OMNIBotics™ Station

INSTRUCTIONS FOR USE

CE 2797

(CE is applied for use of OMNIBotics Station with Knee Application only)

Manufactured by:

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☎ : 800-448-6664
🖷 : 508-822-6030

EC REP

Corin France SAS
157 Rue Lavoisier
38330 Montbonnot Saint-Martin
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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

OMNIBotics Bone Morphing® Technology, OMNIBot®, and OMNIBotics™ are trademarks registered by OMNI.

Patents

The OMNIBotics System, OMNI ART™ Knee Application, Instruments, BalanceBot™ and OMNIBot™ are protected by the following patents: US 10,441,437, US 10,321, 904, US 10,383,638, US 10,285,683, US 9,684,768, US 9,421,019, 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, FR 2 856 268, FR 2 852 223, CA 2,954,125, EP 3 273 868 (FR, GB), AU 2016235175. Other patents pending.

Licenses

The OMNIBotics System 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™ Station Instructions for Use	IFU-037	2 hours	Surgeon and OMNI personnel to be trained annually. Hospital staff on installation and as needed.
OMNIBotics Total Hip Application Instructions for Use*	IFU-034	2 hours	Surgeon and OMNI personnel to be trained annually. Hospital staff on installation and as needed.
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 Total Hip System is only cleared for use in the USA

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 OMNIBotics Station in conjunction with either the OMNIBotics Total Knee System or the OMNIBotics Total Hip System (OMNIBotics Total Hip System is only cleared for use in the USA) .

It facilitates routine use of the system and also the initial troubleshooting and maintenance phases.

This document is intended for anyone intended to use the OMNIBotics Station in a surgery. This includes the surgeon user and surgical staff.

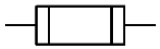
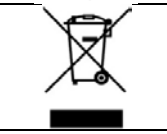
1.2 Scope

This document details instructions for use of the OMNIBotics Station and accessories. This document facilitates set-up of the station and its routine use, as well as basic troubleshooting and maintenance activities. It is intended for any sales representative or hospital staff member that will be assisting in a surgical procedure or providing supervision of the system. These personnel should also be trained on the OMNIBotics software applications and complete any additional training requirements set by OMNI.

Intended Use: The OMNIBotics Station is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures. The OMNIBotics Station is for use solely with OMNIBotics software applications.

1.3 Conventions

	Manufacturer
	Catalogue Reference
	Serial Number
	Date of Manufacture

	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.

1.4 Associated documents

- OMNIBotics Tracker Kit Instructions for Use (IFU-035)
- OMNIBotics Knee System – ART™ Knee Application Instructions for Use (IFU-036)

- OMNI ART and OMNIBot System Instrumentation (IFU-039)
- OMNIBotics BalanceBot Instrumentation (IFU-040)
- OMNIBotics™ Total Hip Application Instructions for Use (IFU-034)
- OMNIBotics CATH Hip Instrumentation Instructions for Use (IFU-035)

1.5 Safety precautions

	**WARNING:** Personnel using the OMNIBotics Station should be trained by a 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:** Always have an appropriate manual instrument set on hand in case of system failure.
	**WARNING:** Before starting an application, check that all instruments and accessories are available for the surgery and that they are the ones listed in the Instructions for Use of the application.
	**WARNING:** The surgeon must be aware that the success of the surgery depends on the surgeon's knowledge and level of experience with the OMNIBotics System. It is the duty of the surgeon to make sure that they understand all relevant technical aspects and regulatory restrictions that apply to the OMNIBotics System, and that he or she receives the proper training from a qualified OMNI Technical Services Representative before using the system.
	**WARNING:** The OMNIBotics Station should **not** be sterilized **under any circumstance**. It should, however, be decontaminated before and after each surgical procedure. For decontamination instructions refer to §3.15
	**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 technical support.

	**WARNING:** Never attempt to disassemble the foot switch to clean the inside of the pedal compartment. This could cause electric shock.
	**WARNING:** Always decontaminate the foot switch after each use. For decontamination instructions refer to §3.15
	**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:** To reduce the risk of electrical hazard never use a multi-outlet power strip to connect the OMNIBotics Station.
	**WARNING:** To reduce the risk of fire hazard do not use the OMNIBotics Station in the presence of flammable anesthetics or other flammable substances.
	**WARNING:** To ensure proper operation all electrical and mechanical maintenance must be performed by an OMNI Technical Services Representative.
	**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 improper use may possibly occur.

	**WARNING:** To avoid electrical shock unplug the OMNIBotics Station from the power supply before replacing a fuse.
	**WARNING:** To avoid performance or safety issues 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 electromechanical device via the equipotential connection, the global system must be compliant with IEC 60601-1.
	**WARNING:** Check before use that the two spare fuses delivered with the system are available. See section 5.2 for fuse replacements.
	**WARNING:** To avoid electric shock, the OMNIBotics Station must be connected only to a supply network with a protective ground.
	**WARNING:** To avoid electrical shock never touch the patient and the contacts on any of the connectors simultaneously.
	**WARNING:** To avoid performance or safety issues Ddo not connect any other units to the enclosure box other than specified components of the OMNIBot 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:** To avoid damage to the system transport should only be undertaken under conditions described in section 3.13

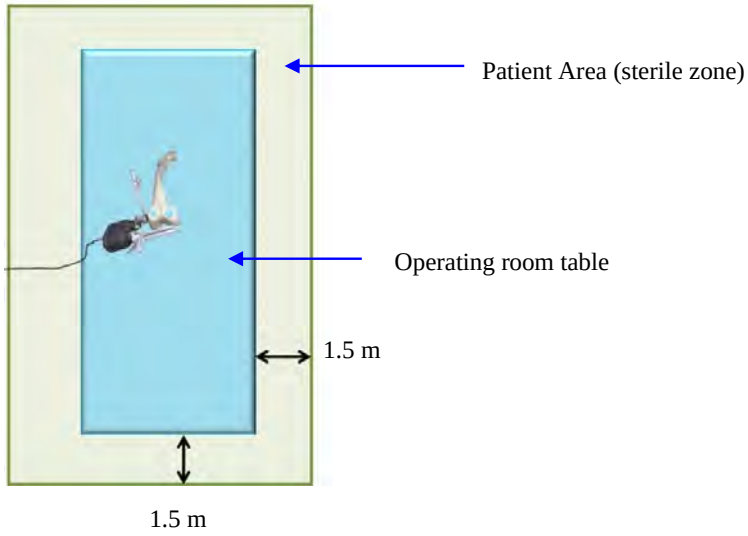
	**WARNING:** To avoid performance or safety issues, any modification to the OMNIBotics system is prohibited.

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

1.6 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 technical support as outlined on page 1. Check that the system is functioning correctly after each time it is transported. To do this, use the diagnostic tools provided by the "Application System". The minimum required tests are to test the localizer, pedal, both touch screens, and OMNIBot (if applicable). For further information, refer to the instructions for use for the "Application System".
	**RECOMMENDATION:** OMNIBotics Station is a tool intended for use by a surgeon. It provides functions that measure, calculate and display specific information about the patient, enabling the surgeon to make decisions. It assists the surgeon in performing optimal surgery, but it must, in no way whatsoever, be used as an automatic system. Suggestions made by the software as a result of data collection, must be regarded from an informed critical viewpoint. As with all computer systems, each gesture must be performed with consideration of the possible errors. This system can only be used by a surgeon fully trained in the conventional operative technique and computer assisted technique. The benefits provided by the system are intended to limit the number and seriousness of failures in relation to a similar procedure performed without OMNIBotics Station assistance.
	**RECOMMENDATION:** Care should be taken when cleaning the localizer due to the delicate nature of the infra-red lenses. Refer to section 3.3 for further information.

	**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 pressing the power switch on the Enclosure Box and then pressing the Power Button on the laptop.
	**RECOMMENDATION:** The OMNIBotics Station must only be powered off by first shutting down the software and then pressing the main power switch on the enclosure.
	**RECOMMENDATION:** In order to avoid any issues while saving the navigation data, please use the blank USB Drive provided in the Universal Tracker Kit.
	**RECOMMENDATION:** Assign a dedicated USB Drive to the station for the storing of case reports.
	**RECOMMENDATION:** Wait at least 10 seconds after turning off the station before restarting.

⚠	**RECOMMENDATION:** The ventilation on the Enclosure Box must not be covered or obstructed.
⚠	**RECOMMENDATION:** All electrical medical equipment in the Patient Area (sterile zone) must be connected together with a potential equalization cable 

2 General Specifications

2.1 OMNIBotics Station Specifications

OMNIBotics™ Station	
Packed dimensions	
Case 1 – Laptop, camera, OMNIBot motor	31 x 20 x 12 in (width x depth x height)
Case 2 – Enclosure, Monitor, Foot switch	34 x 24 x 21 in
Case 3 – Wheelbase, Drawer	33 x 24 x 19 in
Case 4 – Mast, Camera Arm, Docking Station	65 x 23 x 15 in
Unpacked dimensions	20 x 20 x 78 in (width x depth x height)
Weight	150 lbs (approximate)
Environmental conditions for use	Temperature 15 to 30 ° Celsius, Humidity 30 to 75 %, Pressure 70 to 106 kPA
Environmental conditions for storage and transport	Temperature -10 to 50° Celsius, Humidity 30 to 90%, Pressure 70 to 106 kPa
Types of interface	Video: VGA (for additional display screen) Communications: Serial, USB (3.0 x 1, 2.0 x 3) (for writing reports onto a USB drive)
Major power supply depending on the country	AC 100-240 50-60 Hz 8-2A
Length of power cable	5m
Protection	IP20
Foot Switch	
Dimensions	11.8 x 8 x 2 in (width x depth x height)
Weight	5.2 lbs
Protection	IP68
Length of connection cable to the station	5m

2.2 Enclosure Specifications

Enclosure Box	
Dimensions	13 x 16.7 x 9.5 in (width x depth x height)
Weight	20 lbs (approximately)
Interface types	Communication: USB x 2 OMNIBot Motor Unit: Fisher connection BalanceBot Motor Unit: Fisher connection
Protection	IP20

2.3 Electromagnetic Environmental Conditions

Guidance and manufacturer's declaration – electromagnetic emissions

The OMNIBotics Station and both BalanceBot and OMNIBot options (for use with Knee application only) are intended for use in the electromagnetic environment specified below. The customer or user of the OMNIBotics Station and OMNIBot optionshould ensure that the devices are used in such an environment.

