Display, Contrast Monitoring
INSTRUCTIONS FOR USE

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

DEVICE DESCRIPTION
The device consists of a Display (Model CMW-XX) to be used with the DyeVert Plus Disposable Kit or the Contrast Monitoring Disposable Kit during controlled infusion for procedures requiring injection of contrast media. The Osprey Medical wireless Contrast Monitoring System allows for monitoring and display of contrast volumes manually injected.

The Display is compatible with the DyeVert Plus Disposable Kit (DyeVert Plus Module & Smart Syringe) and the Contrast Monitoring Disposable Kit (Pressure Module & Smart Syringe).

CMS CLASSIFICATION
- Type of protection against electric shock: Class 1.
- Degree of protection against electric shock: Type CF applied part
- Equipment not suitable for use in the presence of flammable mixtures

APPLIED PARTS
Smart Syringe, Pressure Transducer of the Pressure Module disposable, Pressure Transducer and 4 Way Stopcock of the DyeVert Plus Module disposable.

ACCESORIES
DC Power supply – Osprey Medical Inc. part # 6130
Power Cord – Osprey Medical Inc. part # 5112-XX

INTENDED USE
The device consists of a Display to be used with the DyeVert Plus Disposable Kit or the Contrast Monitoring Disposable Kit during controlled infusion for procedures requiring injection of contrast media. The Osprey Medical wireless Contrast Monitoring System allows for real-time monitoring and display of contrast volumes manually injected.

INDICATION FOR USE
The device consists of a display to be used with the DyeVert Plus Disposable Kit or the Contrast monitoring Disposable Kit during angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.

CONTRAINDICATIONS
Not for use with power injectors.

WARNINGS
Disposables are for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may create a risk of patient infection which could lead to injury, illness or death.

Do not use if product packaging appears compromised.

The Display is supplied non-sterile and is reusable.

The Display is intended to be used with the DyeVert Plus Disposable Kit or the Contrast Monitoring Disposable Kit only. No substitutions should be made for Osprey Medical System components.

The Display USB port is not intended for user access. Access is to be performed by Osprey Medical personnel. Do not use or connect components to the USB port.

The Display *Osprey Settings* defines system parameters which are not inputted by users; nor do users have access. Access is intended only by Osprey Medical Inc. personnel.

Prior to using the Display, please ensure all labeling of compatible devices being used (such as the DyeVert™ Plus Disposable Kit) is followed. This may include, but is not limited to, considerations regarding type of procedure, patient population or contrast agents.

Please refer to the contrast agent Instructions for Use and Labeling for dosage recommendations, warnings, contraindications, detail of reported adverse event types and detailed directions for use associated with contrast administration.

To avoid the risk of electric shock, the Display must only be connected to a supply mains with protective earth.

No modifications of the Contrast Monitoring System is allowed.

PRECAUTIONS
As with any device used for injecting contrast media into a patient, care should be taken to assure all air has been removed from the lines, prior to injection, to avoid air embolization.

The DyeVert Plus Module is designed to be used with non-diluted, room temperature (non-warmed) contrast media only.

For accurate Smart Syringe % contrast concentration values, ensure system is initially primed with 100% contrast media and the contrast source is 100% contrast.

Be cautious to not over-tighten on luer connection when connecting the DyeVert Plus or Contrast Monitoring disposable components to a manifold.

The DyeVert Plus or Contrast Monitoring disposable components should not be immersed in contrast or saline.

The Display should not be immersed for cleaning.

The Display should only be connected to the power supply with the Osprey Medical supplied power cord. Do not modify or change the supplied power cord. Only a grounded power cord should be used.

Osprey Medical recommends users follow hospital policy/procedure and physician recommendation on the appropriate total cumulative volume of contrast media used in a patient. The Display is not intended to prevent manual injection of contrast media.

User should ensure the Display dwell time is reached prior to Smart Syringe aspiration and if needed, contact Osprey Medical to adjust dwell time to align with user preference. Inaccurate cumulative volume may be displayed if aspiration occurs prior to dwell time is reached.

