ExpandOR™

Medical-Grade Video Streaming System

USER MANUAL

ENGLISH

NDS

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1 Warnings and Cautions

This symbol alerts the user that important information regarding the installation and / or operation of this equipment follows. Information preceded by this symbol should be read carefully in order to avoid damaging the equipment.

This symbol warns user that un-insulated voltage within the unit may have sufficient magnitude to cause electrical shock. Therefore, it is dangerous to make contact with any part inside the unit. To reduce the risk of electric shock, **DO NOT** remove cover (or back). There are no user serviceable parts inside. Refer servicing to qualified service personnel.

This symbol cautions the user that important information regarding the operation and / or maintenance of this equipment has been included. Information preceded by this symbol should be read carefully to avoid damage to the equipment.

This symbol denotes the manufacturer.

This symbol denotes the manufacturer's European Community representative.

To prevent fire or shock hazards, do not expose this unit to rain or moisture. Also, do not use this unit's polarized plug with an extension cord receptacle or other outlets unless the prongs can be fully inserted. The product is designed to meet the medical safety requirements for a patient vicinity device.

This product is a Class I medical device. No modifications are allowed.

This equipment/system is intended for use by healthcare professionals only.

Safety Compliance:
This product is T.U.V. approved with respect to electric shock, fire and mechanical hazards only in accordance with CAN/CSA C22.2 NO. 60601-1 and ANSI/AAMI ES60601-1.

Safety Compliance:
This product meets the requirements of EN60601-1 so as to conform to the Medical Device Directive 93/42/EEC and 2007/47/EC (general safety information).

This product complies to the above standards **only** when used with the supplied medical grade power supply.

Model	ExpandOR
Power Supply	GlobTek GTM91120-3024-T3A
AC Input	100 to 240 Volts at 50 to 60 Hz, 1.0A
DC Output	24 Volts at 1.25 A

Power Cord: Use a hospital grade power cord with the correct plug for your power source.
Disconnect the power cord from the AC mains. The power cord is the only recognized disconnect device.
The MEDICAL EQUIPMENT should be positioned so that its disconnect device is readily accessible.

The product should be powered from a center tapped circuit when used in the US at voltages over 120 volts. Product is intended for continuous operation.

This product is energized from an external electrical power source for class 1 equipment. It is the responsibility of the installer to test the product's earth ground to verify that it complies with the hospital, local and national impedance requirements.

Recycling:

Follow local governing ordinances and recycling plans regarding the recycling or disposal of this equipment.

Declarations of Conformity

FCC and Council Directives of European Standards:

This device complies with Part 15 of FCC rules and 93/42/EEC of the Council Directives of European Standards Directive as amended by 2007/47/EC. 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 undesirable results.

1. Use the specified cables with this device so as not to interfere with radio and television reception. Use of other cables and / or adapters may cause interference with other electronic equipment.
2. This equipment has been tested and found to comply with the limits pursuant to FCC part 15 and CISPR 11. 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.

IEC:

This equipment has been tested and found to comply with the limits for medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical 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 other devices in the vicinity.

FCC, Council Directives of European Standards and IEC:

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 your dealer or an experienced radio/TV technician for help.

Accessory equipment connected to this product must be certified according to the respective IEC Standards (i.e., IEC 60950-1) for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard, IEC 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of system standard IEC 60601-1-1. Whoever is responsible for securing the unit to a system needs to insure that the mounting equipment used with this product complies to IEC standard 60601-1. If in doubt, consult the technical services department or your local representative.

Legal Statement

NDS may sell its products through other medical device manufacturers, distributors and resellers and therefore, purchasers of this NDS product should consult with the entity through which this product was originally purchased regarding the terms of any applicable product warranties provided by such entity, if any.

NDS neither assumes nor authorizes any person to assume for it any other liabilities in conjunction with and/or related to the sale and/or use of its products. To ensure proper use, handling and care of NDS products, customers should consult the product specific literature, instruction manual, and/or labeling included with the product or otherwise available.

