DOME®
by NDSsi

Dome® Sx Display

User's Guide

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About the Display

The Dome® Sx displays are available in 3 and 10 megapixels and contain a TFT LCD panel. The display's thin film transistors, in a transmissive-type display, use an integrated cold cathode fluorescent tube (CCFT) backlight system.

The display is designed for medical imaging in diagnostic settings and comes fully tuned with gamma correction that complies with the DICOM Part 14 Standard. The all-digital design enables the display to produce the sharp, crisp images critical to softcopy medical viewing. Unwanted analog display image artifacts are eliminated.

For display classification and use; environmental guidelines; safety precautions; handling, cleaning and storage tip; and specifications, see "Technical Information" on page 7.

System Requirements

- Windows 7 (x86 or x64) or Windows XP Service Pack 3 (x86 or x64)
- Intel or AMD multi-core processor
- PCI Express x16 lane slot
- 50 MB hard disk space
- 512 MB RAM
- CD-ROM drive
- Power supply, 350 watts or greater

The Dome S10 display, shown here for illustrative purposes. Your display package may contain a Dome S3, Dome S3c, or Dome S10 unit.

DC power adapter

Power cord

DVI cable

DisplayPort cable

Mini USB cable

Quick reference

NOTE: DVI-to-DVI and DisplayPort cables ship in the Dome S3 and Dome S3c display packages. DVI and mini USB cables ship in the Dome S10 display package.

Display Components

Review the following illustrations to identify controls and ports on the front and back panels of the Dome Sx displays.

Front sensor on Dome S3/Dome S3c

MQSA button on Dome S10

The sensor on the front of the Dome S3 and Dome S3c displays allows you to run an auto-conformance test without using a photometer.

The MQSA (Mammography Quality Standards Act) button (lower right, beneath display ID) on the Dome S10 display facilitates any daily, weekly, or annual tests that you have preset via calibration and monitoring software.

Dome S3/Dome S3c connector plate

Dome S10 connector plate

The Dome Sx displays include the following components on the connector plate:

- Power input.
  - On Dome S3, drives power to the display via an 8-pin DIN connector. The power input is 12V ±5% (130 W).
  - On Dome S3c and Dome S10, drives power to the display via a 6-pin DIN connector. The power input is 24V ±5% (150 W).
- USB port.
  - Dome S3/Dome S3c uplink B port. Usage to be defined at a future time.
  - Dome S10 uplink mini-B port. Usage assigned for MQSA button functionality.
- Video input. Drives the data to the display.
  - The Dome S3/Dome S3c display offers two video connector options: a standard DVI connector or a DisplayPort connector.
  - The Dome S10 display offers two standard DVI connectors.
- Reset button. Restores the display configuration to default setting.
- LED lights. Provides information on the status of the display.

Installing the Display

Turn your computer off. Leave the power cord plugged into the grounded outlet. Use the Dome Sx display with the power adapter and video cable shipped.

Warning
In locations where 240V outlets are used, connect the Dome Sx display only to a center-tapped, 240V, single-phase supply (for Canada and the United States only).

Connecting the Video and Power Cables

IMPORTANT! For the Dome S3 or Dome S3c display only. Install either the DVI or the DisplayPort video cable, not both.

To connect the cables

1 Plug one end of the video cable into the video port on the connector plate. Secure the connection.

2 Plug the power cord into the power input port on the connector plate.

3 Plug the other end of the cable into the video port on your computer system. Secure the connection.

4 Plug the other end of the power cord into the power supply.

5 Plug the power supply cord(s) into a grounded AC outlet.

6 Turn on the adapter power before you turn on the computer.

Video Cable Installation on the Dome S10 Display

Note the location of the primary input on the Dome S10 display, shown below, for proper video cable installation. Improper connection may cause VGA boot messages not to appear on the display screen.

Primary video signal input on the Dome S10 connector plate

Technical Information

The design of the Dome® Sx digital display takes into account every known measure to ensure your personal safety. Improper use of the display can result in electric shock, fire, or damage to the display. Read all instructions before setting up the display.

Classification

Shock Protection: Class I.

Degree of Protection Against Electric Shock: No applied part.

Degree of Protection Against Harmful Ingress of Water: Ordinary equipment (IPX0).

Degree of Safety in the Presence of Flammable Anaesthetic Mixture with Air or with Oxygen or Nitrous Oxide: Not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

Mode of Operation: Continuous.

No applied part

Important recycle instruction

HAZARDOUS SUBSTANCE. Lamp(s) inside this product contain mercury. This product may contain other electronic waste that can be hazardous if not disposed of properly. Recycle or dispose in accordance with local, state, or federal laws. For more information, contact the Telecommunications Industry Association at WWW.ECYCLINGCENTRAL.COM. For lamp-specific disposal information, check WWW.LAMPRECYCLE.ORG.

DISPOSAL. Do not use household or municipal waste collection services for disposal of electrical and electronic equipment. EU countries require the use of separate recycling collection services.

