

OneMark® Detection Imaging System

Console and Transducer

Instructions for Use

DEVICE DESCRIPTION

The OneMark® Detection Imaging console and transducer are components of the OneMark Detection Imaging System (DIS). The console is a medical device that, when used with the transducer, provides controls for detecting and imaging the OneMark Breast Localization Marker and its surroundings within a biopsy site or soft tissue site prior to and during surgery.

In addition to imaging the marker, the console also displays audio and visual feedback to indicate the distance and proximity from the transducer to the marker. The console provides a maximum detection range of 50mm from the transducer to the marker. Excision of the lesion is performed using standard surgical technique. The DIS can be used to verify the marker is within the resected sample.

The console and transducer are provided non-sterile. The marker (available separately) is provided single use, sterile. Sterile transducer covers are to be purchased separately.

The OneMark® Breast Localization Marker (marker) is a small, implantable tissue marker pre-loaded in an Applicator delivery system. The marker is made of a hydrogel matrix containing microspheres for distinct visualization with ultrasound and when using the OneMark DIS. The marker contains a metal coil that is permanently visible under standard radiologic imaging per hospital protocol.

INDICATIONS FOR USE

The OneMark Breast Localization Marker is intended to be placed percutaneously in soft tissue (>30 days) to mark a biopsy site or soft tissue intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or detection imaging (OneMark Detection Imaging System), the OneMark Breast Localization Marker is located and may be surgically removed with the target tissue. The OneMark Detection Imaging System is intended only for the detection of the OneMark Breast Localization Marker.

Compatible Components

The following items are required for the proper use of the OneMark DIS. Use of other parts and materials not listed below is contraindicated.

- OneMark Breast Localization Marker
- OneMark Detection Imaging console
- OneMark Detection Imaging transducer

WARNINGS AND CAUTIONS

It is important that the instructions supplied with this Console be read, understood, and followed.

Warnings

- Failure to thoroughly review and adhere to the information contained in these Instructions for Use may pose a potential hazard to the patient and/or user.

- Electric Shock Hazard –To avoid the risk of electrical shock, this equipment must only be connected to supply mains with protective earth ground. The Console must be properly grounded to ensure patient safety. Do not connect the power cord to extension cords or to power plug adapters.
- Electric Shock Hazard – No modification of this equipment is allowed. Do not remove the console cover or USB cover. Removal of the cover may cause electrical shock. Contact View Point Medical for service.
- Electric Shock Hazard – Do not connect wet accessories to the Console. Ensure transducer connector is dry.
- Electric Shock Hazard – Always turn off and unplug the Console before cleaning.
- Fire Hazard – Do not use extension cords.
- Explosion Hazard – This system is not designed for use in an explosive atmosphere.
- Never use any power adapter or cable other than the one specifically supplied with the device.
- Check the OneMark packaging and devices before use for signs of damage, particularly to cables. If the instrument is damaged or gives unexpected performance or operation, then cease using the device and ensure that it is serviced before recommencing use of the device.
- Should the marker fail to be visible, standard surgical practices should be applied to accommodate the appropriate resection method, which may include remarking.
- The OneMark Detection Imaging System is not a substitute or replacement for diagnostic preoperative imaging.

Cautions

- Read all warnings, cautions, and instructions provided with this console before using.
- Read the instructions, warnings, and cautions provided with the marker before using. Specific instructions are not included in this manual.
- Federal law restricts this device to sale by or on the order of a physician.
- This equipment should only be used by a physician trained in its indicated use, limitations, and possible complications of soft tissue surgery techniques.
- Inspect cords for breaks, cracks, nicks, or other damage before every use. If damaged, do not use. Failure to observe this precaution may result in injury or electrical shock to the patient or operator.
- Verify power cord is secure before each use.
- Always switch the instrument off at the mains power outlet, before inserting or removing the power connector from the back of the instrument. Failure to do so may damage the internal instrument electronics.
- Do not leave the Console in SCAN Mode when not in use.
- Connect the power cord to a hospital grade wall outlet having the correct voltage or product damage may result.
- Ensure cables are positioned to prevent trip hazards.
- For best results, operate the instrument in a stable (vibration-free) environment, with the Console placed on a level working surface.
- Do not place Console in contact with other electrical equipment during use.
- The Console is non-sterile. Do not sterilize.
- Do not drop the Console or subject it to rough physical handling during normal use or during storage and transportation.

