to secure the Monitor Holder to the Top Shelf – Figure 40.

6.2.3 **NOTE:** The Monitor Adapter (100 mm / 75 mm VESA mount) faces the front of the cart.

Figure 40: Mount the Monitor Holder from the rear of the Basic Cart.

6.2.4 Monitor Holder Cables

6.2.4.1 Feed the cables through the monitor holder assembly.

6.2.4.2 **NOTE:** It is important that the cables are fed through in the correct direction.

6.2.4.3 Feed the “monitor end” through the Monitor Holder post – Figures 41 and 42.

Figure 41: Monitor cables: Monitor end (right hand) and PC end (left hand).

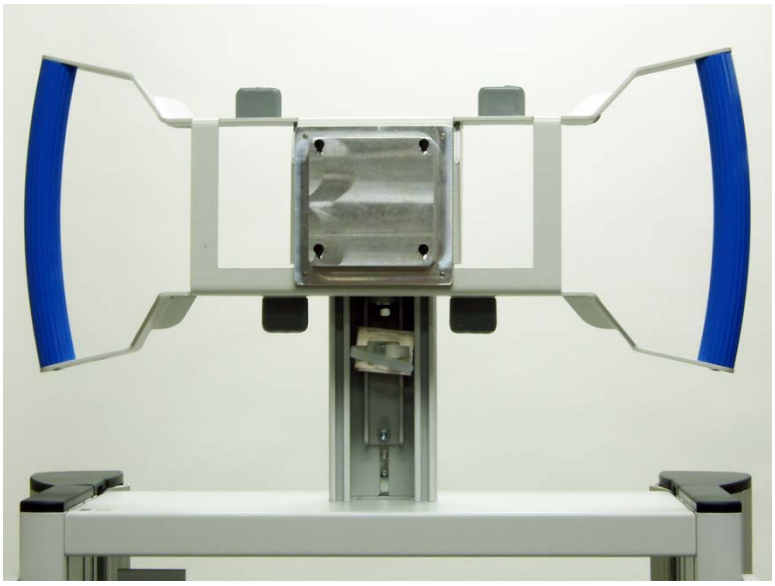


Figure 42: Desired feed direction is from the bottom-up.

6.2.5 **NOTE:** Provide approximately 406 mm (16") of cable available at the monitor side – Figure 43.

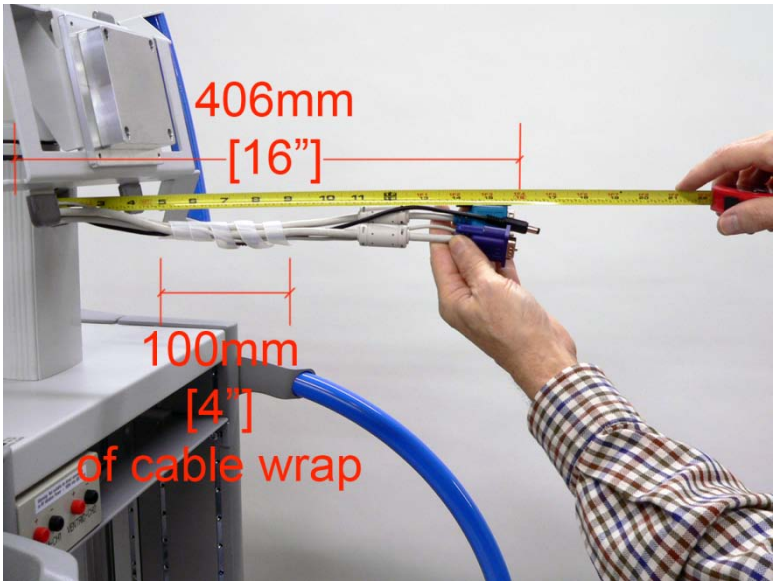


Figure 43: Provide 406 mm (16") of cable lead on the monitor side.

7. ORLab

Components and Accessories

7.1 Unpacking: ORLab

7.1.1 There are three Shipping Cartons required to assemble this cart configuration.

7.1.2 Relocate the Shipping Cartons to an open area that will provide sufficient space to assemble the unit.

7.1.3 Unpack the Shipping Cartons and make sure that you have the components pictured – Figures 44, 45, and 46.

7.1.4 Do not throw away any tools or manuals.

7.2 LCD Touch Monitor

Figure 44: Shipping Carton and LCD Touch Monitor.

7.3 Cardiac Stimulator Carton

7.3.1 Cardiac Stimulator Carton includes: (1) Stimulus Generator Unit; (2) MicroPace User Manual; and (3) Stimulus Connection Box – Figure 45.

Figure 45: Shipping Carton, Cardiac Stimulator and Accessories.

7.4 Laser Printer (U.S.A. Only)

7.4.1 Laser Printer includes Manual and Paper Tray Cover – Figure 46.

7.4.2 **NOTE:** Power Cord Installed on Cart.

Figure 46: Shipping Carton and Laser Printer.