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The OMNIBotics Station and both BalanceBot and OMNIBot options use RF energy only for their internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The OMNIBotics Station and both BalanceBot and OMNIBot options are suitable for use in all establishments, excluding domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	A	
Voltage Fluctuations / Flicker Emissions IEC 61000-3-3	A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The OMNIBotics Station and both BalanceBot and OMNIBot options are intended for use in the electromagnetic environment specified below. The customer or user of the OMNIBotics Station and both BalanceBot and OMNIBot options should ensure that the devices are used in such an environment.			
Immunity test	**IEC60601 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 between phases ±2 kV between phase and ground	±1 kV between phases ±2 kV between phase and ground	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 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OMNIBotics Station and both BalanceBot and OMNIBot options requires continued operation during power mains interruptions, it is recommended that the OMNIBotics Station be powered from an uninterruptible power source.
Power frequency (50/60Hz) 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: UT is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The OMNIBotics Station and both BalanceBot and OMNIBot options are intended for use in the electromagnetic environment specified below. The customer or the user of the OMNIBotics Station and both BalanceBot and OMNIBot options should ensure that the devices are used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the OMNIBotics Station and both BalanceBot and OMNIBot options, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.2 √P d = 1.2 √P 80 MHz to 800 MHz d = 2.3 √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: 
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 OMNIBot option is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the OMNIBot. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the OMNIBoticsTM Station Station and both BalanceBot and OMNIBot

The OMNIBotics Station and both BalanceBot and OMNIBot options are intended for use in an environment in which radiated RF disturbances are controlled. The customer or user of the OMNIBotics Station and both BalanceBot and OMNIBot options can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the OMNIBotics Station and both BalanceBot and OMNIBot options 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 à 80 MHz $d = 1.2 \sqrt{P}$	80 MHz à 800 MHz $d = 1.2 \sqrt{P}$	800 MHz à 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 determined 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.

Note:

The OMNIBotics Station and both BalanceBot and OMNIBot options are ELECTROMEDICAL DEVICES that need special precautions regarding EMC and need to be installed and put into service according to EMC information provided in this document.
The portable and mobile RF communication equipment can affect MEDICAL ELECTRICAL EQUIPMENT.
The use of cables other than those specified may result in increased EMISSIONS or decreased IMMUNITY of the OMNIBotics Station and both BalanceBot and OMNIBot options. Therefore, it is strictly forbidden to use other cables.

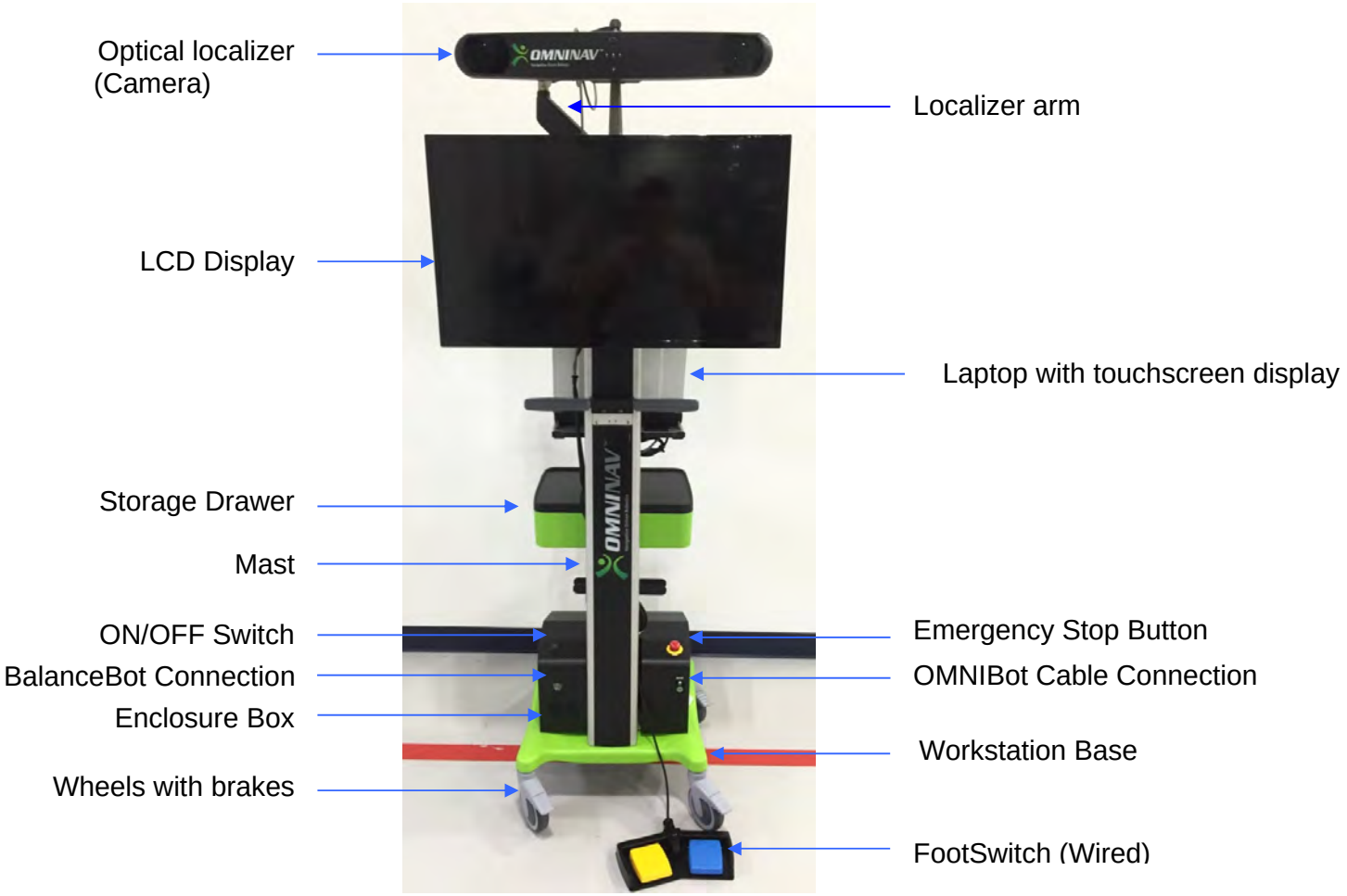
The devices should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the devices should be observed to verify normal operation in the configuration in which it will be used.

2.4 OMNIBotics Station Presentation

The OMNIBotics Station is a computer-assisted surgical device incorporating:

- A mechanical structure, consisting of a Mast attached to a Base (with wheels);
- Electrical and electronic equipment : A LCD display, a laptop, and an optical localizer;
- Ergonomic exterior interfaces: 3-button foot switch and laptop equipped with a touchscreen display;
- MMI software (man/machine interface)

The OMNIBotics Station is the basic element ("Hardware") which can run different software applications. The OMNIBotics System is intended to assist the surgeon during orthopedic surgery by making measurements based on anatomical information input by the surgeon.

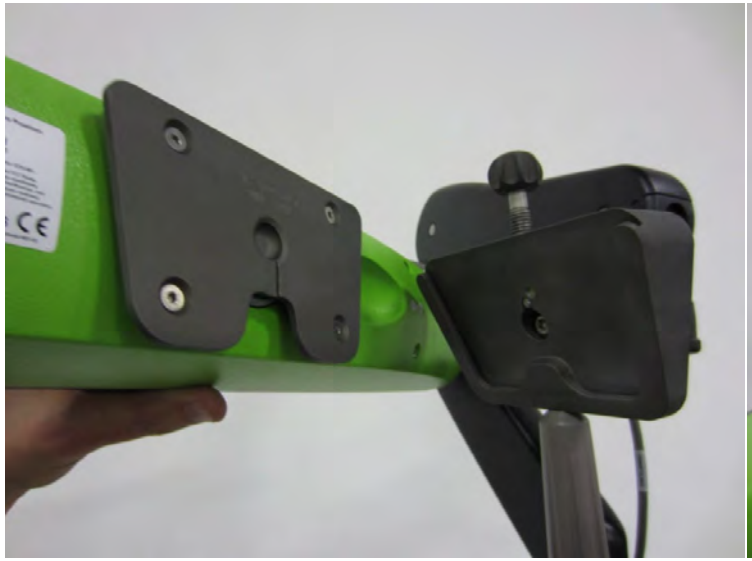


OMNIBotics Station - Front view

3 Using the OMNIBotics Station

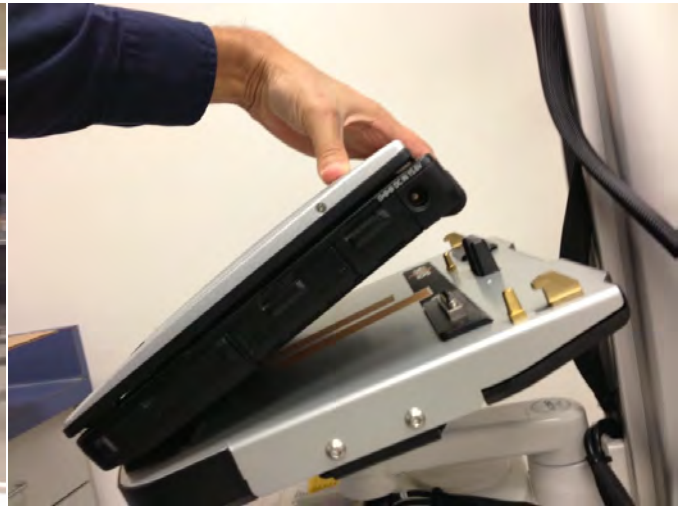
3.1 Camera and Laptop Attachment

1. Open the shipping case containing the camera, laptop, and motor unit (Knee application only). Remove all three and set the motor unit aside for use with the OMNIBot option.
2. Install the camera by sliding the mounting attachment on the back of the camera down into the groove of the mounting bracket found on the camera arm. Tighten the thumb screw on top of the mounting bracket to secure the camera in place. Once secure, plug the camera cable into the back of the camera by aligning the red dots.



	ATTENTION: • Pull connections apart by gripping the connector. Do not pull them apart by tugging on the cable as this can damage the connecting cable and connector pins. • Do not leave cable connectors where they will get damaged, particularly on the floor, where they can easily be stepped on or rolled over by heavy equipment. • Do not put heavy objects on cables or cable connectors. • Never force a connection. • On push-pull connectors, make sure that the red dots on the connectors are lined up with each other before connection (the double keys of the connector should be aligned).
	RECOMMENDATION: It is good practice to disconnect mains power before connecting or disconnecting cables. Failure to do so may cause damage to the equipment.

3. Install the laptop onto the Havis docking station.
    a. Ensure Docking Station is unlocked by depressing the button in Barrel Lock



    b. With the rear of computer elevated, insert the front of the computer into the docking station ensuring the computer's handle extends under the front bracket. Center the computer in the docking station when lowering and ensure the front feet of computer are aligned with the plastic guides on the docking station.