The graphical range indicator displayed when a threshold is entered is not representative of a recommended contrast dosage.

If using a threshold, the physician entered threshold volume should take into consideration renal function through estimated GFR or exogenous measured GFR in cases where an estimated GFR may be inaccurate (i.e. extreme body size, ethnicity, race, sex, age, muscle mass, unusual dietary intake, pregnant women etc.).

POTENTIAL PATIENT ADVERSE EVENTS
Please refer to the contrast agent being used Instructions for Use and Labeling for a detailed list of reported adverse events.

HOW SUPPLIED
The Display is provided non-sterile.

STORAGE
Storage conditions for the Display:
Temp = -20°C to 60°C
Humidity = 10% to 85%, noncondensing
Pressure = 50 kPa to 106 kPa

MAINTENANCE and REPAIR
Maintenance is not required. Contact Osprey Medical if Display repairs are required and for shipping instructions.

DISPOSAL
The Display should not be disposed of by the user. Contact Osprey Medical to arrange for shipment of the Display for disposal.

CLEANING DISPLAY
Non-disposable components (display, powercord) should be cleaned in accordance with hospital policy and procedure with Super Sani-Cloth (or equivalent) or a cloth dampened with 70/30 isopropyl alcohol. Avoid use of solvents or abrasive cleaners which may damage the plastic portion of these components or the touch screen.

OPERATING ENVIRONMENT & CONDITIONS
The system is intended to be used in a standard hospital cath lab environment under the following conditions:
Temperature: 10°C to 27°C (50°F to 80°F)
Relative humidity 0% to 85%, noncondensing
Pressure = 60 kPa to 106 kPa
The system is not intended be used near active high frequency surgical equipment or with magnetic resonance imaging (MRI) where the intensity of electromagnetic disturbances is high.

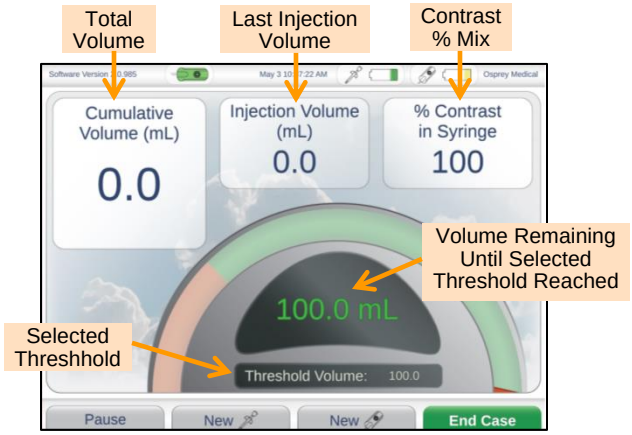
PHYSICIAN TRAINING INFORMATION
Qualified physicians should be knowledgeable with Cath lab procedures, techniques and contrast media usage.

No additional special skills or training is required to operate the Display but physicians should be thoroughly familiar with the Display and compatible disposables, and supporting material including all product labeling. Physicians may contact Osprey Medical to request training.

DIRECTIONS FOR USE

System Overview
The touchscreen Display allows user input for desired contrast use monitoring, per specific individual case. Following input of monitoring parameters, during a case the display shows Injection Volume (individual injection mL), Cumulative Volume (total injected mL), % contrast in injection syringe (e.g. 95% contrast indicates a 5% saline mix) and as applicable a physician selected Threshold Volume (maximum target dose). When 'no threshold' is entered; only the cumulative volume, injection volume and % contrast in injection syringe are displayed.

Case Status



Note: graphical range indicator is not representative of a recommended contrast dosage

The Smart Syringe and associated disposable (DyeVert Plus Module or Pressure Module) have two LEDs to provide user feedback.

- Solid Green (active for 10 seconds) indicates injections will be counted towards cumulative volume
- Flashing Yellow indicates system is paused and injections will not be counted towards cumulative volume

The Control Button (on DyeVert Plus Module or Pressure Module) allows the user to *Pause* the system to suspend contrast accounting.

