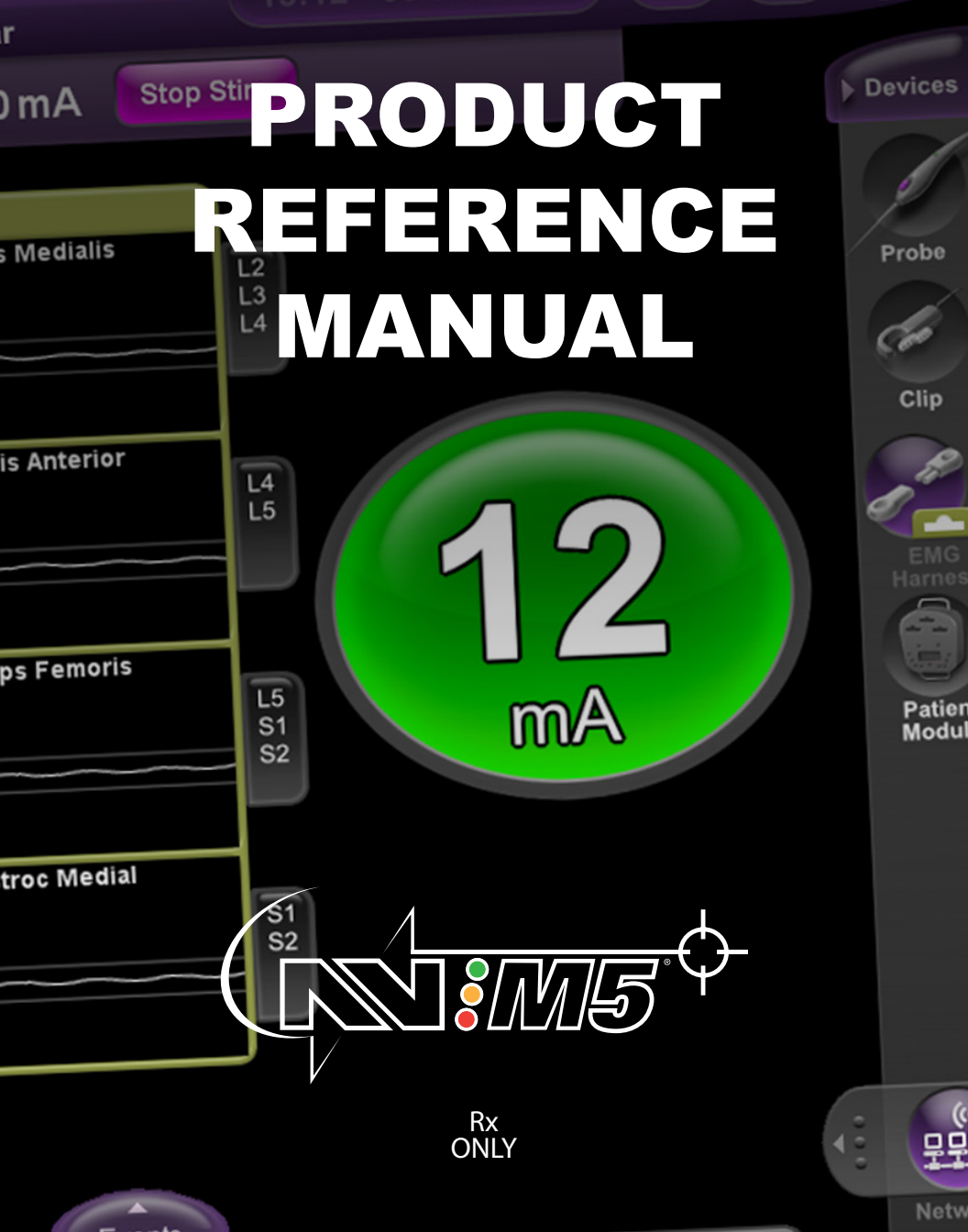
PRODUCT REFERENCE MANUAL



NAVIM5®

Rx
ONLY

INTRODUCTION

The NVM5® System provides surgeon-driven neurophysiologic electromyography (EMG), Motor Evoked Potential (MEP), and Somatosensory Evoked Potential (SSEP) monitoring to nerve roots and the spinal cord during spinal procedures.

Bendini® is the NVM5 Rod Bending System used to bend rods for spinal surgery applications. The system is comprised of a camera and digitizer to register implant locations, NVM5 software to calculate bend angles between each implant and generate bend instructions, and a mechanical bender to manually bend the rod to implant specific contours.

NVM5 Guidance incorporates accelerometers attached to both the C-Arm and to the NuVasive® I-PAS™ needle (accelerometers are microdevices that can measure trajectory) as well as lasers and a Reticle that together assist in aligning the I-PAS needle into the trajectory corresponding with the owl's eye view for pedicle cannulation.

The purpose of this manual is to provide safety, maintenance, and technical guidance for the NuVasive NVM5 System.

Before use of the System, please refer to the detailed on-screen Instructions for Use accessible from the screen of the Control Unit by pressing the "?" in the upper corner. Please see the Software Setup section of this manual.

Care and maintenance of the system is critical for a dependable life of all components. For assistance or technical support, please call the NVM5 Technical Support Team at (877) 963-8768 or contact customer service at (800) 475-9131.

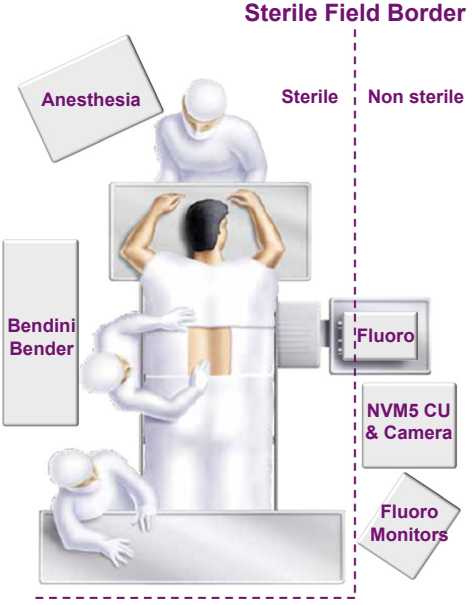
The NVM5 System is a platform for simple, standardized, spine-specific neuromonitoring and surgical efficiency technology.

HARDWARE SET UP

1. Attach the Patient Module to the Control Unit prior to power up of the NVM5® System.
2. Plug the Power Cord into a hospital grade power receptacle.
3. Press the Power Switch.

Bendini® Equipment Setup

- Confirm all equipments are turned on and functioning as desired prior to use.
- Tracking System includes a Camera with an attached IV Pole Clamp and a Cable Box. Cable Box (8210010) contains 3 cables:
  - Camera Cable
  - USB Cable
  - Power Supply Cable



BENDINI® EQUIPMENT SETUP cont.

- Mount Camera onto stand or IV pole using attached locking clamp. Confirm Camera is mounted at the height of the Array during digitization.
- Camera must be at a minimum of 22 inches (1.83 feet), and no more than 52 inches (4.33 feet) away from the patient. The Camera should be orthogonal to the long axis of the patient's spine.
- Plug Control Unit into wall outlet; confirm power is clean and grounded. Press Power Button to turn System on.

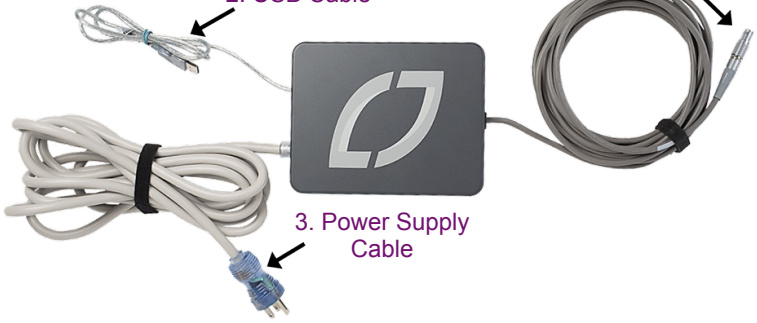
Camera

1. Connect Camera Cable to connection on back of Camera. Line up the red dots on the cable and the Camera to confirm a desired connection.
2. Connect USB Cable to any USB Port Connection on Control Unit.
3. Connect Power Supply Cable to a grounded outlet.