Customers are cautioned that system configuration, software, the application, customer data and operator control of the system, among other factors, affect the product's performance. While NDS products are considered to be compatible with many systems, specific functional implementation by customers may vary. Therefore, suitability of a product for a specific purpose or application must be determined by the consumer and is not warranted by NDS.

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2 About This Manual

This manual is designed to assist the user with operation of the ExpandOR.

A numbered tab on the side of the page indicates the beginning of a section.

Overview

ExpandOR™ is a stand-alone medical-grade video streaming system that enables video streaming across existing networks and provides bi-directional or one-way HD video and audio streaming with low latency. The ExpandOR can transmit a video stream to a single or multiple destinations. The main purpose of the product is to provide a solution for enabling surgeons to conduct bi-directional consultations during surgery, transmit a video stream to an auditorium for educational purposes, or send sample images to a Pathology lab.

Installation and Setup

The ExpandOR is designed to be easy to install and set up by a hospital's IT Department, and be made ready for doctors and nurses to operate it. After initial setup by the IT Department, a doctor or a nurse in the operating room can easily:

- Initiate streaming and/or capturing session
- Enable privacy in compliance with security requirements (such as HIPAA)
- End streaming session

NDS recommends that the installation and initial setup is done by the hospital's IT department by a technician with a basic understanding of networking including an understanding of TCP/IP protocol, IP address, gateway, subnet mask, network port, pinging a device on the same network, and configuring a laptop to work in a corporate/hospital network. After initial setup, IT Department is required to explain to the operating room (OR) staff how the ExpandOR is configured including the following items:

- One-way point-to-point
- Two-way point-to-point
- Multi-Node
- Multicast (Broadcast)
- Configuration to record incoming or outgoing video

Prior to handoff of the ExpandOR to the OR staff, the IT Department must demonstrate functions of the Front Panel buttons. The OR Staff will use the front panel buttons to operate the unit during procedures.

Intended Use and Contraindications

Intended Use:

This device is intended for use in a medical environment to deliver high quality video and graphic images.

Contraindications:

⚠ This device may not be used in the presence of flammable anesthetics mixture with air, oxygen or nitrous oxide. Also, it is not intended for life support applications.

⚠ No part of this product may come in contact with a patient. Never touch the product and a patient at the same time.

⚠ Initial set up must be done by the hospital's IT Department by a technician with a basic understanding of networking including an understanding of TCP/IP Protocol, IP Address, Gateway, Subnet Mask, Network Port, Pinging a device on the same network, configuring a laptop to work in a corporate/hospital network.

⚠ For mission critical applications, we strongly recommend that a replacement unit be immediately available.