The Display is not intended for indefinite continuous use and should be powered down periodically (recommend weekly).

The disconnect component for the Display is the plug for the DC power supply that inserts into the receptacle (outlet) for mains power. To disconnect the device, remove the plug from the receptacle. The Display should be located such that it is not difficult to unplug from the receptacle.

1. Display Set-up and User Settings

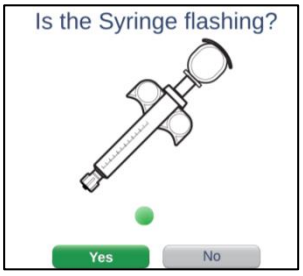
User Settings

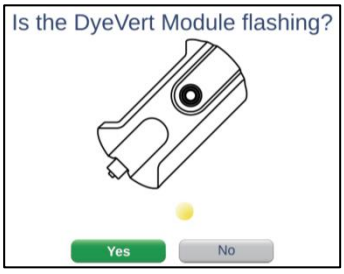
a. **Remove** the Display and the DC Power Supply from protective packaging.
b. **Insert power jack (plug)** of the DC power supply into the receptacle of the Display. Manually tighten the ring nut onto the socket to prevent inadvertent disconnect.
c. **Mount the Display** to a standard IV Pole (18mm to 32mm diameter) using the integral clamp on the back of the Display. Verify that the IV pole is stable when the Display is mounted to it.
d. **Plug Display** electric power cord into DC power supply and an appropriate outlet.
e. **Push Power-On** button.
f. **From Main Menu, select *Settings* then *User Settings***. User Settings designate user configurable display parameters. This is only necessary if changes are desired. To configure settings select applicable parameter:
   1) *Warning Tones* to enable tones "on" for Threshold, Threshold Exceeded, and %Contrast in Syringe.
   2) *Warning Tone Volume* to adjust sound level.
   3) *Threshold Warning %* (applicable only when a selected threshold is entered) specifies the percentage of contrast remaining of a selected contrast volume that will trigger a warning to the user e.g. a threshold of 100mL is selected and a 20% threshold warning is selected. The Display would warn the user when 20mL (20% of 100mL) is reached.
   4) *Concentration Warning %* specifies percentage of contrast in syringe that will trigger a warning to the user, e.g. 60% contrast.
   5) *Tone Selection* to specify type of tones desired.
   6) *Screen Brightness.*
   7) *Facility ID* allows applicable user selected identification, e.g. device location.
   8) Language to allow user to choose English, Espanol, Italiano or Deutsch.
   9) Date/Time
g. **Select *Main Menu*** to return to home screen

NOTE: DyeVert Plus Module Reservoir contrast % concentration is monitored and an alarm will sound when the reservoir contrast % concentration falls below 80%. Contact Osprey Medical for adjustment to the contrast % concentration warning for the reservoir.

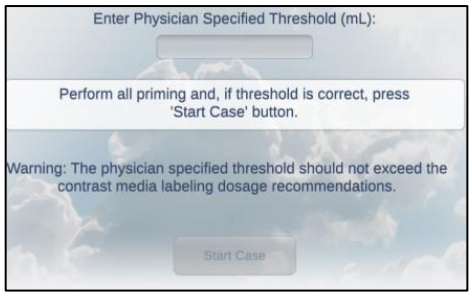
2. New Case Set-Up
a. Push Display Power-On button if applicable.
b. Remove orange pull tabs from disposables (Smart Syringe and DyeVert Plus Module or Pressure Module).
c. Select *New Case*.
d. Confirm wireless connection of the Display, Syringe and DyeVert Plus Module or Pressure Module. Following scanning, the LEDs on the disposables will flash in the same pattern as shown on the Display for proper identification.
   1) Select *Yes* to confirm Syringe flashing.
   2) Select *Yes* to confirm Module flashing.
   Note: Selecting *No* will result in further scanning.
   Note: The green LED on the device will remain on for 10 seconds when the device is connected to the Display.