ENVIRONMENT-FRIENDLY USE PERIOD. Hazardous substances are present. The number encircled by the recycling symbol indicates the safe-use period (in years). China requires the use of recycling services at the end of product life.

Symbol explanations

CAUTION. Read the accompanying text carefully, for proper operation and maintenance of the display system.

DANGEROUS VOLTAGE. Important precautions about electric shock. Read the accompanying text carefully, to prevent damage to display components and to guard your safety.

DIRECT CURRENT.

BAROMETRIC PRESSURE. Transport and storage 12,000 meters (39,400 feet), maximum in unpressurized container.

RELATIVE HUMIDITY. Transport and storage 5% to 90% (noncondensing).

TEMPERATURE. Transport and storage -20° to 60° C.

Intended use

The Dome S series offers AMLCD units designed for viewing medical X-ray images. A Dome Sx display should not be used near patients and should be kept outside of 1.83 m perimeter and 2.29 m vertical.

Dome S3 and Dome S3c are intended for use in displaying and viewing medical images for review and analysis by trained medical practitioners.

Dome S10 is intended for use in displaying and viewing medical images for review and analysis by trained medical practitioners, or for use in displaying and viewing radiographs of the breast for review and analysis by trained medical practitioners.

IMPORTANT: Only the Dome S10 display can be used for review and analysis in mammography. Do not use the Dome S3 or Dome S3c display in mammography review and analysis.

Federal law restricts this device to sale by or on the order of a medical practitioner.

Safety precautions

External equipment intended for connection to signal input, signal output, or other connectors, must comply with the relevant IEC standard (EN/IEC 60601-1 series for medical electrical equipment). In addition, all such combinations (systems) must comply with the standard IEC 60601-1-1, Safety requirements for medical electrical systems.

Equipment not complying to IEC 60601 must be kept outside the patient environment, as defined in the standard as at least 1.5 meters from the patient or the patient support.

Any person who connects external equipment to signal input, signal output, or other connectors has formed a system and is therefore responsible for the system to comply with the requirements of IEC 60601-1-1. If in doubt, speak with a qualified technician.

Safety tips

- Never open the display case, even when the power is off. Dangerous voltage inside may cause electric shock or death.
- To avoid damage to the display, use the grounded power supply and video cable supplied by NDSsi, or use certified replacements.
- Be sure the display is electrically grounded. You must connect the third grounding pin on the US power cord to a grounded outlet. The European power cord does not have a third grounding pin, but it must be plugged into a grounded outlet.
- If you cannot insert the plug into the outlet you plan to use, have a licensed electrician replace the outlet with a properly grounded outlet. If the power cord connects directly into the computer, make sure the computer is grounded.
- Keep the display dry if it is part of a surgical system. The display lacks protection against liquids or spills.
- **In locations where 240V outlets are used, connect the Dome Sx display only to a center-tapped, 240V, single-phase supply (for Canada and the United States).**

GROUNDING RELIABILITY CAN ONLY BE ACHIEVED WHEN EQUIPMENT IS CONNECTED TO AN EQUIVALENT RECEPTABLE MARKED “HOSPITAL ONLY” OR “HOSPITAL GRADE.”

Unpacking and handling tips

The Dome Sx display is a precision instrument that requires proper care to maintain product operation and adherence to specification. Unpack the display and components carefully, then set up and handle the unit properly to avoid damage to the LCD panel.

- Use both hands to grasp the display case when lifting it from the shipping carton, but avoid touching the screen.
- Do not apply pressure to the screen or touch the screen with bare fingers or objects. Pressure can affect image quality. Cosmetics and oils on the skin are both detrimental to the screen and difficult to remove.
- Allow the display to warm up to room temperature before turning it on. Avoid sudden temperature changes in the environment, as this may cause condensation, which damages the display.
- Secure the display properly onto a standard VESA 100-mm mounting unit if you elect not to use the desk stand.
- Do not set up the display near strong light or heat sources.
- Do not block the vents on the back of the display or install the display in a built-in enclosure. Blocked vents cause excessive heat to build up inside the display, increasing risk of fire.
- When installing components, turn off your computer, but leave it plugged into a grounded outlet.
- Do not remove the back cover or disassemble the display. There are no user-serviceable parts inside.

Preventing fire and injury

- Replace the power supply or cables if damaged.
- Use only the power source indicated in this guide or listed on the display.
- Do not plug the power supply into an overloaded AC outlet or extension cord. Overloaded AC outlets and cords can result in electric shock or fire.
- Do not drop or push objects into the display case. Internal components contain high voltage.
- Unplug the power cord from the wall outlet during thunderstorms.
- Do not place magnetic devices, such as motors, near the display.

Cleaning the display

Observe the following guidelines to maintain the display and the LCD screen.

- Use a clean, lint-free, absorbent cotton cloth to clear off any residual glue from removal of the protective film or to remove surface dust. Apply light pressure to remove the dust.
- Dampen a clean cloth with a small amount of isopropyl alcohol to remove glue or dust if the screen is still not clean. Do not saturate the cloth; otherwise, alcohol may seep into the display case and collect in the enclosure. Use a clean, dry cloth to completely remove the alcohol residue.
- Do not use chemically treated dust cloths, acetone, toluene, or harsh solvents on the display case or the screen. They can damage the polarizer and the display case.
- Do not expose the display to water or excessive moisture. Do not allow water or other stains to stand on the unit. Wipe liquids off immediately to prevent damage to the display case and the screen.