7.5 Assembly: ORLab

7.5.1 Monitor Installation

7.5.2 Remove the Monitor Pedestal attached to the monitor.

7.5.3 Place monitor face down on flat surface.

7.5.4 Rotate Monitor Pedestal for easy access to screws.

7.5.5 Remove four screws with 3 mm Hex Key supplied in Tool Kit – Figure 47.

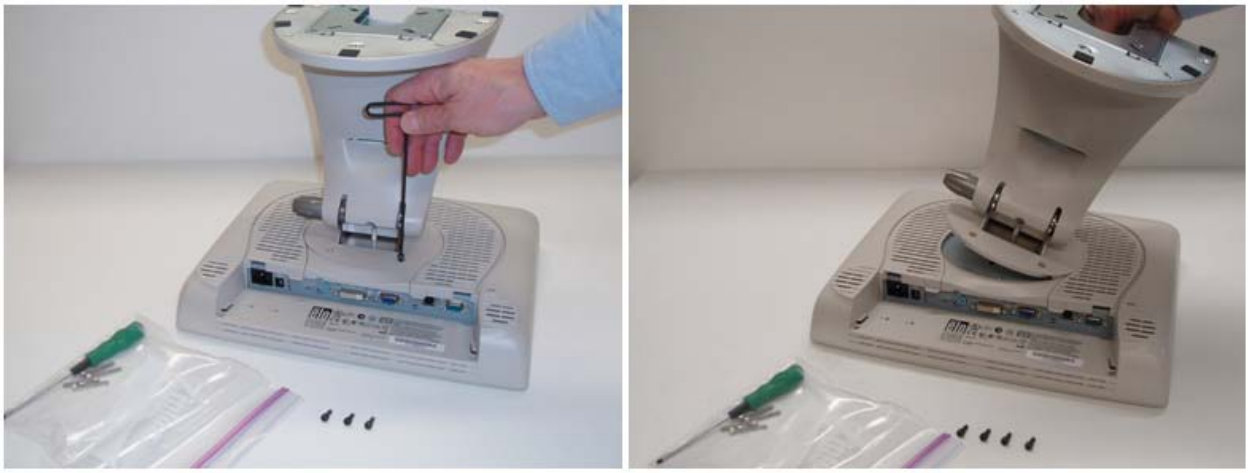


Figure 47: Remove four screws with 3 mm Hex Key supplied in Tool Kit.

7.5.6 Install four M4 x 25 socket cap screws provided in Tool Kit.

7.5.7 The screws should be started, but not screwed in all the way (3 to 5 turns maximum).

7.5.8 Use the 1 o'clock, 5 o'clock, 7 o'clock and 11 o'clock positions as shown in – Figure 48.

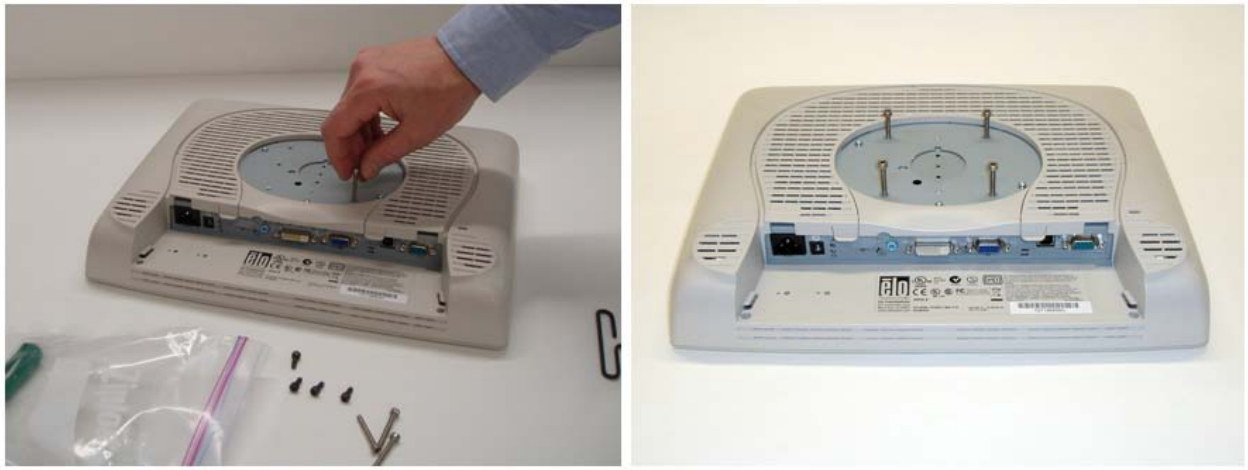


Figure 48: Mount four screws in the 1 o'clock, 5 o'clock, 7 o'clock and 11 o'clock positions as shown in the photo on the right.

7.5.9 Align the four screw heads with the key hole slots on the Monitor Adapter (100 mm / 75 VESA mount) – Figure 49.

7.5.10 Push the monitor against the Monitor Adapter and allow it to slide down about 6 mm (¼") to engage Monitor Adapter (100 mm / 75 mm VESA mount) – Figure 50.

