OMNIBotics Station with iBlock®

INSTRUCTIONS FOR USE OF SHIPPING CRATE AND FIRST SETUP

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CE 2797

EC REP

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Standards

This product complies with the standards for medical electrical devices
EN 60601-1 (2007): Medical electrical equipment (General requirements for basic safety and essential performance)
EN 60601-1-2 (2007): Medical electrical equipment (General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests)
This product has been certified by TÜV Rheinland of North America following UL 60601-1:2003 R4.06, CAN/CSA-C22.2 NO. 601.1-M90, CAN/CSA-C22.2 NO. 60601-1-1-02 (R06), and IEC 60601-1-1:2000.

Copyright

Commercial Brand

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Patents

The OMNIBotics System, OMNI ART™ Knee Application, Instruments, and iBlock® are protected by Patents No's: US 9,220,571, US 9,220,510, US 9,050,132, US 9,033,958, US 8,990,052, US 8,880,152, US 8,626,267, US 8,214,016, US 8,126,533, US 8,096,997; US 7,691,108, EP 1 635 715 (FR, GB), DE 602004048029.0 , EP 1 341 468 (FR, GB), DE 60141248.6, JP 4 182 757, FR 2 856 268, FR 2 852 223. Other patents pending.
Other patents pending.

Licenses

The OMNIBotics Station™ design is the exclusive property of OMNI. Any copying either in part or in whole is strictly prohibited.

Modifications

The information given in this document is subject to modification without notice. We have done our utmost to ensure the accuracy of the information given in this document.

Training options

For safe and effective use of the medical device, the following training courses are recommended:

Name	***Reference***	***Duration***	***Frequency***
OMNIBotics Knee System – ART™ Knee Application Instructions for Use	IFU-036	2 hours	Surgeon and OMNI personnel to be trained annually. Hospital staff on installation and as needed.
OMNIBotics Station Instructions for Use	IFU 037	2 hours	Surgeon and OMNI personnel to be trained annually. Hospital staff on installation and as needed.

Table 1 - Description and reference codes for training courses

CONTENTS

1 Introduction

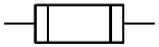
1.1 Purpose of document

This document provides a set of instructions for the use of the shipping crate and of the first setup of the OMNIBotics Station. This document explains how to pack and unpack the OMNIBotics Station as well as how to perform functional testing.

It is intended for sales and technical representatives who will be crating, uncrating, and testing the OMNIBotics Station. These personnel should also be trained on the OMNIBotics Station instructions for use and complete any additional training requirements set by OMNI for assisting a surgical procedure or providing supervision of the system.

1.2 Conventions

	Manufacturer
	Catalogue Reference
	Date of Manufacture

	Serial Number
	Fuse
	Alternating Current
	Potential Equalization
	Temperature limitation for the device

	The equipment must not be disposed of with other rubbish but must be disposed of in a selective collection to be evaluated, reused or recycled.
	Type BF applied part
IP 20	Protection Coefficient
	Pushing prohibited
	Follow instructions for use

	Item is Fragile and should be handled with care
	Humidity limitation for the device
	Atmospheric pressure limitation for the device
	WARNING: This symbol precedes any hazard involving the health and/or safety of users and patients.
	RECOMMENDATION: This symbol precedes any advice on the use of the system, which has no incidence on the health and/or safety of users and patients.

1.3 Associated documents

- OMNIBotics Tracker Kit Instructions for Use (IFU-035)
- OMNIBotics Knee System – ART™ Knee Application Instructions for Use (IFU-036)
- OMNI ART and Iblock System Instrumentation (IFU-039)
- OMNIBotics Station Instructions for Use (IFU-038)

1.4 Safety precautions

	**WARNING:** Personnel using the OMNIBotics Station should be trained by an OMNI Technical Services Representative or by an appropriate person approved by OMNI.
	**WARNING:** The camera is a high-precision optical instrument. Mechanical shock may adversely affect accuracy even if no superficial damage is visible. If damage is suspected, do not use the OMNIBotics Station until accuracy and precision can be verified.
	**WARNING:** Never immerse the OMNIBotics Station in water or other liquid. Liquid spills may damage the system and create electric shock or fire hazards. In this event, immediately turn off the station and call OMNI Customer Service.

	**WARNING:** Always use handles when positioning or moving the device to prevent applying unecessary force to other components or risk of tipping.
	**WARNING:** Never look directly into the laser-emitting aperture of the localizer. The class 2 laser module on the localizer emits radiation that is visible and may be harmful to the human eye. Direct viewing of the laser diode emission at close range may cause eye damage.
	**WARNING:** The OMNIBotics Station should only be connected to a power distribution network with a Type 2 surge protection device.
	**WARNING:** Never use a multi-outlet power strip to connect the OMNIBotics Station.
	**WARNING:** Do not use the OMNIBotics Station in the presence of flammable anesthetics or other flammable substances.

	**WARNING:** All electrical and mechanical maintenance must be performed by a representative approved by OMNI.
	**WARNING:** This system contains a lithium battery. The battery should only be exchanged by authorized service personnel. A risk of explosion from incorrect installation or misapplication may possibly occur.
	**WARNING:** Disconnect the OMNIBotics Station from the power supply before replacing a fuse.
	**WARNING:** Do not connect any other units to the OMNIBotics Station other than specified components of the system.
	**WARNING:** If the OMNIBotics Station is linked to another electromedical device via the equipotential connection, the global system must be compliant with IEC 60601-1.
	**WARNING:** To avoid electric shock, the OMNIBotics Station must be connected only to a supply network with a protective ground.

	**WARNING:** If the iBlock moves uncontrollably, press the Emergency Stop button located on the Enclosure, or disconnect the iBlock cable from the iBlock enclosure.
	**WARNING:** Any modification to the iBlock® system is prohibited.
	**WARNING:** The iBlock® can only be connected to the OMNIBotics Station and can only be used in conjunction with the indicated instruments. Any use not supported by OMNI can damage the iBlock®.
	**WARNING:** Do not connect any units to the enclosure box other than specified components of the iBlock® system.
	**WARNING:** The use of cables other than those specified or manufactured by OMNI may result in change of safety conditions. Therefore, it is strictly forbidden to use non-authorized cables.

