

INSTRUMENTATION AND HARDWARE

Ref.33.22.1000US



USER MANUAL

CAUTION: Federal law (USA) restricts this device to sale by or on the order of physician

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Distributed by MEDACTA USA, Inc, 4725 Calle Quetzal Unit B Camarillo, CA 93012-9101 **1 (800) 901-7836.**

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BEFORE USING THE MEDACTA iMNS™ NAVIGATION SYSTEM, CAREFULLY READ THROUGH THE MANUALS PROVIDED WITH THE SYSTEM AND THE OPERATING TECHNIQUES RELATED TO THE SURGERY TO BE PERFORMED: THE USER IS RESPONSIBLE FOR ANY DAMAGE OR MALFUNCTION CAUSED BY IMPROPER USE OF THE iMNS™ SYSTEM OR OF ANY OF ITS COMPONENTS.

The information contained in this manual and the product to which it refers may be modified by MEDACTA without giving prior notice thereof.

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1. GENERAL DESCRIPTION

1.1 INTENDED USE

The iMNS™ Medacta Navigation System is intended to be used to support surgeon during specific orthopaedic surgical procedures by providing information on bone resections, instrument and implant positioning.

The iMNS™ Medacta Navigation System provides computer assistance to the surgeon based on anatomical landmarks and other specific data obtained intra-operatively that is utilized to place surgical instruments.

Examples of surgical procedures include but are not limited to:

- Total knee replacement
- Minimally invasive total knee replacement



The MEDACTA iMNS™ system does not provide information of diagnostic nature.

Use the iMNS™ system only with the equipment specifically supplied or approved by MEDACTA.

The iMNS™ navigation system must be cleaned and disinfected immediately after use by qualified personnel (see §5.1 Cleaning).

Clean and disinfect the instruments supplied in trays to be used with the iMNS™ navigation system before sterilization following the "Recommendations for the Decontamination and Sterilization of Medacta International SA Reusable Orthopaedic Devices", available from the company's website www.medacta.com or by calling 1 (800) 901-7836.



The iMNS™ system shall not be used to perform surgeries other than the ones indicated in the surgical techniques described in this manual.

Do not use the iMNS™ system in the presence of sources or reflectors of intense infrared radiation as under these conditions the acquisition system is unable to work properly. Additionally, avoid exposing the acquisition system to direct daylight.

In case of knee operations, adequate mobility of the corresponding hip joint is an essential requirement for the effective use of the iMNS™ system.

It is essential to always bear in mind all the warnings related to the surgery to be performed.

1.2 COMPLICATIONS

If the MEDACTA iMNS™ system is improperly used, the following complications may arise including but not limited to:

- Infection
- Incorrect implant positioning
- Failed recovery of the articular functionality

Refer to the respective package insert of the implants for a comprehensive list of complications and information regarding the implants.



Like all electrical devices, the MEDACTA iMNS™ navigation system may be subject to malfunctioning due to improper use or to technical reasons. It is however always possible to complete the surgery with the aid of the standard equipment, which must necessarily be available in the operating theater.

Do not use the iMNS™ system in the presence of flammable materials, such as anaesthetics, solvents, detergents, and gases.

Although the iMNS Navigation System has been tested and declared fully satisfying the electromagnetic compatibility requirements indicated in the standards EN 60601-1-2 2nd ed., radio communication devices, including portable ones, may interfere with the iMNS™ system reducing its accuracy.

1.3 STRUCTURE AND OPERATION

The iMNS system is made up of the following devices:



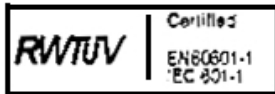
- **Acquisition system (1)**
NDI PASSIVE POLARIS SPECTRA® SYSTEM composed of 2 infrared cameras (*Position Sensor*) equipped with IR LEDs to track the reference arrays.
- **Information processing and display system (2)**
The data are processed and displayed using an Apple iMac® computer running navigation software developed internally by MEDACTA.
- **Interface devices (3 and 4)**
The iMNS™ system is controlled by means of the following devices: keyboard, 3-pedal footswitch, and mouse (optional).
- **Manual Reusable Instruments**
The system works with reusable instruments supplied in trays.

ASA-Schalltechnik GmbH
D-32457 Porta Westfalica

Type: Type: FS3 U1/U1/U1 F
ASA-No.: 8036 0704

max. 25V AC, max. 25 mA
max. 12.5 mW

IP X8



Technical specifications of the 3-pedal footswitch can be found on the label located on the bottom of the unit.

1.4 TRAINING



The system shall be used exclusively by suitably trained personnel.

Studying this manual is an integral part of the training process. Should any part of the manual not be clear, refer to the specialized MEDACTA staff for help.

2. HARDWARE AND INSTRUMENTS

2.1 POLARIS SPECTRA® ACQUISITION SYSTEM

The acquisition system, NDI PASSIVE POLARIS SPECTRA® SYSTEM, consists of a pair of cameras (*Position Sensor*) capable of emitting and receiving infrared rays reflected by special reflectors (*passive markers*) positioned on reference arrays (Figure 1).



Figure 1 – Reference arrays

During the surgeries, different reference arrays are used. Their position is identified and represented by the system in real-time.

Thanks to the binocular vision of the Position Sensor, a triangulation process of the acquired images can be performed (Figure 2), identifying the position of each marker with a tolerance of 0.5 mm. When all 3 markers positioned on the reference array are visible to the Position Sensor, the system is able to reconstruct and represent the position and precise orientation of the body. If some of the markers are not visible, the system blocks the confirmation of the acquisition until the reference array is again fully visible and recognized.

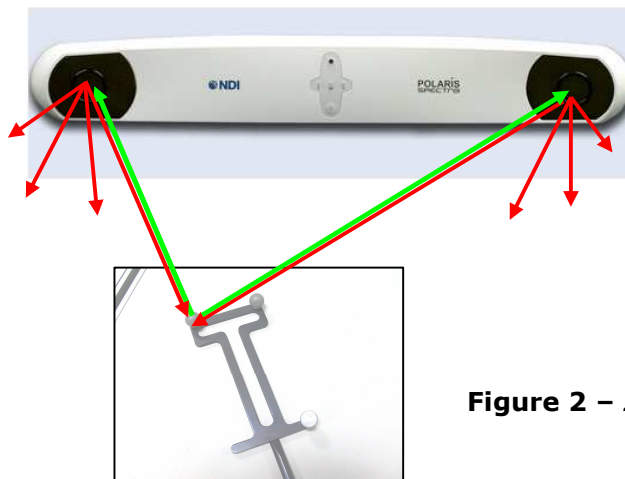


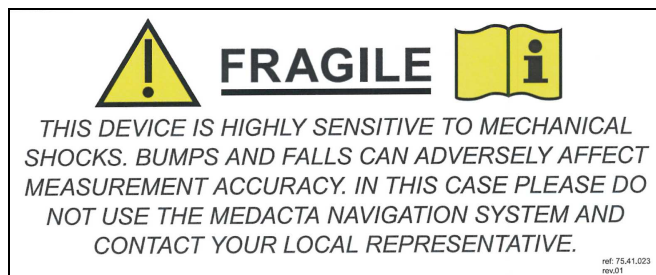
Figure 2 – Image Acquisition



The acquisition system is made up of very sensitive precision instruments. Protect it against bumps and dropping in order not to jeopardize its precision and proper operation. Always position the POLARIS SPECTRA® system on a stable support.