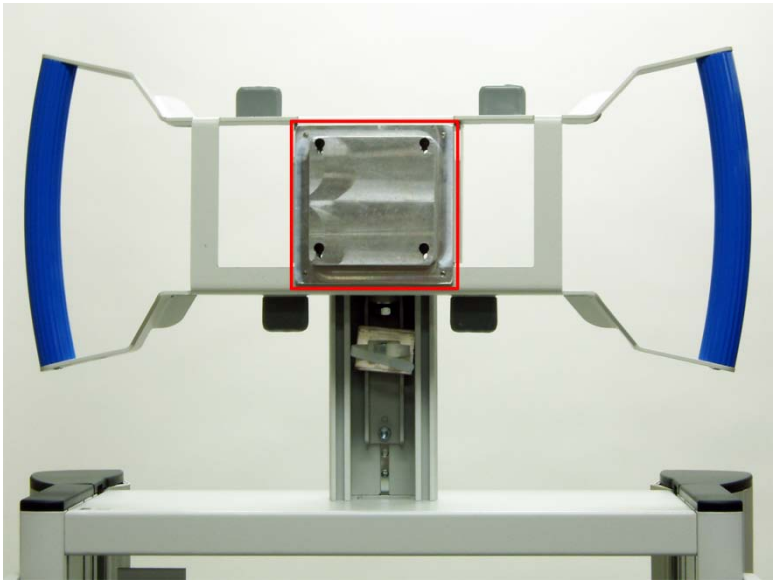


Figure 49: Monitor Adapter (100 mm / 75 mm VESA mount) pictured with four key-hole slots.

Figure 50: (1) Align Cap Screws into key-hole slots; (2) Insert monitor; (3) Seat the Cap Screws (inward and downward motion) onto the Monitor Adapter (the Monitor will hang on Cap Screws); and (4) Tighten all four Cap Screws (do not over-tighten).

7.5.11 Secure the Monitor to the Monitor Adapter (100 mm / 75 mm VESA mount) by tightening the four screws.

7.5.12 Move to the back side of the cart. Use the 3 mm Hex Key, provided in the Tool Kit, to tighten the 4 mounting screws.

7.5.13 **NOTE:** The screws are slightly obscured by the Monitor Mount.

7.5.14 **NOTE:** The location of the four screws is indicated by the red circles – Figure 51.

Figure 51: Left photo shows the location of the four screws. Right photo shows the 3 mm Hex Key being used to tighten the screws.

7.5.15 Route the cables through the monitor post for the monitor.

7.5.16 Monitor cable connectors and receptacles are color-coded – Figure 52.

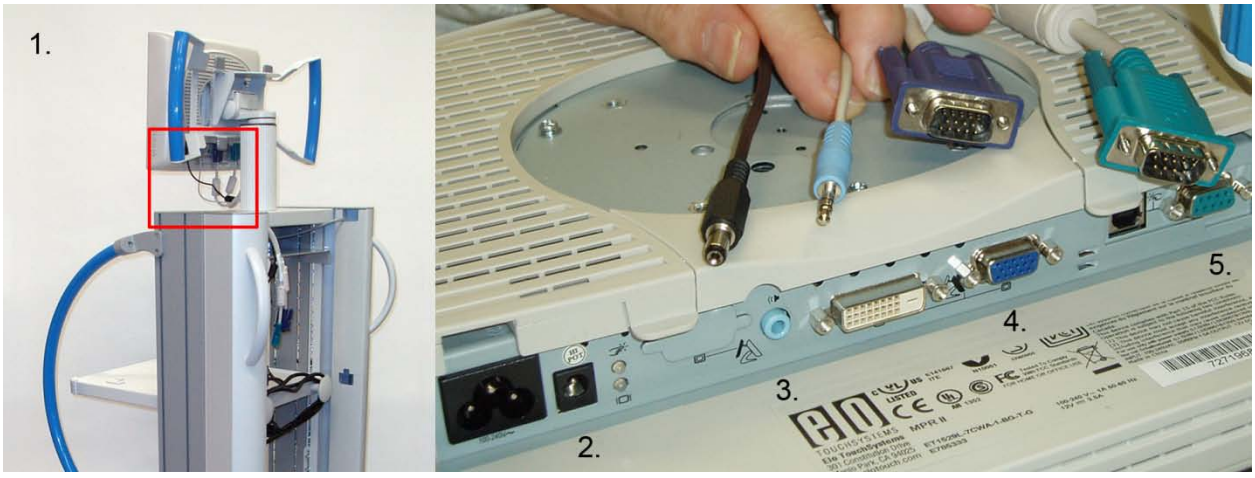


Figure 52: (1) Monitor Cable connections; (2) Monitor Power; (3) Speaker; (4) Video; and (5) Serial.

7.5.17 The monitor power cable has a mounting bracket to prevent it from coming loose. Please attach the mounting bracket – Figure 53.

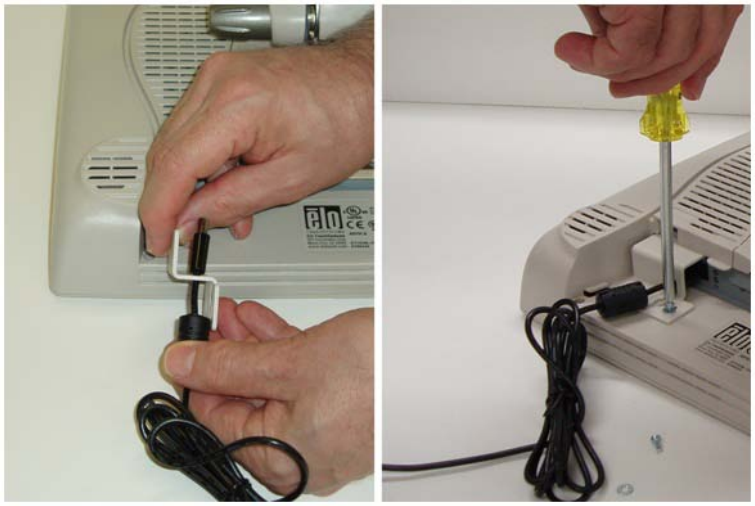


Figure 53: Monitor Power cable must be mounted using the appropriate mounting bracket.