WARNING
DISCONNECT SUPPLY BEFORE SERVICING

AVERTISSEMENT
COUPER L'ALIMENTATION AVANT L'ENTRETIEN ET LE DEPANNAGE

Shipping/storing the display

Keep the display in its shipping container until installation. Return the display to its original container whenever you need to store the unit, move it to another location, or return it for repair. The packaging supplied by the manufacturer protects the display while it is in transit. See environment specifications for more information.

Before returning the display to the container, do the following:

1 Swivel the display panel to landscape mode.
2 Push the panel down to the lowest position.
3 Use the stand lock to anchor the panel.

Disposal information

Follow your local governing ordinance and recycling policy for proper disposal or recycling of display components.

Dome S3 Specification

In locations where 240V outlets are used, connect the Dome S3 display to a center-tapped, 240V, single-phase supply only (for Canada and the United States).

Category	Characteristic Item	Specification
Screen	Type	AMLCD (active-matrix liquid crystal display)
	Screen size diagonal	540 mm (21.3 in.)
	Resolution	1536 x 2048 pixels (portrait) 2048 x 1536 pixels (landscape)
	Pixel pitch	0.2115 mm, 120 dpi
	Pixel arrangement	LCR vertical stripe
	Active area (H x V)	433.2 x 324.9 mm (17.05 x 12.79 in.)
	Grayscale supported	1024 shades of gray (programmable gamma from palette of up to 3061 shades of gray)
	Refresh rate	60 Hz
	Contrast ratio	900:1 typical; 650:1 minimum
	Brightness	1450 cd/m^2 typical; 1150 cd/m^2 minimum
	Pixel rise/fall time	27 ms typical
	Viewing angle (CR 10: 1)	170° (± 85°) horizontal/vertical
Interface	Digital Video In	DVI Rev. 1.0 digital dual-channel connector DisplayPort Revision 1.1a connector
	Display control (brightness/contrast)	DDC2B+
	Display identification	EDID read using DDC2B+
	USB hub (on stand)	N/A
	USB uplink (on display)	Universal Serial Bus Rev. 2.0: 1 uplink B port
	Display status	Dual-stack tricolor LEDs on back of unit
Input formats	Landscape orientation	2048 x 1536 (10-bit per pixel)
	Portrait orientation	1536 x 2048 (10-bit per pixel)
	VGA/XGA	640 x 480 to 1280 x 768 pixels (displayed in portrait orientation)
Physical	Display size (without stand)	475 mm x 363 mm x 99 mm (18.6 in. x 14.3 in. x 3.9 in.)
	Display weight (without stand)	6.6 kg (14.6 lb.) typical
	Display weight (with stand)	9.5 kg (20.9 lb.) typical
	Mounting options	Desktop stand (standard); 100-mm VESA compliant mounting
Power	Adapter	BridgePower BPM130S12F02 (with power switch) (CAUTION: Use only the adapter supplied with unit.)

Power Supply

CAUTION: Use only the power adapter supplied with the Dome S3 display unit; the BridgePower BPM130S12F02 (130W) model.

Category	Characteristic Item	Specification
Power input requirements	Voltage selection	Universal auto switching with medical approvals and PFC
	Voltage	100–240V AC
	Current	3.0 A
	Frequency	50–60 Hz
Power consumption	Wattage	90 W typical
Power output requirements	Voltage	12 V DC ±5%
	Current	10.8 A (130 W)
Physical	Size	228.6 mm x 76.2 mm x 50.8 mm (9 in. x 3 in. x 2 in.)
	Weight	1.3 kg (2.75 lb.)

Reliability

Characteristic item	Specification
Display	MTBF > 50,000 hours
Backlight	MTBF 50,000 hours to 50% brightness with backlight on continuously

Environment

Characteristic item		Specification
EMI shielding		No emission of low-level radiation
Temperature	operating	0° C ~ 40° C
	storage	-20° C ~ 60° C
Humidity	operating	20% ~ 90% Relative Humidity (noncondensing)
	storage	5% ~ 90% Relative Humidity (noncondensing)

Dome S3c Specification

In locations where 240V outlets are used, connect the Dome S3c display to a center-tapped, 240V, single-phase supply only (for Canada and the United States).