- Never clean the Console using an excessively wet cloth, or by washing it under running water.
- Do not clean the Console with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the unit.
- The console, transducer/cable assembly, and the marker applicator of the OneMark DIS are MR Unsafe and should not be used in the MR environment.
- The implanted OneMark Breast Localization Marker is MR Conditional. See Marker IFU for details.
- Lift transducer from tissue when not actively scanning to limit ultrasound energy to levels as low as reasonably achievable (ALARA). Users should use the device to detect markers and are advised to lift the transducer off tissue when interrogation is not active to insure the principles of ALARA application of the transducer.

CONTROLS, INDICATORS, AND RECEPTACLES

The Console is controlled using a touch-screen LCD. When imaging, the detector sends pulsed sound energy to excite the marker and then compares changes in the motion between pulse sets from the reflected sound energy. The pulses cause higher variation at locations where markers have been placed as compared to the energy level in unmarked areas. The system highlights the marker location on an LCD display using a color map overlay on a low-resolution gray scale background. The system indicates the marker's location using additional audio and visual feedback such as x-y crosshairs centered over the marker.

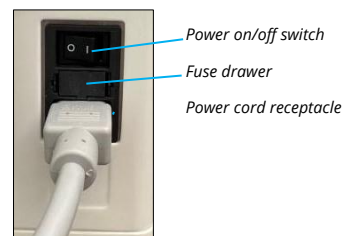
The OneMark Detection Imaging System provides localization of the OneMark Breast Localization Marker where transducer-to-marker distance is within the accuracy/detection range of ± 5 mm over the operating range of 50mm.

CONSOLE SETUP AND OPERATION

Front Panel



Back Panel



IMPORTANT: The OneMark DIS is intended for use by suitably qualified, trained and authorized physicians and/or operating room staff. View Point Medical takes no responsibility for the possible misuse or use by inadequately qualified staff.

Setting up the Console

1. Place the Console on a stable flat surface.

2. Plug the Console power cord into the rear panel receptacle.
3. Insert the power cord into a grounded power outlet.
4. Install the transducer as follows:
 - Insert the zero-insertion-force transducer connector into the console jack
 - When fully seated, rotate the locking mechanism at the top of the connector
 - The transducer head can be stored by placing in the holster mounted on the side of the console.
5. Cover the transducer with a sterile sheath before use. Ensure sterile ultrasound gel is applied on the transducer head within the sheath and outside the sheath.

NOTE: The console should be positioned in a way that the audio and visual feedback can be seen and heard comfortably by the surgeon at all times.

Operating the Console

6. Turn on the Console by pressing the rear power switch on (|). Verify the following:
 - Display on the console lights up, shows a splash screen with the View Point Medical logo and product name.
 - The console will check that the transducer is connected and validate the transducer. See *Troubleshooting Guidelines* for management of failed transducer check and transducer recognition failure conditions.
 - When the transducer is checked and validated, the system will automatically display an active scan. The user may scan at this time.
7. Perform the localization procedure by placing the transducer head perpendicular to the skin or soft tissue. Ensure that no air gaps are present between the transducer head and tissue.
8. Use the transducer to scan the area of interest at a moderate speed, moving no faster than 2" per second.
9. When the transducer detects the marker, the Console will display an image of the marker. It will also emit an audible feedback that increases in cadence as the transducer is placed closer and centered over the marker. The transducer-to-marker distance measurement will also display when the marker is detected.

NOTE: When not in use, press "freeze scan" to stop emitting. The display will show FROZEN in the top left hand corner. To reinitiate scanning, hit the "start scan" button again.

IMPORTANT: Should the marker fail to be visible, refer to preoperative radiologic imaging and other standard surgical practices for localization.