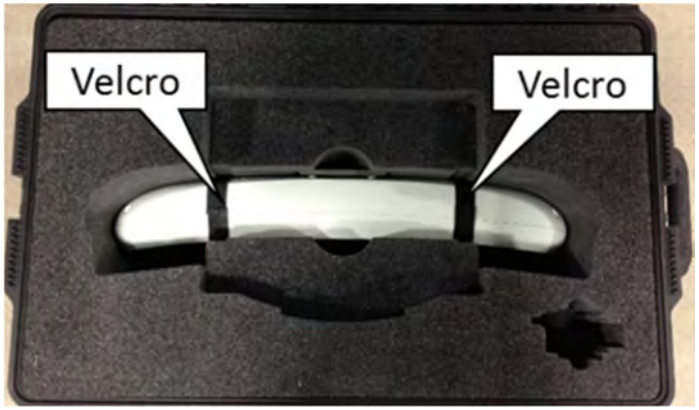
    c. Lower the back of computer onto the docking station, ensuring the computer properly aligns with both Locator Pins in Docking Station. With the computer seated on docking station, apply light downward pressure to the rear of the computer and pull the Front Latching Handle forward until latched.

d. If you are leaving the computer unattended at any time, secure it to the Docking Station with the supplied key.

3.2 Camera and Laptop Disassembly

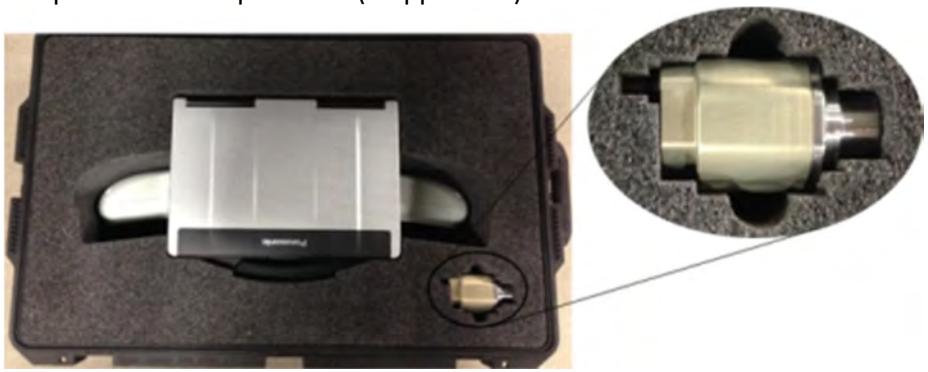
1. Ensure required shipping case for camera, laptop, and motor unit is available and open.
2. Ensure all components have been properly cleaned and disinfected before transport.

3. Unplug camera cord.
4. Unscrew the knob on top of the camera mount and slide camera out of the mount.
5. Undo 2X orange Velcro straps and place camera in camera pocket.
6. Secure camera with 2X orange Velcro straps.



6. Depress Barrel Lock to unlatch the Docking Station from the computer. Once unlatched grip both sides of laptop and carefully lift out of the Docking Station, rear end first.
7. Place laptop in the laptop pocket of the shipping case so handle is facing away from the hinge of the case.

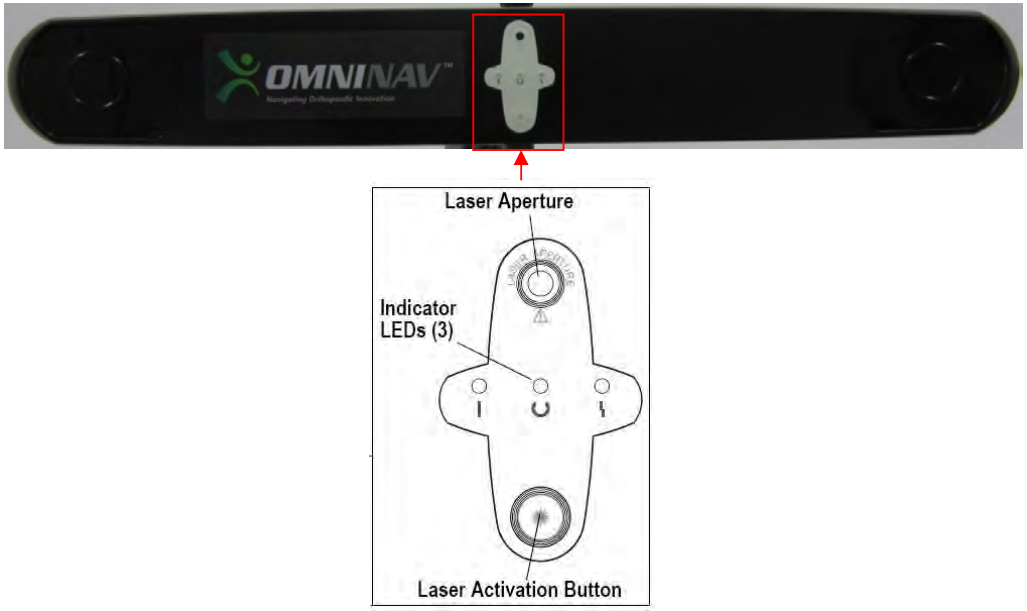
8. If transporting motor unit ensure the OMNIBot cable has been unplugged and the enclosure has been removed.
9. Place motor unit in motor unit pocket of transport case (if applicable).



10. Close lid of transport case and secure with 5X external latches.

	RECOMMENDATION: The camera and laptop are intended to be transported in their shipping cases only. Carrying them by hand, unprotected, should be avoided.

3.3 Camera Information



Laser activation Button: Press the button to activate the laser. The laser will only remain lit while this button is pressed.

Power LED (Green)	Status LED (Green)	Error LED (Amber)	Camera Status
Flashing	(Any state)	(Any state)	The camera is warming up. The power LED will stop flashing and light steady green when camera is ready for use.
Solid	Solid	Off	The camera is ready for use.
Solid	Solid	Flashing	The camera must be returned to OMNI.
Solid or off	Solid	Solid	The camera must be returned to OMNI.

Solid	Off	Solid	The camera must be returned to OMNI.

The laser can be activated whether the localizer is powered on or off. When the localizer is switched on, the laser draws its power from the system. When the system is not switched on, the laser derives its power from an internal battery. If the laser battery in your system needs to be replaced, contact technical support.

Laser Specifications and Standards

The positioning laser is a class 2 laser, with a wavelength of 635 nm and a maximum output of 1 mW. The localizer containing a positioning laser conforms to the followings standards:

- ANSI Z136.1 (2000)
- IEC 60825-1 (2001)
- FDA/CDRH 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No. 50, dated July 26, 2001

The label shown below is located on the back of the localizer and lists the laser specifications and safety information.

ATTENTION: Use only 70% isopropanol and a lens cleaning solution formulated for multi-coated lenses (for example, AR66) to clean the Position Sensor. Other fluids may cause damage to the illuminator filters. Do not use any paper products for cleaning. Paper products may cause scratches on the illuminator filters.

RECOMMENDATION: Regularly inspect the Position Sensor for cleanliness. The Position Sensor, particularly the illuminator filters and lenses, should be cleaned only when necessary. The frequency of cleaning must be determined by the user. This may include "in-use" cleaning.

Camera Cleaning Procedure

1. Remove dust from each illuminator filter and lens, using a photographic lens duster (brush). Gently wipe the surface in one direction only, by pulling the brush across the surface.

2. Gently wipe the illuminator filters and lenses with disinfectant wipes containing 70% isopropanol. Continue cleaning the remainder of the Position Sensor, taking care not to wipe debris from the Position Sensor case onto the illuminator filters or lenses. Avoid prolonged contact between the wipes and the Position Sensor.

3. Clean the illuminator filters and lenses, using a commercial lens cleaning solution formulated for multi-coated lenses (for example, AR66) and a clean knitted microfibre optical cleaning cloth (for example, Hitecloth). Avoid prolonged contact between the lens cleaner and the illuminator filters and lenses.

3.4 Laptop Information

	**ATTENTION:** Lithium Battery! This computer contains a lithium battery to enable the date, time, and other data to be stored. The battery should only be exchanged by authorized service personnel or the manufacturer. A risk of explosion from incorrect installation or misapplication may possibly occur.
	**ATTENTION:** Do not place any electronic or magnetic objects on or near the laptop, as this may trigger the lid sensor and cause the laptop screen to temporarily go dark. Pay particular attention not to place a smartphone on the laptop.
	**ATTENTION:** Do not use the Fn-F3 shortcut on the laptop keyboard. This will result in a change to the system display and will require a restart of the system.

	**RECOMMENDATION:** When transporting, carrying, or shipping the computer, make sure the computer is turned off. Remove all external devices, cables and other protruding objects. Do not drop or hit the computer against solid objects. Do not leave the display open. Do not grip the display part.
	**RECOMMENDATION:** Do not put anything (e.g. a piece of paper) between the display and the keyboard.

	**RECOMMENDATION:** If transporting with your belongings on an airplane, be sure to take it with you as a carry-on and never put it in your checked luggage.
	**RECOMMENDATION:** The touch pad is designed to be used by finger-tip. Do not place any object on its surface and do not press down strongly with sharp-pointed or hard objects that may leave marks (e.g. nails, pencils and ball point pens). Use only the included stylus to touch the touchscreen.
	**RECOMMENDATION:** Avoid any harmful substances such as oil from getting into the touch pad. The cursor may not work correctly.
	**RECOMMENDATION:** This computer is designed to minimize shock to parts such as the LCD and the hard disk drive and equipped with a drip-proof keyboard, but no warranty is provided against any trouble caused by shock. Be extremely careful when handling the computer.

3.5 Positioning in the Operating Theater

Refer to the appropriate Application IFU for station postioning with respect to the patient and OR table.

Positioning in the operating theatre is carried out simply by holding the two mast handles and then moving the station on its wheels. The OMNIBotics Station base features two brake casters and two steering casters (wheels). Each caster has a lock lever which is depressed to activate, and can be deactivated by lifting back up. The steering casters (dark grey lock levers) can be locked in line with base, making straight steering easier. The brake casters (light gray lock lever) can be locked to prevent cart from rolling easily. Both brake casters must be locked to fully prevent the cart from rolling.

The position of the OMNIBotics Station with reference to the patient and the equipment present will depend on the surgical procedure being performed. For more information on the positioning of the station, refer to the instructions for use manual for the relevant software application.

In order to position the camera in the optimal position, it is possible to use the camera laser finder which can be accessed by pressing the button located on the front of the camera.