Camera Cable

Control Unit USB

1. Camera Cable
2. USB Cable
3. Power Supply Cable



SOFTWARE SET UP

After pressing the Power Button, the display will show a series of power up checks and then the NuVasive® display screen during system loading.

TO ACCESS QUICK REFERENCE MANUAL:

When the Site Selection Screen appears, press the “?” button in the upper right corner. The Quick Reference Manual will then be available. This button is also available at any time with any other NVM5® Screen.

Press to access Quick Reference Manual

INSTRUMENTS & ACCESSORIES

NVM5® Monitoring Accessories

- Dual Surface Electrodes

- Dual Needle Electrodes

- MEP Stimulation Electrodes (Corkscrew Electrodes)

NVM5 Surgical Accessories

- Clip and Inline Activator

- Probe

INSTRUMENTS & ACCESSORIES cont.

NVM5® Surgical Accessories cont.

- I-PAS™ Needle

- Navigated Guidance Integrated I-PAS Clip

- XLIF® Dilators

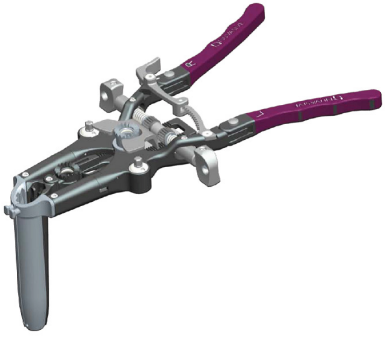
- XLIF Stimulating Electrode

- Insulating Sheath

INSTRUMENTS & ACCESSORIES cont.

NVM5® Compatible Stimulation/Dissection Instruments and Accessories

- MaXcess® Retractor



- Taps / Drills

- Pedicle Probe (in combination with Insulating Sheath)

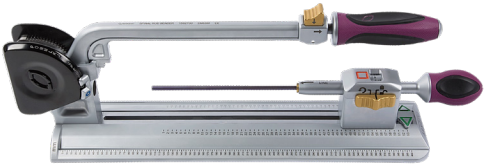
- Screw Drivers

- Insulated Dilators

INSTRUMENTS & ACCESSORIES cont.

Bendini® Instruments & Accessories

- Bendini Spinal Rod Benders



- Camera Tracking System

- Bendini Pointers

- Bendini Array

CLEANING INSTRUCTIONS

NVM5® CONTROL UNIT AND PATIENT MODULE

The NVM5 Control Unit and Patient Module are not intended for sterilization. If necessary, use only 70% isopropanol to clean the NVM5 Control Unit and Patient Module. Additionally, they may be cleaned with a soft towel or wipe dampened with a mild detergent and water solution according to standard hospital practices.

PRECAUTION: Do not allow liquids to enter the Control Unit or Patient Module, as this may result in damage or malfunction of the NVM5 System.

NVM5 BENDINI CAMERA

The NVM5 Bendini Camera and associated cables are not intended for sterilization. Use only 70% isopropanol and a lens cleaning solution formulated for multi-coated lenses to clean the Camera. Other fluids may cause damage to the illuminator filters. If necessary, they may be cleaned with a soft towel or wipe dampened with a mild detergent and water solution according to standard hospital practices.

PRECAUTION: Do not use any solvent to clean the Bendini® System. Solvents may damage the finish and remove lettering.

PRECAUTION: Do not use any paper products for cleaning. Paper products may cause scratches on the illuminator filter.

Sterile Instrument Cleaning and Decontamination

All instruments intended to be sterilized must first be thoroughly cleaned using the validated methods prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896) before sterilization and introduction into a sterile surgical field. The steam sterilizable components of the NVM5 System are to be packaged in an FDA-cleared sterilization wrap prior to placement in an autoclave. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896).

How Supplied

The NVM5 Disposable Accessories are single-use devices supplied sterile. Sterile, single-use only products should NOT be re-sterilized. Do not use if package is opened or damaged. Do not use after the expiration date specified on the product label. Do not use if the product is damaged in any way. Discard after use. Reusable accessories should not be sterilized before use.

Bendini® Tracking System
To clean the Camera, proceed as follows:

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 Camera, taking care not to wipe debris from the Camera case onto the illuminator filters or lenses. Avoid prolonged contact between the wipes and the Camera.

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 microfiber optical cleaning cloth (for example, Hitecloth). Avoid prolonged contact between the lens cleaner and the illuminator filters and lenses.

CLEANING & DECONTAMINATION

Bendini Instruments
All instruments must first be thoroughly cleaned using the following validated methods before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer for full processing. Cleaning instructions for the Bendini Spinal Rod Bender and Pointer instruments are as follows:

1. Prior to soaking the instruments in an enzymatic cleaning solution, rinse the instruments under cool running tap water and wipe off any residual soil or debris with a disposable towel. Confirm that any lumens, cracks or crevices are flushed out by rinsing under running cool tap water.
2. Prepare an enzymatic cleaning solution, such as MetriZyme®, per manufacturer's recommendations using warm tap water. Place the instruments in the solution in the open position (as appropriate) and allow to soak for a minimum of 50 seconds. While soaking, actuate the instruments through a full range of motion (as appropriate for the specific instrument) to allow complete penetration of the cleaning solution.
3. After the 50 seconds soak time, remove the instruments and wipe any soil or debris using a disposable towel. Then, place the instruments into a fresh batch of an enzymatic cleaning solution using warm tap water. Brush the entire surface of the instrument with a soft bristled brush. Actuate the instruments through a full range of motion while brushing and confirm all hard to reach areas have been brushed. Use a sterile syringe and lumen brush to clean hard to reach areas and flush each end of the instruments with a minimum of 60 mL.
4. Remove the instruments from the detergent and rinse by agitating and actuating in RO/DI water for a minimum of 30 seconds. Flush all hard to reach areas with a sterile syringe at each end of the instrument with a minimum of 60 mL.
5. Use a low foaming, neutral pH, phosphate-free cleaning solution and prepare per manufacturer's recommendations using warm tap water in a sonication unit. Allow the instruments to sonicate for 10 minutes. Instruments should be properly placed to maximize cleaning and to avoid damage or dislodgement of instruments and components.
6. Remove the instruments from the detergent and rinse by agitating and actuating in ambient RO/DI water for a minimum of 30 seconds. Actuate the instruments through a full range of motion while rinsing and flush all hard to reach areas with a sterile syringe at each end of the instruments with a minimum of 60 mL.
7. Transfer the instruments into the washer for processing. Position the instruments to allow for proper drainage. Below is the validated and recommended cycle:

Phase	Recirculation Time	Water Temperature	Detergent Type & Concentration *(If applicable)*
Pre-wash	2 minutes	Cold Tap Water	N/A
Enzyme Wash	2 minutes	Hot Tap Water	MetriZyme (1 oz/gallon) or Equivalent (Per Manufacturer's Instructions)
Wash	2 minutes	65.5°C (set point)	MetriZyme (1 oz/gallon) or Equivalent (Per Manufacturer's Instructions)
PURW Rinse	1 minute	43°C	N/A
Drying	15 minutes	90°C	N/A

CLEANING & DECONTAMINATION cont.

8. Dry the instruments using a clean soft towel.
Visually inspect the instruments following performance of the cleaning instructions prescribed above. Confirm there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present during visual inspection, repeat the cleaning steps above. Otherwise, contact your NuVasive® representative – contaminated instruments should not be used, and should be returned to NuVasive.

All instrument moving parts should be well lubricated. Be careful to use surgical lubricants and not industrial oils.
Note: Certain cleaning solutions such as those containing bleach or formalin may damage some instruments and must not be used.
Contact your NuVasive representative for any additional information related to cleaning and sterilization of NuVasive surgical instruments.

These sterilization instructions do not apply to instruments provided sterile.

All instruments and implants are provided non-sterile and must be sterilized prior to use. All components are sterilizable by steam autoclave using standard hospital practices.

The implants and instruments can be sterilized using the provided standard open cases or Aesculap® closed cases (standard or PrimeLine™ lid). Small baskets, trays, and other types of accessories, especially with covers or lids, not provided by NuVasive for a specific system should not be used. Only NuVasive standard open cases, and Aesculap closed cases (standard or PrimeLine lid) are validated for use with NuVasive products.

For standard open cases, devices are to be packaged in a FDA-cleared sterilization wrap prior to placement in an autoclave.