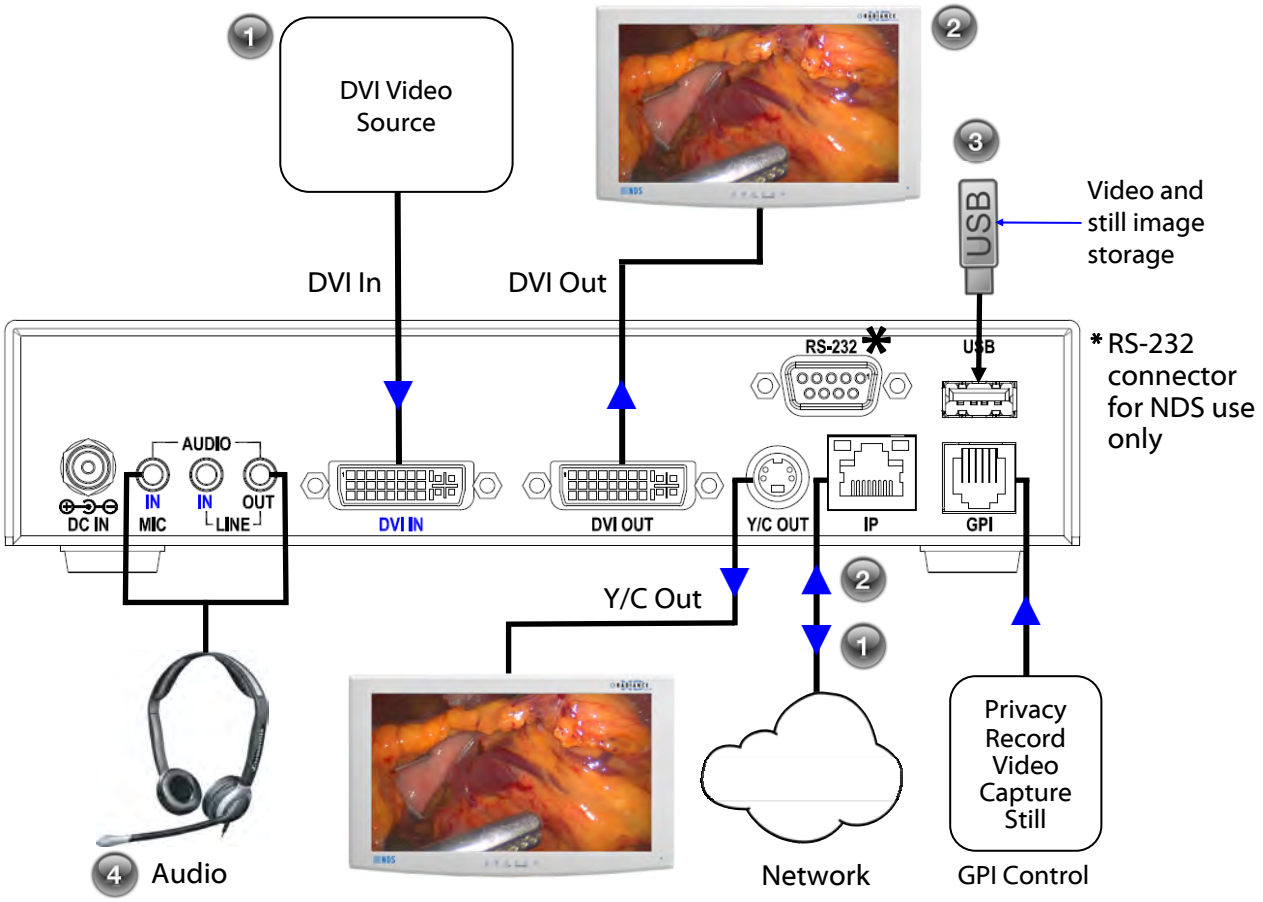
Specifications

DC Input	24 VDC / 1.25 A
DC Power Consumption (nominal)	22W
AC Power Consumption (nominal)	30W
System Weight	1.3lbs. (0.59 Kg)
Environmental	
Operating Temperature	+32 to 104^{0}F (0 to 40^{0}C)
Operating Humidity	20 to 85% RH
Storage Temperature	-4 to +122^{0}F (-20 to +50^{0}C)
Storage Humidity	5 to 85% RH
Operating Altitude	6600 ft. (2,000 M)
Storage Altitude	33,000 ft. (10,000 M)

Specifications are subject to change without notice. Contact factory for current specifications.

3 ExpandOR Connections

The diagram below shows the devices that may be connected to the ExpandOR. The unit's application will determine which of these devices is required. The devices required for a given function are described in the Connections Options list below.



Connections Options:

1. **Transmit**:
   Network connection must be set up and connected. Connect **DVI-D** source to **DVI-IN** port to stream to the configured destination(s). Network video monitor, audio, **DVI-OUT, USB**, and **GPI** are all optional.
2. **Receive**:
   Network connection must be set up and connected. Connect **DVI-D** display to **DVI-OUT** to display received stream. Network video monitor, audio, **DVI-IN, USB**, and **GPI** are all optional.
3. **Record:**
   To record video stream or capture still images, a USB drive must be inserted into the USB port. Implement Option 1 or Option 2 above as appropriate.
4. **Audio:**
   To transmit and receive audio, a microphone must be connected to the **IN MIC** connector and headphones or an amplified speaker must be connected to the **OUT LINE** connector. Additionally, Options 1 or 2 above must be implemented.