Before use, inspect the system and make sure that it is intact and clean. Should this not be the case, the measuring accuracy would be jeopardized.

The following label is located on the top of the position sensor:




Do not use transparent materials (glass, Plexiglas, or any other materials) to protect or shield the POLARIS SPECTRA® system during the acquisitions. Even transparent materials or clear plastic in the line-of-sight of the cameras may degrade system performance.

The machine must be properly grounded in order to operate safely. Do not bypass the grounding using three-to-two-prong adapters.

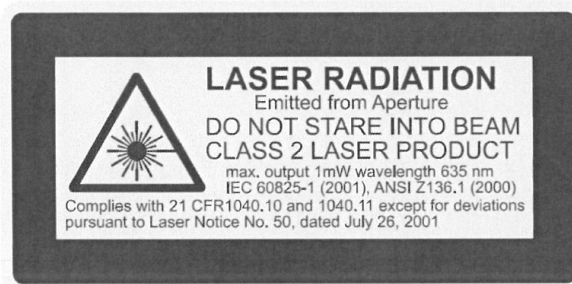
The POLARIS SPECTRA® system is not designed to perform absolute measurements. Use of the system to carry out absolute measurements may produce inaccurate results. The manufacturer recommends using a reference instrument whenever possible to assure that there are no measuring inaccuracies due to environmental or time causes.

Do not connect or disconnect the camera system when the power supply unit is live, as this might damage the system.

Never disconnect the power cables or the 14-pin cable of the Position Sensor when the amber light () on the front of the Position Sensor is on. Make sure that the system has been turned off before disconnecting any of these cables.

Do not look directly into the Class 2 laser-emitting aperture. Take precautions to ensure that patients do not look directly into it. Direct viewing of the laser diode emission may cause eye damage.

The following label is located in the back of the unit. Please read it carefully.



Use of laser controls or adjustments or performance of laser-related procedures other than those specified herein may result in hazardous radiation exposure.



Information about the Polaris Spectra in use (Item ID, Serial Number and manufacturing date) are reported on a label located on the back of the unit.

2.2 IMAC® COMPUTER

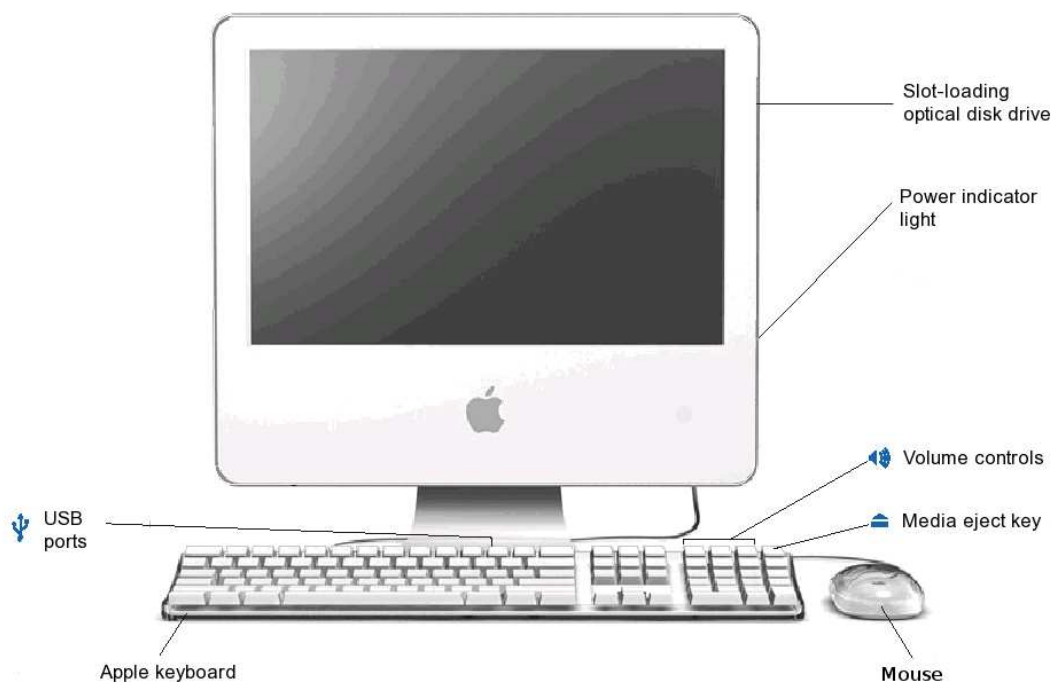


Figure 3 – Frontal view of iMAC Computer

MEDACTA has chosen to use the integrated Apple iMac® computer for data processing and display. This compact and highly reliable system reduces wiring complexity and space required in the operating theater. It also allows setting up the iMNS™ system with a few simple operations.

On the base of the iMAC computer support is located a label indicating the manufacturer name and the machine serial number.





Figure 4 – Rear view of iMAC Computer



The machine must be properly grounded in order to operate under safety conditions. Do not bypass the grounding using three-to-two-prong adapters.

To prevent risks of overheating, do not obstruct the ventilation opening on the rear of the device.

Do not insert any object in the ventilation opening on the rear of the device.

As the iMac[®] system cannot be sterilized, never place it in a sterile field for any reason whatsoever.

Before proceeding with the cleaning operations, check that the system is off and that all the cables have been disconnected.

**Do not turn off the system by pressing the power button.
To turn off the system exit the navigation software.**

Do not sterilize the iMac® system or any of its parts in an autoclave.

Never disconnect the power cable when the system is on.

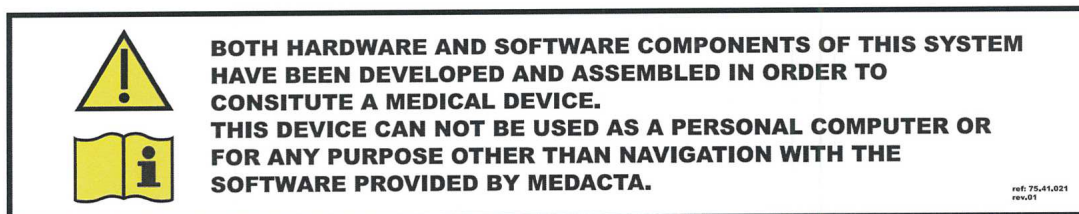
Do not immerse the system in water. Do not let water or other liquids penetrate the system in any way.

To clean the outside of the computer use a soft and clean cloth. Do not spray any liquid directly onto the computer. Refer to § 5.1 for cleaning instructions.

IMPORTANT NOTICE:

The iMAC computer provided with **the iMNS can not be used for any purpose other than navigation with the software provided by MEDACTA.**

Please carefully take in account the label located on the back of the iMAC computer and reported here:



Mini-DVI, Ethernet (10/100/1000Base-T), Audio line-in, Headphone out and FireWire 400 ports are NOT used by the navigation system. In particular, Ethernet port is NOT FOR PHONE CONNECTION.

This label is positioned above the Ethernet port on the back of the iMAC computer.