For information regarding closed Aesculap cases, please refer to appropriate Instructions for Use provided by Aesculap. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the following parameters:

Method: Steam	Method: Steam
Cycle: Pre-Vacuum	Cycle: Pre-Vacuum
Temperature: 270°F (132°C)	Temperature: 273°F (134°C)
Exposure Time: 4 minutes	Exposure Time: 3 minutes
Minimum Dry Time: 30 Minutes	Minimum Dry Time: 30 minutes
Minimum Cool down Time: 40 minutes	Minimum Cool down Time: 40 minutes

Sterile Components

The Array is an Ethylene Oxide sterilized single-use disposable. Packaged individually, the Array is assembled to a steam sterilized Pointer in the sterile field. After the Bendini System is used, the Array is unassembled from the Pointer and disposed of.

Do not attempt to clean or reprocess the Array.

Please refer to the two package inserts for the Spinal Rod Bender & Pointer and the Array for important labeling information regarding those Bendini System components.

MAINTENANCE

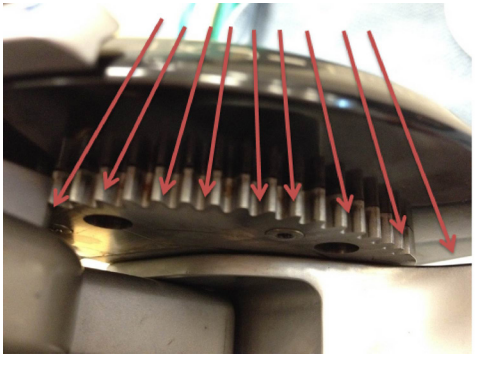
Prior to each use, the NVM5® System should be inspected and tested as follows:

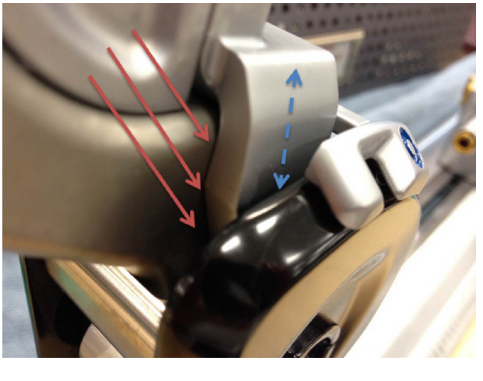
Control Unit Inspection
- Inspect the touch screen for damage and confirm that all labels are legible and in good condition.
- Confirm that the power cord insulation is in good condition and that there are no exposed wires.
- If any damage is observed, the device must be taken out of service and returned to NuVasive®.

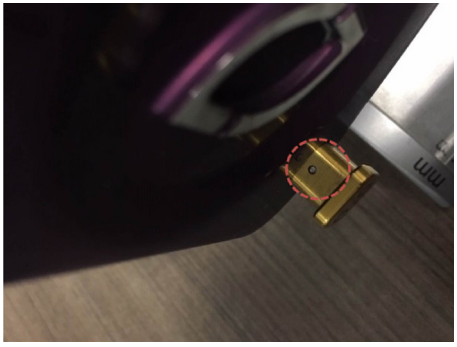
Patient Module Inspection
- Insert the Patient Module cable connector into the corresponding Control Unit receptacle and confirm that it seats fully.
- Confirm that the cable insulation and Patient Module housing are in good condition and that there are no exposed wires.
- If any damage is observed, the device must be taken out of service and returned to NuVasive.

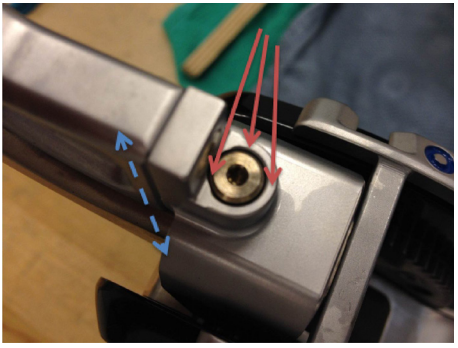
Camera Inspection
- If the Camera has suffered damage or an impact, which has affected its calibration, the amber colored LED will appear on the Camera face, and / or alert message will appear on the Bendini® software.
- The software message will state “Camera communication error. Requires calibration.”
- If this error is observed, please contact NuVasive Customer Service to coordinate equipment servicing.

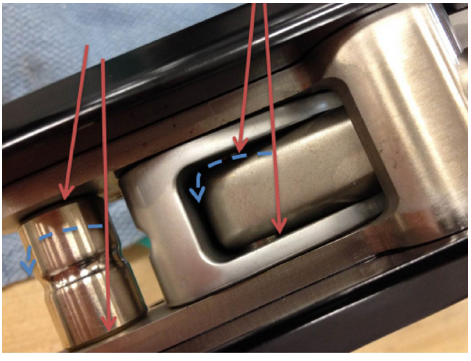
Bendini Bender
The user can apply standard medical lubrication for the Bendini Benders following the instructions and images below:
Step 1: Confirm instrument is free of debris, damage, and deformities
Step 2: Wipe down instrument with 70% isopropanol
Step 3: Lubricate with instrument lubricant in areas below and confirm screws are secure
Step 4: Wipe off any excess instrument lubricant

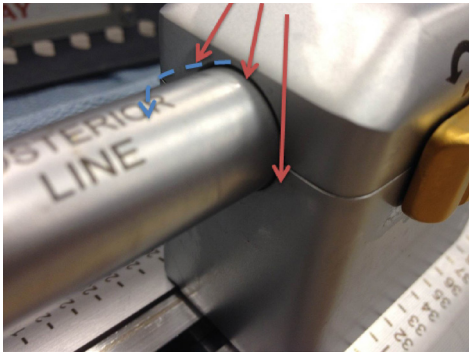








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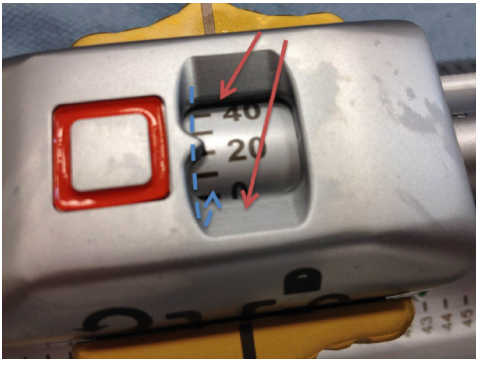
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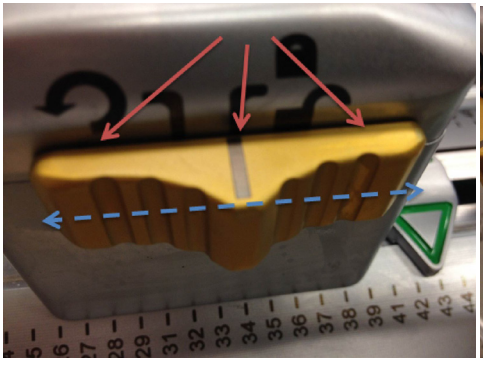