Category	Characteristic Item	Specification
Screen	Type	AMLCD (active-matrix liquid crystal display)
	Screen size diagonal	540 mm (21.3 in.)
	Resolution	1536 x 2048 pixels (portrait) 2048 x 1536 pixels (landscape)
	Pixel pitch	0.2115 mm, 120 dpi
	Pixel arrangement	R,G,B vertical stripe
	Active area (H x V)	433.2 x 324.9 mm (17.05 x 12.79 in.)
	Color supported	16.7 million colors; 256 shades of gray (programmable gamma from palette of up to 2041 shades)
	Refresh rate	60 Hz
	Contrast ratio	750:1 typical; 600:1 minimum
	Brightness	700 cd/m^2 typical; 550 cd/m^2 minimum (when new)
	Pixel rise/fall time	24 ms typical (14 ms Tr/10 ms Tf)
	Viewing angle (CR 10: 1)	170° (± 85°) horizontal/vertical
Interface	Digital Video In	DVI Rev. 1.0 digital dual-channel connector DisplayPort Revision 1.1a connector
	Display control (brightness/contrast)	DDC2B+
	Display identification	EDID read using DDC2B+
	USB hub (on stand)	N/A
	USB uplink (on display)	Universal Serial Bus Rev. 2.0: 1 uplink B port
	Display status	Dual-stack tricolor LEDs on back of unit
Input formats	Landscape orientation	2048 x 1536 (24-bit per pixel; 30-bit per pixel via DisplayPort)
	Portrait orientation	1536 x 2048 (24-bit per pixel; 30-bit per pixel via DisplayPort)
	VGA/XGA	640 x 480 to 1280 x 768 pixels (displayed in portrait orientation)
Physical	Display size (without stand)	472 mm x 363 mm x 102 mm (18.6 in. x 14.3 in. x 3.9 in.)
	Display weight (without stand)	6.4 kg (14.0 lb.) typical
	Display weight (with stand)	9.3 kg (20.5 lb.) typical
	Mounting options	Desktop stand (standard); 100-mm VESA compliant mounting
Power	Adapter	BridgePower BPM150S24F05 (with power switch) (CAUTION: Use only the adapter supplied with unit.)

Power Supply

CAUTION: Use only the power adapter supplied with the Dome S3c display unit; the BridgePower BPM150S24F05 (150W) model.

Category	Characteristic Item	Specification
Power input requirements	Voltage selection	Universal auto switching with medical approvals and PFC
	Voltage	100–240V AC
	Current	2.5 A
	Frequency	50–60 Hz
Power consumption	Wattage	108 W typical
Power output requirements	Voltage	24 V DC ±5%
	Current	6.25 A (150 W)
Physical	Size	223.5 mm x 63.5 mm x 38.1 mm (8.8 in. x 2.5 in. x 1.5 in.)
	Weight	0.8 kg (1.8 lb.)

Reliability

Characteristic item	Specification
Display	MTBF > 50,000 hours
Backlight	MTBF 50,000 hours to 50% brightness with backlight on continuously

Environment

Characteristic item		Specification
EMI shielding		No emission of low-level radiation
Temperature	operating	0° C ~ 35° C (10° C ~ 35° C within specification)
	storage	-20° C ~ 60° C
Humidity	operating	20% ~ 90% Relative Humidity (noncondensing)
	storage	5% ~ 90% Relative Humidity (noncondensing)

Dome S10 Specification

In locations where 240V outlets are used, connect the Dome S10 display to a center-tapped, 240V, single-phase supply only (for Canada and the United States).

Category	Characteristic Item	Specification
Screen	Screen size diagonal	762 mm (30.0 in.)
	Resolution	4096 x 2560 pixels (landscape)
	Pixel pitch	0.158 mm, 161 dpi
	Pixel arrangement	Single pixel, IPS structure
	Active area (H x V)	645.1 x 403.2 mm (25.40 x 15.87 in.)
	Grayscale supported	1024 shades of gray (programmable gamma from palette of up to 4096 shades of gray)
	Refresh rate	50 Hz
	Contrast ratio	850:1 typical; 700:1 minimum
	Brightness	1250 cd/m^2 typical; 1000 cd/m^2 minimum (when new)
	Pixel rise/fall time	35 ms typical (20 ms Tr/15 ms Tf)
	Viewing angle	170° (± 85°) horizontal/vertical
Interface	Digital Video In	2x DVI Rev. 1.0 digital dual-channel connector
	Display control (brightness/contrast)	DDC2B+
	Display identification	EDID read using DDC2B+
	USB hub (on stand)	N/A
	USB uplink (on display)	Universal Serial Bus Rev. 2.0: 1 uplink mini-B USB port
	Display status	Dual-stack tricolor LEDs on back of unit
	MQSA	Two color bottom facing LEDs on front of unit with push-button activation
Input formats	Landscape orientation	4096 x 2560 (10-bit per pixel)
	Portrait orientation	2x 2048 x 2560 (10-bit per pixel)
	VGA/XGA	640 x 480 to 1280 x 1024
	Screen type	AMLCD (active-matrix liquid crystal display)
Physical	Display size (without stand)	699 mm x 473 mm x 79 mm (27.5 in. x 18.6 in. x 3.1 in.)
	Display weight (typical)	7.7 kg (17 lb.) without stand; 10.9 kg (24 lb.) with stand
	Mounting options	Desktop stand (standard); 100-mm VESA mounting (optional)
Power	Adapter	BridgePower BPM150S24F05 (with power switch) (CAUTION: Use only the adapter supplied with unit.)