2.3 REOMED® 600 ISOLATION TRANSFORMER

The iMac® system is connected to the mains through the REOMED® 600 isolation transformer equipped with a protection against short-circuits and overloads and a current limiter. The transformer is equipped with a power switch and EMC line filter.



Figure 5 –REOMED 600



Electrical device operating at potentially hazardous or lethal voltages: the maintenance operations must be carried out by qualified personnel.

Pull the plug from the mains socket before any installation or maintenance operations.

Before using the unit, check that the mains voltage is compatible with that of the device (see §3.4.3).

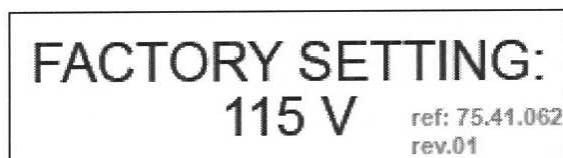
Do not use the device in the presence of flammable or hazardous substances.

To prevent the risk of electric shocks, protect the transformers and cables used against moisture.



The system is supposed to function under a 115 V voltage.

This label is positioned on the back of the Reomed® isolation transformer.



2.4 INSTRUMENTS

For information related to the navigation instruments, refer to the software instructions for use.

Refer to the "Recommendations for the Decontamination and Sterilization of Medacta International SA Reusable Orthopaedic Devices", available from the company's website www.medacta.com or by calling 1 (800) 901-7836



Before every surgery, make sure that the instruments have been properly sterilized and that they are in such conditions as to adequately perform their function.

Before sterilizing the reference arrays, remove the markers from the supports.

THE MARKERS ARE FOR SINGLE USE ONLY: do not re-sterilize them, do not re-use them.

Re-sterilizing or re-using the markers may deteriorate the reflecting properties and the system may not be able to recognize the reference array.

The user is responsible to follow the directions for properly handling the components.

Always have the instrumentation for non-navigated surgeries sterilized and ready as a back up to any navigated surgical procedure.

3. INSTALLATION AND START

To facilitate transport and at the same time guarantee adequate protection, the Medacta iMNS™ navigation system is supplied in two rigid cases with appropriately shaped foam rubber linings.

One case contains the Polaris Spectra® Position Sensor (c), the support tripod (a) and the REOMED® 600 isolation transformer (b).



Figure 6 – First iMNS transport case

The other case contains the iMac® system (e) complete with keyboard (d), 3-pedal footswitch (h), USB and power cables (g), Host UBS Converter and feeder of the Polaris Spectra® system (f).

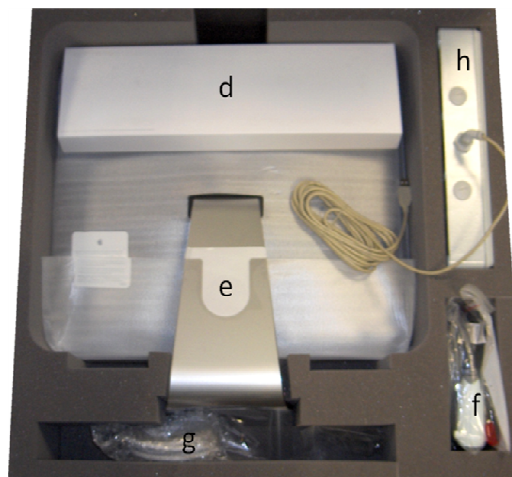
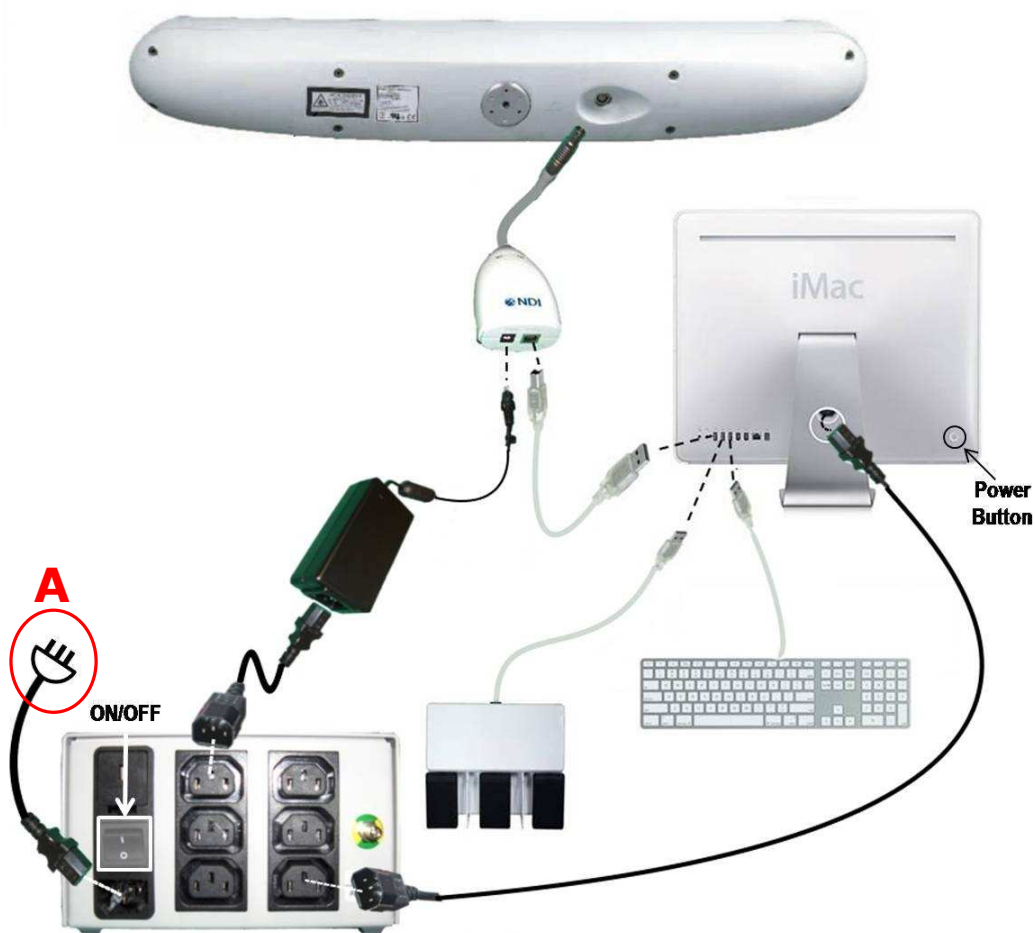


Figure 7 – Second iMNS transport case



Do not use cables or accessories other than those listed in this manual. The use of other cables or accessories may result in increased emission and/or decreased immunity of the Polaris Spectra System and may lead to personal injury.

3.1 WIRING DIAGRAM



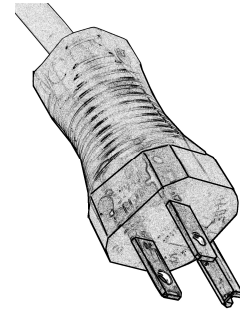


Electrical plugs and their sockets differ by country in shape, size and type of connectors.

Make sure that the supplied mains power connector (A) matches your local socket.