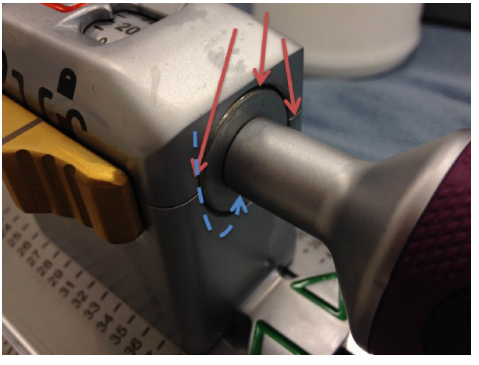

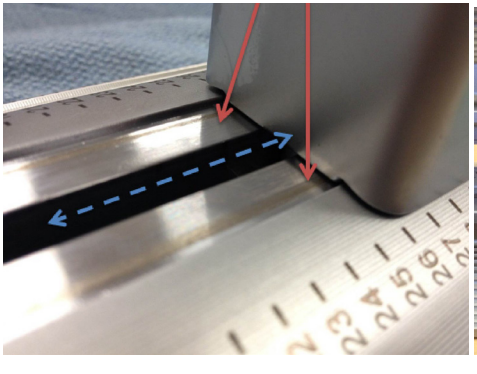

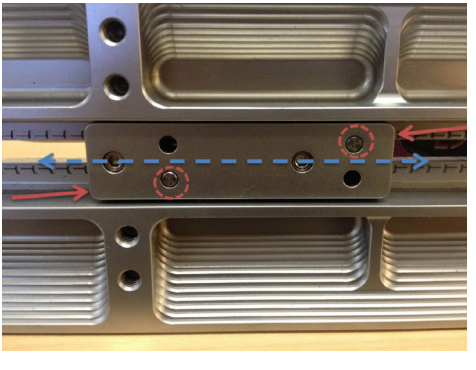

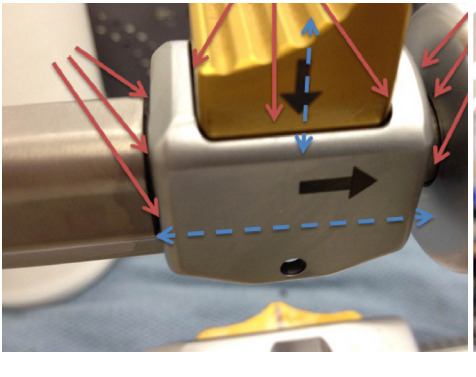

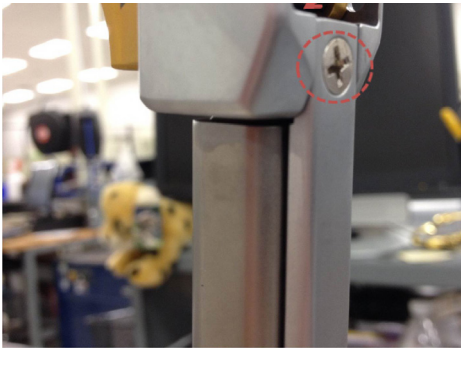

Electrical Safety Test
Upon initial receipt, and every 12 months thereafter, the NVM5 System should be inspected and an Electrical Safety Test should be performed, including leakage current testing, to confirm that the device continues to comply with applicable electrical safety standards for hospital grade medical devices.

Preventive Maintenance
It is strongly recommended that the NVM5 System undergo factory inspections and maintenance procedures every 12 months. Contact NuVasive Customer Service at 1(800) 475-9131 to arrange preventive maintenance.

Service and Repair
The NVM5 System has no user serviceable parts inside. Servicing and repair is to be performed only by NuVasive or its authorized agent.

Environmental Protection

Disposal of Equipment and Accessories
The disposable leads and accessories used with the NVM5 System are only intended for single-use, and must be discarded in accordance with standard hospital practices for controlling medical waste.

NVM5 Control Unit and Patient Module
The NVM5 System components such as the Control Unit, Patient Module, Bendini Camera, Keyboard, and associated electronics are not disposable. Contact NuVasive for assistance on proper disposition of non-disposable components.

INDICATIONS AND SAFETY

Indications for Use

The NVM5® System is a medical device that is intended for intraoperative neurophysiologic monitoring during spinal surgery. The device provides information directly to the surgeon, to help assess a patient's neurophysiologic status. NVM5 provides this information by electrically stimulating nerves via electrodes located on surgical accessories and monitoring electromyography (EMG), transcranial or lumbar motor evoked potential (MEP), or somatosensory evoked potential (SSEP) responses of nerves. The System also integrates Bendini® software used to locate spinal implant instrumentation for the placement of spinal rods.

- XLIF® (Detection) – The XLIF (Detection) function allows the surgeon to locate and evaluate spinal nerves, and is used as a nerve avoidance tool.
- Basic & Dynamic Screw Test – The Screw Test functions allow the surgeon to locate and evaluate spinal nerves by providing proximity information before, during or after bone preparation and placement of bone screws.
- Free Run EMG – The Free Run EMG function identifies spontaneous EMG activity of spinal nerves by continually displaying a live stream waveform of any mechanically induced myotome contractions.
- Twitch Test (Train of Four) – The Twitch Test Function allows the surgeon to assess moderate degrees of neuromuscular block in effect by evaluating muscle contraction following a train of four stimulation pulses.
- MEP – Transcranial or lumbar (i.e., conus in region of L1-L2) stimulation techniques for motor evoked potentials are used to assess for acute dysfunction in axonal conduction of the corticospinal tract and peripheral nerves. The MEP function provides an adjunctive method to allow the surgeon to monitor spinal cord and motor pathway integrity during procedures with a risk of surgically induced motor injury.
- SSEP – The SSEP function allows the surgeon to assess sensory spinal cord function in surgical procedures during which the spinal cord is at risk.
- Remote Reader – The Remote Reader function provides real-time remote access to the NVM5 System for a monitoring physician outside of the operating room.
- Guidance – The Guidance function is intended as an aid for use in either open or percutaneous pedicle cannulation procedures in the lumbar and sacral spine (L1-S1) of adult patients, and when used in conjunction with radiographic imaging and EMG, allows the surgeon to assess the angulation of system accessories relative to patient spinal anatomy for the creation of a cannulation trajectory for bone screw placement.
- Bendini - The Bendini Spinal Rod Bending function is used to locate spinal implant system instrumentation (screws, hooks) to determine their relative location to one another to generate bend instructions to shape a spinal rod. A surgeon is able to use those instructions and bend a rod using the Bendini Bender, a mechanical rod bender.

INDICATIONS AND SAFETY cont.

Contraindications

The NVM5® System may not be effective, and is not intended for use, when neuromuscular block or epidural blocks have been used for, or in conjunction with, anesthesia. Contraindications to use of transcranial Motor Evoked Potential (MEP) monitoring include epilepsy, cortical lesions, convexity skull defects, raised intracranial pressure, cardiac disease, proconvulsant medications or anesthetics, intracranial electrodes, vascular clips or shunts, and cardiac pacemakers or other implanted biomedical devices. Otherwise unexplained intraoperative seizures and possibly arrhythmias are indications to abort MEP.

Medical conditions that contraindicate the use of the NuVasive® Bendini® Spinal Rod Bending System and its associated applications include any medical conditions that may contraindicate the medical procedure itself.

CONTRAINDICATION: Neuromuscular Block or paralytics should not be in effect during the use of NVM5 EMG as they might interfere with the electromyography readings.

CONTRAINDICATION: Do not use the NVM5 System in conjunction with high frequency electromagnetic diathermy devices. Failure to do so may result in patient burns at the electrode sites.

CONTRAINDICATION: Use of MEPs is contraindicated in patients with a history of head injury, cerebral aneurysm, stroke, seizures, other neurological impairments, or patients with metal plates or fragments in their head.

CONTRAINDICATION: Do not attempt to use this device when using paralyzing agents on the patient, as nerve surveillance may be compromised.

CONTRAINDICATION: Do not use cutaneous electrodes for stimulation (stimulation electrodes) if the patient has a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

CONTRAINDICATION: Minimize coupling with electrosurgical equipment when setting up the NVM5 System. Some actions that may help reduce electrical coupling include: locate the electrosurgical patient return pad as close to the surgical site as practical; route the monopolar and bipolar electrosurgical wiring together and away from any other patient connected leads and electrodes; minimize the activation of electrosurgical instruments while they are not in patient contact; plug the electrosurgical generator equipment into a separate power outlet from any other patient-connected electrical device; and use the lowest electrosurgical power setting that achieves the surgical requirement.

CONTRAINDICATION: NVM5 electrodes (surface, corkscrew, and needle electrodes) are not intended to come into contact with the central nervous system (CNS) or dural sac. These electrodes should only be placed on the surface of the skin of the patient or sub-dermally. To avoid incorrect use of NVM5 electrodes, no NVM5 electrodes should ever be placed within the surgical site.

WARNINGS AND PRECAUTIONS

Warnings and Precautions

Read all instructions and understand all warnings and cautions before using the NVM5® System and accessories. Failure to do so may lead to serious medical consequences. Refer to the Instructions for Use accompanying other NuVasive® devices before use with the NVM5 System to assure proper and safe use of these devices.

WARNING: Patients with implanted electronic devices, such as cardiac pacemakers, should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.

WARNING: The MEP modality is capable of generating outputs exceeding 2mA RMS/cm² in every stimulation current (from 200 to 1500mA)/pulse (1 to 8) combination. Prolonged stimulation at outputs greater than 2mA RMS/cm² may result in skin burns.

WARNING: Chronically compressed nerves, or severely compressed nerves in an acute setting, are known to be less sensitive to depolarization currents (i.e., have significantly higher depolarization current values). They are also less likely to demonstrate significant changes in their threshold depolarization current values immediately following nerve decompression. Under such circumstances, exercise caution in interpreting displayed data.