	**WARNING:** The green sleeve connector of the iBlock cable must be connected to the Enclosure Box. The gray sleeve connector of the iBlock cable must be connected to the iBlock cover.
	**WARNING:** Transport should only be undertaken under conditions described in section 2 with OMNI-approved shipping containers.

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.

1.5 Special conditions for use

	**RECOMMENDATION:** Read and understand the entire user manual and associated documents before using the OMNIBotics Station.
	**RECOMMENDATION:** Access to the computer and electrical systems contained in the OMNIBotics Station is strictly reserved for personnel approved by OMNI.

	**RECOMMENDATION:** The user must check the external appearance of the station after each time it is transported; if a mechanical anomaly is detected, do not use the station. Call Customer Service set on page 1. Check that the system is functioning correctly after each time it is transported. To do this, follow the paragraph 4 Functional check.
	**RECOMMENDATION:** Always engage the brakes of the OMNIBotics Station when in use.
	**RECOMMENDATION:** Do not tilt the OMNIBotics Station more than 10° with reference to the horizontal. Always put the station in the transport position before transporting the station.
	**RECOMMENDATION:** Never disconnect or connect the localizer while the station is in use.
	**RECOMMENDATION:** Follow the electrical connection details for the OMNIBotics Station shown on the identification label.

	**RECOMMENDATION:** The OMNIBotics Station must only be powered on by first the power switch on the enclosure box and then the power button on the laptop.
	**RECOMMENDATION:** The OMNIBotics Station must only be powered off by first shutting down the software and then the main power switch on the enclosure.
	**RECOMMENDATION:** Wait at least 10 seconds after turning off the station before restarting.
	**RECOMMENDATION:** When transporting, carrying, or shipping the computer, make sure the computer is turned off. Remove all external devices, cables, PC cards and other protruding objects. Remove USB Drive. Do not drop or hit the computer against solid objects. Do not leave the display open. Do not grip the display part.

2 Transport and Storage conditions

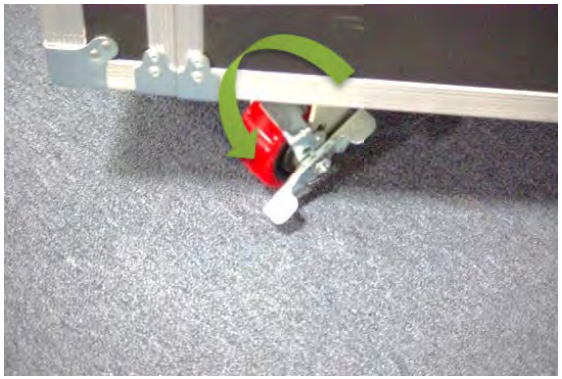
Temperature	-10°C to 50°C (14°F to 122°F)
Humidity	30% to 90%
Pressure	70kPa to 106kPa

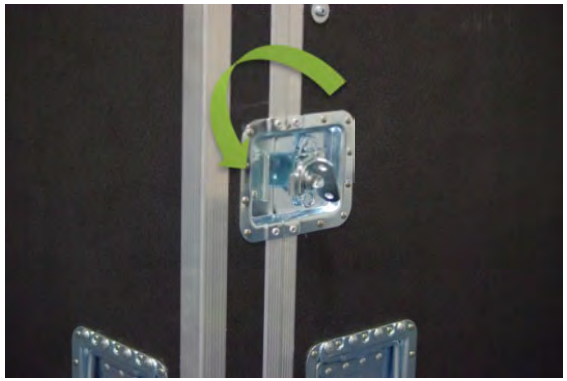
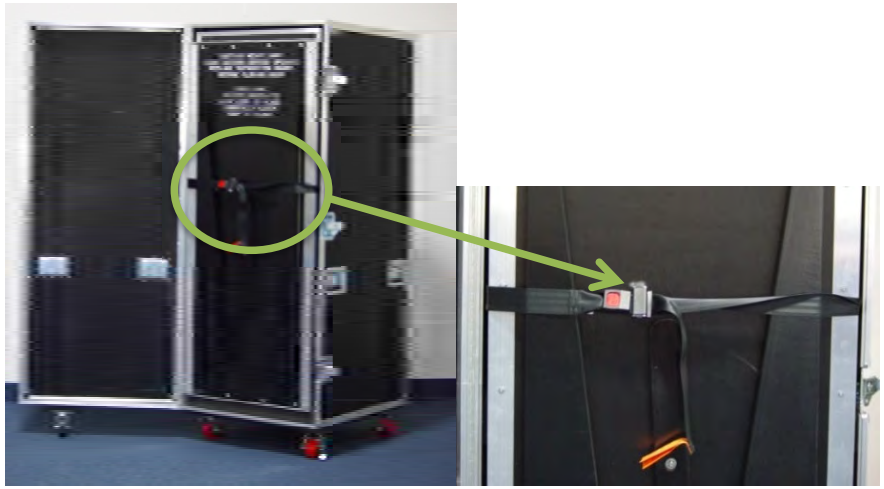
3 System uncrating and crating

3.1 Required tools

LIST OF THE MEANS (TOOLS, RESOURCES, INFORMATION)		
Designation	**Supplier**	**Supplier / mean reference and Version**
1/8” Allen Key	NA	NA
Bubble wrap	NA	NA
Packing tape	NA	NA

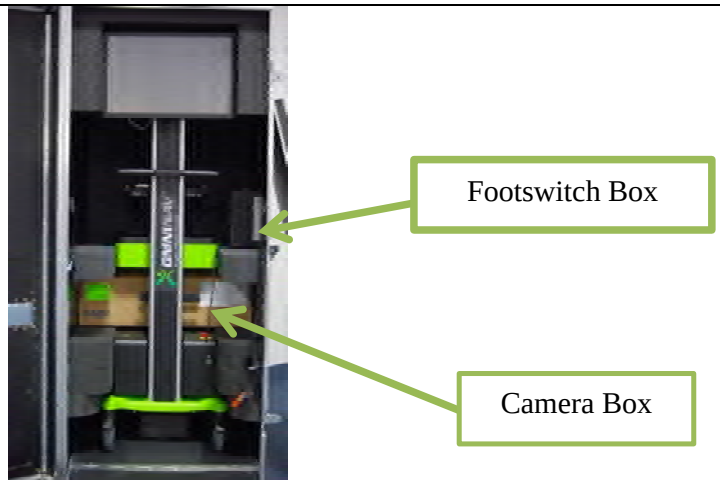
3.2 System uncrating

Step	Description of the operation	Verification
1.	Lock the 2X front wheel brakes of crate.	