The monitor can be adjusted in two directions to achieve an optimal viewing angle. To rotate the monitor side to side simply push or pull gently on the sides of the monitor until desired position is achieved. To tilt the monitor up or down loosen the black knob located on top of the monitor mount and push or pull gently on the top and bottom of the monitor. When desired position is achieved, tighten black knob.

Tilting the monitor

Moving the monitor side to side

3.6 Connecting the Power Supply and Switching On

Do not attempt to use the device without connecting the power cable. Remove the power cable from the drawer and connect it to the Enclosure Box. Plug the cable into an electrical outlet.

Set the main switch on the top of the enclosure box to position **I**. The system will initialize itself: the localizer will "bleep" twice and two green lights should appear, one constant and the second blinking and then constant. The orange LED on the main monitor will turn on.

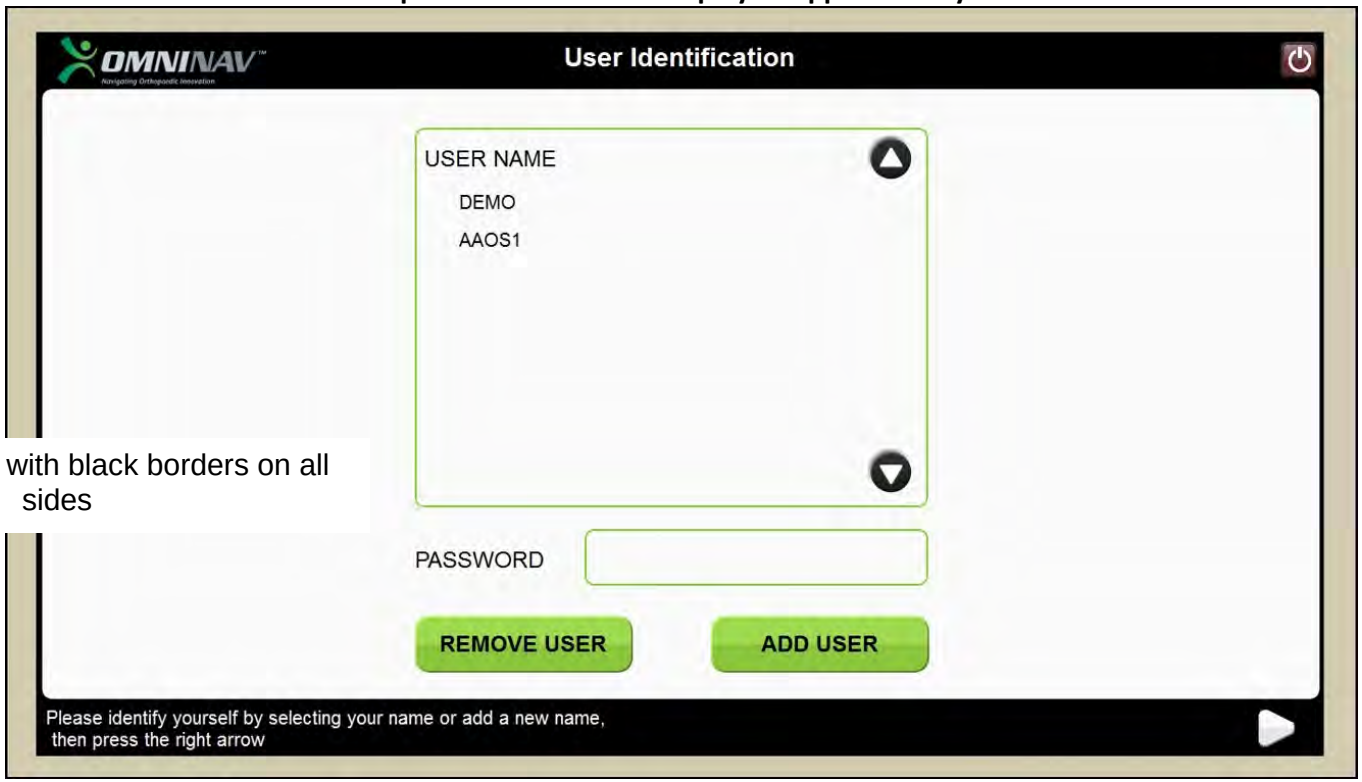
If the green motor unit power indicator light does not turn on, check that the OMNIBotics Station is correctly connected to the power supply and check the position of the Emergency Stop. The Emergency Stop button can be reset by rotating the button clockwise. If the problem persists, contact technical support.

The laptop must be powered on separate to the Main Power of the OMNIBotics Station. Once the Main Power is switched on turn the power on to the laptop. This will take you to the Start screen of the Application System.

⚠	**RECOMMENDATION:** You should allow a camera warm up time of approximately 2 minutes. The Power LED will stop flashing and light steady green when the camera is ready for use.

When powered on correctly the start screen should appear as shown below. If the resolution appears different, consult the screen resolution re-set procedure in the troubleshooting section of this document (Section 4) and/or contact technical support.

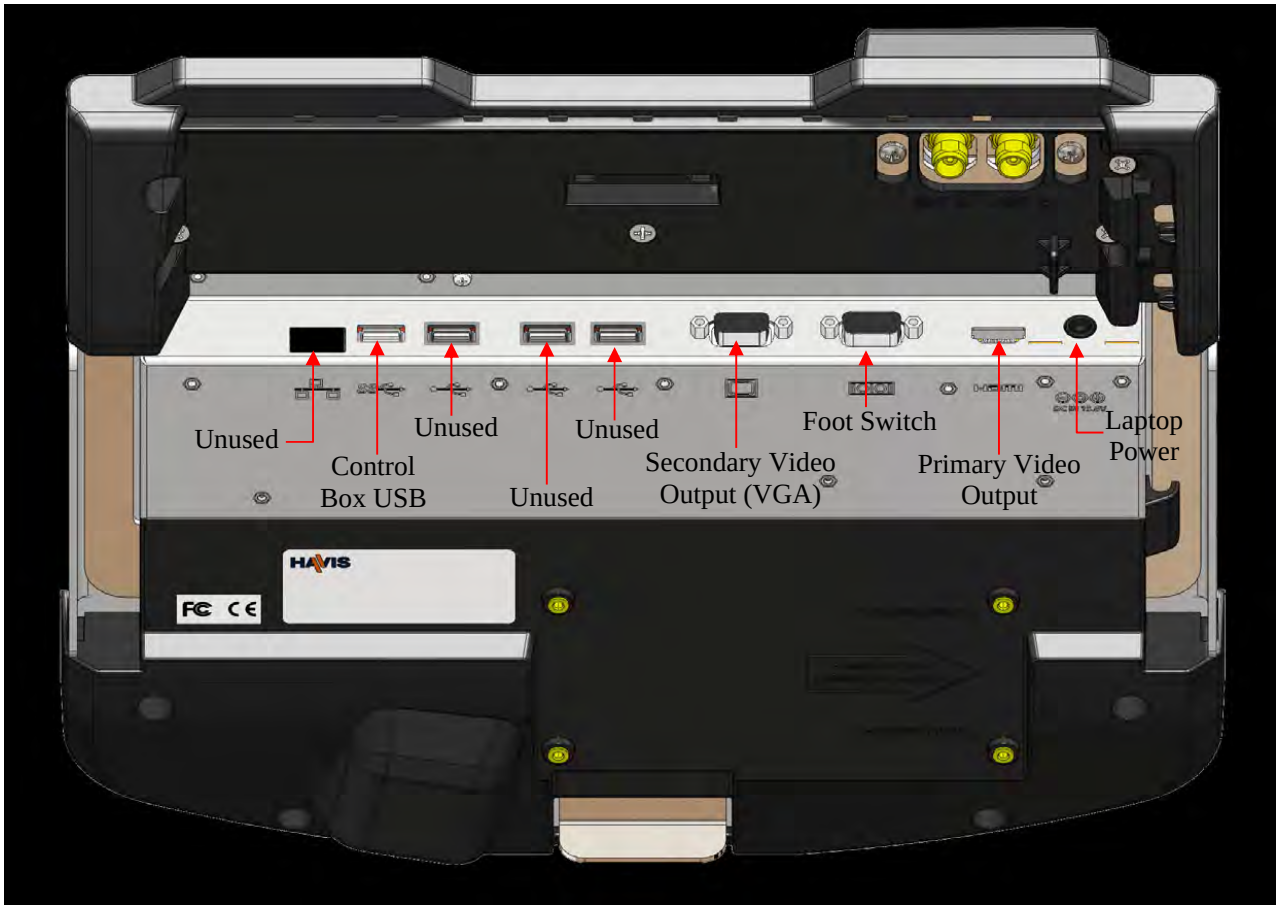
Example of correct screen display of Application System



Offset to the left with black borders on all sides

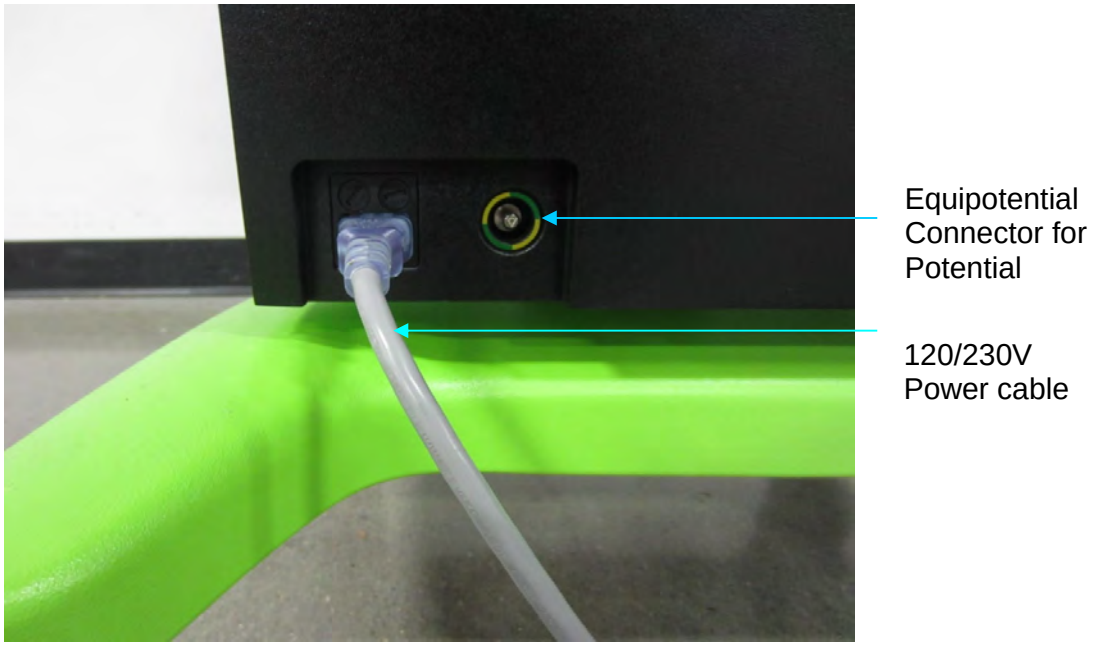
Display fills entire screen with black trim fully showing on top and bottom.
No cropping or black bars present.