7.5.18 Similarly, the Video and Serial Cables have mounting screws to prevent them from loosening over time – Figure 54.

7.5.19 **NOTE:** Do not over-tighten.

Figure 54: Mounting screws on the Video and Serial Cables must be tightened using a flat head screw driver.

7.5.20 MicroPace PC Installation

7.5.21 Prepare the MicroPace PC for mounting by applying two Velcro strips from the Tool Kit to the outside edges of PC Housing – Figure 55.

Figure 55: Apply two Velcro strips to the outside edges of PC Housing.

7.5.22 Mount the MicroPace PC on the left side of the top shelf – Figure 56.

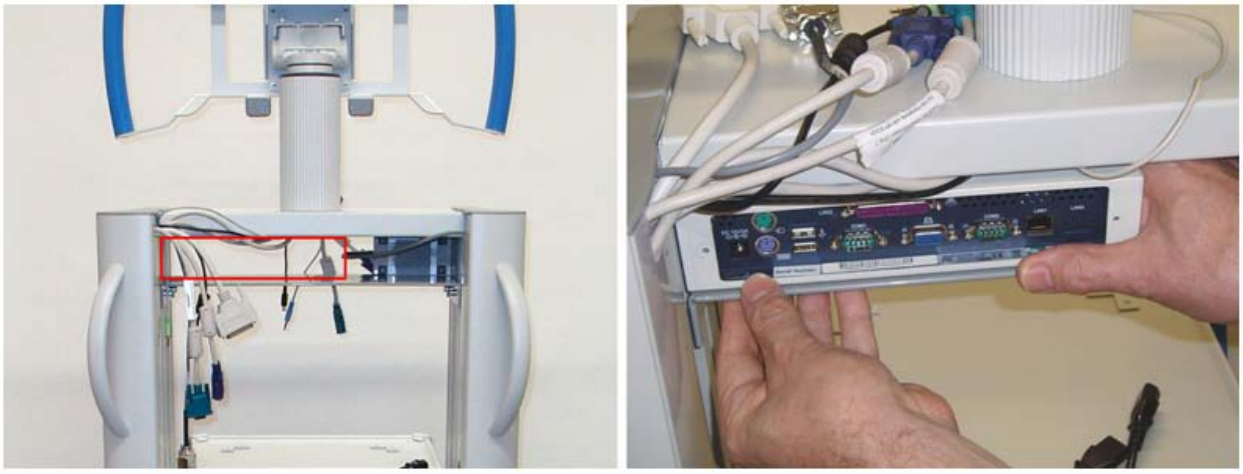


Figure 56: Mount the MicroPace PC on the left side of the top shelf.

7.5.23 Apply firm pressure to the top of PC (near the edges) until securely attached – Figure 57.

Figure 57: Apply firm pressure to the top of PC (near the edges) until securely attached.

7.5.24 Connect cables to rear of PC – Figure 58.

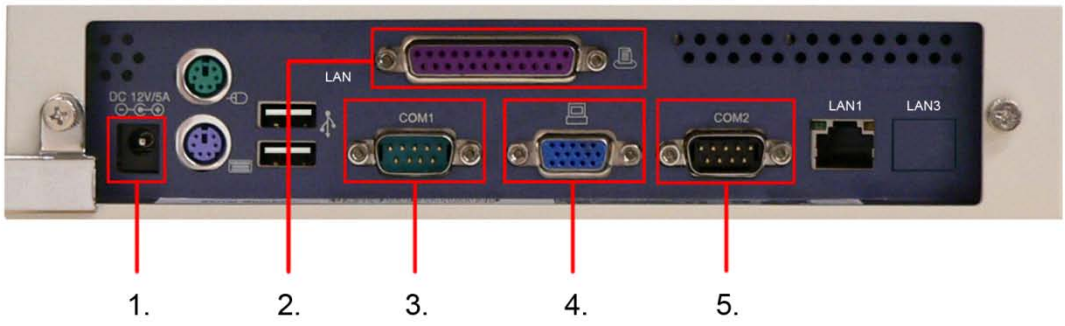


Figure 58: (1) PC Power; (2) Printer; (3) COM1 MicroPace Serial; (4) Video; and (5) COM2 Monitor Serial.

7.5.25 Install the strain relief connector for the CPU Power Cable and tighten the thumb screws on the Video, COM1, COM2, and Printer Cables– Figure 59.

Figure 59: Left photo shows the attachment of the strain relief connector the CPU Power. The right photo shows tightening the thumb screws, required on the Video, COM1, COM2, and Printer Cables.

7.5.26 Stimulus Connection Box Installation

7.5.27 Prepare Stimulus Connection Box for mounting by applying one Velcro strip from Tool Kit in the center of the Stimulus Connection Box as shown in – Figure 60.