After Surgery

10. Dispose of the sterile sheath and clean the transducer per the instructions in the cleaning section below.
11. Power down the console by pressing the power button on the side of the console.
12. To move the console, ensure the console is powered down, then toggle the rear power switch to the off position (O).
13. Store the clean transducer in the holster on the side of the console.
14. Unplug the power cord from the wall outlet.

CARE & CLEANING

Warnings

- When sterilizing a transducer, ensure that the sterilant strength and duration of contact are appropriate for sterilization. Be sure to follow the manufacturer's instructions. If a pre-mixed solution is used, be sure to observe the solution expiration date.
- Follow the recommendations of the cleaner or disinfectant manufacturer.
- Electric Shock Hazard – Always turn off and unplug the Console before cleaning.
- Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

Cautions

- Using non-recommended disinfectants, using incorrect solution strengths, or immersing a transducer deeper or longer than recommended can damage or discolor the transducer and voids the transducer warranty.
- The use of isopropyl alcohol (rubbing alcohol), denatured ethyl alcohol, and alcohol-based products on all transducers is limited. The only parts that may be cleaned with alcohol are the connector housing and the transducer housing and lens. Ensure that the solution is only 91% or less isopropyl alcohol or 85% or less denatured ethyl alcohol. Do not clean any other part of a transducer with alcohol (including cables or strain reliefs), because it can damage those parts of the transducer. This damage is not covered by the warranty or your service contract.
- Attempting to clean or disinfect a transducer, cable, or connector housing by using a method other than the procedures here can damage the device and voids the warranty.
- When handling a transducer, do not bump the transducer on hard surfaces. Do not allow sharp objects, such as scissors, scalpels, or cauterizing knives, to touch transducers or cables. Do not use a surgeon's brush when cleaning transducers. Even the use of soft brushes can damage transducers. Do not use a brush on the connector housing label. Do not use paper products or abrasive products when cleaning a transducer. They damage the soft lens (acoustic window) of the transducer. The use of abrasive industrial wipes such as Wypall X60 can damage the lens.
- During cleaning, disinfection, and sterilization, orient the parts of the transducer, connector housing, or cable that must remain dry higher than the wet parts, until all parts are dry. This helps keep liquid from entering unsealed areas of the transducer.
- When cleaning and disinfecting transducers, do not allow any fluid to enter the connector through the electrical contacts, strain reliefs, connector housing, or areas surrounding the locking lever shaft. When wiping or spraying the connector, wipe or spray only the outer surfaces. If available, place a connector-cover splash guard over the electrical contacts to help prevent fluid from entering the connector housing. Damage due to fluids in these areas is not covered by the warranty or your service contract.
- Never sterilize the transducer with autoclave, gamma-radiation, gas, steam, or heat sterilization techniques. Severe damage will result. Avoidable transducer damage is not covered by the warranty or service contract.
- Do not expose the transducer to cleaning and disinfectant agents for extended periods of time. Limit the time that transducers are exposed to cleaning and disinfectant agents to the minimum time recommended by the manufacturer.
- Before storing transducers, ensure that they are thoroughly dry. If it is necessary to dry the transducer lens (acoustic window) after cleaning, use a soft, dry, lint-free cloth and a gentle blotting motion. Aggressive wiping or scrubbing can damage the lens.

- Do not clean the Console with abrasive cleaning or disinfectant compounds, solvents, or other materials that could scratch the panels or damage the console.

Console

1. Turn off the Console and unplug the power cord from the wall outlet.
2. Thoroughly wipe all surfaces of the Console, including transducer holster, and power cord with a mild cleaning solution or disinfectant such as a Sani Cloth AF3. Do not wipe the transducer connector jack.

Follow universal, generally accepted practices when handling components that have come in contact with blood or tissue.

Follow the procedures approved by your institution or use a validated infection control procedure. Do not allow fluids to enter the Console. The Console cannot be sterilized.

Transducer

General Cleaning

These general cleaning instructions must be followed for the transducer and its cables and connectors. The transducer must be cleaned after each use. Cleaning the transducer is an essential step before effective disinfection or sterilization. First clean and then disinfect or sterilize the transducer following the appropriate procedures.