3.7 Laptop Docking Station Connections



3.8 Enclosure Box Connections

Enclosure Box connections – Front View



Enclosure Box connections – Back View

3.9 Foot Switch Operation

A wired foot switch comes standard and is stored on top of the drawer as shown below. Pressing the blue and yellow pedals will make you move forward and back in the protocol.

A protective bag around the foot switch during use is recommended to keep the device clean.

3.10 Application System

Overview

The **APPLICATION SYSTEM** is an operating system environment dedicated to the OMNIBotics Station.

With the **APPLICATION SYSTEM** it is possible to:

- Start an application
- Shut down the OMNIBotics Station.
- Save the last Surgical Navigation Reports for an Application
    - o One last, 50 last, or all reports on a USB key
- Test and verify the functional state of the Navigation System: calibration of the tactile screen, test the optical camera, foot switch, OMNIBot and BalanceBot.
- Recalibrate the laptop touchscreen screen.

NOTE: Surgical Navigation Reports stored onto the system and accessible via the Application System are anonymous and contain no protected health information (PHI).

Starting an Application

Once the OMNIBotics Station is started, it is necessary to identify user to access main page of the Application system:

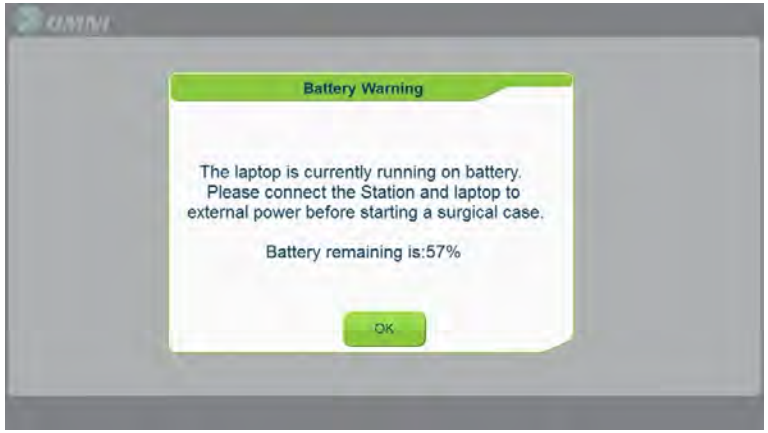
1. Select name of the user in the list.
2. Type user password – see NOTES below.
3. Log in with the right arrow.

If user name is not yet registered on the station, then press “ADD USER” and follow indications on screen.

It is also possible to suppress an existing user account by pressing “REMOVE USER”. The user password will be required.

NOTES:

- Password must be a minimum of 6 characters using uppercase letters, lowercase letters and numbers. It must not contain the user name.
- Password is mandatory to access the system.
- After 6 consecutive unsuccessful login attempts, the user account will be automatically locked. For unlocking your user account you must contact OMNI Customer Service.

	If the OMNIBotics Station is not connected to external power supply or if the laptop is not correctly docked onto the Station, then the Application System will display a “Battery Warning” message. It is then highly recommended to remedy to the issue before starting a clinical application. NOTE: the same “Battery Warning” will pop-up again if a clinical application (Knee or Hip) is launched with laptop still running on battery.
	Once the user is identified then Application System main page is displayed. It lists all applications installed on the system. 1. Choose the language you wish to use for the Application System and applications*. 2. Select the application to start. 3. Start the selected application with the right arrow. The application will then automatically start with same language as Application system. *In Application System 2.3, only English and French are available.

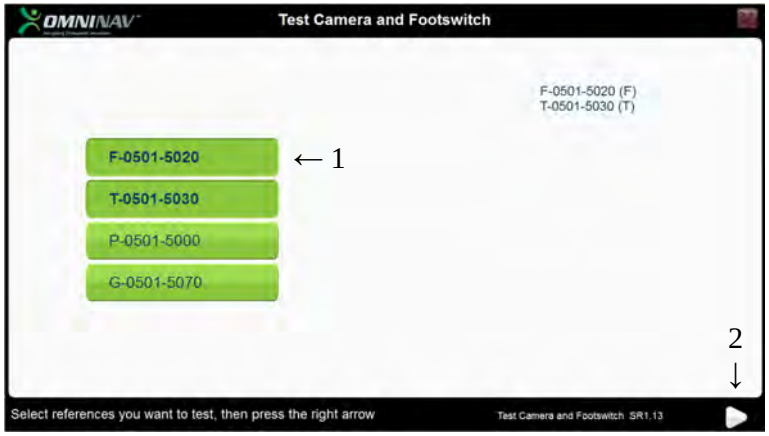
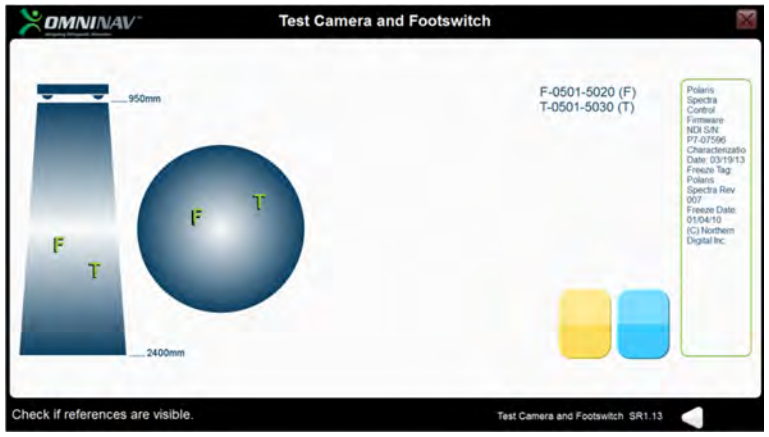
Verifying the Calibration of Laptop Touchscreen

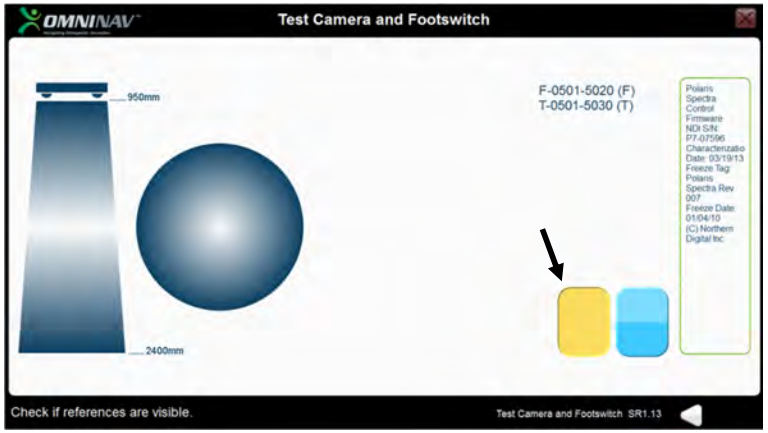
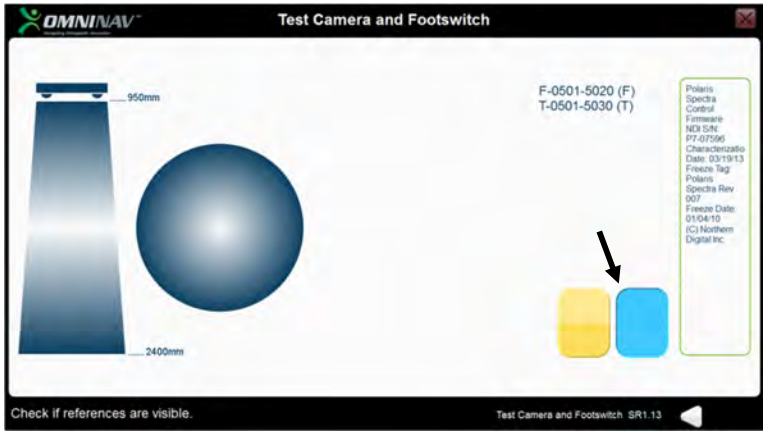
When touching the screen, a pointer should appear under your finger tip. If this is not the case, proceed to the Screen Calibration. See Screen Calibration section below.

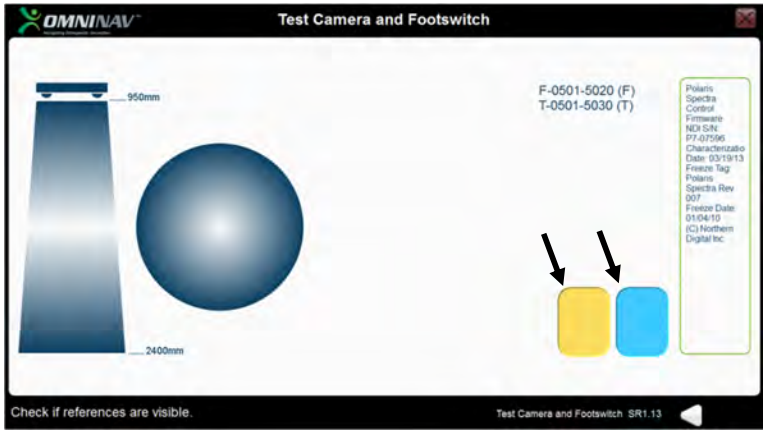
Using the Application System Tools

Test the camera and foot switch

With this tool, it is possible to check if the camera and the foot switch are functioning correctly. You can also check the visibility of the references to the Camera.

	1. Click on the references that you wish to test. 2. Proceed with the right arrow to access the test screen.
	Once the camera is connected, show a reference to the camera and check its visibility on the screen.

	Check that the yellow pedal is functioning correctly by pressing it with your foot. The yellow foot switch icon on the screen will be highlighted.
	Check that the blue pedal is functioning correctly by pressing it with your foot. The blue foot switch icon on the screen will be highlighted.

	Check that the black button is functioning correctly by pressing it with your foot. Both the blue and yellow foot switch icons on the screen will be highlighted.

Screen calibration

This tool allows you to calibrate the touch screen of the OMNIBotic™ Station Laptop

	After starting Screen Calibration tool, a second screen will appear inviting you to select the screen you want to calibrate. 1. Select “Screen Calibration Laptop”. 2. Proceed with the right arrow to access the corresponding calibration tool. Note: In this version of the station the “Screen Calibration External Monitor” is not available.