Cable Bend Radius

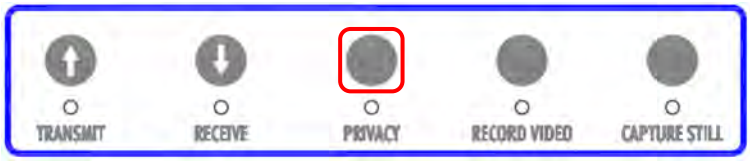
⚠ NDS recommends that the bend radius of metallic cables be no less than 2.5 inches (63 mm) or 7 times the diameter of the cable whichever is greater. Sharper bends may damage the cable and/or degrade the video signal.

ExpandOR allows streaming a surgical video of a patient in the OR/procedure room to one or multiple hospital destinations. The steps required to transmit from the ExpandOR in the operating room to a single ExpandOR within the hospital are shown below. Confirm with your IT department that the ExpandOR's parameters are set appropriately for your specific use prior to operation.

1. Press the power button until the ring illuminates. All 5 LEDs will flash twice. About 1 minute is required to boot up.

2. Press the **TRANSMIT** button in front panel until the LED below it turns on.

3. If during an operation or procedure, you decide not to transmit sensitive patient information, simply press the **PRIVACY** button, as shown below, until the LED below it turns on. Turn privacy off by pressing the **PRIVACY** button until the LED turns off. See page 8 for more on **PRIVACY**.



4. To record the video stream and/or capture images, verify with your IT department that the ExpandOR is configured for video streaming and/or capturing images. Start recording video by pressing the **RECORD VIDEO** button, as shown below, until the LED below it turns on. To stop recording video, press the **RECORD VIDEO** button until the LED turns off. See page 9 for more on **RECORD VIDEO**.

5. Pressing the **CAPTURE STILL** button as shown below, captures a video frame as a still image saved to the USB drive. The **CAPTURE STILL** LED flashes once during the capture. See page 9 for more on the **CAPTURE STILL** function.

6. Press the **TRANSMIT** button again to end transmission, turning off the **TRANSMIT** LED. If video was being recorded, ending transmission will also stop video recording and turn off the **RECORD VIDEO** LED.

5 Receive

ExpandOR can receive streaming surgical video of a patient in the operating room/ procedure room from another ExpandOR in the hospital. This section explains how to accomplish this task.
The steps required to receive surgical video from another ExpandOR within the hospital are shown below. Prior to operating the unit, please confirm with your IT department and verify that the unit's parameters are set for your intended use.

1. Press the power button until the ring illuminates.

2. Press **RECEIVE** button on the front panel until the LED below it turns on.

3. If you want to record the video stream and/or capture images, verify with your IT department that the ExpandOR is setup for video streaming and/or capturing images. If it is, then proceed as shown below. Start recording video by pressing the **RECORD VIDEO** button, as shown below, until the LED below it turns on. Stop recording video by pressing the RECORD VIDEO button until the LED below it turns off. See page 9 for more on **RECORD VIDEO**.

4. Pressing the **CAPTURE IMAGE** button as shown below, causes the LED below it to flash. One image is captured per button press. See page 9 for more on **CAPTURE IMAGE.**

5. Stop receiving by pressing the RECEIVE button as shown in Step 2 above. The **RECEIVE** LED turns off. If video was being recorded, ending receive also ends video recording and the **RECORD VIDEO** LED is turned off.

ExpandOR can simultaneously receive and transmit streaming patient surgical video in the operating room/procedure room from one ExpandOR to another ExpandOR in the hospital. The steps required to simultaneously transmit and receive surgical video to/from the intended ExpandOR within the hospital are shown below. Prior to operating the unit, please confirm with your IT department that the ExpandOR parameters are set appropriately for your specific use.