Wireless Connection Confirmation





e. Physician specified threshold (when applicable): Enter value (mL) or "0" for no threshold.



f. Assemble disposables to applicable cath lab components (e.g. manifold) and perform priming.

DO NOT select *Start Case* until device priming is completed.

3. Start Case

ENSURE ALL PRIMING IS COMPLETED BEFORE PRESSING *Start Case*.

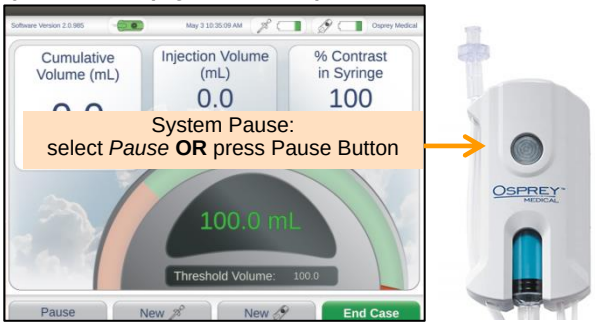
a. **Select *Start Case*** to begin contrast accounting.
b. **Perform procedure**.

4. Pause/Resume System Operation

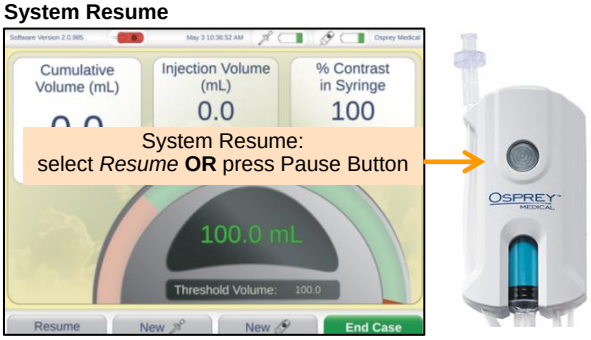
When system is in "Pause" mode, cumulative contrast accounting is suspended. "Resume" mode allows contrast accounting.

a) **To Pause** select *Pause* on Display or press Module pause button. LED's on Smart Syringe & Module will blink yellow and background on Display will change to yellow.
b) **To Resume**, aspirate contrast into Smart Syringe (resumes automatically), or select *Resume* on Display, or press Module pause button. LED's on Smart Syringe and Module will be green for 10 seconds and Display will return to normal cloud background.

System Pause (e.g. saline flush)



System Resume

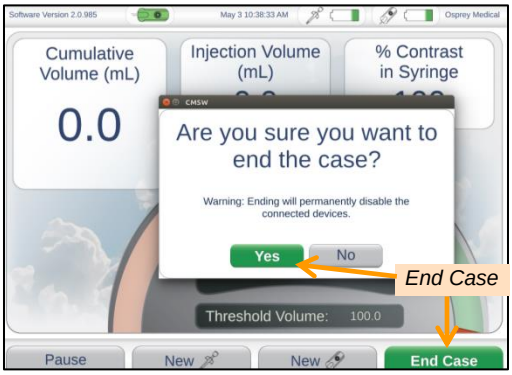


4. End Case

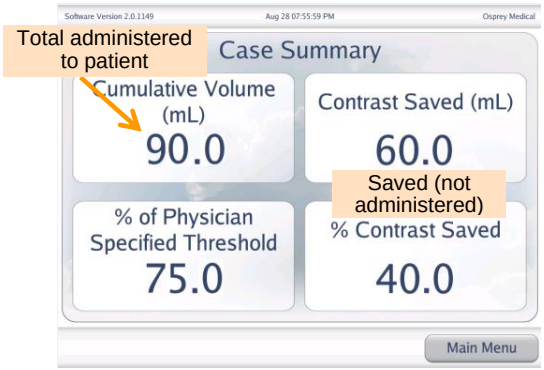
a. **Select *End Case and* confirm *Yes***.
Caution: Ending case will permanently disable communication between the Display and disposables.