Power Supply

CAUTION: Use only the power adapter supplied with the Dome S10 display unit; BridgePower BPM150S24F05 (150W).

Category	Characteristic Item	Specification
Power input requirements	Voltage selection	Universal auto switching with medical approvals and PFC
	Voltage	100–240V AC
	Current	2.5 A
	Frequency	50–60 Hz
Power consumption	Wattage	138 W maximum
Power output requirements	Voltage	24 V DC ±5%
	Current	6.25 A (150 W)
Physical	Size	223.5 mm x 63.5 mm x 38.1 mm (8.8 in. x 2.5 in. x 1.5 in.)
	Weight	0.8 kg (1.8 lb.)

Reliability

Characteristic item	Specification
Display	MTBF >50,000 hours
Backlight	MTBF 50,000 hours to 50% brightness with backlight on continuously

Environment

Characteristic item		Specification
EMI shielding		No emission of low-level radiation
Temperature	operating	5° C ~ 35° C (within specification)
	storage	-20° C ~ 60° C
Humidity	operating	20% ~ 90% Relative Humidity (noncondensing)
	storage	5% ~ 90% Relative Humidity (noncondensing)

Video Modes

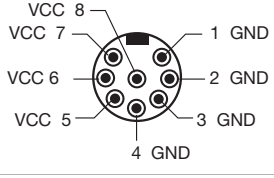
Resolutions expressed in pixels (W x H).

Display	Resolution	Orientation	Palette	Bits per pixel
Dome S3	1536 x 2048 2048 x 1536	Portrait Landscape	32-bit	10
Dome S3c	1536 x 2048 2048 x 1536	Portrait Landscape	True Color	24; 30 (DisplayPort only)
Dome S10	2x 2048 x 2560 (non-span mode)	Portrait	32-bit	10
	4096 x 2560 (horizontal span mode)	Landscape	32-bit	8 (Windows 7); 10 (Windows XP)

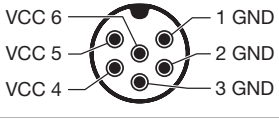
Connector Plate

All Dome Sx displays have a DVI connector. The Dome S3 and Dome S3c displays also have a DisplayPort connector.

Display	Video Port	DIN Connector	Power Input	Adapter
Dome S3	DVI and DisplayPort	8-pin	12V ±5% (130 W)	BPC BPM130S12F02 (with power switch)
Dome S3c	DVI and DisplayPort	6-pin	24V ±5% (150 W)	BPC BPM150S24F05 (with power switch)
Dome S10	DVI	6-pin	24V ±5% (150 W)	BPC BPM150S24F05 (with power switch)



8-pin connector on Dome S3 display



6-pin connector on Dome S3c and Dome S10 displays

LED Status Lights

The two LEDs on the back panel of the Dome Sx displays provide information about the display.

- LED A describes the digital-link status between the display controller and the interface.
- LED B describes the display-panel status. it shows any faults currently in the panel.

Power-up sequence information from LED

LED A	Action/Sequence	LED B	Action/Sequence
Dark	Initial power-on	Flashing yellow	Initial power-on
Blink yellow	Self test	Solid yellow	Power-on self test
Dark	One (1) second after power -on	Flashing green	Self test pass

LED A status information after initial power-on

LED Status	Description
Solid green	Functional link – normal operation
Flashing yellow	Link working, unrecognized sync information

LED B status information after initial power-on

LED Status	Description
Solid green	Functional system – normal operation
Flashing green	Fault
Solid yellow	DDC power-on, 12V/24V power not detected
Alternating green/yellow	POST failure

NOTE: A red LED or combination of red LEDs indicates a hardware or software fault. Contact Dome Technical Support for assistance.

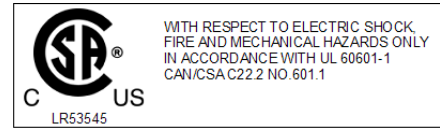
Troubleshooting

Problem	Possible Cause	Solution
No image appears on the screen	Computer is OFF.	Power on the machine.
	Power cord is not securely connected.	Tighten power cord connection and turn on computer.
	Video cable connected incorrectly.	Make sure the first display of a dual-headed system or the only display of a single-headed system is connected to the primary port on the display controller.
Conflict with driver version	A previous version of the display driver is still installed on the computer system.	Remove any existing display driver before you install a more recent version.
	The installation CD contains a file older than the one currently on your system.	The Confirm File Replace dialog box appears if the installation CD contains a file older than the one currently on the system. Click No to the question, Over-write the newer file? Or, click No to All.
Unable to set the maximum or native resolution of the display	The function Hide all modes that this monitor cannot display is selected on a subdialog of the Windows Display Properties dialog.	When using commodity graphics boards on Windows XP systems, make sure the check box for the function is empty (unchecked).
	A single-link commodity graphics board is in use.	When using commodity graphics boards with the Dome Sx displays, be sure to install a DualLink DVI graphics board.