WARNING: The NVM5 System contains no user serviceable parts inside, and servicing (other than that explicitly defined elsewhere in this manual) must be performed by the manufacturer or its authorized agent.

WARNING: Do not use the NVM5 System in the presence of explosive gases. The device is not explosion proof.

WARNING: To minimize the risk of electric shock, always connect the Patient Module cable to the Control Unit before connecting the Patient Module to the patient EMG leads. Also, always disconnect the patient EMG leads before removing the Patient Module cable from the Control Unit.

WARNING: MEP scalp stimulation electrodes can deliver a high voltage shock. To avoid shock, never handle both electrodes at the same time. Ensure both electrodes are securely and properly attached to the patient before initiating any test.

WARNING: MEP stimulation may introduce additional hazards to the patient through use. Examples of these hazards include: tongue or lip laceration, mandibular fracture, seizure, cardiac arrhythmia, and scalp burn.

WARNING: A Red Channel may indicate a disconnected or separated electrode or poor electrode impedance. If a failed channel or channel that has been disabled is accepted, responses from this channel will not be detected during stimulation. This could lead to a false-negative result if the myotome is innervated by the spinal level under test. Free Run events on this channel will not be detected.

WARNINGS AND PRECAUTIONS cont.

WARNING: To avoid trans-thoracic stimulation, ensure both MEP electrodes are properly attached to the patient's scalp or abdomen before initiating any test.

WARNING: To avoid bite injuries, the patient must be fitted with a bite block before initiating transcranial MEP testing.

WARNING: MEP stimulation may induce violent muscle contractions throughout the patient's body. Secure physical restraints should be used, and surgical operations should be discontinued before and during MEP stimulation. Ensure the surgeon is well notified prior to any MEP testing.

WARNING: Only use electrodes supplied with the NVM5® System. Use of other electrodes may adversely affect results.

WARNING: Do not place stimulation electrodes over the patient's neck because this could cause severe muscle spasms resulting in closure of the patient's airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

WARNING: Do not place stimulation electrodes across the patient's chest because the introduction of electrical current into the chest may cause rhythm disturbances to the patient's heart, which could be lethal.

WARNING: Do not place stimulation electrodes over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins); and

WARNING: Do not place stimulation electrodes over, or in proximity to, cancerous lesions.

WARNING: Electrodes should be applied only to normal, intact, clean, healthy skin.

WARNING: The size, shape, and type of electrodes may affect the safety and effectiveness of electrical stimulation and recording.

WARNING: Using stimulation electrodes that are too small or incorrectly applied could result in discomfort or skin burns.

WARNING: Use caution if electrodes are applied over areas of skin that lack normal sensation;

WARNING: Keep electrodes out of the reach of children;

WARNING: Replace self-adhesive electrodes if they no longer stick firmly to the patient's skin.

WARNING: The patient may experience skin irritation and burns beneath the stimulation electrodes applied to their skin; and

WARNINGS AND PRECAUTIONS cont.

WARNING: The patient may experience headache and other painful sensations during or following the application of electrical stimulation near their eyes and to their head and face.

WARNING: Do not run any NVM5® stimulation while Bendini® is the active displayed screen;

WARNING: Setting Free Run threshold too high may result in missed free run alert;

WARNING: If system data acquisition seems inaccurate or if the software application does not initiate or malfunctions during use, and recommended steps to restore the system are not successful, abort use of the system.

WARNING: The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide.

WARNING: A red tracking icon on the GUI (Graphic User Interface) indicates that the system is not actively tracking a Digitizer. In the event a red tracking icon is observed, verify the appropriate operating ranges have been achieved and that the unit is correctly assembled. Reposition and/or reconnect the unit as necessary until a green tracking icon is achieved.

WARNING: The Bendini System has been successfully tested against the requirements of IEC 60601-1-2. However, radio frequency (RF) interference could hamper its operation or the operation of other nearby electrical devices. If you suspect either of these conditions, move the conflicting equipment farther apart, separate the equipment with a RF barrier, or discontinue use of the system.

WARNING: Movement of the patient during the course of data acquisition may result in inaccurate measurements. Efforts to immobilize the patient during data acquisition should be taken to restrict movement of the patient. If movement of the patient during data acquisition is observed or suspected, start the sequential data acquisition process from the beginning in order to ensure accurate measurements.

WARNING: Movement of the Camera during the course of data acquisition may result in inaccurate measurements. Efforts to immobilize the Camera during data acquisition should be taken to restrict movement of the tracking system. If movement of the Camera during data acquisition is observed or suspected, start the sequential data acquisition process from the beginning in order to ensure accurate measurements.

WARNING: Do not transport or store the Camera outside the recommended storage temperature range, as this may cause the system to go out of calibration. Reliance on data provided by an out of calibration Camera may lead to inaccurate measurements.

WARNING: Do not obstruct the normal flow of air around the Camera (for example, draping or bagging the Camera). Doing so will affect the Camera's operational

environment, possibly beyond its recommended thresholds. Reliance on data provided by a Camera that is outside of recommended thresholds may lead to inaccurate measurements.

WARNING: Reliance on data provided by the Camera without an uninterrupted optical path may lead to inaccurate measurements.

WARNING: Do not use the NuVasive® Bendini® System Camera without inspecting it for cleanliness and damage both before and during a procedure. Reliance on data provided by an unclean or damaged Camera may lead to inaccurate measurements.

WARNING: Do not use the Spinal Rod Bender if the product is damaged in any way.

WARNING: Do not use the Array if the product is damaged in any way.

PRECAUTION: The long-term effects of cutaneous electrodes for electrical stimulation and/or recording are unknown;

PRECAUTION: Exercise caution when increasing max stimulation. Higher stimulation may result in increased movement, which may impact retractor position.

PRECAUTION: Do Not Implant the Instruments. Complications to the patient may include, but are not limited to:
- Nerve damage, paralysis, pain, or damage to soft tissue, visceral organ, or joints.
- Dural leak in cases of excessive load application or impingement of close vessels, nerves, and/or organs by slippage or misplacement of the instrument.
- Bony fracture, especially in the case of deformed spine or weak bone.
- Infection, if instruments are not properly cleaned and sterilized.
- Breakage of the device, which could make necessary removal difficult or sometimes impossible, with possible consequences of late infection and migration. Breakage could cause injury to the patient.
- Pain, discomfort, or abnormal sensations due to the presence of the device.

PRECAUTION: The instruments should be carefully examined prior to use for functionality, excessive wear, or damage. A damaged instrument should not be used as this may increase the risk of malfunction and potential patient injury.

PRECAUTION: Instruments should be protected during storage and from corrosive environments. All non-sterile parts should be cleaned and sterilized before use. Inspect all components for damage before use. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

PRECAUTION: The physician should take precautions against putting undue stress on the spinal area with instruments. Any surgical technique should be carefully followed. It is important that the surgeon exercise extreme caution when working in close proximity

to vital organs, nerves, or vessels, and that the force applied to the instrumentation is not excessive, to prevent potential injury to the patient.

PRECAUTION: If system data acquisition seems inaccurate or if the software application does not initiate or malfunctions during use, and recommended steps to restore the system are not successful, abort use of the system.

PRECAUTION: Inspect all system components and packaging for damage before use. Do not use sterile components if packaging is opened or damaged. If components are visibly damaged, do not use the system.

PRECAUTION: The system is not suitable for use in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide.

PRECAUTION: Over-bending, notching, striking, and/or scratching of implants with any instrument should be avoided to reduce the risk of breakage. The physical characteristics required for many instruments do not permit them to be manufactured from implantable materials. If any broken fragments of instruments remain in the body of a patient, they could cause allergic reactions or infections. If an instrument breaks in surgery and fragments go into the patient, these pieces should be removed prior to closure and should not be implanted.

PRECAUTION: During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

PRECAUTION: Do not use the NVM5 System in conjunction with, or in the presence of magnetic resonance (MR) devices. The NVM5 System is not compatible with the magnetic fields associated with magnetic resonance (MR) devices.

PRECAUTION: Do not use the NVM5/Bendini Spinal Rod Bending System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

PRECAUTION: When using “Other” screws, user must confirm the distal tip of the Pointer fits and fully seats in the screw shank. The Hybrid Pointer may act as an option to use with “Other” Systems, if proper fit is confirmed. User discretion is advised when using Bendini with “Other” screws.