1. Press the power button until the ring illuminates.

2. Press **TRANSMIT** button in front panel.

3. Press **RECEIVE** button on the front panel.

If you want to record the video stream and/or capture images, verify with your IT department that the ExpandOR is setup for video streaming and/or capturing images. If it is, then proceed as shown below. Start recording video by pressing the **RECORD VIDEO** button, as shown below, until the LED below it turns on. Stop recording video by pressing the **RECORD VIDEO** button until the **RECORD VIDEO** LED turns off. See Record Video Feature on page 9 for more information about this function.

5. Pressing the **CAPTURE IMAGE** button as shown below, causes the LED below it to flash. One image is captured per button press. See Capture Still Feature on page 9 for more information about this function.

6. Stop transmitting by pressing the **TRANSMIT** button as shown in Step 2 above. Stop receiving by pressing the **RECEIVE** button as shown in Step 3. The **TRANSMIT** LED and the **RECEIVE** LED turn off. If video was being recorded, ending receive also ends video recording, turning off the **RECORD VIDEO** LED.

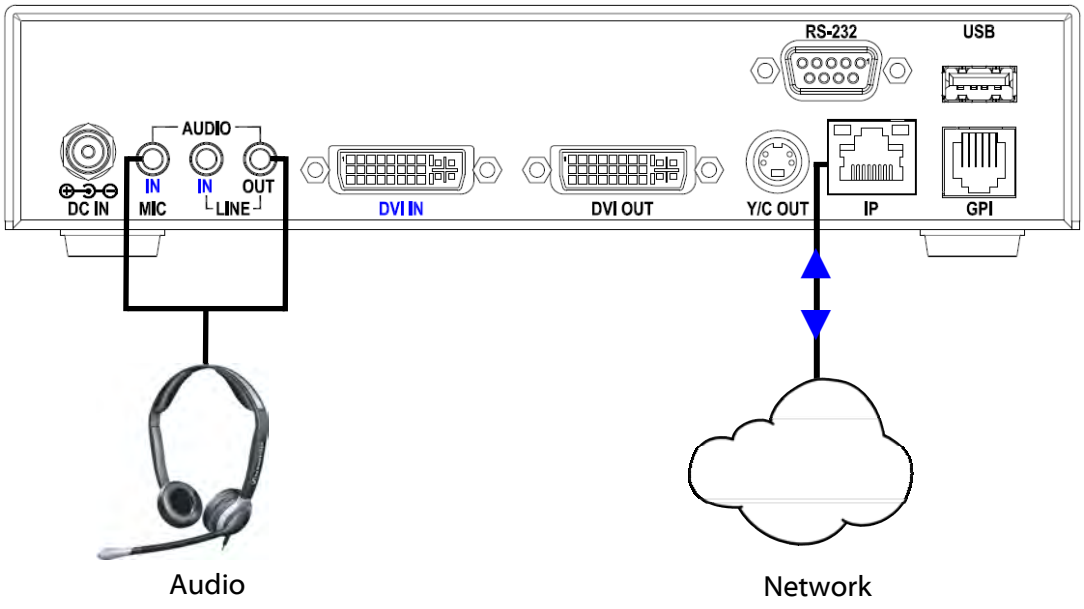
7 Transmitting to Multiple Locations

The ExpandOR can transmit streaming surgical video of a patient in the operating room/procedure room to multiple ExpandORs in the hospital. The steps required to transmit surgical video to multiple ExpandORs within the hospital are shown below. Prior to operating the unit, please confirm with your IT department that the unit's parameters are set appropriately for your specific use.

The ExpandOR is capable of simultaneously transmitting (broadcasting) to multiple locations. The IT department can set it up if required. When the ExpandOR has been configured for broadcasting, press the TRANSMIT button, shown below, to begin broadcasting to destinations defined in the ExpandOR configuration.