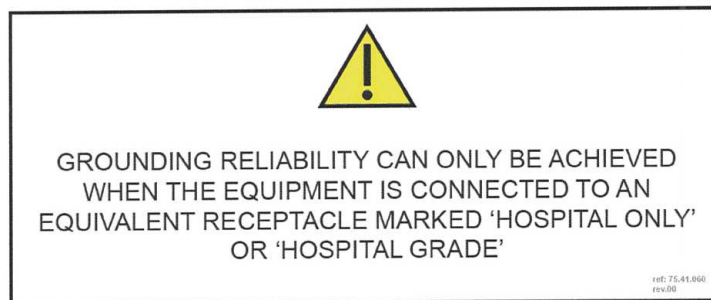
Do not connect any other electrical devices than those shown to the outlets of the REOMED isolation transformer.

Mains power connector supplied with iMNS for the US market is displayed in the picture on the right



In order to achieve an appropriate grounding reliability, the equipment must be connected to an equivalent receptacle marked 'Hospital Only' or 'Hospital Grade'.

Please take into account the following warning label, applied on the mains power supply unit:



3.2 ASSEMBLING THE MARKERS ON THE REFERENCE ARRAYS

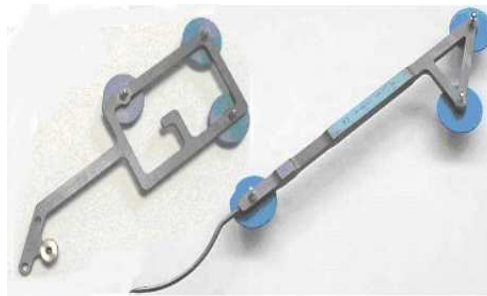


Figure 8 – Reference arrays



Before each surgery, apply the sterile markers on each reference array. The markers are pressure-fitted on the special supports.

Only use markers supplied by MEDACTA. Using different markers from those supplied by MEDACTA may result in a loss of accuracy.

Make sure that the markers are firmly inserted and at the end of their stroke on the pin.

In addition to the markers, the discs shown in the figure 8 must be assembled on the pointer and the G-shaped reference array. They are indispensable for accurate acquisition. Do not proceed with navigation if the discs have not been fitted.

STERILE MARKERS ARE FOR SINGLE USE ONLY!

Do not re-sterilize them.

Do not re-use them.

Re-sterilizing or re-using the markers may deteriorate the reflecting properties and the system may not be able to recognize the reference array.

3.3 ASSEMBLING THE SUPPORT TRIPOD

Open the cases by lifting the tabs of the closing mechanism and turning them anticlockwise (figure 9).

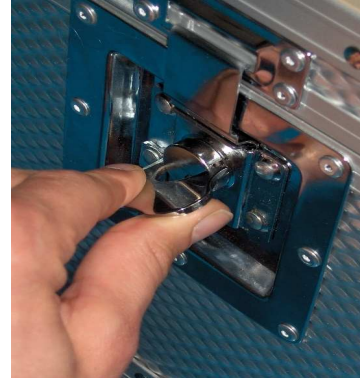


Figure 9 – Case locking system

Take the support tripod out of the case, slide the locking device (P in Figure 10) to release the opening and open the tripod legs wide apart.

Releasing the locking device (P) secure the legs in open position (Fig. 10 -b-) ensuring that they are firmly in place.

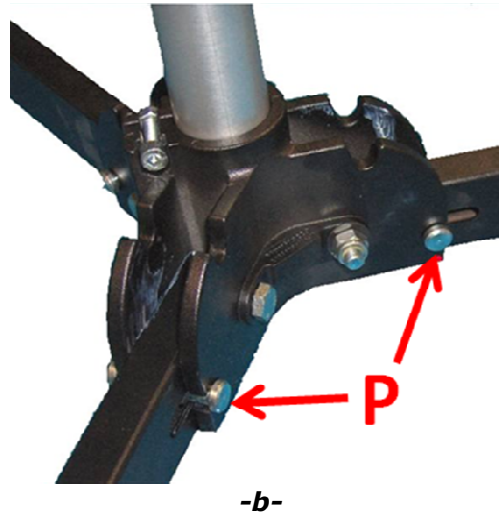
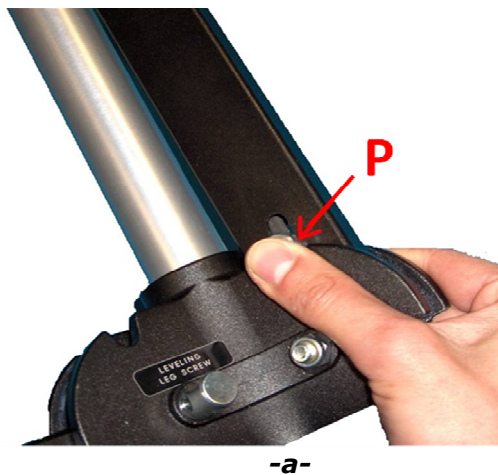


Figure 10 – Tripod base

Position the ball joint (G in figure 11) of the Polaris Spectra® system on the tripod stem and, turning the fastening knob (M), securely tighten the locking device to prevent the joint from slipping from the stem.



Figure 11
Position Sensor on the Tripod



Figure 12 – Adjusting tripod height.

Extend the tripod by sliding out the telescopic rods. Once the desired height has been reached, securely tighten the locking devices by turning the fastening knobs (figure 12).

Make sure that the structure is stable.

Knocking or dropping the Polaris Spectra® system may cause irreparable damage.

During acquisition, even small system vibrations may lead to inaccurate and unreliable results.

Stability of the system will be enhanced if the locking latches on the castors are depressed.

3.4 INSTALLING AND TURNING ON THE SYSTEM



System installation requires wiring of different components. Make sure that this operation is carried out in such a way as to minimize the space used in the operating theatre and the risk of accidental detachment of the connectors during surgery.

Should one of the connectors accidentally slip out of its seat, check the integrity of the cable and the connector. Make sure to reinsert the connector in the correct socket and check device functioning. In some cases, the system will have to be restarted.

3.4.1 Polaris Spectra® acquisition system wiring

To provide power supply to the Polaris Spectra® acquisition system, follow the steps below.

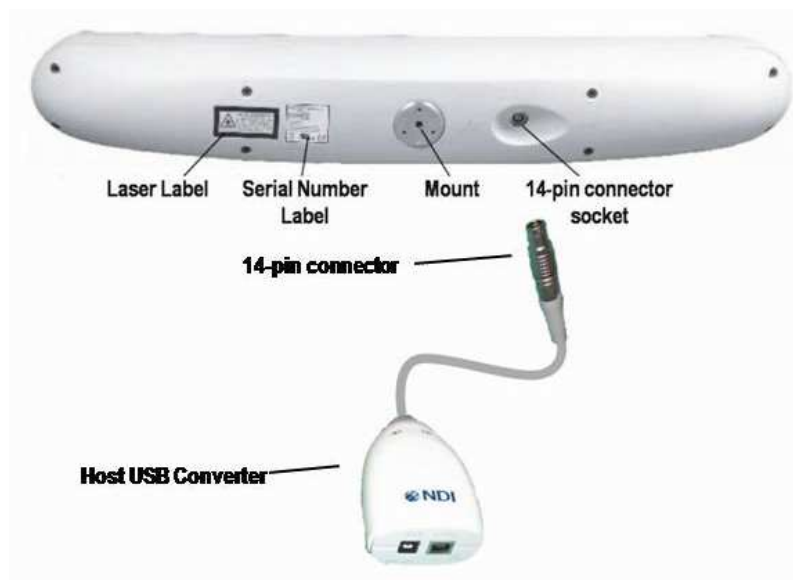


Figure 13 – Polaris Spectra Acquisition System

Insert the 14-pin connector of the Host USB Converter in the corresponding socket on the rear of the Position Sensor (Figure 13).