PRECAUTION: Improperly placed corkscrews may result in poor responses or no responses, even with high electrical current stimulus.

PRECAUTION: Proper handling, insertion and placement of electrodes is critical for safe and accurate EMG monitoring. Needles should be at least 1” apart. Please follow your hospital’s medical waste ‘sharps’ guidelines for proper and safe disposal of needle electrodes.

WARNINGS AND PRECAUTIONS cont.

PRECAUTION: Inspect all system components and packaging for damage before use. Do not use sterile components if packaging is opened or damaged. If components are visibly damaged, do not use the system.

PRECAUTION: Do not use alcohol to clean the Touch Screen on the Control Unit.

PRECAUTION: Do not allow liquids to enter the Control Unit or Patient Module, as this may result in damage or malfunction of the NVM5® System. Avoid dripping any fluids into any Bendini® equipment. Disconnect the power and allow the system to dry if you suspect fluids may have entered any part of the System.

PRECAUTION: The NVM5 System is not protected against the effects of defibrillation. Do not use in conjunction with a defibrillator.

PRECAUTION: While the NVM5 System is designed to assist in the electromyographic location of spinal nerves in proximity to the surgical site, it is not intended to take the place of thorough knowledge of spinal anatomy and appropriate surgical technique, nor should the information provided by the system be construed as definitive indicators of nerve location. Such factors as the distance from the nerve, the position and placement of electrodes, individual muscle and/or nerve responses, the proximity and strength of sources of electrical interference, and other patient and environmental factors, may influence the operation. If, in the judgment of the clinician, this resistance is sufficient to preclude safe placement of instruments, the procedure should be suspended.

PRECAUTION: To avoid trans-thoracic stimulation, the Stimulation Anode should not be located on the chest or upper back. Place this electrode on the lower abdomen, gluteus, or upper flank.

PRECAUTION: To optimize accuracy of EMG recording, the EMG Common electrode should be located between the site of stimulation and the recording electrodes (e.g., on the flank).

PRECAUTION: The NVM5 System contains sensitive electronic components which may be damaged by electrostatic discharge (ESD). While safeguards have been designed into the System, normal precautions should be taken to avoid causing ESD impulses to occur directly on the EMG input electrodes. For example, it is recommended that before touching the EMG electrodes, the operator should touch the barrel of the main cable connector between the Control Unit and the Patient Module to reduce any accumulated charge on the operator.

PRECAUTION: Prior foraminal or extraforaminal surgery may leave scar tissue at the site of surgery which can result in undue resistance to instrument insertion. Exercise care in inserting instrumentation in such circumstances to prevent the application of excessive force that can damage internal structures.

WARNINGS AND PRECAUTIONS cont.

PRECAUTION: The NVM5® System is to be used only as an adjunct to medical judgment and appropriate surgical practices. Dilator insertion and advancement should be conducted only after careful analysis of radiographic images of the operative target area. While a positive EMG detection by the NVM5 System can be associated with a high level of certainty that a nerve is in close proximity to the Dilator tip, the absence of such an EMG detection cannot be construed as a certain indication that no nerves are close to the Dilator tip. Do not advance Dilator probes until all available data have been considered.

PRECAUTION: Do not advance the Dilator faster than the rate of update of Detection data.

PRECAUTION: A thorough cleaning and preparation of the dermal surface prior to placement of recording electrodes is required to assure proper adherence and sensitivity of the electrodes. It is recommended to apply sufficient skin preparation to achieve acceptable electrode impedance. Caution should be exercised during skin preparation and electrode removal. Excessive preparation and/or sudden removal may lead to skin reaction and abrasion.

PRECAUTION: In preparing the sites for EMG Electrode placement, patient sensitivity to disinfecting and sterilizing agents (e.g., alcohol, povidine, etc.), electrode materials, and adhesive tapes and electrode backings should be considered to prevent skin reactions.

PRECAUTION: Using the provided electrode placement instructions, extreme care should be taken to confirm that the recording electrodes have been placed on the correct muscle groups, and on the correct side of the patient, before plugging the EMG Harness into the Patient Module. Failure to follow these instructions may result in the display of inadequate information necessary for data interpretation.

PRECAUTION: There may be a noticeable muscle twitch in either or both legs during the stimulation. This will subside after a few seconds. Do not attempt to restrain the legs to prevent them from twitching, as this will interfere with the EMG signals.

PRECAUTION: If the patient moves, or is moved, during the course of surgery, electrode positions may be disturbed. In such instances, electrode positions should be re-examined to confirm proper location, adequacy of contact, and security of connections. Run electrode test to affirm adequacy of EMG electrode contact.

PRECAUTION: If the intended level of surgery changes intraoperatively, EMG Recording Electrode placement may no longer be appropriate for monitoring one or more of the nerves at or near the operative site. In such an event, the EMG Recording Electrode placement should be should be altered, commensurate with change.

PRECAUTION: Movement of the patient during stimulation can cause excessive electrical “noise” and/or false EMG (noise) artifacts.

WARNINGS AND PRECAUTIONS cont.

PRECAUTION: The use of electrosurgical equipment near the NVM5® System's EMG Electrodes may damage the Patient Module or Control Unit.

PRECAUTION: Over-abrading can cause serious topical reaction to the patient. Always apply using the preferred patient preparation technique.

PRECAUTION: Do not touch the electrode sites with your fingers/skin as this may compromise the conductivity between the patient's skin and electrode.

PRECAUTION: Connection of a patient to electrosurgical equipment and to the NVM5 System simultaneously may result in burns at the site of the electrodes and possibly damage the NVM5 System circuitry.

PRECAUTION: Do not use the NVM5 System in conjunction with, or in the presence of magnetic resonance (MR) devices. The NVM5 System is not compatible with the magnetic fields associated with magnetic resonance (MR) devices.

PRECAUTION: Operation of the NVM5 System in close proximity to shortwave or microwave therapy equipment may produce instability in the electrical stimulator output.

PRECAUTION: Do not attempt to repair the NVM5 System. Any malfunction which does not respond to remedies identified in this Guide (see 'TROUBLESHOOTING' section in the Quick Reference Manual) can only be addressed by manufacturer's service. We require that the device be returned to NuVasive® for any such inspection, service, or repair.

PRECAUTION: Proper handling, insertion, and placement of needle electrodes is critical for accurate monitoring.

PRECAUTION: Improperly placed or bent needles increase the risk of needle breaking off in the patient.

PRECAUTION: Do not attempt to straighten bent needles because this may cause stress and weaken the needle causing it to break off in the patient.

PRECAUTION: Needles are sharp and extreme care must be taken during handling.

PRECAUTION: Do not allow liquids to enter the Stimulation Probe or Stimulation Clip, as this may result in damage or malfunction of the NVM5 System.

PRECAUTION: Do not use saline irrigation in the vicinity of the Stimulation Electrodes while operating the System. Saline solutions may lead to shunting of the stimulation current resulting in improper operation.

PRECAUTION: Avoid fluid contact with all cable connections.

WARNINGS AND PRECAUTIONS cont.

PRECAUTION: Avoid contact between any of the NVM5® System's electrical connections and any other conductive parts, including those connected to protective earth/ground.

PRECAUTION: Remain alert for audible indications of EMG-like activity as an indicator of nerve trauma. Lack of audible feedback may indicate speaker system malfunction.

PRECAUTION: The NVM5 System will not be able to reliably detect EMG impulses on channels degraded by noise. If an Impedance Test Error occurs, immediate attention should be directed toward correcting the problem by checking the electrode placement, securing the electrodes with tape, and eliminating any other sources of the noise. If excessive ambient noise persists or if a noise error message appears, check the position of all leads and electrodes, and position them as far away from other electronic equipment as possible. Observe the EMG signals using the free run, or evoked potentials display to determine the nature of the noise.

PRECAUTION: Poor electrode impedance may create susceptibility to electrical interference, which can adversely affect system performance.

PRECAUTION: Connection of the NVM5 System to unapproved equipment may result in dangerous levels of patient leakage currents. Use only approved NuVasive® accessories with the NVM5 System. Do not use cables or accessories other than those provided with the system.

PRECAUTION: Audible alert notification of spontaneous EMG events will not be generated when the NVM5 System is used with the "Mute" setting activated. To receive all possible audible alerts when using the NVM5 System, ensure that the "Mute" setting is not activated.