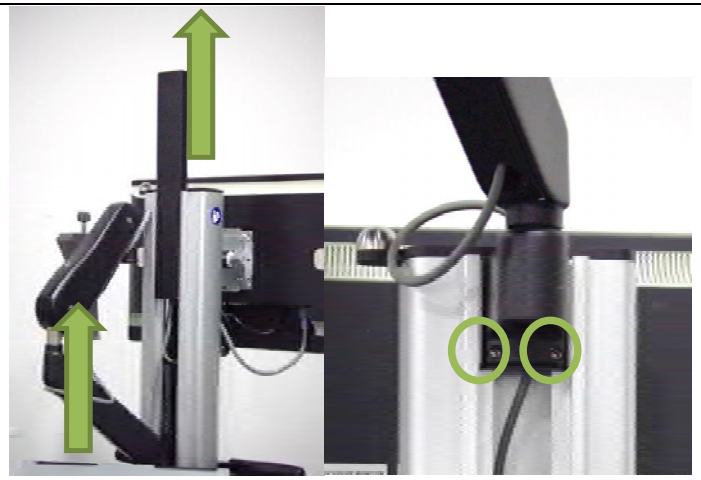
2.	Unlock transport case by removing cable ties (if applicable), flipping latches out, and turning counterclockwise.	
3.	Open the crate door and unbuckle belt. **Use caution as contents may fall forward.**	

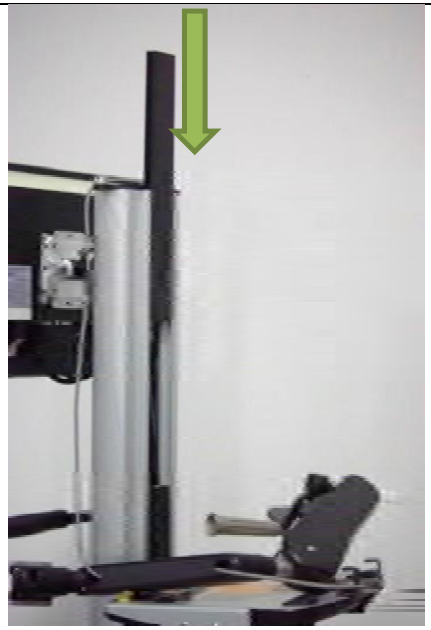
4.	Open the two triangular side supports of the ramp and secure by rotating central support piece. Central support should be approximately horizontal when secured.	
5.	Lower ramp.	

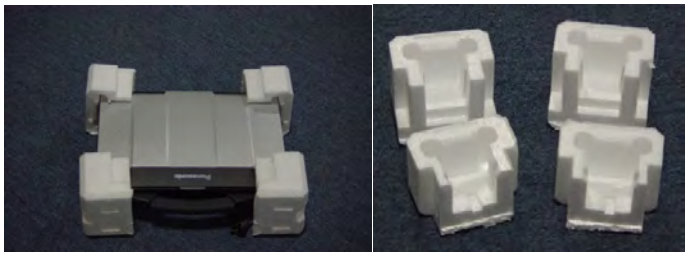
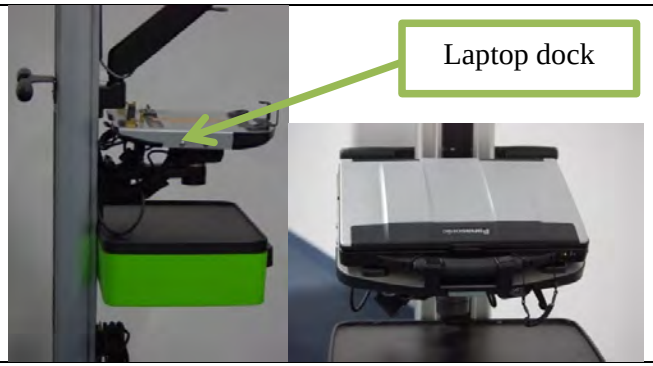
6.	Remove separation board and set aside.	
7.	Remove laptop box that is located on the ground under the station.	

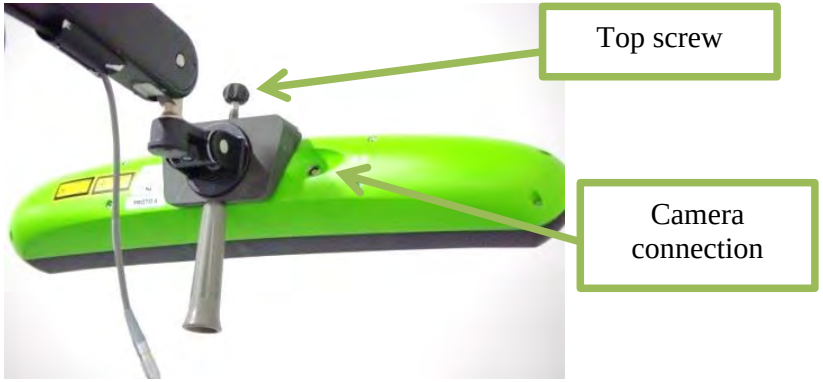
8.	Remove footswitch from side pocket and place it on top of the drawer. Roll system out of transport crate. **Use caution when moving the device down the ramp. It is topheavy and may tip.** Remove camera box.	
9.	Remove enclosure foam block (underneath enclosure) and return material to crate for future use.	

10.	Remove bubble wrap from footswitch/station and leave material inside crate for future use.	
11.	Remove bubble wrap from camera arm bracket and leave it inside the crate for future use.	

12.	Remove small channel cover 4 by sliding it up and out of the top of the mast. Then loosen 2X screws, using 1/8'' allen key, in camera arm and slide arm upward completely out of the mast temporarily. Do not pinch or stretch camera cable when moving arm.	

13.	Remove channel cover 3 from drawer. Install channel cover 3 into mast so circular cut-out is facing down. Slide downwards until it bottoms out. Install channel cover 4, with label facing up, and slide downwards until it meets channel cover 3. Camera cable should sit behind channel covers.	
14.	Re-install camera arm so it is mounted flush with the top of the mast. Tighten 2X screws to secure arm.	