As shown in figure 14, connect the A end of the USB cable to the sockets (⇄) and the power adapter cable of the power supply unit to the special socket (≡) of the Host USB Converter.

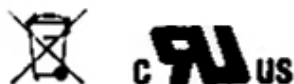


Figure 14 – Host USB Converter wiring

Insert the Y end of the power cable in the Polaris Spectra® power supply unit.

ITEM ID: 8700338.001.05
 MODEL: Polaris USB Converter - 4.5m cable
 SERIAL No: U1-00642
 MFG DATE

Information (Item ID, Model and Serial Number) are reported on a label located on the back of the USB Converter.



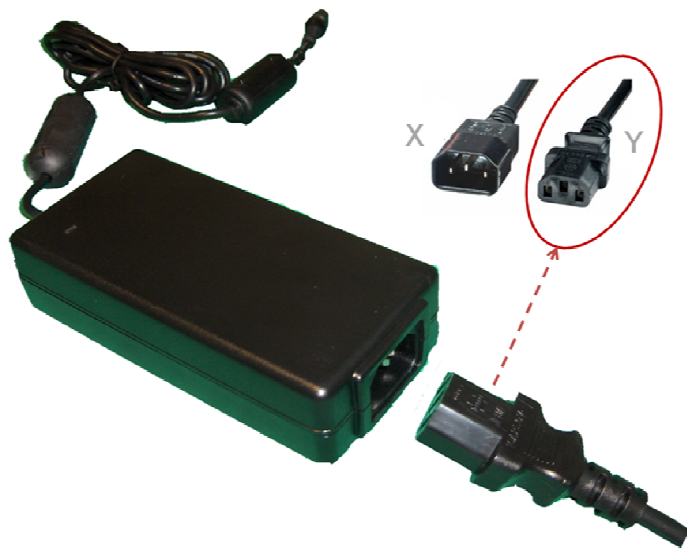


Figure 15 – Polaris Spectra Power Supply Unit wiring

APS ADVANCED POWER SOLUTIONS	
MODEL:APS49ES-24021 LF	
Power Supply for Medical Use	
AC INPUT	DC OUTPUT
100-240V~	24V---2.1A
1.0A	INDOOR USE ONLY
50/60Hz	
	PS JET
	ADVANCED SYSTEMS CO.,LTD.
	アドバンスシステムズ株式会社
SN 00018	CE
WK 0714	UL
	E164433
	TEL:(825)734-3060
	MADE IN CHINA

Detailed information about the power supply are displayed on the label located on the unit.

3.4.2 iMAC[®] Computer wiring:

As shown in the figure below, connect the Host USB Converter to the iMAC[®] system inserting the B end of the USB cable in one of the three socket (↔) on the rear of the iMAC[®] screen.

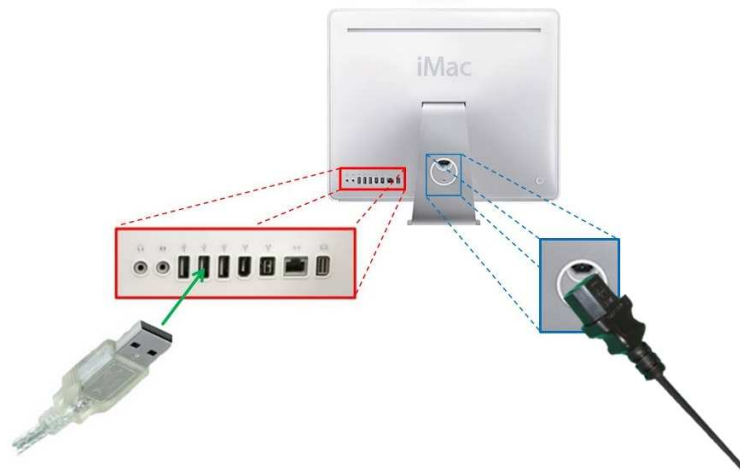


Figure 16 – iMAC Computer wiring

Connect the keyboard to another one of the USB ports (↔). If a wireless keyboard (optional) is available, switch on the keyboard with the switch located on the lower face of the device. Check that the green LED comes on.

Connect the footswitch to one of the USB ports (↔) on the body of the iMac[®] system or to one of the USB ports located on the keyboard, using the special adapter if necessary.

Connect the mouse (optional) to one of the USB ports (↔) on the body of the iMac[®] system or on the keyboard.

It is advisable to insert the keyboard and the footswitch in a transparent plastic bag large enough to cover as much cable as possible. Close the bag around the cable using some adhesive tape.

3.4.3 REOMED® 600 isolation transformer wiring:

Connect the X end of the iMAC® power cable in one of the sockets (C in figure 17) of the REOMED® 600 isolation transformer, likewise insert the power cable of the Polaris Spectra in another of these sockets.

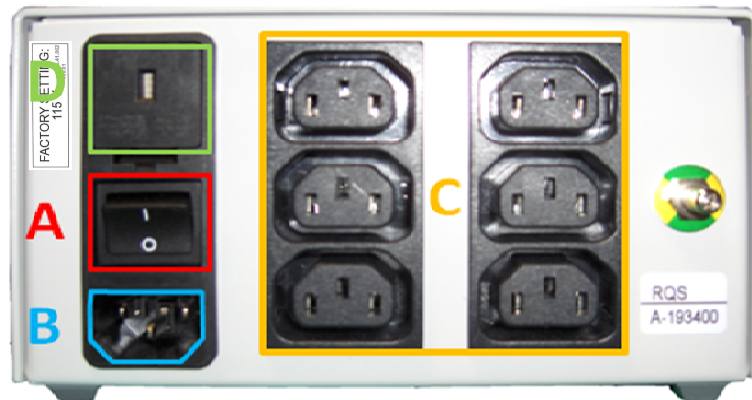


Figure 17 – REOMED 600 wiring

Check that the switch (A in figure 17) is set to OFF (O) and insert the remaining power cable into the input socket of the isolation transformer (B in figure 17) and into the mains power outlet.



Connect the REOMED® 600 isolation transformer to an electric system in compliance with the national regulations regarding electrical safety in the operating theater. In case of doubt, refer to qualified technical staff.

Check that the input voltage agrees with the local mains voltage reading the number you can see through the slot of the fuse-holder on the transformer's rear (D in figure 17). (230 for 220V mains voltage – 115 for 110V mains voltage). If the voltages disagree, refer to the qualified technical staff.

When replacing input fuses only use the same type supplied with the unit. See section 6.1.4 for the fuse specifications.