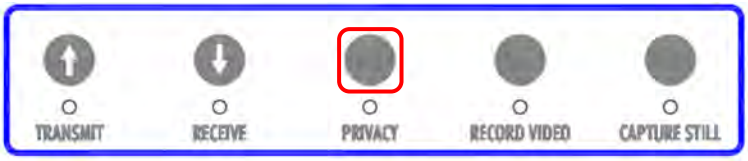
Audio Setup

The ExpandOR can be configured to transmit and receive audio with its surgical video stream. If your application requires audio, your IT department can configure the ExpandOR to support audio out and audio in, and provide the appropriate audio equipment. ExpandOR to ExpandOR allows bi-directional communication. ExpandOR can stream one way to a PC using ViewOR (provided on the ExpandOR CD). See Configuration Options on page 10 for a detailed description of ExpandOR device to device communications.



The purpose of the Privacy Mode is to prevent transmission of sensitive parts of a surgical video stream. When privacy is enabled, the receiving end will see the screen shown below and audio will be muted.

Privacy is enabled or disabled by pressing the **PRIVACY** button on the front panel. When Privacy Mode is on, the LED below the **PRIVACY** button will be on. When the Privacy Mode is off, the LED will be off.



Note: HIPAA is the Health Insurance Portability and Accountability Act, which sets the standard for protecting sensitive patient data.

Record and Capture Features

The ExpandOR can record surgical video and/or capture still images. Contact your IT department to verify that your ExpandOR is set up for this application. After your IT department verifies that your ExpandOR is correctly configured, follow the steps below to record video or capture still images.

Record Video Feature

⚠ 1. A USB drive must be installed in the USB connector on the back of the ExpandOR before using this feature. USB drives must be USB 2.0 or better, capable of a minimum write speed of 5 MB/sec

Video recording starts when the **RECORD VIDEO** button, shown below, is pressed. The **RECORD VIDEO** LED illuminates when the **RECORD VIDEO** button is pressed and will remain on throughout the recording session. If the available free storage space drops below 200 MB, the **RECORD VIDEO** LED will begin blinking.

Recorded video streams are saved in the Transport Stream (.ts) format, and are stored in the **Video** folder of the installed USB drive.

Note: The record stream feature may be configured to record either the output video stream or the incoming video stream. Your IT department can tell you how the ExpandOR is configured.

Capture Still Feature

⚠ A USB drive must be installed in the USB connector on the back of the ExpandOR before using this feature.

Pressing **CAPTURE STILL** button, as shown below, captures a single frame from either the transmitting or receiving video stream. After pressing the button, the **CAPTURE STILL** LED flashes once as the captured frame is stored on the USB drive. Subsequent frames can be captured after the capture flash.

Note: If the **CAPTURE STILL** LED flashes three times after pushing the button, the image has failed capture.

Captured images are saved as a .jpg files, and are stored in the **Image** folder of the installed USB drive. No additional action by the user is required.

Note: The capture feature may be configured to capture frames from either the output video stream or

The ExpandOR can transmit to and receive from an ExpandOR or can transmit to a computer. Signal capabilities of an ExpandOR are constrained by the device with which it is communicating. The table below each device shows direction parameters for device combinations.

From ExpandOR

Signal	Direction
Transmit	Yes
Receive	Yes
Both	Yes

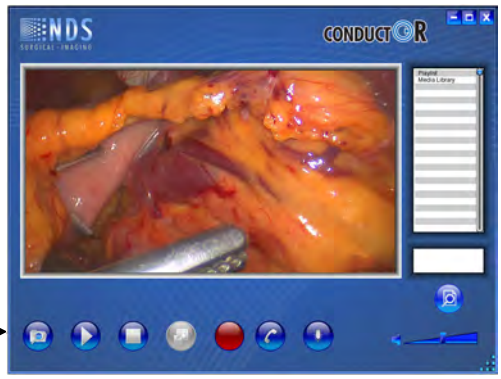
To ExpandOR

Signal	Direction
Transmit	Yes
Receive	Yes
Both	Yes

From ExpandOR

Signal	Direction
Transmit	Yes
Receive	No
Both	No

To PC



Signal	Direction
Transmit	No
Receive	Yes
Both	No

Cleaning Instructions

⚠ Prior to cleaning and surface disinfection, the unit should be turned **OFF** and disconnected from its power source.