15.	<u>If laptop is part of crate contents:</u> Remove laptop from packaging and leave packaging in crate for future use. <u>If laptop is not part of crate contents:</u> Empty laptop box can be returned to crate for future use.	
16.	<u>If laptop is part of crate contents:</u> Attach Laptop to dock. See OMNIBotics Station with iBlock IFU in Station drawer for laptop attachment instructions.	

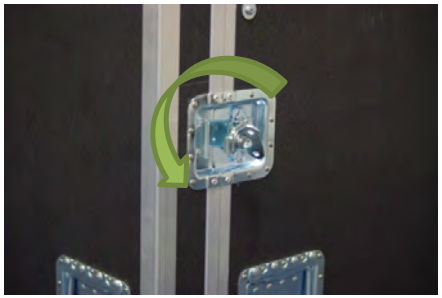
17.	<u>If camera is part of crate contents:</u> Remove Camera from packaging and return package to crate. <u>If camera is not part of crate contents:</u> Empty camera box can be returned to crate for future use.	
18.	<u>If camera is part of crate contents:</u> Insert into camera arm bracket and secure with top screw.	

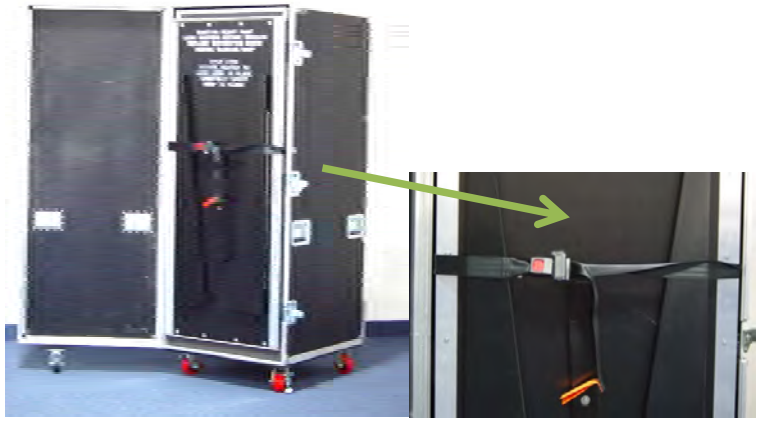
19.	<u>If camera is part of crate contents:</u> Attach cable. See OMNIBotics Station with iBlock IFU for camera attachment and connection instructions. Plug the camera cable into the back of the camera by aligning the two red dots.	
20.	Perform functional testing outlined below (section 4) before any surgical use of the station.	

21.	Replace separation board (foam side facing inward towards device)	
22.	Lift ramp and rotate central support piece to allow folding of two triangular ramp sides. When ramp is upright secure with buckle. NOTE: Face of ramp should fit flat against opening of crate. If ramp is not closing fully check placement of device and separation board. Do not force.	

23.	Close lid of transport crate and close 3X latches.	

3.3 System package for shipping

Step	Description of the operation	Picture
1.	Lock the 2X red front wheel brakes of crate.	
2.	Unlock transport case by removing cable ties (if applicable), flipping latches out, and turning counterclockwise.	

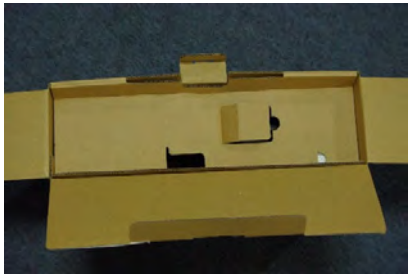
3.	Open the crate door and unbuckle belt. **Use caution as contents may fall forward.**	
4.	Open 2X triangular side supports of ramp and secure by rotating central support piece. Central support should be approximately horizontal when secured.	

5.	Lower ramp.	
6.	Remove separation board and set aside.	

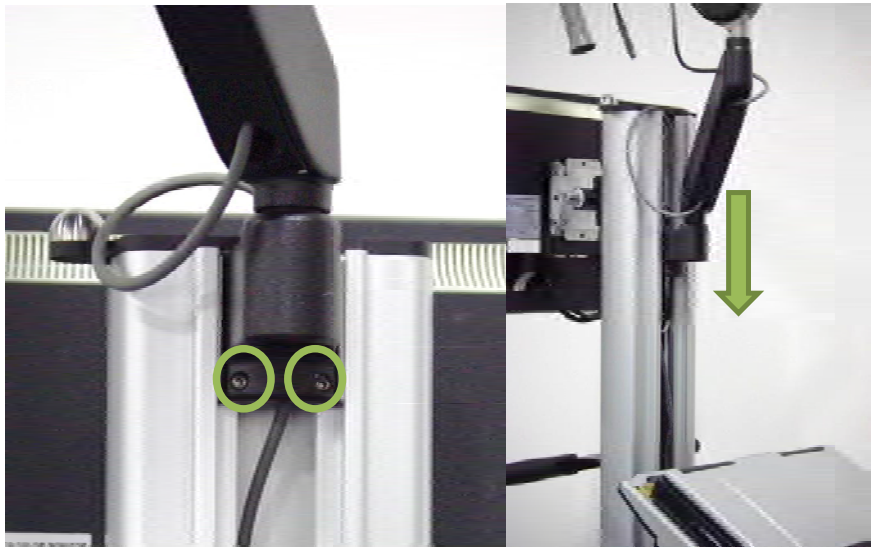
7.	Remove camera and laptop boxes. Remove enclosure foam block.	
8.	Before preparing the station for shipment, ensure it is properly shut down, cleaned, and disinfected per OMNIBotics Station with iBlock IFU.	

9.	<u>If camera is part of crate contents:</u> Unplug power cable by pulling back on the connector sleeve. Remove camera from the camera arm by untightening the top screw and sliding out.	
10.	<u>If camera is part of crate contents:</u> Place the camera in its cardboard packaging (with included packaging materials) in orientation shown. Secure package with tape.	