Note: Case summary screen appears showing cumulative volume of contrast administered to patient and % of physician threshold. Additionally if utilizing the DyeVert Plus System, contrast saved (mL and %) will display.

Note: To view summaries for previous cases, from *Main Menu* select *Settings, User Settings, Case History.*



Case Summary



System Discontinuation- Display
Select *Power Down* from the main menu.

System Discontinuation- Disposables
The Module disposables and Smart Syringe contain batteries. Discard Smart Syringe, Module disposable and single-use contrast source according to hospital procedures.

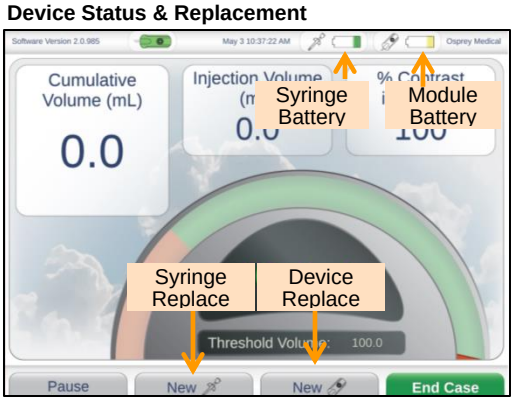
Follow local governing ordances regarding disposal. Do not incinerate as the enclosed batteries may explode at excessive temperatures.

Case Management and Modifications
The Module disposable and Smart Syringe contain batteries. Battery icons display status as green (OK), yellow (low- approximately 10 minutes remaining) or white (depleted). If depleted, Display will automatically require replacement of the disposable or end case.

During a case, if required the Smart Syringe or Module disposable may be replaced.

To Replace Disposable
1. **Select *New (Syringe)* or *New (Module)***.
2. **Confirm *Yes*** to replace or *No* to cancel.
3. Following replacement of the device, **confirm wireless connection**.

Device Status & Replacement



Possible Alarm Messages

Error Message	User Actions
Smart Syringe Concentration Alarm	No action required. System keeps track of whether the concentration has once again risen above the minimum warning percentage. If this occurs the software resets the syringe concentration warning state such that if the concentration falls below the minimum again, the warning tone will re-sound.
Threshold % Alarm and Threshold Reached Alarm	No action required. This alarm is for notification purposes only.
Low Battery Alarm (Disposables)	User must replace the disposable, end the case or allow the battery to continue depleting while continuing the case. Monitoring capability will continue until No Battery Alarm sounds.
No Battery Alarm (Disposables)	User must replace the disposable or continue case without monitoring capability.

Possible User Error Messages

Error Message	User Actions
"The connected Syringe is not calibrated properly. Please connect another device to continue."	Replace the Smart Syringe.
"The connected DyeVert is not calibrated properly. Please connect another device to continue."	Replace the DyeVert Plus Module disposable
"No syringe or DyeVert data received."	End case and replace the Smart Syringe and DyeVert Plus Module disposable
"No syringe or pressure module data received."	End case and replace the Smart Syringe and Pressure Module disposable
"A previous case ended abnormally. Restart the case?"	Select "Yes" to restart the case, "No" to end the case
"Unable to connect to the Syringe. Please replace the unit."	Replace the Smart Syringe
"Unable to connect to the DyeVert. Please replace the unit."	Replace the DyeVert Plus Module disposable
"Unable to connect to the Pressure Module. Please replace the unit."	Replace the Pressure Module disposable
"Database Error: failed to initialize database."	Perform a hard shutdown of the Display by holding the power button down for >5 seconds, then restart the Display by pressing the power button once. If the problem persists, contact Osprey Medical
"Database Error: failed to add case."	Contact Osprey Medical
"Database Error: failed to update case."	Contact Osprey Medical
"Database Error: errors occurred writing injection records for the case."	Contact Osprey Medical
"Database Error: failed to mark all unfinished cases as abandoned."	Contact Osprey Medical

DyeVert Plus Contrast Modulation/Monitoring System and Contrast Monitoring System FCC Information

Display Contains FCC ID: Z64-WL18SBMOD
DyeVert Plus Module FCC ID: 2AHUPDV
Smart Syringe FCC ID: 2AHUPSS
Pressure Module FCC ID: 2AHUPPM

Classifications per IEC 60601-1 / UL 60601-1:

Degree of Protection:	Type CF-Applied Part
Enclosure Degree of Ingress Protection:	IP31
Mode of Operation:	Noncontinuous

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.