PRECAUTION: Placement of recording electrodes within close proximity of one another (less than one inch) may prevent the NVM5 System from recording differential responses. To ensure differential responses can be recorded, position the recording electrodes at least 1 inch from each other.

PRECAUTION: Avoid contaminating the passive reflective markers on the Array with any liquid or solid materials to ensure the proper functioning of the Bendini® System.

PRECAUTION: Applying excessive force to the Digitizer when acquiring locations of implants can result in inaccurate measurements due to movement of the patient anatomy.

PRECAUTION: The accuracy of data acquisition can be influenced through the non-coaxial alignment of the Digitizer while registering points – consider keeping the alignment of the Digitizer coaxial to the implant when registering its location in order to get the best results.

WARNINGS AND PRECAUTIONS cont.

PRECAUTION: Do not push or pull connectors in constricted areas. Doing so may damage the connectors.

PRECAUTION: Do not put heavy objects on cable connectors. Doing so may damage the connectors.

PRECAUTION: Pull connections apart by gripping the connector. Do not pull them apart by tugging on the cable as this can damage the connecting cable. Never force a connection or a disconnection.

PRECAUTION: Switch off power to the system before cleaning it.

PRECAUTION: Do not use aerosol sprays near the equipment as these sprays can damage circuitry.

PRECAUTION: Do not use any solvent to clean the Bendini® System. Solvents may damage the finish and remove lettering.

PRECAUTION: Do not autoclave any of the Bendini System components except for the Bendini Spinal Rod Bender, or the Pointer instruments. Autoclaving any other components may damage the system.

PRECAUTION: Do not attempt to bypass the grounding prong on the power cord by using a three-prong to two prong adapter. The system must be properly grounded to ensure safe operation.

PRECAUTION: The Bendini System contains no serviceable parts inside, and servicing must be performed by the manufacturer or its authorized agents.

PRECAUTION: Use only 70% isopropanol and a lens cleaning solution formulated for multi-coated lenses to clean the Camera. 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.

PRECAUTION: When making minor bend adjustments to the rod using a manual rod bender, minimize the number of additional bend manipulations to prevent potential over bending of the rod.

PRECAUTION: Verify that all relevant instrumentation has been properly cleaned and sterilized before surgery.

PRECAUTION: Do not use cables or accessories other than those provided with the system.

WARNINGS AND PRECAUTIONS cont.

PRECAUTION: Do not exceed the recommended electrical ratings for the system. Exceeding the ratings could damage the system.

PRECAUTION: The system mouse and keyboard are not designed for sterilization, and may be damaged if sterilization is attempted.

PRECAUTION: System components are fragile. Use care when handling system components.

PRECAUTION: Avoid dripping any fluids into any enclosure on the Bendini® System. Disconnect the power and allow the system to dry if you suspect fluids may have entered any part of the System.

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

GRAPHICAL SYMBOLS

	Alternating Current	REF	Catalog Number
	Main Power ON	SN	Serial Number
	Main Power OFF	LOT	Lot Number
	Consult Instructions Before Use	QTY	Quantity
	Consult Instructions Before Use. Available on the NuVasive website at www.NuVasive.com	MATL	Material
	Type BF Equipment		Atmospheric Pressure
	Dangerous Voltage		Storage Conditions: Relative Humidity
	Single Use Only		Storage Conditions: Temperature
	Use By	EC REP	European Community Representative
	Potential Equalization Terminal	STERILE R	Sterilization by Irradiation
	Manufacturer	STERILE EO	Sterilization by Ethylene Oxide
	Date of Manufacture		Electronic Equipment: Dispose of Properly
	No Latex		Non-ionizing electromagnetic radiation
	Warning, Laser Beam		Caution

TECHNICAL SPECIFICATIONS

EMG Monitor

Number of Channels:	32
Frequency Response:	45Hz to 1.5kHz
A/D Converter:	16 bit resolution
Full Scale Span:	± 4,096 mV
A/D Sampling Rate:	9.6 kHz
Common Mode Rejection Ratio:	Greater than 90dB
Audio Output:	100 Hz to 5 kHz response, Independent volume controls for EMG and Alarm

EMG Stimulation Output

Waveform:	Rectangular, Monophasic Pulse
Polarity:	Cathodic
Output Regulation:	Constant Current
Pulse Width:	200 microseconds ± 2%
Current Pulse Amplitude:	1 to 90mA (dependent on electrode impedance)
Load Impedance:	200 to 8,000 ohms
Stim Rate:	up to 5 Hz
Maximum Voltage:	300V

Display Accuracy and Precision

Stimulation current display accuracy, the greater of 1 mA or 10%

display resolution: 1024 x 768 pixels, 16 bit color

Control Unit Power Requirements

Voltage:	100-240 VAC
Frequency:	50/60Hz
Current:	3A
Operating System:	Windows XP, Windows 7

Wifi-802.11g Wireless Antenna or 10/100 Base - TX Ethernet

RAM:	1 GB
Processor:	Single Core, minimum 2.0 GHz
Free USB Ports:	2
Hard Drive:	Minimum 8 GB free space

TECHNICAL SPECIFICATIONS cont.

MEP Stimulation Output

Waveform:	Rectagular, Monophasic Pulse
Polarity:	Polarity Selectable
Output Regulation:	Constant Current
Pulse Width:	50 microseconds
Pulse Intervals:	1 to 4 milliseconds
Current Pulse Amplitude:	0 to 1500 mA (dependent on electrode impedance)
Pulse Rate:	1 Hz
Maximum Voltage:	1000V
Multipulse:	1-8 Pulses

Max. number of pulses in a burst while maintaining limit of: 125 mJ/s
Voltage Applied

I (mA)	100	200	300	400	500	600	700	800	900	1000
100	8	8	8	8	8	8	8	8	8	8
200	8	8	8	8	8	8	8	8	8	8
300	8	8	8	8	8	8	8	8	8	8
400	8	8	8	8	8	8	8	7	6	6
500	8	8	8	8	8	8	7	6	5	4
600	8	8	8	8	8	6	5	5	4	4
700	8	8	8	8	7	5	5	4	3	3
800	8	8	8	7	6	5	4	3	3	3
900	8	8	8	6	5	4	3	3	3	2
1000	8	8	8	6	4	4	3	3	2	2
1100	8	8	7	5	4	3	3	2	2	2
1200	8	8	6	5	4	3	2	2	2	2
1300	8	8	6	4	3	3	2	2	2	1
1400	8	8	5	4	3	2	2	2	1	1
1500	8	8	5	4	3	2	2	2	1	1

Note: Transcranial MEP stimulation exceeds 2 mA rms/cm2. Confirm that the corkscrew electrodes are secure prior to starting stimulation.

As shown in the chart, Transcranial MEP stimulation is limited to 125 mJ/sec. The chart allows the user to estimate the number of pulses permitted given a current voltage (based on an impedance of 1 kΩ).

MEP Stimulator Power Requirements

Voltage:	100-240 VAC
Frequency:	50/60 Hz
Current:	0.75

TECHNICAL SPECIFICATIONS cont.

SSEP Stimulation Output

Waveform:	Rectangular, Monophasic Pulse
Polarity:	Polarity Selectable
Output Regulation:	Constant Current
Pulse Width:	50 to 300 microseconds
Current Pulse Amplitude:	1 to 100mA (dependent on electrode impedance)
Stim Rate:	1.7 Hz to 5.7 Hz
Maximum Voltage:	300V

SSEP Monitor

Number of Channels:	7
Frequency Response:	45Hz to 300Hz
A/D Converter:	16 bit resolution
Full Scale Span:	± 2,048 mV
A/D Sampling Rate:	9.6 kHz
Common Mode Rejection Ratio:	Greater than 74dB

Bendini® Power Requirements

Voltage:	100-240 VAC
Frequency:	50-60Hz
Current:	1.2-0.63 A

Classifications

- The NVM5® System is a Class I, Type BF Applied Part device with respect to protection against electric shock.
- The NVM5 System is considered Ordinary Equipment – IPX0 – in that it is not protected against water ingress.
- The NVM5 System is not suitable for use in the presence of flammable anesthetic mixtures.
- The NVM5 System is classified suitable for Continuous Operation.
- Only equipment and accessories complying with EN 60601-1 and approved for use with the NVM5 System may be connected.
- The Bendini System is a Class I Device with respect to protection against electric shock.
- The Bendini System is considered Ordinary Equipment – IPX0 – in that it is not protected against water ingress.
- The Bendini System is not suitable for use in the presence of flammable anesthetic mixtures.
- The Bendini System is classified suitable for Continuous Operation.