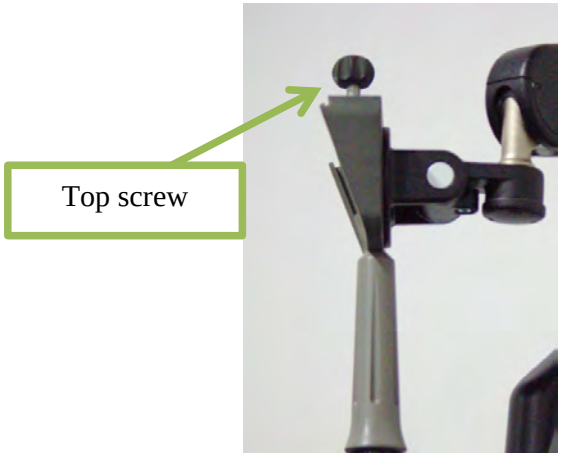
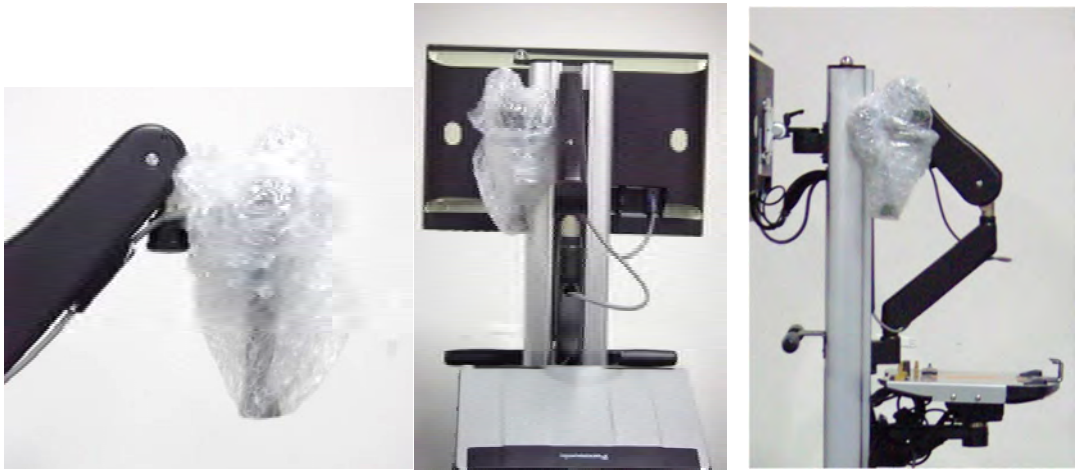
11.	Insert camera package between foam supports as shown and push to the back of the crate.	

12.	<u>If laptop is part of crate contents:</u> Remove laptop from unit and place in original cardboard packaging (with included packing materials). Secure package with tape.	   

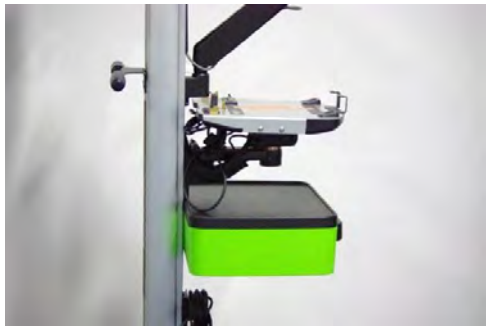
13.	Remove top two small channel covers and place to the side. Use care so as not to scratch or otherwise damage channel covers.	 738

14.	Loosen 2X screws in camera arm and slide arm downward until the top of the camera bracket is slightly below the top of the mast. Do not pinch or stretch camera cable when moving arm. Retighten screws to secure arm. It may be necessary to move the laptop dock slightly out of the way to avoid interference.	

15.	Reinstall small channel cover number 4 above camera arm. Small channel cover 3 can be placed in the storage drawer.	 

16.	Tighten top screw of camera bracket to secure for shipment.	
17.	Wrap camera bracket and top portion of camera arm in bubble wrap. Place camera arm in orientation shown. Ensure ample bubble warp cushioning between the bracket and the mast.	

18.	Ensure monitor is vertical and facing forward (not tilted or swung to either side of the mast). Ensure monitor tilt lock screw is tightened for security during shipment	
19.	<u>If power cord is part of crate contents:</u> Ensure power cord is removed and stowed in drawer. <u>If motor unit is part of crate contents:</u> Wrap motor unit in bubble wrap and also store in drawer	

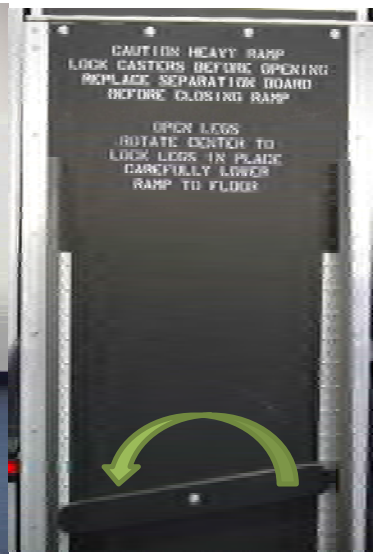
20.	Place laptop dock in lowered, flat orientation. Dock should be centered above drawer (not swung to either side of the mast). Ensure tilt knob is locked.	
21.	Wrap footswitch in bubble wrap and place on top of the drawer.	

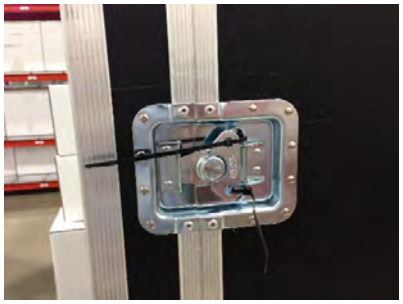
22.	Ensure enclosure lock screw is properly secured. The flat edge of the screw should be facing towards the mast.	 
23.	Insert enclosure foam block underneath enclosure (between enclosure bottom and cart base)	

24.	Roll system into transport crate so the mast handles are facing outwards. Use caution when moving the device onto and up the ramp. Wheels should be angled towards you allowing the station to fit all the way in crate. Do not damage cord of wired footswitch if present.	

25.	Place the wrapped footswitch in the foam box.	
26.	Place laptop box underneath device wheelbase.	

27.	Replace separation board (foam side facing inward towards device).	

28.	Lift ramp and rotate central support piece to allow folding of two traiangular ramp side supports. When ramp is upright secure with buckle. NOTE: Face of ramp should fit flat against opening of crate. If ramp is not closing fully check placement of device and separation board. Do not force.	 
29.	Close lid of transport crate.	

30.	Secure all 3X latches with zipties	

4 Functional check

This testing procedure is used to ensure the components of the OMNIBotics Station™ are functioning correctly. It outlines a list of required operations that should be performed and details the acceptance critiera for each.