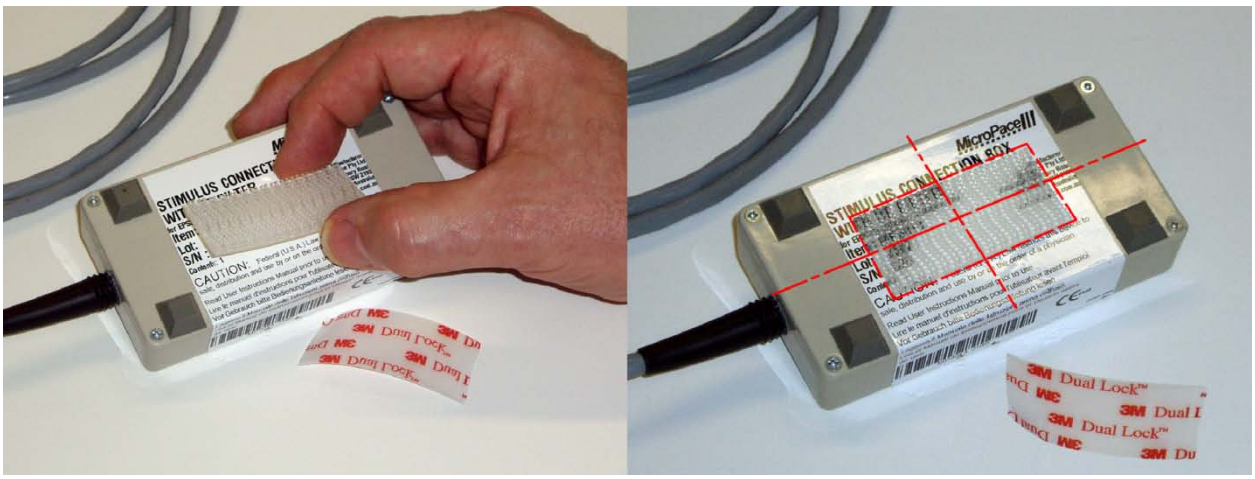


Figure 60: Preparation of the Stimulus Connection Box by mounting Velcro Strip.

7.5.28 Mount Stimulus Connection Box on the left side of the top shelf as shown in – Figure 61.

Figure 61: Successive photos showing the mounting of the Stimulus Connection Box.

7.5.29 Route the Stimulus Connection Box cable down the Left power column.

7.5.30 Remove the Power Column Cap and Covers as shown in – Figure 62.

Figure 62: Remove the Power Column Cap and Covers to find the cable ties inside the Power Column.

7.5.31 Then, secure the cable to the inside of the Power Column using the cable ties pre-mounted in the top and bottom of the Power Column.

7.5.32 Place the cable inside the cable tie loop, connect the cable tie loop, and tighten.

7.5.33 Reinstall the Power Column Covers and Cap as shown in – Figure 63.

Figure 63: Reinstall the Power Column Covers and Cap.

7.5.34 The two red circles depict cable entrance and exit locations – Figure 64.

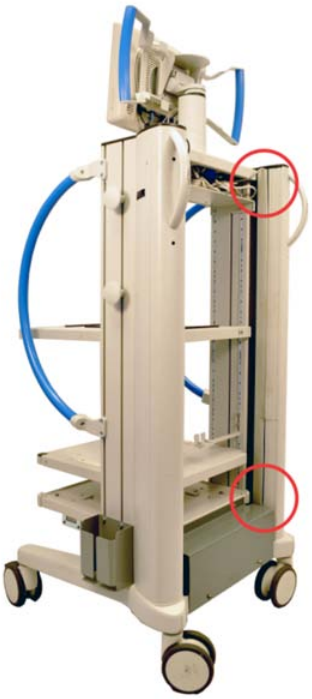


Figure 64: The red circles in this photograph show the entry and exit locations of the Stimulus Connection Box cable.

7.5.35 Reinstall the Cable Cover as shown in – Figure 65.

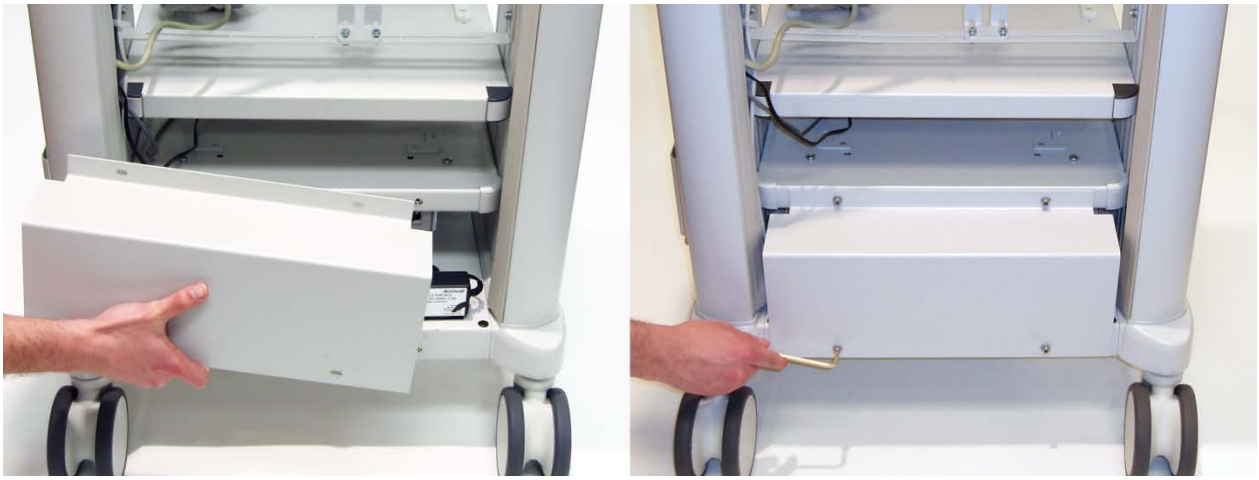


Figure 65: Reinstall the Cable Cover.