TECHNICAL SPECIFICATIONS cont.

Environmental Conditions (per EN 60601-1 and ISTA 2A)

Operating Conditions

Temperature:	+10º C to +40º C
Humidity:	30% to 75% Relative Humidity
Atmospheric Pressure:	700 hPa to 1,060 hPa (525 mmHg to 795 mmHg)

Non-Operating Conditions

Temperature:	+10º C to +40º C
Humidity:	30% to 75% Relative Humidity
Atmospheric Pressure:	700 hPa to 1,060 hPa (525 mmHg to 795 mmHg)
Shock:	5 cm drop height

Transportation and Storage Conditions

Temperature:	-20º C to +60º C
Humidity:	5% to 95% Relative Humidity (non-condensing)
Atmospheric Pressure:	500 hPa to 1,060 hPa (375 mmHg to 795 mmHg)
Shock and Vibration:	Per ISTA 2A (International Safe Transit Association)

Physical Size

Control Unit:	17” W x 10”D x 18”H (43 x 25 x 46 cm)
Patient Module:	9”W x 5”D x 9”H (23 x 13 x 23 cm)
Camera and Clamp:	11”W x 2.5”D x 3”H (28 x 7 x 8 cm)
Cable Box Assembly:	7”W x 5.5”D x 2”H (17 x 14 x 5 cm)
Pelican case:	22”W x 18”D x 9”H (56 x 46 x 23 cm)

Weight

Control Unit:	24 lbs. (10.9 kg)
Patient Module:	10 lbs. (4.5 kg)
Camera and Clamp:	2.0 lbs. (0.9 kg)
Cable Box Assembly:	4.2 lbs. (1.9 kg)
Pelican case:	10.6 lbs. (4.8 kg)

PRECAUTION: *The NVM5® System is not protected against the effects of defibrillation. Do not use in conjunction with a defibrillator.*

TECHNICAL SPECIFICATIONS cont.

Guidance and manufacturer's declaration—electromagnetic emissions		
The **NVM5**® System is intended for use in the electromagnetic environment specified below. The customer or the user of the **NVM5** should confirm that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment--guidance**
RF emissions CISPR 11	Group 1	The **NVM5** System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The **NVM5** System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration—electromagnetic immunity			
The **NVM5** is intended for use in the electromagnetic environment specified below. The customer or the user of the NVM5 should confirm that it is used in such an environment.			
Immunity test	**IEC 06901 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	±1 kV for power supply lines ±0.5kV for input/output lines	±1 kV for power supply lines ±0.5kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 1000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short Interruptions and voltage variations on power supply Input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycles <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	<5 % U_T (>95% dip in U_T) for 0.5 cycles <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 **NVM5** requires continued operation during power mains interruptions, it is recommended that the **NVM5** be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	If image distortion occurs, it may be necessary to position the **NVM5** further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE - U_T is the a.c. mains voltage prior to application of the test level.			

TECHNICAL SPECIFICATIONS cont.

Guidance and manufacturer's declaration—electromagnetic immunity

The **NVM5**® is intended for use in the electromagnetic environment specified below. The customer or the user of the **NVM5** should confirm that it is used in such an environment.

Immunity test	IEC 06901 test level	Compliance level	Electromagnetic environment—guidance
			Portable and mobile RF communications equipment should be used no closer to any of the **NVM5** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 Vrms 80 kHz to 2.5 MHz	3 V/m[c]	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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, 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 equipment used exceeds the applicable RF compliance level above, the equipment should be observed to confirm normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

b Over the frequency range 150 KHz to 80 MHz field strengths should be less than 3 V/m.

c The Impedance Meter Accessory has a compliance level of 2 V/m in the range 80 MHz to 2.5 GHz.

TECHNICAL SPECIFICATIONS cont.

Recommended separation distances between portable and mobile RF communications equipment and the NVM5®

The **NVM5** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the **NVM5** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the **NVM5** 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 MHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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.

Guidance and manufacturer's declaration—electromagnetic immunity

The **NVM5** is intended for use in the electromagnetic environment specified below. The customer or the user of the **NVM5** should confirm that it is used in such an environment.

Immunity test	IEC 06901 test level	Compliance level	Electromagnetic environment—guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 10 MHz 0.3 mVrms 10 MHz to 20 MHz 0.03 mVrms 20 MHz to 80 MHz	The **NVM5** must be used only in a shielded location with a minimum RF shielding effectiveness and, for each cable that enters the shielded location, a minimum RF filter attenuation of 80 dB from 10 MHz to 20 MHz, 100dB from 20 MHz to 80 MHz, and 80 dB from 80 MHz to 100 MHz. (The minimum at 20 MHz is 100 dB and the minimum at 80 MHz is 80 dB.) See page 25 of the service manual. Field strengths outside the shielded location from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than 3V/m.[a] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	0.3 mV/m 80 MHz to 100 MHz 3 V/m 100 MHz to 2.50 GHz	

NOTE 1 - These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 2 - It is essential that the actual shielding effectiveness and filter attenuation of the shielded location be verified to assure that they meet the minimum specification.

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, 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 outside the shielded location in which the system is used exceeds 3 V/m, the system should be observed to confirm normal operation. If abnormal performance is observed, additional measures may be necessary, such as relocating the system or using a shielded location with a higher RF shielding effectiveness and filter attenuation.

EMC Labeling For Camera Tracking System

Cables and Accessories
The following table lists the cable and accessories that may be used with the Polaris Vicra Tracking System while still maintaining compliance to the emissions and immunity requirements of IEC60601-1-2:2001.

Use of cables or accessories, other than those listed in the following table, may result in increased emissions and/or decreased immunity of the Polaris Vicra Tracking System and may result in personal injury.

Manufacturer's Declaration for Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions - CISPR11	Group 1	The Polaris Vicra Tracking System does not emit electromagnetic energy in order to perform all its intended functions.
RF emissions - CISPR11	Class A	The Polaris Vicra Tracking System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions - IEC61000 3-2	Class D	
Voltage fluctuations/ flicker emissions IEC61000-3-3	Complies	

Manufacturer's Declaration for Electromagentic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Observe precautions when connecting or disconnecting cables at ports identified with the ESD warning symbol
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrical Fast Transient (EFT)/burst IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for I/O lines	±2 kV for power supply lines. ±1 kV for I/O lines	Care must be taken to route all patient-coupled cables away from high power, high current or other cables or sources that may induce electrical fast transients into the patient-coupled cables. If such interference is suspected, the cables should be re-routed and/or the source of the interference shielded or otherwise isolated
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	NA
	±2 kV common mode	±2 kV common mode	
Dips/Interruptions/ Variations on power supply input IEC 61000-4-11	<5% U_t for 0.5- cycles	<5% U_t for 0.5- cycles	NA
	40% U_t for 5- cycles	40% U_t for 5- cycles	
	70% U_t for 25- cycles	70% U_t for 25- cycles	
	<5% U_t for 5 sec	<5% U_t for 5 sec	
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.

TECHNICAL SPECIFICATIONS cont.

EMC Labeling For Camera Tracking System (Cont.)

Electromagnetic Immunity - Not Life Supporting

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHZ to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Polaris Vicra Tracking System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where 'P' is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 'd' is the recommended separation distance in metres. 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: U_t is the AC mains voltage prior to the application of the test level.

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 accurately predicted. 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 where the Polaris Vicra System is used exceeds the applicable RF compliance level above, observe the system to confirm normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Polaris Vicra System.

b. Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.
These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. If an electromagnetic interference is suspected, it is the responsibility of the user to assess the electromagnetic environment in their location.

Recommended Separation Distances

Rated maximum output power of transmitter (watts)	Separation distance according to frequency of transmitter (metres)		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.117	0.117	0.233
0.1	0.369	0.369	0.737
1.0	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.
These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

TECHNICAL SPECIFICATIONS cont.

EMC Labeling For Camera Tracking System (Cont.)

Radio Frequency Emissions

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions:

1. This device may not cause harmful interference and,
2. This device must accept any interference received, including interference that may cause undesired operation.

Note:	This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: --Reorient or relocate the receiving antenna. --Increase the separation between the equipment and receiver. --Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. --Consult the dealer or an experienced radio/TV technician for help.

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