This functional check should be performed prior to any surgical use after any time the OMNIBotics Station™ is transported.

If the OMNIBotics Station™ fails to meet any of the acceptance critiera do not use in surgery and contact technical support.

4.1 Required tools, resources and information

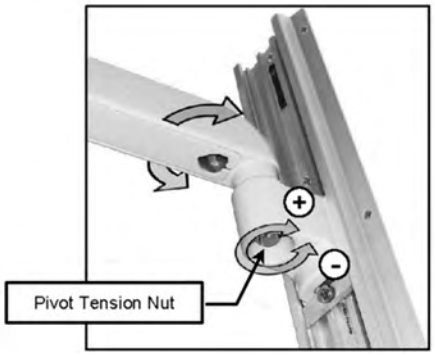
Designation	Supplier	Supplier / mean reference and Version
1/2” Socket (extended socket may be required to reach all joints)	N/A	N/A
3/4” Socket (extended socket may be required to reach all joints)	N/A	N/A
1/8” Allen Key	N/A	N/A
5/32” Allen Key	N/A	N/A
P, T, F, or G Array	OMNI	0501-5000, 0501-5030, 0501-5020, OR 0501-5070
Non-Sterile Demo Markers	OMNI	1301-1000
USB Flash Drive	N/A	N/A
Motor Unit	OMNI	4144-6000
iBlock Cover	OMNI	4144-4000
iBlock Enclosure	OMNI	4144-7000
iBlock Deattachable Cable	OMNI	4144-5000

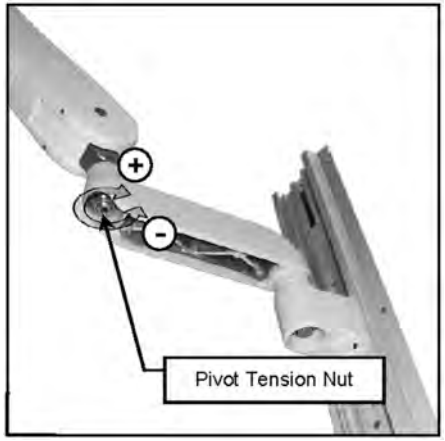
4.2 Functionnal check

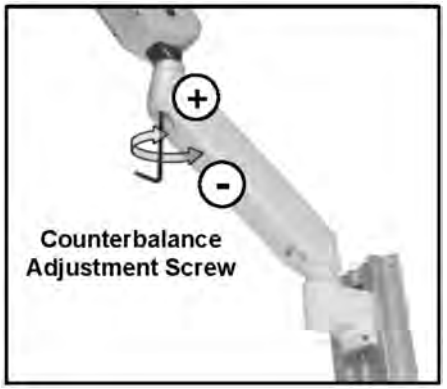
Step	Description of the operation	Mean	Picture	Acceptance Criteria
1.	Verify brake casters. Lock brake wheels by pressing down on the lock flippers of the 2X mast-side wheels (light gray).	Manual		Station will not roll when locking mechanism is engaged.

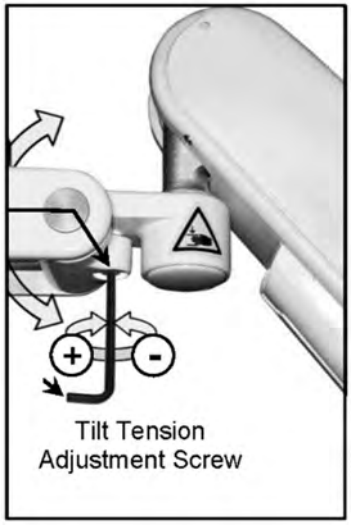
2.	Verify steering casters. Lock steering wheels by pressing down on the lock flippers of the 2X opposide side wheels (dark gray).	Manual		Wheels will lock in a position that is parallel to the sides of the base (as pictured) and help keep the station straight while rolling.
3.	Verify docking station tilt function. Loosen lock lever underneath the dock and apply gentle pressure to the dock. Tighten lock lever and repeat.	Manual		When lock lever is disengaged, docking station should tilt freely. When lock lever is engaged, docking station should remain in place and the tile mechanism should remain locked when

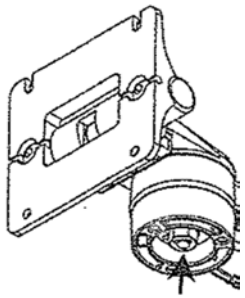
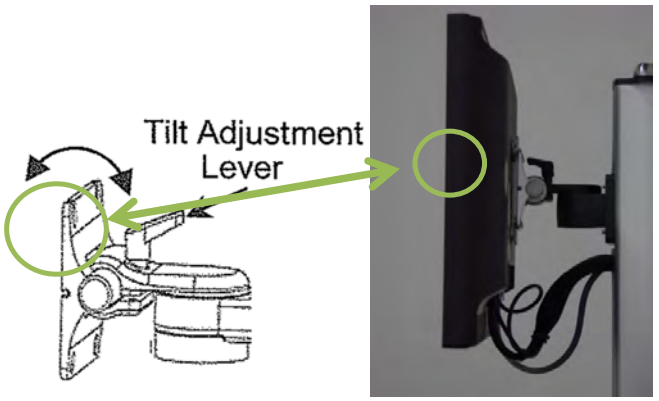
				gentle pressure is applied to the dock.
4.	Verify laptop swivel arm. Apply pressure to the sides of the dock and arm to pivot the docking station around the mast. Ensure both joints are moved. If required: The pivot tension bolt can be tightened or loosened to adjust the motion of the swivel arm with the 1/2” Socket.	1/2” Socket		Docking station will move when pressure is applied, but does not swing loosely while rolling/transporting the station.

5.	Verify Camera Arm bottom swivel. Grasp the handle of the camera arm and move the camera arm around. Place the arm in a set position. If required: The pivot tension bolt can be tightened or loosened to adjust the motion of the swivel arm with the 3/4” Socket.	3/4” Socket		Camera arm bottom swivel will rotate freely when arm is moved, but stays in place when set and does not swing loosely while rolling/transporting the station.