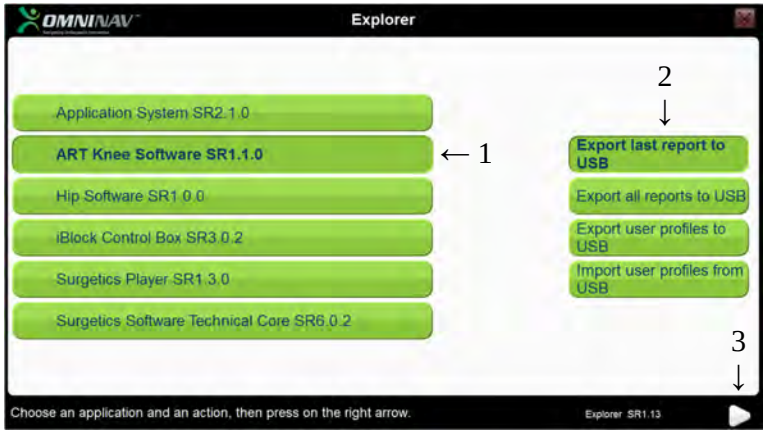
Note: If you cannot use the touch screens to start this tool because the screen is completely decalibrated, you can start the calibration by using the track pad of the station Laptop.

Laptop screen calibration	
	Press briefly on the black cross **on the Laptop screen** with your finger. Repeat this step for the other black crosses as they appear on the screen.
	When done, press the 'yes' button in the following dialog box. NOTE: If this is not possible, press "Esc" on the Laptop keyboard and restart Laptop screen calibration

Explorer tool

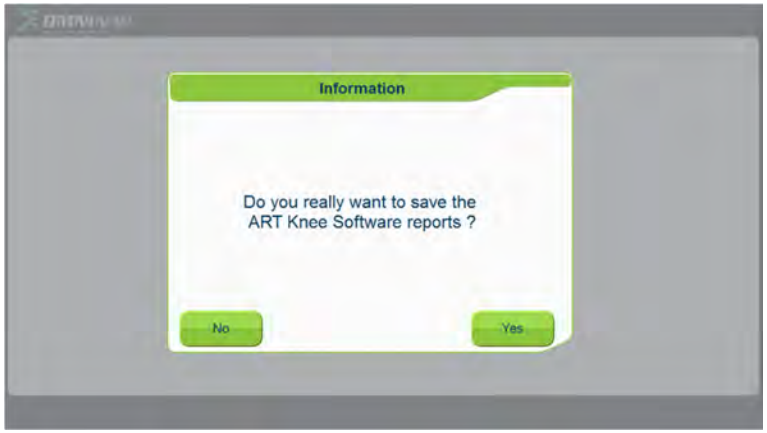
With this tool, it is possible:

- To copy the reports for an application on a USB key.

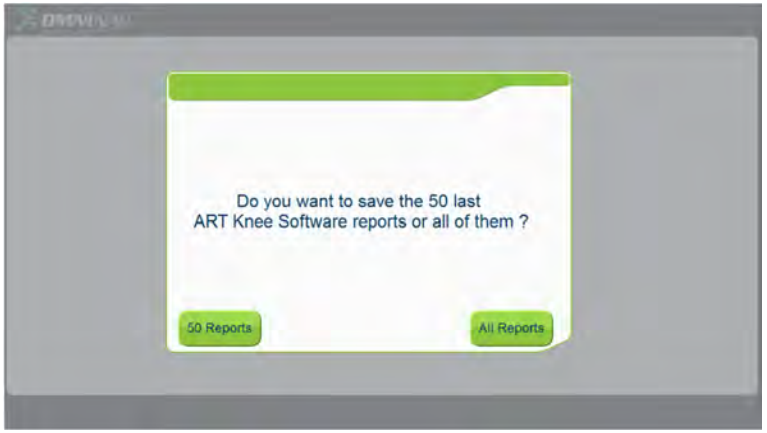


1. Select the application.
2. Select the action to perform (Export last Report or all Reports)
3. Proceed with the right arrow.

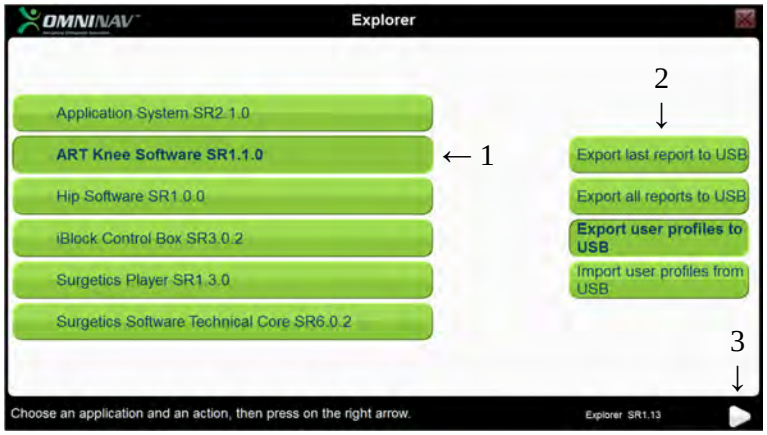
Export last report on USB



After inserting a USB key in one of the Laptop USB ports, press 'Yes' to proceed.

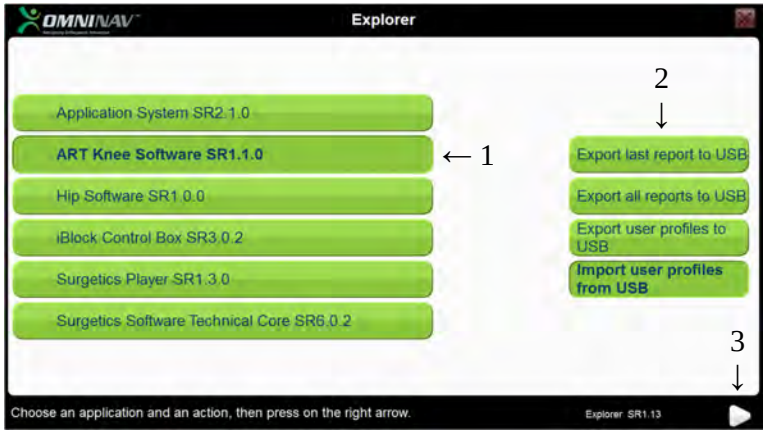
Export all reports on USB	
	After inserting a USB key in one of the Laptop USB ports, press '50 Reports' or 'All Reports' to proceed.

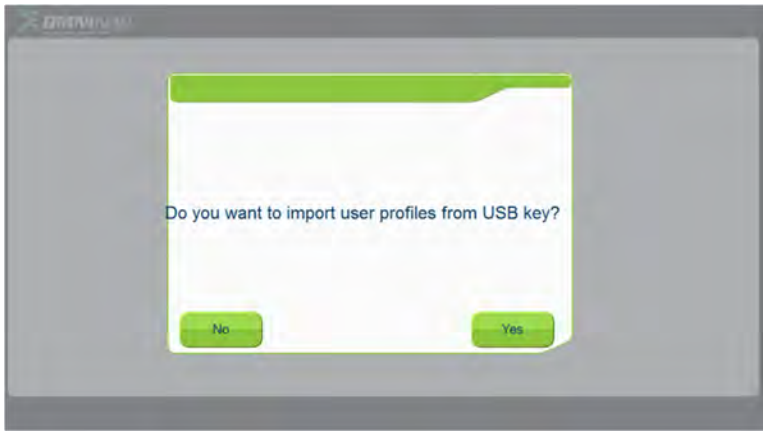
- To export the user profiles for an application to a USB key.

	1. Select the application. 2. Select the action to perform (Export user profiles to USB) 3. Proceed with the right arrow. NOTE: Only profiles for the identified user and the selected application will be exported. If needed, repeat operation for each application and each user.

Export user profile to USB	
	After inserting a USB Drive in one of the Laptop USB ports, press 'Yes' to proceed.

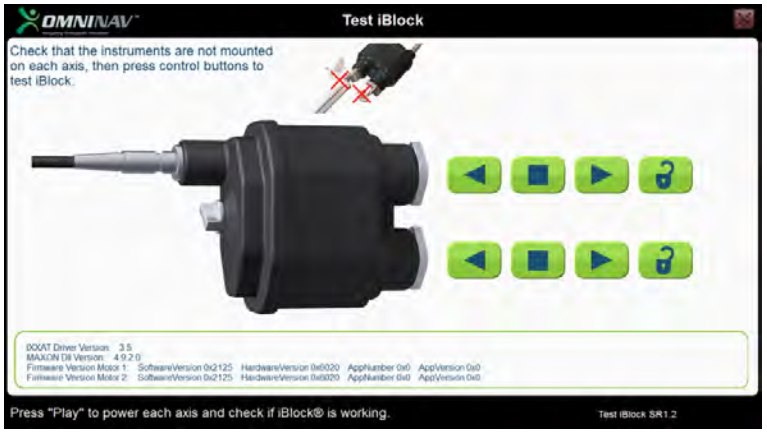
- To import the user profiles for an application from a USB key.

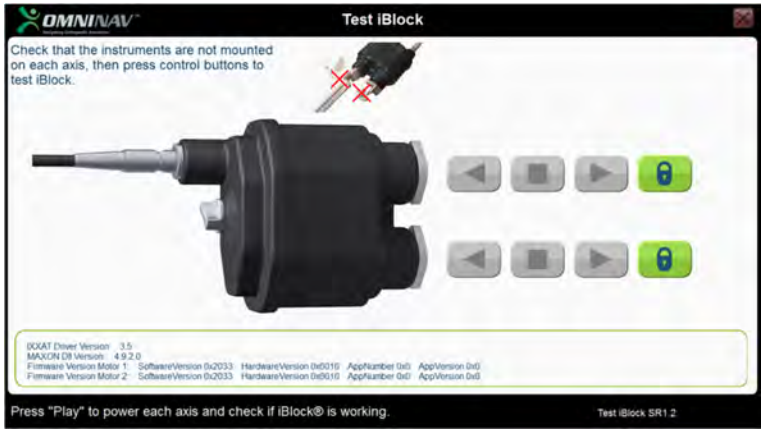
	1. Select the application. 2. Select the action to perform (Import user profiles from USB) 3. Proceed with the right arrow. NOTE: Only profiles for the identified user and the selected application will be imported. If needed, repeat operation for each application and each user.

Import user profile from USB	
	After inserting a USB drive in one of the Laptop USB ports, press 'Yes' to proceed.

<u>Test the OMNIBot (for ART Knee Application)</u>

This tool allows you to verify that the OMNIBot is functioning correctly. Connect the OMNIBot to the Enclosure Box of the OMNIBotics Station. Verify that the instruments are not mounted on the OMNIBot axes before starting the tool.