7.5.36 Laser Printer Installation

7.5.37 Position the printer on top of Printer Shelf. Make sure that the handle recesses line up with the brackets mounted on the top of the Printer Shelf – Figure 66.

Figure 66: Line up with the brackets mounted on the top of the Printer Shelf with the handle recesses on the bottom of the printer.

7.5.38 Next, attach Printer Cable and Power Cable to rear of printer as shown in – Figure 67.

Figure 67: Attach Printer Cable and Power Cable to rear of printer.

7.5.39 Lastly, install the Printer Cable Bracket on the AC Power cable as shown in – Figure 68.

7.5.40 Installation of the Printer Cable Bracket will require the use of 10 mm Combination Wrench and 10 mm Allen Wrench provide in the Tool Kit.

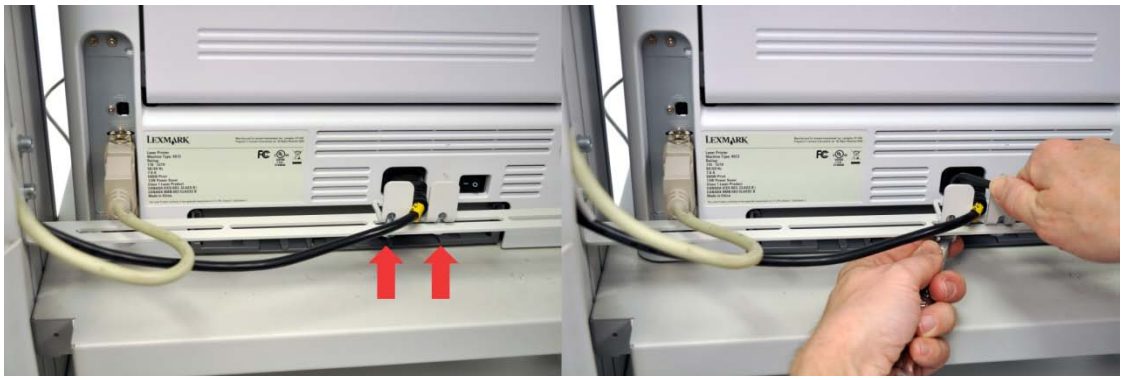


Figure 68: Install the Printer Cable Bracket on the AC Power cable.

7.5.41 Stimulus Generator Installation

7.5.42 Position the Stimulus Generator on bottom shelf. Ensure the feet on the bottom of the Stimulus Generator fall within brackets mounted on the Stimulus Generator Shelf – Figure 69.

Figure 69: Position the Stimulus Generator on bottom shelf.

7.5.43 Connect Power and Serial Cables to rear of the Stimulus Generator and tighten thumbscrews with Straight Blade Screwdriver supplied in Tool Kit. Do not over tighten the thumbscrews – Figure 71.

7.5.44 Connect the Pace Output Cable to front of Stimulus Generator – Figure 70.

7.5.45 **NOTE:** Connect the Pace Output Cable to the 'Patient' connector (Green), not the 'EMERGENCY FIXED PACE OUTPUT' connector (Red) – Figure 70.

Figure 70: Connect the Pace Output Cable to the 'Patient' connector on the front of Stimulus Generator.

7.5.46 Connect the Power and Serial cables to the rear of the Stimulus Generator – Figure 71.

Figure 71: Connect Power and Serial Cables to rear of the Stimulus Generator.

8. Instructions: Adding cryoICE and Cryo Cart Kit to ASC2

8.1 The ASC2 Cart (also referred to as the ORLab Cart)

8.1.1 The ASC2 Cart is 450 mm wide and commonly referred to as an ORLab Cart. It is 50 mm wider and has larger casters than the earlier ASC1, 400 mm cart. The ASC1 is also referred to as an ORLab Cart.

8.1.2 Figure 72 identifies the differences between the ASC1 and ASC2 carts.

Figure 72: Cart Comparison.

8.1.3 Shelf Comparison: In addition, the ASC2 Cart may have any one of two different ASU, ASB and cryoICE BOX Shelves – Figure 73.

8.1.4 **NOTE:** See Section 5.2 for Custom Shelf Instructions – Figure 29.

8.1.5 **NOTE:** See Section 8.2 for Standard Shelf Instructions – Figure 74.