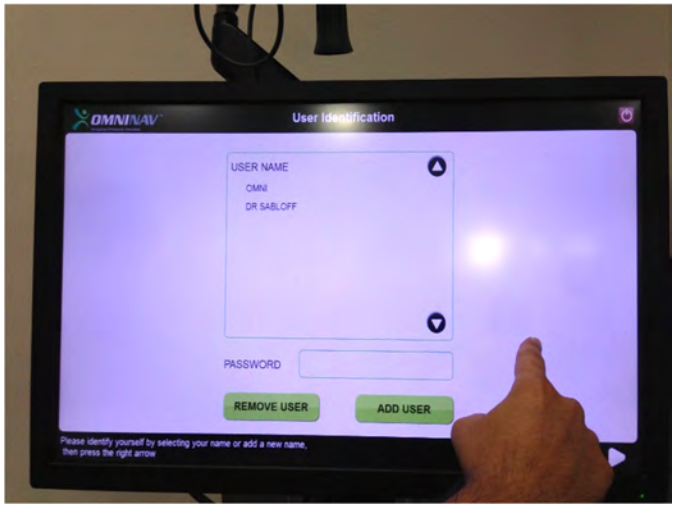
6.	Verify Camera Arm middle swivel. Grasp the handle of the camera arm and move the camera arm around. Place the arm in a set position. If required: The pivot tension bolt can be tightened or loosened to adjust the motion of the swivel arm with the 3/4” Socket.	3/4” Socket		Camera arm middle swivel will rotate freely when arm is moved, but stays in place when set and does not swing loosely while rolling/transporting the station.

7.	Verify Camera Arm middle counterbalance. Grasp the handle of the camera arm and move the camera arm around. Place the camera arm at a set height. If required: The middle counterbalance screw can be tightened or loosened to adjust the motion of the swivel arm with the 1/8” Allen.	1/8” Allen		Camera arm middle counterbalance will move freely when arm is moved, but camera arm does not rise or fall when position is set.

8.	Verify docking handle. Remove camera from bracket. Dock magnetic camera handle to mating dome feature on the mast cap.			Camera arm does not rise or become undocked when magnetic dock is engaged.
9.	Verify Camera tilt tension. Grasp the handle of the camera arm and tilt the camera. Place the camera at a set angle. If required: The tilt tension adjustment screw can be tightened or loosened to adjust the motion of the swivel arm with the 5/32” Allen.	5/32” Allen		Camera tilt will move freely when handle is moved, but camera does not rise or fall when position is set.

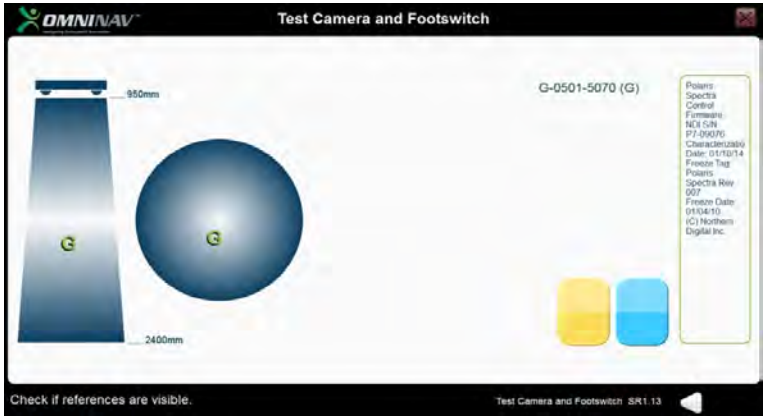
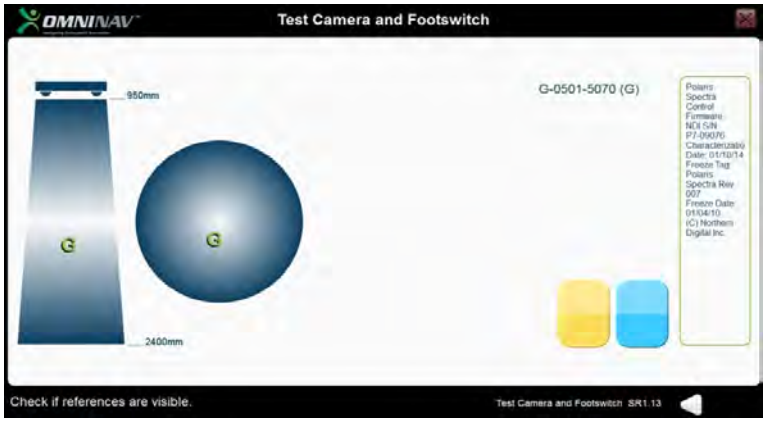
10.	Verify monitor swivel. Gently grasp the sides of the monitor and apply pressure to rotate around monitor around the mast. If required: The pivot tension bolt can be tightened or loosened to adjust the motion of the swivel arm with the 1/2” Socket.	1/2” Socket	 Swivel Tension Nut	Monitor will move when pressure is applied, but does not swing loosely while rolling/transporting the station.
11.	Verify monitor tilt. Loosen tilt lever above monitor swivel and apply gentle pressure to the top/bottom of the monitor. Tighten tilt lever and repeat.	Manual/Adjustment lever		When tilt lever is disengaged, monitor should tilt freely. When lock lever is engaged, monitor should remain in place and not yield to gentle pressure.

12.	Verify power. Plug power cord (in station drawer) into enclosure and wall electrical outlet. Turn on black on/off swich on the enclosure.	Enclosure power switch	   	Front camera LEDs turn on and camera beeps Green LED above the iBlock connection turns on. (If light is not on, ensure emergency stop button is not engaged.) Front monitor light turns on.