Recommended supplies:

- Soft moist cloth
 - Compatible cleaners or cleaning wipes for the transducer, cable, and connector
 - Soft, dry, lint-free cloth
1. After every patient, remove the sterile sheath and dispose.
 2. Remove the sterile ultrasound transmission gel from the transducer by using a soft moist cloth dampened with potable water or an approved cleaning or disinfectant wipe. Use a gentle wiping motion to remove gel from the lens.
 3. Disconnect the transducer from the console.
 4. Remove any remaining gel from the transducer and lens by using running water (not to exceed 43°C (110°F)) and a soft sponge or gloved hand. If running water is not available, use a pre-moistened soft cloth, such as a flushable cleansing cloth. Use a gentle wiping motion to remove gel from the lens. When cleaning the connector, do not allow any fluid to enter the connector through the electrical contacts, strain reliefs, connector housing, or areas surrounding the locking lever shaft. When wiping or spraying the connector, wipe or spray only the outer surfaces of the connector housing.
 5. To remove any particulate matter or body fluids that remain on the transducer, cable, or connector, use commercially available cleaning wipes or sponges (enzymatic or nonenzymatic),

or a soft cloth lightly dampened in a mild soap. Enzymatic cleaners are generically approved for use.

6. When cleaning the lens, use a gentle wiping motion.
7. To remove remaining particulate and cleaning residue, use cleaning wipes or sponges according to the manufacturers' instructions, or rinse thoroughly with potable water up to the immersion point shown in the figure following this procedure.
NOTE: If you use cleaning wipes or sponges, it may be unnecessary to rinse the transducer with water. Always follow the product label recommendations.
8. Allow the device to air dry or use a soft, dry, lint-free cloth to dry the transducer. To dry the lens, use a blotting motion instead of a wiping motion. Wet surfaces have the potential of diluting the disinfectant.
9. Examine the device and cable for damage such as cracks, splitting, sharp edges, or projections. If damage is evident, discontinue use of the device and contact your View Point Medical representative.

When disinfecting or sterilizing the transducer, follow the label instructions for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. If a pre-mixed solution is used, be sure to observe the solution expiration date.

Low-Level Disinfection

Low-level disinfection of the transducer uses the spray or wipe method, with a low- or intermediate-level disinfectant such as Oxivir, a Hydrogen Peroxide-based wipe. Low-level disinfection protocol should be applied when the transducer comes into contact with intact skin (ex: transcutaneous scanning), or in a non-sterile environment or step of the procedure, or when general cleaning is deemed necessary. Refer to high-level or sterilization disinfection instructions below for instructions when the transducer is used intraoperatively in a sterile procedure. Before performing this procedure, read the warning and cautions and precautions stated above.

1. Follow all general cleaning instructions as described in the above section.

Wipe or spray the transducer, cable, and connector housing with the disinfectant, following disinfectant label instructions for temperature, wipe durations, and duration of disinfectant contact. Ensure that the disinfectant solution does not enter the connector.

- a. When disinfecting the connector housing, wipe or spray only the outer surfaces; do not allow any type of fluid to enter through the strain relief, electrical contacts, or areas surrounding the locking lever shaft.
2. If the disinfectant label instructions require it, rinse with potable water.
3. Allow the device to air dry. You may use a soft, dry, lint-free cloth to dry the transducer. To dry the lens, use a blotting motion instead of a wiping motion.
4. Examine the transducer for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the transducer and contact your View Point Medical representative.

High-Level Disinfection

High level disinfection is recommended when the transducer is used in sterile tissue with a sterile cover (although sterilization may also be performed if deemed necessary). High-level disinfection requires immersion in a high-level disinfectant solution (see example list of compatible, FDA approved solutions in figure B). Before performing this procedure, read the warning and cautions and precautions stated above.