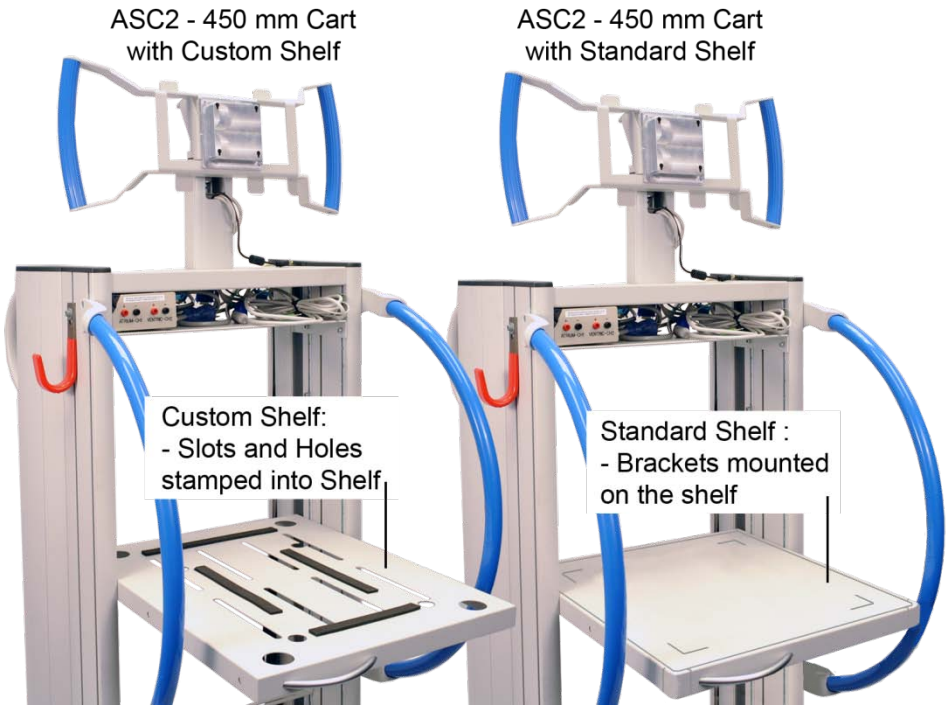


Figure 73: Shelf Comparison: See Section 5.3 for Custom Shelf or Section 8.2 for Standard Shelf Instructions.

8.2 Assembly: cryoICE BOX on ASC2 with Standard Shelf

8.2.1 Carefully place the cryoICE BOX on its top to access the rubber feet.

8.2.2 Using the 3 mm Hex Key provided in your Tool Kit; unfasten and remove the two larger front rubber feet in Position 1 and replace them in Position 3 – Figure 74.

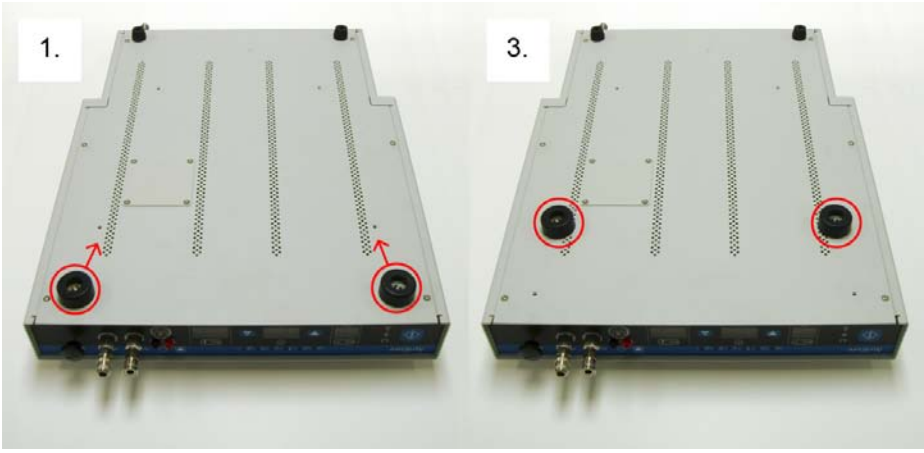


Figure 74: Move the two larger front rubber feet from Position 1 to Position 3.

8.2.3 **NOTE:** The ASC2 is configured with two different Isolation Transformers: (1) a Toroid brand; and (2) a Powertronix brand. The Isolation Transformers can be found under the bottom shelf. Reference Figures 75 and 76 to correctly identify the Isolation Transformer configured on the cart to determine proper electrical connection for the cryoICE BOX.

8.2.4 **PRECAUTION:** If the cryoICE Box is connected to a grounded hospital AC power receptacle, it must be connected into the same grounded hospital AC power receptacle as Isolation Transformer.

8.2.5 **NOTE:** Do not plug the cryoICE BOX into the Toroid Isolation Transformer. The Toroid transformer is 1000VA and does not have the capacity to power the ORLab system and cryoICE Box. If the cart is configured with the Toroid transformer, the cryoICE Box must be connected into the grounded hospital AC power receptacle.

8.2.6 **NOTE:** The Powertronix Isolation Transformer is designed to handle the cryoICE Box power requirements. The cryoICE Box can be connected into a grounded hospital AC power receptacle or it can be connected to the Powertronix Isolation Transformer.

8.2.7 **NOTE:** Reference the instruction manuals received with the cryoICE Box and Cryo products to assemble the cryoICE Box and Cryo Cart Kit to the ASC2 cart.

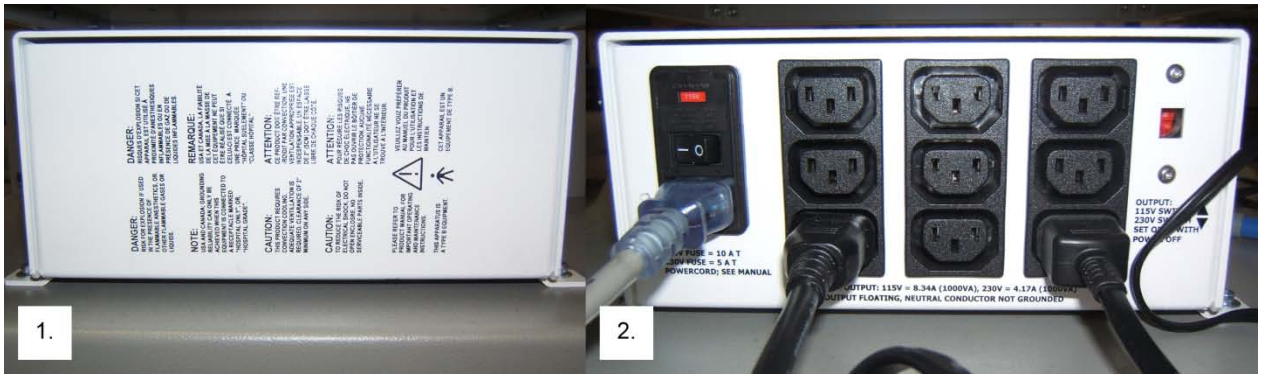


Figure 75: (1) Toroid Isolation Transformer Identification (Front of Cart View); and (2) Depicts the connections (Back of Cart View – rear panel removed).