Detailed technical specifications of the REOMED® 600 can be found on the label located on one side of the unit:

MEDICAL ISOLATING TRANSFORMER

Article-No	BV65B5167Axx
Supply voltage	115V/230V
Frequency	50 / 60 Hz
Power input	600 VA
Fuse F1;F2	T6,30/T3,15A 5x20
Rated output voltage	230V by 6 Outputs
Rated output current	2,60 A
Case protection	IP 20
Protection class	I



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MEDIZINISCHER TRENNTRANSFORMATOR

Artikel-Nr	BV65B5167Axx
Eingangsspannung	115V/230V
Frequenz	50 / 60 Hz
Leistungsaufnahme	600 VA
Sicherung F1;F2	T6,30/T3,15A 5x20
Ausgangsspannung	230 V an 6 Ausgängen
Ausgangsstrom	2,60A
Schutzart	IP 20
Schutzklasse	I



MADE IN GERMANY



3.4.4 Turning on the iMNS®

Turn on the REOMED® 600 isolation transformer by setting the switch (A in figure 17) to ON (I).

Check that the LED on the power supply unit and the green Power LED (I) on the Host USB Converter become on and the Power LED (I) on the front of the camera starts flashing (figure 18).

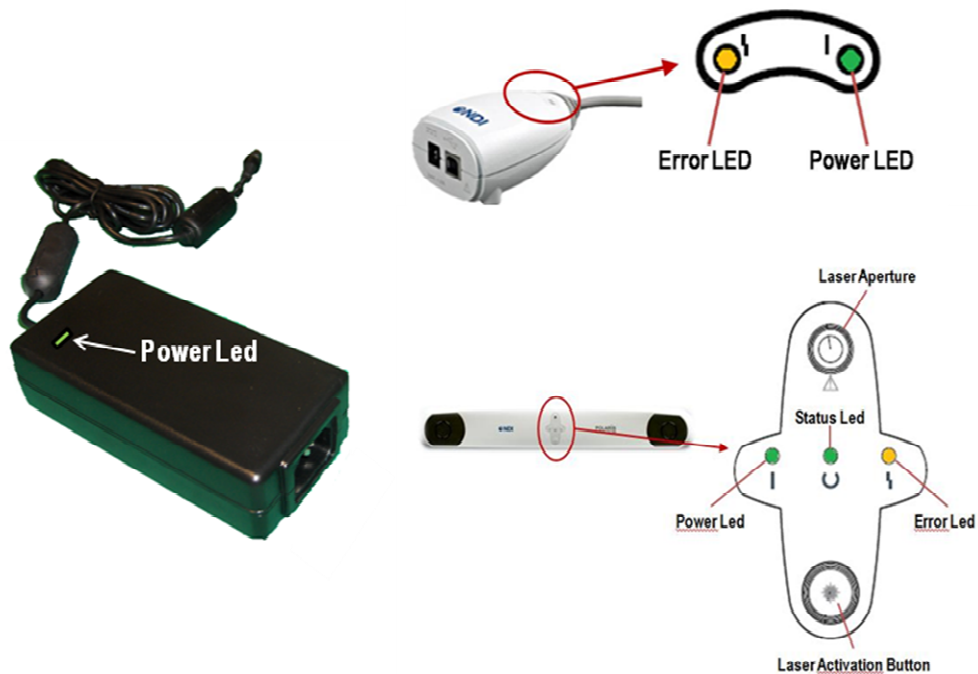



Figure 18 – LEDs on Polaris Spectra System

When the power LED stops flashing, you can hear two beeps.



Never disconnect the power cable or the 14-pin cable when the amber light (error LED ) on the front of the Position Sensor (figure 18) is on. Check that the system is off before disconnecting any of these cables.

It is advisable to wait 20 minutes from the turning on the system before proceeding with the acquisitions. The device requires a warm-up and thermal stabilization period before being able to operate with maximum accuracy. During warm-up the Power LED of the Position Sensor flashes, once this LED is steady, the system is ready to use.

To prevent damaging the cables, do not to bend them excessively.

The power supply unit must be located outside the patient vicinity under ALL operating conditions.

Do not obstruct the normal flow of air around the Position Sensor (e.g. draping or bagging it). Doing so will affect the Position Sensor's operational environment, possibly beyond its recommended thresholds.

It is the responsibility of the system integrator and/or the end-user to ensure that the system is appropriately configured for the operating conditions.

When these steps have been completed, the acquisition system is connected and powered.

Finally, start the iMAC[®] Computer using the power button.



Figure 19 – iMAC Computer

3.5 STARTING AND USING THE NAVIGATION SOFTWARE

For the instructions on the startup and use of the software, refer to the enclosed software manuals.



THE iMAC® COMPUTER PROVIDED WITH THE iMNS™ SYSTEM HAS UNDERGONE HARDWARE AND SOFTWARE MODIFICATIONS TO OPTIMIZE PERFORMANCE OF THE NAVIGATION PROGRAM. AS A RESULT, IT IS NO LONGER POSSIBLE TO USE iMAC® AS A PERSONAL COMPUTER OR FOR OTHER APPLICATIONS DIFFERENT FROM NAVIGATION WITH THE SOFTWARE SUPPLIED BY MEDACTA.

Some applications has the possibility to jump form one screen to another by mean of dedicated shortcuts. This label summarizing the available shortcuts is optionally available, positioned in front of the iMAC computer.

Verify available shortcuts for the software in use by pressing F5

F1	= Save a snapshot
F5	= List of shortcuts
F6	= Navigation settings
F7	= Camera positioning
F8	= Confidence test
F9	= Pre-surgery analysis
F12	= Back to current step



ref: 99.30.99 rev. 01

4. TROUBLESHOOTING

PROBLEM DESCRIPTION	TROUBLESHOOTING
1. INSTALLATION	
1.1 Problem in assembling the camera support tripod	Follow the assembly instructions.
2. SETUP	
2.1 Turning on	
2.1.1 The system does not turn on	Check the power cable
2.1.2 The camera does not turn on	Check the power cables
3. STARTING THE SYSTEM	
3.1 A fault occurs	In case of a fault, follow the on screen instructions Contact technical service
4. LOGIN	
4.1 A keyboard problem occurs	Check the cable that connects the keyboard to the main unit
5. NAVIGATION	
5.1 The footswitch does not transmit the signal to the system	Check the connection to the iMac computer Disconnect and reconnect the footswitch cable ¹ Then check manually via the keyboard
5.2 The system turns off unexpectedly	Check the power cable
5.3 The main unit does not see the camera	
5.3.1 The camera is off	Check the connection cables
5.3.2 The camera is on but the main unit cannot communicate with it	Check that there is not too much natural light in the room. Check the integrity ² of the cameras, and that there are no scratches and marks on the POLARIS SPECTRA® Position Sensor Check that there are no light sources shining directly on the camera Check the camera position Check the USB connection between the Host USB Converter and the iMAC

5.3.3 One or more reference array are not visible to the camera	Clean the passive markers Check proper assembly of the passive markers Check that the field of view of the camera is unobstructed Check the camera position Check the integrity of the reference arrays Remove from the field of view of the camera all the reference arrays not currently in use
	¹ In some rooms, for construction reasons, an electrostatic charge may build up on the footswitch, which interferes with the proper operation of the device.
	² The presence of scratches or marks on the body of the POLARIS SPECTRA® system may be an indication that it has not been handled with the due care. In this case, suspend use of the navigator and contact the Technical Service to have the functions checked and recalibrated, if necessary.