Cleaning:
Thoroughly wipe all exterior surfaces with a lint-free cloth that has been dampened with an acceptable cleaning agent. Acceptable cleaning materials are listed below. Remove residual detergent by wiping all exterior surfaces with a lint-free cloth dampened with distilled water.

Disinfecting:
Disinfect the unit by wiping all exterior surfaces with a lint-free cloth dampened with 80% Ethyl Alcohol. Allow the unit to air dry.

⚠ **Cautions:**
Do not allow liquids to enter the interior of the unit, and do not permit exterior surfaces to come into contact will unacceptable solvents such as those listed below, as severe damage to the unit may result.

Acceptable Cleaning Materials:
Vinegar (distilled white vinegar, 5% acidity)
Ammonia-based glass cleaner

Acceptable Disinfecting Material:
Ethanol 80 % by volume

Unacceptable solvents:
MEK (Methyl Ethyl Ketone)
Toluene
Acetone

Note: The acceptable cleaning and disinfecting materials listed above have been tested on NDS products and, when used as directed, do not harm the product's finish and or its plastic components.

Electromagnetic Compatibility Tables

All medical electronic devices must conform to the requirements of IEC 60601-1-2. Precautions, adherences to the Electromagnetic Compatibility (EMC) guideline information provided in this manual and verification of all medical devices in simultaneous operation are required to ensure the electromagnetic compatibility and co-existence of all other medical devices prior to a surgical procedure.

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

The following EMC tables are provided for your reference:

- "Electromagnetic Emissions" on page 13
- "Electromagnetic Immunity" on page 14
- "Recommended Separation Distances" on page 15

Electromagnetic Emissions

Emissions	Compliance	Electromagnetic environment-- guidance
RF emissions CISPR 11	Group 1	The product 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 B	The product 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	Compliance	

Electromagnetic Immunity

Guidance and Manufacturer's Declaration: Electromagnetic Emissions

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

Immunity Test	Immunity Test
Electrostatic discharge (ESD) IEC 61000-4-2	±2, ±4, ±6, ±8kV contract discharge ±2, ±4, ±6, ±8, ±15 kV air discharge
Radiated RF field IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80% AM 1 kHz
Proximity fields from wireless transmitters IEC 61000-4-3	80MHz to 2.7 GHz. 3V/m Spot Tests: 385 MHz. at 27V/m; (710, 745, 780, 5240, 5500, 5785) MHz. at 9V/m; (450, 810, 870,930, 1720, 1845, 1970, 2450) MHz. at 28V/m
Electrical fast transient / burst IEC 61000-4-4	±2 kV, AC mains ±1 kV, I/O ports 100 kHz PRR
Surge IEC 61000-4-5 AC mains, Line to Ground AC mains, Line to Line	 ±0.5, ±1, ±2 kV ±0.5, ±1 kV
Conducted RF IEC 61000-4-6	3 V (0.15MHz - 80MHz) 6 V ISM Bands 80% AM 1 kHz
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m - 50 or 60 Hz
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% dip, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods (50/60 Hz) Interrupt 100% drop, 5 sec

Note:

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the product is used exceeds the applicable RF compliance level above, the product should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the product.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the product

The product is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled.

The customer or the user of the product can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product as recommended below, according to the maximum output power of the communications equipment.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the (ME EQUIPMENT or ME SYSTEM), including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power (W) of transmitter	Separation distance, in meters according to frequency of transmitter		
	150kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7GHz
0.01	0.12	0.12	0.23
0.10	0.38	0.38	0.73
1.00	1.20	1.20	2.30
10.00	3.80	3.80	7.30
100.00	12.00	12.00	23.00

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

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

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

WARNING: Combinations of accessories that are not listed in the instruction manual may only be used if they are intended exclusively for a given use and do not affect the performance, safety, and EMC characteristics of the medical device.

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