Figure 76: (1) Powertronix Isolation Transformer Identification (Front of Cart View); and (2) Depicts the connections (Back of Cart View – rear panel removed).

8.2.8 **NOTE:** The ASC1 Cart requires unique components and instructions for adding the cryoICE Box.

8.2.9 **NOTE:** Call Customer Service, if you have an ASC1 Cart and need to add the cryoICE Box.

9. Installation Checklist

9.1 Must Be Performed and Returned

9.1.1 **NOTE:** The Installation Checklist must be performed, signed, and returned before first 'live' case after installation of the following items: (1) Basic Cart; (2) ASU / ASB Components and Accessories; (3) Cryo Cart Kit; (4) cryoICE BOX Components and Accessories; (5) ORLab Cart Kit ; and ORLab Components and Accessories.

9.1.2 All items must pass for installation to verify proper functioning of the ASU, ASB, ORLab, and cryoICE BOX.

9.1.3 Return the Installation Checklist to AtriCure Customer Service by any of the following means: (1) Scan and email: customerservice@atricure.com (preferred); (2) Fax: 513.755.4567; or (3) Mail: AtriCure, Inc., 2952 Crescentville Road, West Chester, OH 45069 USA.

Item	Test Method	Expected	P/F	Observed
Basic Cart				
1. Inspect the Basic Cart for any signs of physical damage.	Visually verify that all Basic Cart components are present and in good working condition.			
ASU / ASB				
1. Inspect the ASU / ASB Components and Accessories for any signs of physical damage.	Visually verify that all ASU / ASB Components and Accessories are present and in good working condition.			
Cryo Cart Kit				
1. Inspect the Cryo Cart Kit for any signs of physical damage.	Visually verify that all Cryo Cart Kit components are present and in good working condition.			
cryoICE BOX				
1. Inspect the cryoICE BOX Components and Accessories for any signs of physical damage.	Visually verify that all cryoICE BOX Components and Accessories are present and in good working condition.			

ORLab Cart Kit				
1. Inspect the ORLab Cart Kit for any signs of physical damage.	Visually verify that all ORLab Cart Kit components are present and in good working condition.			
ORLab				
1. Mains Isolation	Visually verify that all MicroPace ORLab™ Stimulator components – PC, SGU, Laser Printer, and LCD Touch Screen, are connected to the supplied Medical Grade Mains Isolation Transformer, and secured so cord cannot be disconnected from Isolation Transformer without use of a tool.	All components plugged into Isolation Transformer and cords secured.		
2. SGU POST	Energize the SGU and observe all LED's during Power On Self Test (POST).	All LED's light momentarily (except Emergency Fixed Rate Pace) and no errors appear on SGU display.		
3. Software Application Launches OK	Observe launch of ORLab™ Stimulator Software Application without error messages.	The ORLab Current Study screen appears with no error message.		
4. Stimulation path & Polarity OK	Configure Stimulator to stimulate Chan1 at 25 mA 2 ms at 100 ppm. Insert Test LED (MOP3058) INTO Stimulus Connection Box, MP3014, Chan1, red connector to red, black to black. Start pacing and verify yellow LED lights with each pulse. IF red LED lights then polarity is reversed.	Yellow LED flashes with each stimulus.		

5. Emergency Fixed Rate Pacing OK	Connect Test LED to Chan2 output of Stimulus Connection Box; change the connector from the SGU Pace Output (green socket) to the Emergency Fixed Rate Pacing Output (red socket). Observe pacing. Restore stimulus cable to green 'Pave Output socket.	Pacing sound is emitted and yellow test LED lights at 100 ± 20% ppm. 'Battery OK' indicator lights after 1-4s.		
6. External ECG Visible	Connect ORLab™ SGU's ECG-1 INPUT to your third party ECG Monitor. Use an ECG Stimulator to verify that ORLab displays ECG on its screen.	ECG is seen on Stimulator screen (top channel).		
7. Touch screens active	Verify LCD screen touch function by starting and stopping Emergency pacing and exiting and re-entering Application.	Pacing starts on sustained press of Emergency button and stops with press of Pace On/Off.		
8. Printer functional	Print Test one page from Review screen.	Printer prints Review Screen Page as displayed on the screen.		
9. Biomed Engineering approval	Health facility's Biomedical Engineering Dept. is generally required to test and accept the installed system for electrical safety; ensure that this has been done.	Biomedical Engineering acceptance verified.		
10. Customer trained	Responsible customer representative has been trained as per above training.	Customer able to perform items in Section 6.1 above.		

Health Facility Name	
Health Facility Location	
ORLab Stimulus Generator Unit Serial No.	
Installation officer name	
Installation officer signature	
Date	