For questions or service requests contact Medacta customer support:

www.medacta.ch
info@medacta.ch

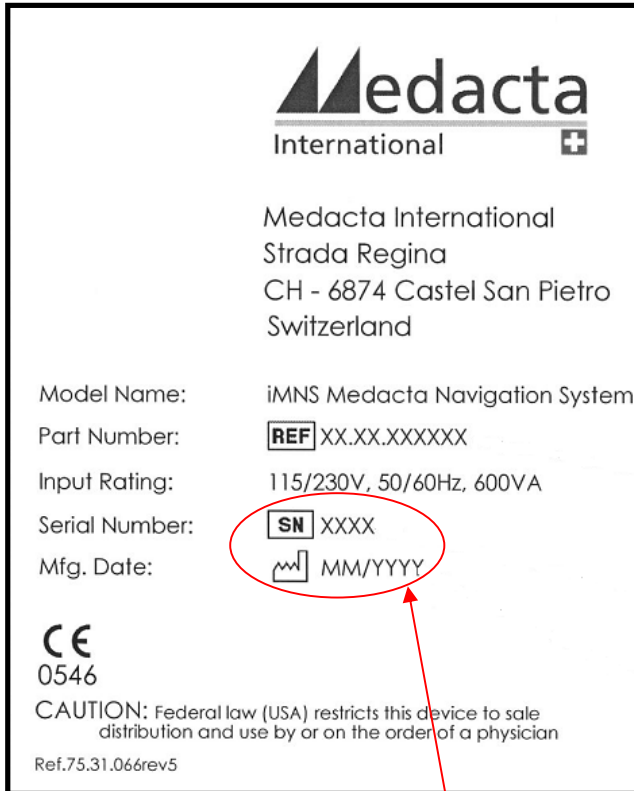
1 (800) 901-7836.

or the sales representative in your country.

Before contacting Technical Service, make sure that the following information is available:

- System serial number (located on the identification plate –see below)
- Installed software version
- Possibly reference to the component for which assistance is being requested
- Any error message that has appeared and a description of the problem

The identification plate is located on the top of the Reomed[®] isolation transformer.






Serial Number
Manufacturing
Date






4.1 POLARIS SPECTRA® LEDS

The power, status and error LEDs on the Position Sensor indicate the status of this component as described in the following table (Figure 18).

 Power Led (green)	 Status Led (green)	 Error Led (amber)	Meaning and Action Required
Flashing	(Any state)	(Any state)	The power LED will stop flashing and light steady green when system is ready for use.
Solid	Solid	Off	The Position Sensor is ready for use; no faults
Solid	Solid	Flashing	Minor recoverable fault.
Solid or off	off	Solid	Major recoverable fault.
Solid	off	Solid	Non-recoverable fault. Return the Position Sensor for service.
off	off	Off	Voltage is out of range. Check the Position Sensor, Host USB Converter, or cables.

On the Host USB Converter there are two LEDs (Figure 18): the Power LED (green light) and the Error LED (amber light). They show the status of this component as described below.

 Power Led (green)	 Error Led (amber)	Meaning and Action Required
Solid	Off	The Host USB Converter works; no faults
Solid	Solid	There's a fault. Unplug the cable of the power supply unit from the special socket () of the Host USB Converter. Wait approx. 10 seconds and then plug it in again. If the Error LED is still on, disconnect the Position Sensor. If the Error LED goes off replace the Position Sensor, otherwise check or replace the Power Adapter or the Host USB Converter.
Off	Off	Voltage is out of range. Check the power cables.

4.2 AUDIO CODES

The Position Sensor is able to emit audio tones which provide an audible indication of the system status.

When the power is initially applied to the system or the system is reset, the Position Sensor emits two beeps indicating proper operation.

If a fault condition occurs the system will emit two beeps every three seconds. In this case please contact Medacta for technical service.

4.3 CLEANING AND MAINTENANCE

4.4 CLEANING

As the iMNS system cannot be sterilized, never place it in a sterile field for any reason whatsoever.

Before proceeding with the cleaning operations, check that the iMNS system is off and all the cables have been disconnected.

To clean the iMNS Navigation System use soft and clean cloth moistened with 70% isopropyl alcohol solution or specific products such as KENDALL CURITY® Alcohol Preps or Sani-Cloth® wipes.

Additional care must be taken when cleaning the Position Sensor (see following paragraph).

Do not immerse any part of iMNS system in water and do not let water or other liquids penetrate the system in any way.

Do not sterilize the iMNS system or any of its parts in an autoclave.

Do not use spray detergents on or near the iMNS system. Spray detergents might penetrate the system and damage the circuits.

Do not use solutions containing chlorinated solvents, aromatic solvents (paint thinners, naphta,...), acetone, ammonia, benzene, xylene.

Do not use hard, pointed or abrasive objects to clean the iMNS Navigation System.

4.4.1 Polaris Spectra® System cleaning

Before cleaning the lenses of the Position Sensor, remove any possible trace of dust using compressed air (or, preferably, nitrogen) or a brush made for cleaning photographic lenses. Gently wipe the surface in one direction only, by pulling the brush across the surface.

To disinfect the lenses and the remainder of the Position Sensor disinfectant wipes containing 70% isopropanol (for example, KENDALL CURITY® Alcohol Preps) can be used.

For actual cleaning, use a commercial lens cleaning solution formulated for multi-coated lenses (for example, AR66) and a clean knitted microfibre optical cleaning cloth (for example, Hitecloth)

Do not use paper towels on the lenses as this might scratch them. NEVER use water, soap, detergents or other liquids on the lenses.

When you clean the remainder of the Position Sensor, take 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.

Dirt, blood or damp on the markers may hamper their recognition by the acquisition system. In this case, clean them by gently dabbing them with a soft and dry cloth.

If any traces of blood have dried, remove them with a wet cloth and then dry the markers.

Should this not be sufficient, replace the dirty markers.

4.5 IMNS[®] SYSTEM MAINTENANCE AND REPAIR

The iMNS navigation system must undergo maintenance and be checked at least every 24 months. Regular maintenance will ensure full functionality of the system.



THE REPAIR, MAINTENANCE AND CHECKING OPERATIONS SHALL BE CARRIED OUT EXCLUSIVELY BY SPECIFICALLY TRAINED PERSONNEL AUTHORIZED BY MEDACTA

To ship the MEDACTA iMNS system use the original containers with all the protective wrappings to prevent damaging the system.

Do not transport or store the system outside the recommended storage temperature range , this may cause the system to go out of calibration.

In the following table the **transportation and storage** environmental conditions are summarized.

Specification	Value
Atmospheric Pressure	70 kPa to 106 kPa
Relative Humidity	10% to 90% non-condensing
Temperature	-10°C to +50°C

This label reminding the storing condition is positioned on the top of the Reomed[®] isolation transformer.