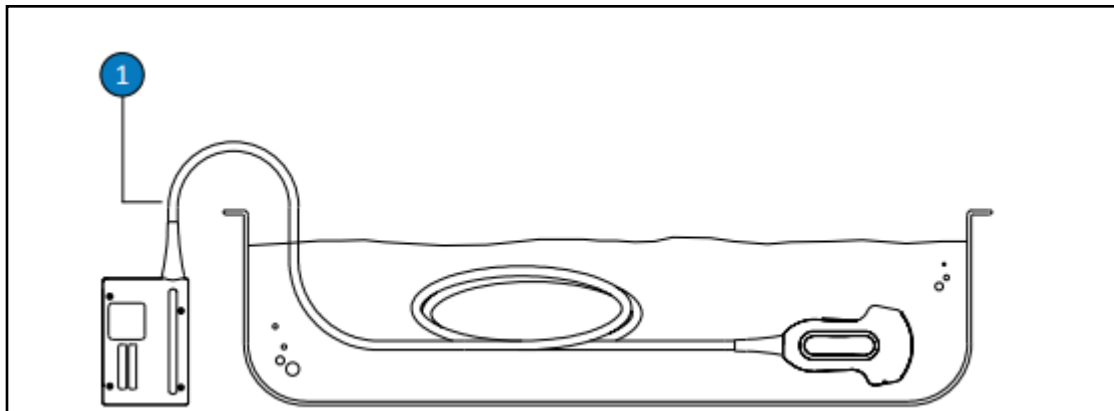


Figure A: Immersion Point for Transducer

1. Do not immerse beyond this point. Do not immerse the connector, connector strain relief, or cable that is within 5 cm (2 in) of the connector strain relief. (Up to 5 cm from the strain relief is the maximum allowable immersion point of the cable—you are not required to immerse to that point if it is unnecessary.)

Sterilization

Sterilization is required if the transducer enters otherwise sterile tissue without a sterile cover. Sterilization requires immersion in a cleaning solution indicated for device sterilization (see example list of compatible, FDA approved solutions in figure B). The main difference between sterilization and high-level disinfection is the length of time that the transducer is immersed and the type of disinfectant or sterilant that is used. Before performing this procedure, read the warning and cautions and precautions stated above.

Caution: Never sterilize the transducer with autoclave, gamma-radiation, gas, steam, or heat sterilization techniques. Severe damage will result. Avoidable transducer damage is not covered by the warranty or service contract.

Recommended supplies:

- Soft moist cloth
- Compatible high-level disinfectants for the transducer and cable
- Soaking container
- Soft, dry, lint-free cloth

1. Follow all general cleaning instructions as described in the above section.

2. Disinfect the connector housing and cable according to the procedures in the 'Low-Level Disinfection' section above.
3. After cleaning, choose a high-level disinfectant or sterilant that is compatible with the transducer (see figure B below). Follow the label instructions for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. If a pre-mixed solution is used, be sure to observe the solution expiration date.
4. Immerse the transducer into the appropriate disinfectant or sterilant for the transducer as shown in *Figure A: Immersion Point for Transducer*. Follow the instructions on the disinfectant or sterilant label for the duration of transducer immersion. Do not immerse transducers longer than the minimum time needed for your level of disinfection. For sterilization, remove the transducer from the sterilization solution after the recommended sterilization time has elapsed.
5. Using the instructions on the disinfectant or sterilant label, rinse the transducer up to the point of immersion (with sterile water if sterilizing).
6. Allow the device to air dry. You may use a soft, dry, lint-free cloth to dry the transducer. To dry the lens, use a blotting motion instead of a wiping motion.
7. Examine the transducer for damage, such as cracks, splitting, fluid leaks, or sharp edges or projections. If damage is evident, discontinue use of the transducer and contact your View Point Medical representative.

Figure B: Example list of compatible, FDA-approved high-level disinfectants (HLD) and sterilants (S).

General information provided in the table below can also be found at (<https://www.fda.gov/medical-devices/reprocessing-reusable-medical-devices-information-manufacturers/fda-cleared-sterilants-and-high-level-disinfectants-general-claims-processing-reusable-medical-and>) . For more detailed instructions, follow the label instructions of the chosen solution for preparation, temperature, solution strength, and duration of contact. Ensure that the solution strength and duration of contact are appropriate for the intended clinical use of the device. If a pre-mixed solution is used, be sure to observe the solution expiration date.