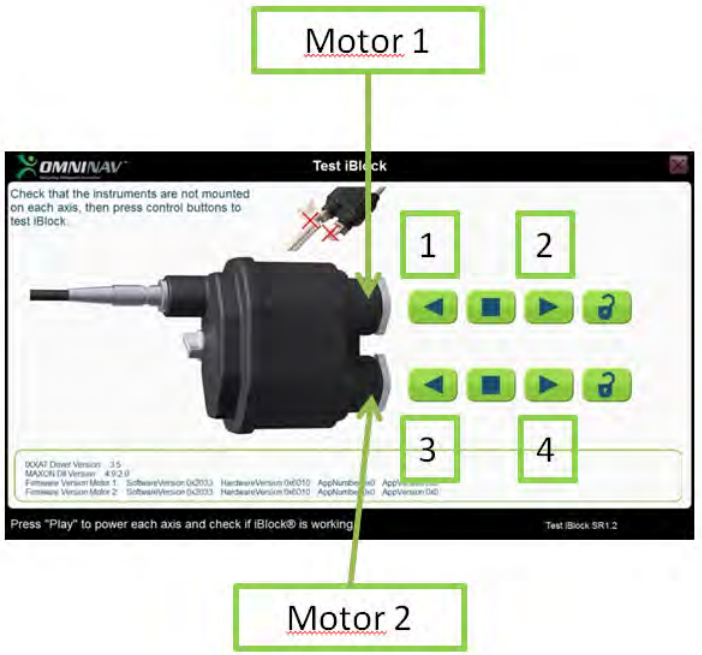
13.	Verify laptop. Press the gray button in the top center of the laptop to power it on.	Laptop power button		Laptop powers on and software image is displayed on the laptop and external monitor screens.
14.	Verify accuracy of external monitor touchscreen. Press any location on the monitor screen. If necessary: Run screen calibration tool from application system (see Instructions for Use for the "OMNIBotics Station ™ with iBlock")	Touchscreen		Pointer appears below finger when screen is pressed and follows finger when moved around. If buttons are pressed they perform the desired function.

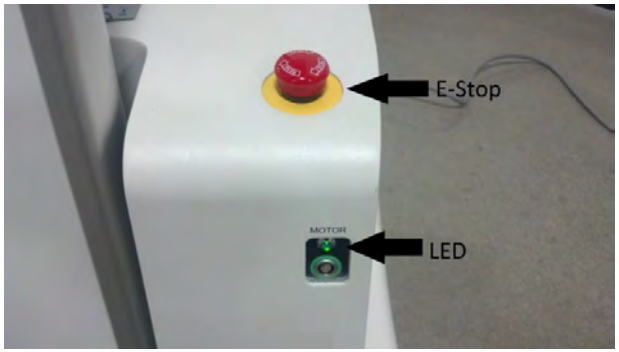
15.	Verify accuracy of laptop touchscreen. Press any location on the monitor screen. If necessary: Run screen calibration tool from application system (see Instructions for Use for the "OMNIBotics Station ™ with iBlock")	Laptop Touchscreen		Small diamond-shaped target appears below finger when screen is pressed and follows finger when moved around. If buttons are pressed they perform the desired function.
16.	Verify Intel Control Panel shortcut. Press and hold SHIFT-ALT-I keys in succession and release.	Laptop keyboard		Intel Control Panel appears Exit Panel by pressing the "X" in the upper right corner.

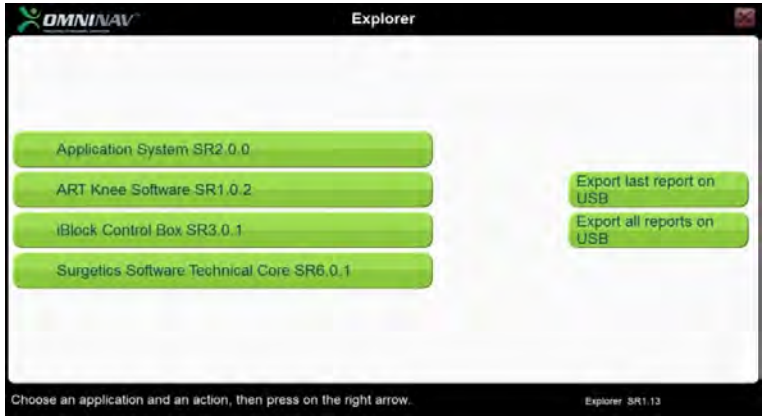
17.	Select any username and press the white arrow. If there are no users to select, add a user by pressing the Add User button.	User Identification Screen		Application System tools menu is displayed
18.	Verify camera and footswitch. Select “Test camera and footswitch” function in the application system and press right arrow.	Application system tools menu		Test camera and footswitch menu is displayed.

19.	Verify camera. Select the desired test array in the camera test menu. Hold the selected instrument in the camera field of view and move around.	P, T, G, or F array with markers		Corresponding letter of test array is displayed in the camera field of view. Letter moves when test array moves. Letter should not be blinking.
20.	Verify foot switch. Press Blue pedal of foot switch. Press Yellow pedal of foot switch.	Footswitch		When foot switch is pressed, corresponding pedal is highlighted on the screen.

21.	Verify iBlock. Connect an assembled iBlock motor unit, enclosure, and cable to the station enclosure. Plug the green end of the cable into the station and the gray end of cable into the iBlock. Do not attach any of the iBlock attachments to the axes of the iBlock. Select “Test iBlock” function in the application system and press right arrow.	Application system tools menu iBlock Motor Unit (4144-6000) iBlock Cover(4144-4000) iBlock Enclosure (4144-7000) iBlock Deattachable Cable (4144-5000)		Test iBlock screen is displayed.

22.	Verify iBlock. Press 1 and check that motor 1 is moving counter clockwise Press ■ Motor should stop moving Press 2 and check that motor 1 is moving clockwise Press ■ Motor should stop moving Press 3 and check that motor 2 is moving counter clockwise Press ■ Motor should stop moving Press 4 and check that motor 2 is moving clockwise Press ■ motor	iBlock Motor Unit (4144-6000) iBlock Cover(4144-4000) iBlock Enclosure (4144-7000) iBlock Deattachable Cable (4144-5000)		iBlock connects to system successfully. iBlock axes move as specified.

	should stop moving			
23.	Verify emergency stop. Start Test iBlock tool. Press both buttons (2 and 4) to activate both motors. Press emergency stop button.	iBlock Motor Unit (4144-6000) iBlock Cover(4144-4000) iBlock Enclosure (4144-7000) iBlock Deattachable Cable (4144-5000)		Both axis of the iBlock stop and the Green LED turns off. It is acceptable for an error message to appear on the screen. It can be exited.

24.	Verify explorer tool. Select “explorer” tool from application system menu and press right arrow.	Application system tools menu (explorer)		Explorer screen is displayed.
25.	Verify explorer tool. Select “ART Knee Software” option. Press “Export all reports on USB”. Plug a USB stick. Press white bottom arrow. Select “50 reports” option. Wait until the data is recorded on the USB stick.	USB flash drive		Reports burn successfully on USB flash drive Use an additional compter to check that the files have been correctly exported.

26.	Verify drawer contents: Open station drawer and check for 2X replacement fuses and 2X IFUs (Station and Software).	Visual		Items listed are present