5. TECHNICAL SPECIFICATIONS, CONFORMITY, CLASSIFICATIONS, ELECTROMAGNETIC COMPATIBILITY

5.1 TECHNICAL DATA AND CONFORMITY

In the following table the **operating environmental conditions** of the iMNS™ System are reported.

Specification	Value
Atmospheric Pressure	70 kPa to 106 kPa
Relative Humidity	30% to 75% non-condensing
Temperature	+10°C to +30°C

The iMNS Medacta Navigation System has been tested and declared complying with the Standard CEI-EN 60601-1 and amendments A1, A11, A12 and A2, together with the Standard EN 60601-1-1.

The iMNS Medacta Navigation System has been tested and declared complying with the Standard EN 60601-1-2 2nd edition.



Ref. 75.41.029 rev.00
 SN:.....

Test execution date:.....

Data di esecuzione del test

Date d'exécution du test

Testdurchführungsdatum

Fecha de ejecución de la prueba



Use by:.....

Utilizzare entro

À utiliser avant

Verfallsdatum

Utilizar antes de

Signature:.....

Firma

Signature

Unterschrift

Firma

This label is located on the back of iMAC computer base and shows the expiring date of electrical safety test validity. The frequency of the test is fixed in at least 2 years.

5.1.1 Polaris Spectra® Technical Specification

THE NDI PASSIVE POLARIS SPECTRA® SYSTEM has been tested and declared complying with IEC 60601-1-2, Sec. Ed., 2001 (Medical Electrical Equipment - Collateral Standard: Electromagnetic compatibility - Requirements and tests).

The POLARIS SPECTRA® system has been tested for electrical safety and risk of fire. No other physiological effects have been evaluated.

The ambient operating temperature range of the Polaris Spectra® System is dependent upon the physical location of the Host USB Converter. If the Host USB Converter is located where it may get in touch with the patient, the operating ambient temperature ranges from +10°C to +30°C. Otherwise, if the Host USB Converter is placed outside this patient vicinity, the operating ambient temperature range permitted for the system is +10°C to +40°C.

Although the POLARIS SPECTRA® system can operate in a wide temperature range (10°C-30°C), all the performances specified, including accuracy, are based on characterization and calibration performed at 20°C.

All the NDI acquisition systems are designed for use of specific NDI components only.

Do not use the POLARIS SPECTRA® system in radioactive environments. The system has not been tested nor approved for use in radioactive environments.

Position Sensor

- Maximum Update Rate: 60 Hz
- Input Voltage: 18-32 VDC
- Power Consumption: 13.5 W

Host USB Converter

- Input Voltage: 24 VDC
- Output Voltage: 26 VDC
- Power Consumption: <2 W

Power Adapter

- Input Voltage: 100 VAC to 240 VAC, 50/60 Hz
- Output Voltage: 24 VDC @ 2.1 A
- Power Consumption: 50 W (max.) (24 W typical)

14-pin Position Sensor cable

- permanently connected to the Host USB Converter
- various lengths (max 30 m)
- screened

USB cable

- A-B male
- double shielded
- 5 m

Positioning Laser

The positioning laser is a Class 2 laser, with a wavelength of 635 nm and a maximum output of 1mW. The Polaris Spectra System containing a positioning laser conforms to the following 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

Power Adapter Output Cable

- Cable AC Line Cord
- permanently connected to the power adapter
- plug-in jack connector

Power Adapter Power Cable

- medical grade AC line cord

Electromagnetic Immunity Standards

- IEC 61000-4-2: ± 6 kV in contact, ± 8 kV in air
- IEC 61000-4-4: ± 2 kV for the power lines, ± 1 kV for the I/O lines
- IEC 61000-4-5: ± 1 kV differential, ± 2 kV common
- IEC 61000-4-11: $< 5\%U_t$ for 0.5 cycle, $40\%U_t$ for 5 cycles, $70\%U_t$ for 25 cycles, $< 5\%U_t$ for 5 sec
- IEC 61000-4-8: 3 A/m
- IEC 61000-4-6: 3 V
- IEC 61000-4-3: 3 V/m

5.1.2 iMac® Computer Technical Specifications

Hardware summary:

- Computer model: iMAC
- CPU type: Intel Core 2 Duo
- CPU number: 1
- CPU speed: 2 GHz
- Memory: 1 GB RAM

Power supply:

- Voltage: 100-240V AC
- Rate: 50-60 Hz

Monitor data:

- Monitor type: 20" LCD
- Resolution: 1680 x 1050 pixels

DVD burner data:

- SuperDrive 8x
- CD-burner: -RW
- DVD-burner: +R DL, +RW

Certifications and conformity:

- CE 0984
- ICES-003 Class B
- FCC ID: BCGA1115
- IC: 579C-A1115

5.1.3 Acquisition Device Support Tripod Technical Specifications

Made up of MA299 stem + ball joint MA486

Minimum height: 117.2 cm

Maximum height: 281.2 cm

Load at maximum extension at 10° inclination: 2.7 kg

Weight 5.2 kg

Maximum clearance on ground: 75 cm

Panoramic rotation: 360°

Lateral inclination: -90°/+90°

Stem diameter: 35, 30, 25 mm

5.1.4 REOMED[®] 600 Isolation Transformer

Input voltage: 115V / 230 V, 50 / 60 Hz

Output voltage: 230 V, 50 / 60 Hz on 6 sockets - EN60320

Current: 2.6 A

Power: 600 VA
















Equipped with input fuse: F1=6.30A T F2=3,15A T(5x20)

Case protection IP 20

Protection class I

The REOMED[®] 600 complies with the Low Voltage Directive 73/23/EEC.

6. APPENDIX - EQUIPMENT SYMBOLS

SYMBOL	MEANING	LOCATION
	Attention/Caution Consult accompanying documents	iMac computer Polaris Spectra Position Sensor Host USB converter Polaris Spectra power adapter REOMED 600 3-pedal footswitch
	Refer to accompanying documentation	iMac computer Polaris Spectra Position Sensor
	Laser warning Consult accompanying documents	Polaris Spectra Position Sensor
	ON (power: connection to the mains supply)	Polaris Spectra Position Sensor Host USB converter REOMED 600
	OFF (power: disconnection from the mains supply)	REOMED 600
	Status (see user manual)	Polaris Spectra Position Sensor
	Error (see user manual)	Polaris Spectra Position Sensor Host USB converter
	Laser Activation button	Polaris Spectra Position Sensor
	Connection Port	Polaris Spectra Position Sensor
	Recycle where possible or return to manufacturer	Polaris Spectra Position Sensor Host USB converter Polaris Spectra power adapter REOMED 600
	Direct Current (DC)	Host USB converter Polaris Spectra power adapter
	Alternating Current (AC)	iMac computer Polaris Spectra power adapter
	USB port / USB plug	iMNS identification plate Host USB converter 3-pedal footswitch
	ON/OFF button	iMac computer
	Indoor use only	Polaris Spectra power adapter

7. APPENDIX – ACRONYMS AND ABBREVIATIONS

AC	Alternating Current
CD	Compact Disc
DC	Direct Current
DVD	Digital Versatile Disc
EMC	Electromagnetic Compatibility
IR	Infra Red
LED	Light Emitting Diode
RAM	Random Access Memory
USB	Universal Serial Bus