Regulatory Compliance

Canada, European Union, United States

This display has been tested and found to comply with IEC/EN 60601-1 and IEC/EN 60601-1-2 standards, and is certified to meet medical standard CAN/CSA C22.2 No. 601.1 and UL 60601-1.



Dome S3, Dome S3c, and Dome S10

The medical display, in addition to meeting medical requirements, has been tested and found to comply with the limits for Federal Communications Commission (FCC) Class A computing devices in a typically configured system since many medical offices are located in residential areas. It is the system integrator's responsibility to test and ensure that the entire system complies with applicable electromagnetic compatibility (EMC) laws.

Warning to Users of Dome Sx Displays

The Dome S3, Dome S3c, and Dome S10 displays are Class A products. In a domestic environment, either of these products may cause radio interference, in which case the user may be required to take adequate measures.

Radio transmitting equipment, cellular phones, etc. shall not be used in close proximity of the devices, since this could influence the performance of the device.

Particular precaution must be considered during use of strong emission sources, such as High Frequency surgical equipment and similar, so that, for example, the HF-cables are not routed on or near the devices. If in doubt, contact a qualified technician or your local representative.

We offer state-of-the-art displays suitable to the European market, CE-marked displays based on compliance with counsel directive 93/42/EEC—commonly referred to as the Medical Device Directive (MDD). The following summarizes our qualification of these displays as it relates to compliance with the MDD.

The European Medical Device Directive requires that the intended use of the device be defined. The intended use of these displays is "to display alphanumeric, graphic, and image data as inputted from any type of medical device." Specifically, the Dome S3 and Dome S3c displays are intended for use in displaying and viewing medical images for review and analysis by trained medical practitioners. The Dome S10 display is intended for use in displaying and viewing medical images for review and analysis by trained medical practitioners, or intended for use in displaying and viewing radiographs of the breast for review and analysis by trained medical practitioners. These displays do not provide a measurement function in any way, and it is the device and systems manufacturer's responsibility to verify its function in the integrated device or system.

The display was classified as required by the MDD according to Annex IX of the directive and the medical device (MEDDEV) guidance available at the time of classification. Because the display uses electrical energy and has no direct patient connections and—by itself—no medical utility, the display is classified according to Rule 12 as an MDD Class I device, component, or accessory. The MDD states that manufacturers of Class I medical devices or accessories shall satisfy the requirements in regard to design and manufacturing controls, that is, the applicable assessment route to be used for CE-marking under the MDD, and it shall carry the CE mark according to Annex XII of the directive, with no Notified Body annotation.

The applicable safety standards for an MDD Class I display are EN 60601-1:1990 along with A1:1993, A12:1993, A2:1995, and A13:1996, as well as IEC 60601-1:1988 along with A1:1991 and A2:1995. To help the medical device designer evaluate the suitability of these displays, NDSsi has also conducted EMC testing to IEC 60601-1-2 as it can be applied. The display with its power supply alone does not represent a functional medical device. Hence, NDSsi configured a minimal operating system to exercise the display. The resulting data are made available to interested parties.

This is informative data, not certification data. Certification data must be obtained by the device or system integrator according to Article 12 of the MDD titled "Particular procedure for systems and procedure packs." Paragraph 2 clearly outlines the device or system integrator's responsibility in this matter.

In summary, NDS Surgical Imaging is CE-marking these displays under the Medical Device Directive, which establishes compliance to the basic medical safety standards. However, EMC compliance can only be accomplished in the configured medical device or system and is the responsibility of the device or system manufacturer. NDSsi has the necessary documentation such as IEC 60601-1 notified body and other third-party test reports and certifications, a risk/hazard analysis, an essential requirements checklist, and the NDS Surgical Imaging International Electrotechnical Commission (IEC) declaration of conformity.

NDS Surgical Imaging, located in San Jose, Calif., USA, is the manufacturer of these displays in the meaning of the directive. As required by the MDD in Article 14, NDS Surgical Imaging, not residing in the European Economic Area (EEA), has a European representative, NDS Surgical Imaging — Nijverheidscentrum 28, 2761 JP Zevenhuizen, The Netherlands (phone +31-180-63-43-56; fax +31-180-63-21-91).

In the opinion of NDS Surgical Imaging registration required to put this device into commerce is the responsibility of the medical device/system manufacturer, and NDS Surgical Imaging supports this requirement by providing a European Commission (EC) declaration of conformity. If NDS Surgical Imaging supplies a display to an end user, rather than a device manufacturer, it is the end user's responsibility to ensure continued compliance with the MDD of the system in which the display is integrated.

The supplier will make available on request, circuit diagrams, component part lists, etc.

For vigilance reporting as required under Article 10 of the MDD, NDS Surgical Imaging will provide any information requested by competent authority to support any reported incident investigation by such an authority.

EU Declaration of Conformity for Medical Application

A Declaration of Conformity has been filed for this product. For additional copies of the Declaration of Conformity document, contact NDS Surgical Imaging.