Solution/ System	Manufacturer	Active Ingredient	Sterilant Contact Conditions	High Level Disinfectant Contact Conditions
Cidex Plus	Advanced Sterilization Products	Glutaraldehyde	See Metricide Plus 30 instructions.	Metricide Plus 30 instructions.
MetriCide Plus 30	Metrex Research, Inc.	3.4% Glutaraldehyde	10 hrs at 25°C 28 days Maximum Reuse Contact conditions based on AOAC Sporidical Activity	90 min at 25°C 28 days Maximum Reuse FDA accepted Metricide 28 as identical to Cidex Plus.

			Test only. FDA accepted Metricide 28 as identical to Cidex Plus formula.	
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TROUBLESHOOTING

General Troubleshooting Guidelines

If the Console malfunctions, check for conditions that may have caused the problem:

- Check the Console for visible signs of physical damage.
- Verify that the power cord is connected to the Console and power outlet.
- Verify that the transducer cable is connected and attached properly.
- Use the table below to help identify and correct specific conditions.

Condition	Recommendation
System Error	Power-cycle the console. Contact service if error persists
Transducer Not Recognized	Confirm the OneMark Detection Imaging transducer is properly connected, and press continue. Do not perform a scan with any transducer apart from the OneMark Detection Imaging transducer.
Transducer Check Failed	Reconnect transducer to try again. Contact service if error persists.

CYBERSECURITY

If a user becomes aware of or suspects any cybersecurity events, they should immediately contact support at the contact information provided in the labelling.

The device hardware and software is encrypted to protect the device software from cybersecurity events and has been tested to ensure these protections.

COORDINATED VULNERABILITY DISCLOSURE

- When an vulnerability patch or fix is ready for release, the company discloses it by releasing an advisory to affected stakeholders, specifically to all affected patients.
- The disclosure of the vulnerability and its remediation shall be done at a specific scheduled UTC date and time.
- The disclosure information shall be published on the company website.
- In the event of a critical update, users are directly notified via email or phone.
- Following is the information disclosed:
 - Overview of the identified vulnerability, its nature, potential impact, affected devices and SW versions.

- Actions taken to mitigate the vulnerability, including details on software updates, patches, or other remediation measures.
- Risk assessment of vulnerability, outlining the potential risks to patient safety, data integrity, and overall device functionality if any.

END OF LIFE

At the end of support, the company may no longer be able to reasonably provide security patches or software updates. If the device needs to remain in service following the end of support, the company will communicate through the coordinated vulnerability disclosure the potential cybersecurity risks that can be expected to increase over time.

Software Bill of Materials (SBOM)

The software bill of materials (SBOM) may be available for certain customers dependent on the service agreement. Explicitly providing this information within the User Manual could dramatically increase the cybersecurity risks to the device by openly discussing the potential attack vectors. Please contact support for additional information.

MAINTENANCE AND SERVICE

The Console must be serviced by View Point Medical. To ensure proper performance, the console should be checked for any signs of damage or wear before each use and storage. This includes the housing, integrity of switches, and power cord. Should abnormalities be discovered by the user, the user should contact View Point Medical. Do not use a damaged console.

The console contains no user serviceable parts and should not be opened by the user. Please contact View Point Medical for service.

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TECHNICAL SPECIFICATIONS

All specifications are nominal and subject to change without notice.

General

OneMark Detection Imaging Console	
Dimensions (H x W x D)	24.8 cm x 34.3 cm X 26.26 cm (9.75 in. x 13.5 in. x 10.33 in.)
Console Weight	10 kg (22 lb.)
Power Cord Length	(12 ft) 3.6 m
Power Connector Type	Standard IEC-320 Receptacle
System Power Input	120 V ~± 10%, 60 VA, 60 Hz

Fuses (Qty 2)	5A, 250 V
Accessory Connector Type	Zero Insertion Force (ZIF)-QLC260

OneMark Detection Imaging Transducer	
Cable Length	1.3 m (6 ft)
Transducer Weight	1 kg (2.2 lb.)