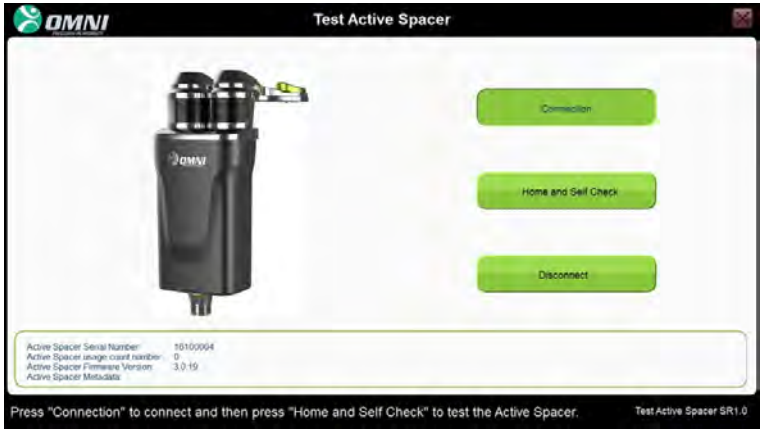
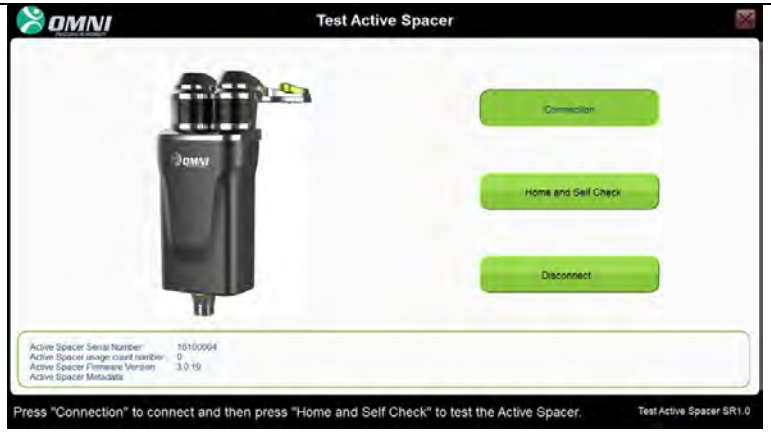
	The  button will turn the corresponding motor axis in one direction. The  button will turn the corresponding motor axis in the opposite direction. The  button will stop the corresponding motor axis from turning. The  button will unlock the corresponding motor axis rendering it free to rotate by hand.

	The motor control buttons are not accessible when the axes are unlocked. The  button will lock the motors and turn the motor control buttons back on.

<u>Test the BalanceBot (for ART Knee Application)</u>

This tool allows you to verify that the BalanceBot is functioning correctly. Connect the BalanceBot to the Enclosure Box of the OMNIBotics Station.

	Click "Connection" to connect the BalanceBot and wait for the "BalanceBot Connected" status message then click "OK" 

	Once the BalanceBot is connected one can read the following information from the ActiveSpacer embeded memory (EEPROM): • Serial Number • Usage Count Number • Firmware Version • Calibration information (Metadata)
	Click “Home and Self Check” to proceed with a full BalanceBot verifications and wait for the “BalanceBot passed Self Check” status message then click “OK” 

Logging Off

	Once all applications are closed log off with the left arrow.

3.11 Shut Down and Storage

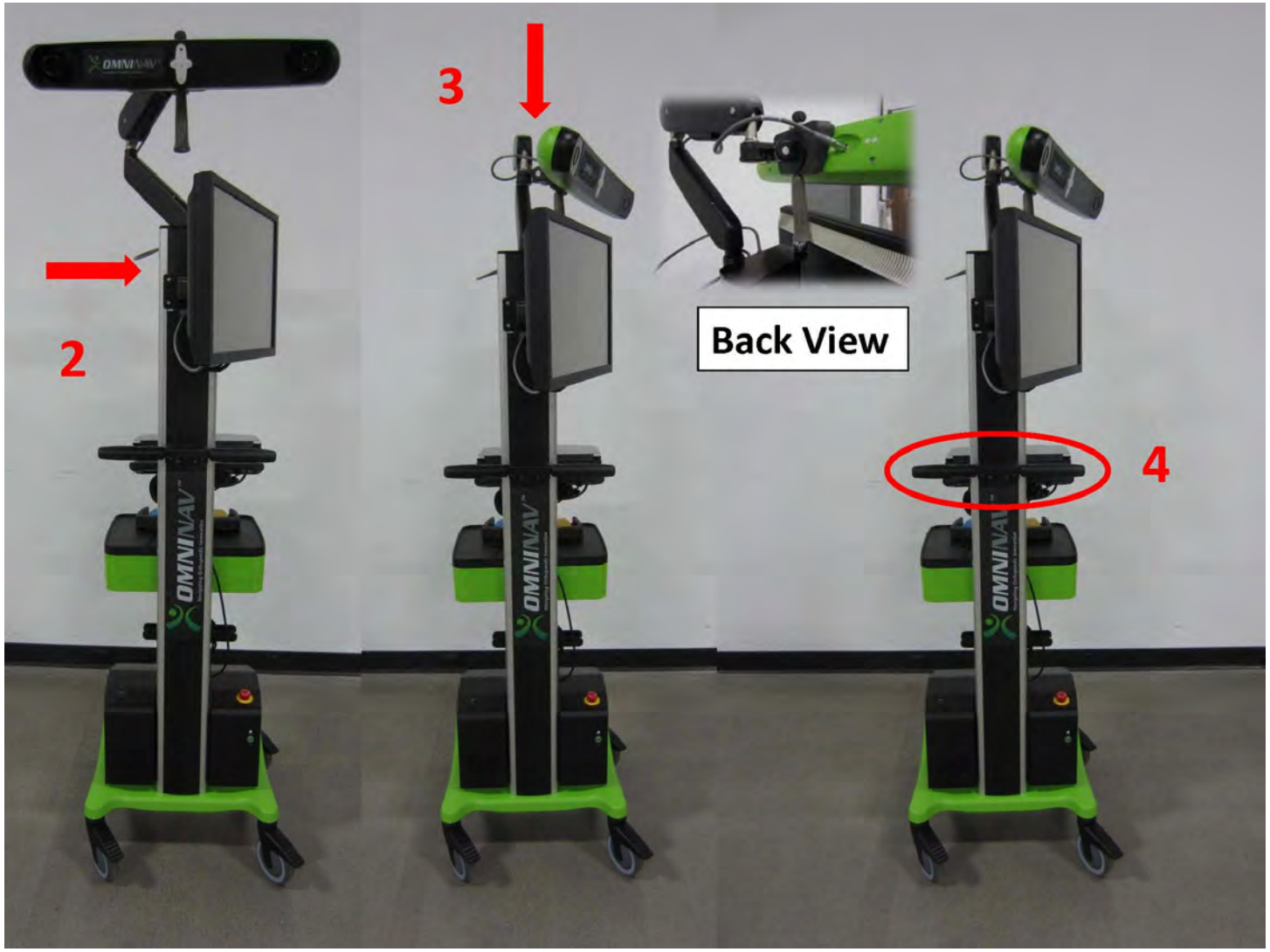
1. Exit the "Application System" by clicking on the icon  at the top right of the screen.
2. Wait for a few seconds until the screen turns black.
3. Switch the Stop/Start switch to **0.**
4. Disconnect the power cable from the electric supply and enclosure box.
5. Coil the power cable and put it in the drawer.
6. Clean and decontaminate the station (see section 3.14).
7. Coil the foot switch cable in the cord wrap and place the foot switch on the drawer.
8. Unlock the wheels and place in transport position (see section below) to move to storage area.

The OMNIBotics Station may then be moved to be stored.

When the OMNIBotics Station is not in use in the operating theatre it must be stored in a room which meets the environmental characteristics described in Section 2. The OMNIBotics Station must never be stored in places where staff or equipment pass frequently in order to avoid damage to the screen or localizer.

3.12 Transportation Instructions

1. Before preparing the unit for transport, ensure the unit is properly shut down and the cables and foot switch are properly stowed per instructions outlined in section 3.12.
2. Rotate the touchscreen LCD Display so it is facing to the right of the station.
3. With the camera arm facing straight back, rotate the camera to the right and lower it so that the camera handle magnetically engages with the dome on top of the mast cap.
4. Wheel station to the necessary location using 2X Handles.


2
3
Back View
4

3.13 Decontamination of the OMNIBotics Station

The OMNIBotics Station must be decontaminated each time before and after installation or use in the operating theatre. Use a decontamination product to wipe down the entire exterior of the OMNIBotics Station, including the foot switch. DO NOT wipe the camera lenses directly as these surfaces are very sensitive.

When decontaminating the OMNIBotics Station

- Decontaminate with a soft cloth moistened with a quaternary ammonium solution (such as Morning Mist Neutral Disinfectant)
- Do not use solvents or detergents.

4 Troubleshooting

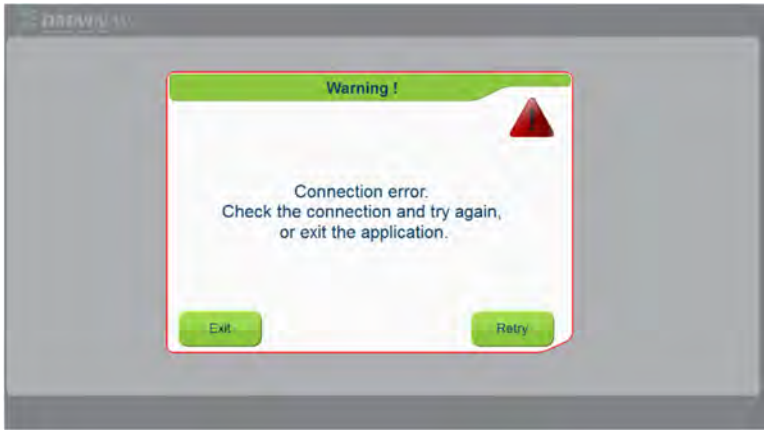
Problem	Possible Cause / Suggested Action
The OMNIBotics Station does not start when it is switched on.	➢ Verify that the electrical outlet is in working order. ➢ If the camera LED indicators do not illuminate as well, a fuse may be blown. Please call technical support for assistance. ➢ If the LEDs on the camera or the ON/OFF button are lit try launching the laptop by pressing the power button. If the laptop does not turn on the BIOS parameters may have been changed and/or the BIOS battery may need to be replaced. Please call technical support.
During the procedure the laptop freezes or locks up and becomes unresponsive.	➢ This is most likely a Windows-based error. However, sometimes the software can become unresponsive for a period of time so wait a few minutes before you turn the laptop off. If the laptop is frozen and cannot recover you will be forced to shut the laptop down. All data from your procedure will have been lost. If resections have not been made you may start a new procedure from the beginning. If any resections have been made, please revert to conventional surgical instruments for the remainder of your resections.
The foot switch is not responding.	➢ Check that the pedal is correctly connected to the back of the docking station. If the connections appear ok then there may be a mechanical problem that needs repair. Please use the touchscreen controls for the remainder of the case and call technical support to arrange a repair or replacement.
An error message appears at the start of the application indicating the camera is not connected properly.	➢ Check that the camera connection plug is inserted properly into the back of the camera. Once checked and/or replugged, wait at least 10 seconds before you try to reconnect. If the connections appear ok, try to restart the system. If problems persist call technical support for assistance.
Cannot advance to the next screen when the blue pedal or blue arrow is pressed.	➢ This may be a step where visibility of the reference arrays is required in order to advance in the application. Make sure the reference arrays are visible to the camera.
The enclosure box does not appear to be ON.	➢ Check that the power switch is on. ➢ Check that the emergency stop button is not pressed down.