The Dome Sx digital flat-panel display meets the essential health and safety requirements, is in conformity with, and the CE marking has been applied according to the relevant EU Directives listed below, using the relevant section of the following EU standards and other normative documents;

EU EMC Directive 2004/108/EC

EU Electromagnetic Compatibility Directive

EN 60601-1-2 Medical Electrical Equipment	Collateral standard electromagnetic compatibility requirements
EN 55011	Limits and methods of measurements for radio interference characteristics of industrial, scientific, and medical equipment
IEC 1000-3-2	Harmonic emissions
IEC 1000-3-3	Voltage fluctuations/flicker emissions
IEC 1000-4-2	Electrostatic discharge requirements for industrial process measurement and control equipment
IEC 1000-4-3	Radiated electromagnetic field requirements for industrial process measurement and control equipment
IEC 1000-4-4	Electrically fast transients for industrial process measurement and control equipment
IEC 1000-4-5	Surge requirements
IEC 1000-4-11	Voltage variations/dips/interrupts
IEC 1000-4-6	Conducted immunity
IEC 1000-4-8	Magnetic field immunity
CE	Conformance to the Medical Device Directive 93/42/EEC
EN 60601-1 Medical Electrical Equipment	Part 1: General requirements for safety

U.S. FCC Compliance Statement

Class A Digital Device: Dome S3, Dome S3c, or Dome S10 Display

This device complies with Part 15 of the FCC Rules.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment.

This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications.

Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment under FCC rules.

Each Dome Sx display has one or more of the following certifications.

China

China Compulsory Certification regulating safety and EMC.
GB4943-2001
GB9254-2008
CB17625.1-2003

Class A — Dome S3, Dome S3c, and Dome S10

声　明

此为A级产品，在生活环境中，该产品可能会造成无线电干扰。在这种情况下，可能需要用户对其干扰采取切实可行的措施。

Germany

TÜV Rheinland GM Mark for medical products.

Japan

Voluntary Control Council for Interference by information technology equipment sold in Japan.

Class A — Dome S3, Dome S3c, and Dome S10

この装置は、情報処理装置等電波障害自主規制協議会（ＶＣＣＩ）の基準に基づくクラスＡ情報技術装置です。この装置を家庭環境で使用すると電波妨害を引き起こすことがあります。この場合には使用者が適切な対策を講ずるよう要求されることがあります。

Class B

この装置は、情報処理装置等電波障害自主規制協議会（ＶＣＣＩ）の基準に基づくクラスＢ情報技術装置です。この装置は、家庭環境で使用することを目的としていますが、この装置がラジオやテレビジョン受信機に近接して使用されると、受信障害を引き起こすことがあります。
取扱説明書に従って正しい取り扱いをして下さい。

Korea

Korea Certification.

NDSsi Dome® Display Products
Warranty and Service Terms and Conditions

STANDARD LIMITED WARRANTY

COVERAGE: NDS Surgical Imaging, LLC (hereinafter "NDSsi") warrants this product to be in compliance with the specifications provided by NDSsi and to be free from defects in material and workmanship as defined in such specifications. Subject to the conditions set forth below, NDSsi agrees to repair or replace any defective part of the enclosed unit for the length of period indicated on the chart below.

NDSSI PRODUCT	STANDARD WARRANTY COVERAGE
Dome® E Series Radiology Displays	• Standard 5-year "repair and return" warranty • Industry-leading 10-year backlight warranty on grayscale displays* • Industry-leading 5-year backlight warranty on color displays† ‡
Dome® S Series Radiology Displays	• Standard 5-year "repair and return" warranty • Industry-leading 10-year backlight warranty on grayscale displays • Industry-leading 5-year backlight warranty on color displays
Dome® GX Display	Standard 3-year "repair and return" warranty

* If, within 10 years of initial purchase, the maximum output of the Dome Ex/Sx grayscale display is determined by NDSsi to be less than 300 cd/m^2, NDSsi will repair or replace the display at its sole discretion. The displays must have been run at or below the CXtra default brightness setting as configured from the factory.

† If, within 5 years of initial purchase, the maximum output of the Dome Ex/Sx color display (excluding the Dome E4c) is determined by NDSsi to be less than 250 cd/m^2, NDSsi will repair or replace the display at its sole discretion. The displays must have been run in native color mode at or below the CXtra default brightness setting as configured from the factory.

‡ If, within 5 years of initial purchase, the maximum output of the Dome E4c color display is determined by NDSsi to be less than175 cd/m^2, NDSsi will repair or replace the display at its sole discretion. The displays must have been run in native color mode at or below the CXtra default brightness setting as configured from the factory

EXCLUSIONS – WHAT IS NOT COVERED

1 Any product with a defaced, modified, or removed serial number.
2 Damage, deterioration or a malfunction resulting from accident, misuse, neglect, fire, water, lightning, or other acts of nature, unauthorized product modification, or failure to follow instructions supplied with the product.
3 Cosmetic damage including, but not limited to: scratches, cracks, dents, markings, glue and adhesive residue.
4 Any damage of the product due to shipment.
5 Any damage caused by factors external to the product, such as electric power fluctuation or failure.
6 Normal wear and tear, including backlights dimming over time, or image retention resulting from displaying fixed images for long periods of time.
7 Removal, installation, and set-up service charges.
8 Failures not reported within the warranty term.
9 Any NDSsi products purchased through a distributor, reseller, or medical device manufacturer other than NDSsi (each, an "Intermediary"), where such Intermediary provides direct warranty service to its end-user customers in connection with such product.*

DISCLAIMER

This limited product warranty sets forth your sole and exclusive remedy and NDSsi's sole and exclusive liability under the Standard Limited Warranty described herein.

THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, WHICH EXTEND BEYOND THE DESCRIPTION CONTAINED HEREIN INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT.

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* Note that NDSsi sells its products through distributors, resellers, and other medical device manufacturers which prefer to provide their end-user customers with direct warranty support. Contact NDSsi Customer Care to determine if the product that you purchased is covered by this Standard Limited Warranty or whether you need to contact the Intermediary through which you purchased the product for warranty service.

NDSSI'S LIABILITY IS LIMITED TO THE COST OF REPAIR OR REPLACEMENT OF THE PRODUCT. NDSSI SHALL NOT BE LIABLE FOR THE FOLLOWING:

1 DAMAGE TO OTHER PROPERTY CAUSED BY ANY DEFECTS IN THE PRODUCT, DAMAGES BASED UPON INCONVENIENCE, LOSS OF USE OF THE PRODUCT, LOSS OF TIME, LOSS OF PROFITS, LOSS OF BUSINESS OPPORTUNITY, LOSS OF GOODWILL, INTERFERENCE WITH BUSINESS RELATIONSHIPS, OR OTHER COMMERCIAL LOSS, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
2 ANY OTHER DAMAGES, WHETHER INCIDENTAL, INDIRECT, CONSEQUENTIAL OR OTHERWISE.
3 ANY CLAIM AGAINST THE CUSTOMER BY A THIRD PARTY.

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

This warranty gives you specific legal rights. You may have other rights, which may vary from locality to locality. Some localities do not allow limitations on implied warranties and/or do not allow the exclusion of incidental or consequential damages, so the above limitations might not apply to you.

WARRANTY SERVICE - REPAIR & RETURN – (US AND CANADA ONLY)

- Our standard warranty service is "Repair and Return". Repair and Return requires the defective unit to be returned to our service location for repair.
- Our service location will repair your unit within ten (10) business days. The service time-period does not include in-transit shipping time to or from our service location.
- Cost of shipment of the defective unit to NDSsi is the responsibility of the customer. Cost of shipment of the repaired unit to Customer is the responsibility of NDSsi (duties and taxes to Canada are not included).
- NDSsi reserves the right in its sole discretion to provide Customer with a comparable refurbished replacement unit in lieu of repair of customer's defective unit.
- If NDSsi is unable within a reasonable time to repair or replace the defective unit, it shall refund the purchase price for the product paid by the customer (exclusive of taxes, installation and shipping related fees).

CONTACTING NDSSI CUSTOMER CARE

PRODUCT LINE	Dome®
TOLL FREE	(866) 961-9340
LOCAL	(503) 620-3787
E-MAIL	medicalsupport@ndssi.com
HOURS	6 A.M. – 5 P.M. Pacific Time, Monday –Friday

1 Contact NDSsi Medical Support during the hours listed above. Have your NDSsi model number and serial number available. You may be required to provide proof of purchase as a condition for receiving warranty service.

2 Our representative may perform troubleshooting and diagnosis of the problem by telephone or e-mail. If our representative is unable to fix the problem by telephone or e-mail, we will issue a Return Material Authorization (RMA) for the nonfunctioning unit and provide return instructions.

3 Upon receipt of the returned product, a service technician will evaluate the unit and confirm the failure description provided by the customer.

   (a) If the found failure type is covered under warranty, the repair, parts, labor and shipment back to the customer will be at no charge.

   (b) If the found failure type is not covered under warranty, NDSsi's then current evaluation fee will apply in addition to the cost of parts, labor and the return shipment.

   (c) If the unit is within the warranty period but the customer does not provide a problem description and the service technician cannot determine the failure (no problem found – "NPF") NDSsi's then current evaluation fee will apply in addition to return shipment.

PAYMENT FOR NONWARRANTY EVALUATIONS AND REPAIRS AND OTHER EVALUATION CHARGES: Nonwarranty repairs requested by customer will be performed at NDSsi's then current rates for any nonwarranty repairs and will include applicable evaluation fees and the cost of return shipping (if customer requests that NDSsi ship the repaired product). NDSsi further reserves the right in its sole discretion to request pre-payment for any nonwarranty repairs, NPF evaluations, and return shipping charges prior to return of the product to customer. Any invoiced amount not paid when due shall be subject to a service charge equal to the lesser of one and one-half percent (1.5%) per month or the maximum rate permitted by law. If NDSsi undertakes collection or enforcement efforts, customer shall be liable for all costs thereof, including attorney's fees. NDSsi reserves the right to suspend warranty coverage to any customer who is in default of payment until such payment has been made.

NDS Surgical Imaging, LLC
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