Safety Classification

Mode of Operation	Continuous operation
External Electrical Power Source	Class I Equipment
Degree of Protection against Electrical Shock	Type BF Equipment
Medical Electrical Equipment Safety	IEC 60601-1
EMC Emissions/ Immunity – Medical Electrical Equipment	IEC 60601-1-2
Ultrasonic Medical Diagnostic and Monitoring Equipment - Medical Electrical Equipment	IEC 60601-2-37

Electromagnetic Compliance (EMC)

CISPR 11:2015 Industrial, scientific and medical (ISM) radiofrequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement

IEC 61000-3-2:2018 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)

IEC 61000-3-3:2013, Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current ≤ 16 A

IEC 61000-4-2:2008, Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test

IEC 61000-4-3:2020, Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radiofrequency, electromagnetic field immunity test

IEC 61000-4-4:2012, Electromagnetic compatibility (EMC) - Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test

IEC 61000-4-5:2014, Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test

IEC 61000-4-6:2013, Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radiofrequency fields

IEC 61000-4-8:2009, Electromagnetic compatibility (EMC) - Part 4-8: Testing and measurement techniques - Power frequency electromagnetic field immunity test

IEC 61000-4-11:2020, Electromagnetic compatibility (EMC) - Part 4-11: Testing and measuring techniques - Voltage dips, short interruptions, and voltage variations immunity tests.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment 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 in.) to any part of the OneMark Detection Imaging System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

CAUTION: Do not actively scan with the OneMark Detection Imaging System while electrocautery is active.

CAUTION: Electrostatic discharge at or over 16kV may affect the console's touch screen functionality.

Table of Acoustic Output per Track 3, Output Display Standard in IEC 60601-2-37

Acoustic output Parameter	Value
Ispta.3 (mW/cm ²)	244
Isppa.3 (W/cm ²)	314
Pr.3 (MPa)	3.06
PD (uS)	1.42
PRF (Hz)	297
Center Freq (MHZ)	2.79
MI	1.81

Electromagnetic Emissions

Guidance and Manufacturer's Declaration - Emissions

The OneMark Detection Imaging System is intended for use in the electromagnetic environment specified below. The customer or user of the OneMark Detection Imaging System should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The ONEMARK DETECTION IMAGING SYSTEM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The ONEMARK DETECTION IMAGING SYSTEM is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Complies	
Flicker IEC 61000-3-3	Complies	

Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Immunity			
The OneMark Detection Imaging System is intended for use in the electromagnetic environment specified below. The customer or user of the OneMark Detection Imaging System should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete, or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/O's	±2kV Mains N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Conducted, RF, EM Field IEC 61000-4-6	3 V _{rms} 6 V _{rms}	3 V _{rms} 6 V _{rms}	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips IEC 61000-4-11	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the OneMark Detection Imaging System requires continued operation during power mains interruptions, it is recommended that the OneMark Detection Imaging System be powered from an uninterruptible power supply or a battery.

Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage prior to application of the test level.			

Electromagnetic Immunity to RF wireless communications equipment

Guidance and Manufacturer's Declaration - Immunity						
The OneMark Detection Imaging System is intended for use in the electromagnetic environment specified below. The customer or user of the OneMark Detection Imaging System should ensure that it is used in such an environment.						
Test Frequency MHz	Band ¹ MHz	Service ¹	Modulation ²	Maximum Power W	Distance Meters	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation ² 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ³ ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation ² 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ² 18 Hz	2	0.3	28
1720 1845 1970	1700-1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ² 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ² 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11a/n	Pulse modulation ² 217 Hz	0.2	0.3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

¹ For some services, only the uplink frequencies are included.

² The carrier shall be modulated using a 50 % duty cycle square wave signal.

³ As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Accessories

The following accessories are for use with the OneMark Detection Imaging System.

Accessory	Cord Length
09-9004-01	1.8 m (6 ft)
AC Power Cable 120VAC	5 m (16.4 ft)

Symbols

Symbol	Designation
	Catalog number
	Serial number
	Date of manufacture
	Consult instructions for use
	Type BF applied part
	Caution: Consult accompanying documents
	Do not use if package is damaged