	➢ Check that the power cable is plugged in and the electrical outlet is working. ➢ A fuse may be blown. If a green light is not indicated on the front of the enclosure box, please contact technical support.
The Enclosure Box makes an abnormal sound when the OMNIBotics Station is switched on.	➢ The enclosure box needs repair. Discontinue use. Please contact technical support to arrange repair of the enclosure box.
The OMNIBotics Station loses power during surgery.	➢ The laptop is equipped with a battery and should remain on during a brief power outage. When power is returned to the system, the camera and OMNIBot should reconnect. If the laptop resets due to loss of power (for example, if the battery is dead) all data from the previous procedure will be lost. In this case, if any resections have been made, then finish the procedure with conventional instruments. ➢ If resections have not been made on either the femur or tibia or both, you may start a new procedure. If you are then only navigating either the femur or tibia, a modification will have to be made to the workflow in the surgeon preferences page.
An error message appears when logging in the Application System indicating that the user account has been blocked	➢ You have expired the maximum number of unsuccessful login attempts and your account has been blocked. 1. Contact OMNI Customer Service to initiate the account unlocking procedure 2. Create a new user account to access to the system and its applications
Screen display does not match correct image shown in Section 3.7	1. Click the red power icon at the top right of the screen and follow system prompts to shut down the laptop NOTE: Rest of station should remain on 2. Wait a few seconds until the screen goes blank 3. Power the laptop on again 4. If system still does not display correct resolution, please contact technical support.

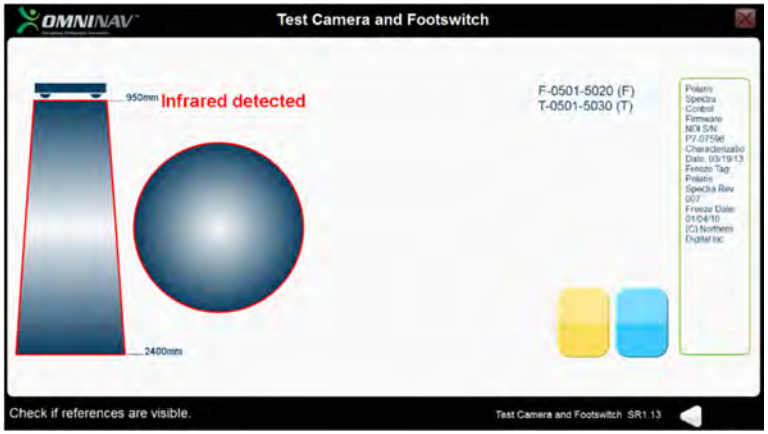
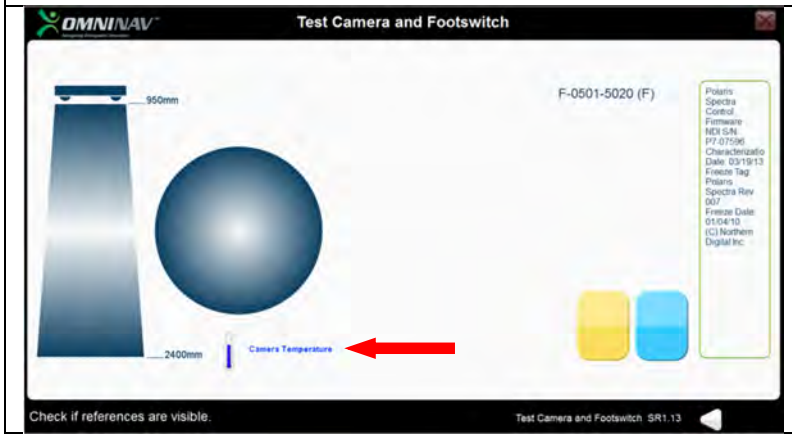
SCREEN DECALIBRATION

The station Laptop touch screen is de-calibrated to the extent that it is not possible to use the touch screen functions.
See Screen Calibration portion of Section 3.11 to recalibrate the screen.

TEST CAMERA AND FOOT SWITCH



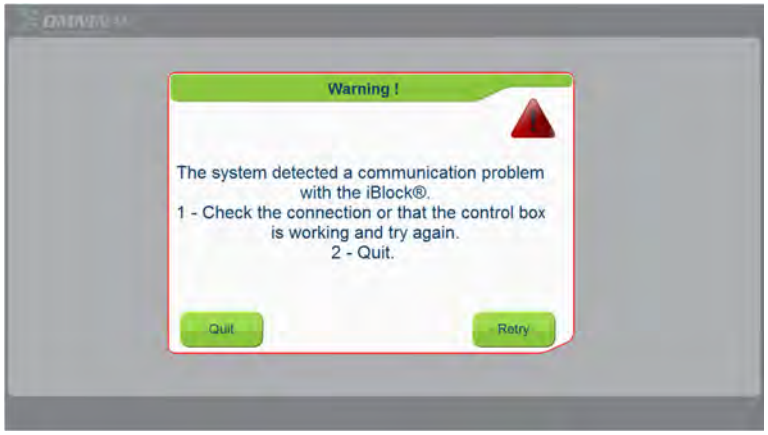
Check that the cable connected to the camera is connected correctly and press the retry button.
If the connection still does not work, contact OMNI technical support.

	The following screen indicates infrared light interference with the camera (OR lights, presence in front of the camera). The references cannot be tracked. Try repositioning the camera to reduce the interference.
	The following screen indicates that the camera warm up phase is not completed yet (2min). The references can still be tracked but accuracy of the tracking can be affected.

TOUCH SCREEN CALIBRATION

In case of a failed calibration of the **Laptop** screen, press 'OK" and restart the procedure from the screen selection page as described in Screen Calibration portion of Section 3.11.

TEST THE OMNIBot



Verify that the Enclosure Box is correctly connected to the Laptop Docking Station at the OMNIBot connection level (USB).
Verify that the Motor Unit Power Indicator Light is on.
Verify that the OMNIBot is correctly connected to the Enclosure Box:

- At the level of the Enclosure Box (Motor Cable GREEN Sleeve)
- At the level of the Motor Enclosure (Motor Cable GREY Sleeve)

Retry.

Quit and restart "Test OMNIBot" tool.

If the tool is still not able to connect to the OMNIBot, contact your distributor technical support.

5 Maintenance and Repairs

5.1 General Maintenance

Contact technical support in the event of any problem or doubt about the correct operation of the station.

Inform the manufacturer immediately if any problems are identified which may have serious consequences for the patient or users of the system.

Annual preventive maintenance on the OMNIBotics Station is recommended by OMNI to guarantee proper operation of the device over the entire life span. This includes annual camera calibration verification.

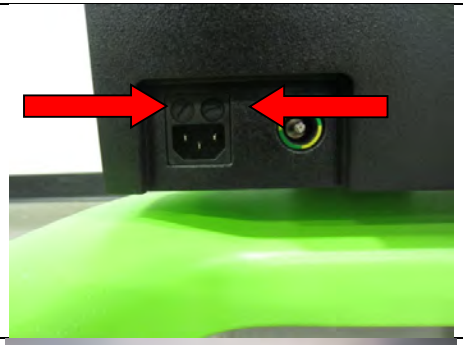
Warning: After the expiration of the warranty and in absence of a service contract, OMNI disclaims all responsibility in the case of a malfunction of the system.

Only an OMNI approved qualified service personnel are allowed to service the OMNIBotics Station

In the case of unauthorized maintenance, the warranty provided with the equipment will be totally void.

5.2 Fuse Replacement

	**WARNING:** Disconnect the OMNIBotics Station from the power supply before replacing the protective fuse.
	**WARNING:** Only fuses provided by OMNI with reference NV-FUSE0 must be used to replace damaged fuses.
	Fuse replacement should only be performed by qualified technical staff or OMNI approved qualified service personnel.

Open the fuse compartments directly above the power cable connection using a flat head screwdriver.		
Replace both fuses with new ones and replace compartment.		

6 Product Recycling

For an OMNIBotics Station that is no longer in use, please contact technical support to arrange for recycling of the product.

Life expectancy of the OMNIBotics Station is 10 years.

7 Product Codes

The OMNIBotics NV Series can be ordered in the following configurations under the corresponding product codes:

Category	Description	Product Code
Camera	OMNIBotics Station Camera - Branded	NV-CAM01
	OMNIBotics Station Camera - Branded	NV-CAM02
Power Cord	OMNIBotics Station Power Cord, US	NV-CRD01
	OMNIBotics Station Power Cord, EU	NV-CRD02
	OMNIBotics Station Power Cord, AUS	NV-CRD03
	OMNIBotics Station Power Cord, UK	NV-CRD04
	OMNIBotics Station Power Cord, Switzerland	NV-CRD05
	OMNIBotics Station Power Cord, South Africa	NV-CRD06
	OMNIBotics Station Power Cord, Israel	NV-CRD07
Laptop	OMNIBotics Station Laptop, ART Knee and Total Hip for US	NV-LPT04
	OMNIBotics Station Laptop, ART Knee for EU	NV-LPT05
	OMNIBotics connected Station Laptop, US	NV-LPT07-US
	OMNIBotics connected Station Laptop, OUS	NV-LPT07-OUS
Cart	OMNIBotics Station Cart, NON-UPS, Wired – Branded	NV-CRT01
	OMNIBotics Connected Station Cart	NV-CRT07
Case	OMNIBotics Station Case - Laptop, Camera, Motor Unit	NV-CAS01
	OMNIBotics Station Crate – Full System	NV-CAS02
Motor Unit	OMNIBot Motor	4144-6000