WARNING: Changes or modifications to the Display, DyeVert Plus Module, Smart Syringe or Pressure Module not expressly approved by Osprey Medical, Inc. could void the user's authority to operate the equipment.

ELECTROMAGNETIC INTERFERENCE PRECAUTIONS

This equipment has been tested and found to comply with the limits for a Group 1 Class B device, pursuant to IEC/EN 60601-1-2, 4th edition. These limits are designed to provide reasonable protection against harmful interference. This equipment, if not installed and used in accordance with the instructions, may cause harmful interference to other equipment. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 other equipment.
- Increase the separation between the display and the other equipment.
- Connect the other equipment into an outlet on a circuit different from that to which display is connected.
- Consult Osprey Medical Inc. for help.

WARNING: Portable and mobile RF communications equipment may affect the devices. The Display should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Display should be observed to verify normal operation.

WARNING: Use of accessories, transducers and cables other than those specified or provided by Osprey Medical, Inc. could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

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 Display or disposables, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

If performance of the system is lost or degraded due to electromagnetic interference, the procedure may continue without contrast monitoring.

The Display and disposables have Bluetooth transceivers using short-wavelength UHF radio waves in the ISM band from 2.4 to 2.485 GHz. The transceivers and effective radiated power are compliant to IEEE 802.15.1 Bluetooth standard and the Bluetooth SIG Working Group specification Version 4.0+.

Guidance and manufacturer's declaration – electromagnetic emissions

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

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Display 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	
IEC 61000-3-2		Not Applicable
		The Display is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes, provided the following warning is heeded: WARNING: The Display is intended for use by healthcare professionals only. The Display may distrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as re-orientating or relocating the Display or shielding the location.

Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6kV contact +/- 8kV air	Pass	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	+/- 2kV for power supply lines +/- 1kV for input/output lines	Pass	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1kV line(s) to line(s)	Pass	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 cycle 40% U_T(60% dip in U_T for 5 cycle 70% U_T(30% dip in U_T for 25 cycle <5% U_T(>95% dip in U_T for 5 s	Pass	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CMS display requires continued operation during power mains interruptions, it is recommended that the CMS display be powered from an uninterruptible power supply or battery.

Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Pass	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a.c. mains voltage prior to application of the test level

Guidance and manufacturer's declaration - electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the system, 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√P
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.5 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b]

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

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

The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 2.3√P
0.01	.12	.12	.23
0.1	.38	.38	.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 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.

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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Packaging Symbol Definitions					
	Expiration Date YYYY-MM. Use by last day of month (MM).		Manufacturer and date of manufactured	STERILE EO	Sterilized by ethylene oxide
	Refer to Operating Instructions		Keep Dry	REF	Model number
	Single Use	CE	European Conformity	LOT	Lot Number
RxOnly	Prescription Only		Do Not Use if Package is Damaged		EN IEC 60601-1 applied part Type CF Defibrillation-proof
	Temperature Limit		Humidity Limitation		Atmospheric Pressure Limitation
SN	Serial Number				
IP31	Protected aginst vertically falling water when the enclosure is vertical and ingress of solid foreign objects greater than or equal to 2.5mm (0.1 in.) diameter per IEC 60529				
CLASSIFIED UL E485882	UL Mark for the United States for Medical – General Medical Equipment as to Electrical Shock, Fire and Mechanical Hazards Only in Accordance with ANSI/AAMI ES 60601-1 (2005)+AMD (2012) and UL 60601-1.				

German Translation

Italian Translation