



High-Resolution Sprayer



User Guide

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Midmark™ High-Resolution Sprayer User Guide

Preface

The Midmark™ High-Resolution Sprayer User Guide is intended for the certified users of the Midmark High-Resolution Sprayer only. This document contains proprietary and confidential information of Midmark. No part of this document may be duplicated or transmitted in any form without prior written consent of Midmark.

Every effort has been made to verify this guide's completeness and accuracy. Midmark makes no warranty or guarantee as to its accuracy or applicability for use. Information in this guide is subject to change without notice.

Dental/Orthodontic professionals and their assistants or hygienists are the primary users. It is expected that these users will have had training and clinical experience with common dental hand tools, prevention of cross-contamination, and disinfection procedures and will be trained on the care, maintenance and usage of the Midmark High-Resolution Sprayer.

The sales force and trainers are secondary users. It is expected that any secondary users using the product in-vivo will have had appropriate training for such (e.g., they were previously dental assistants/hygienists). They are expected to have training in prevention of cross-contamination and disinfection procedures.

Other user may include individuals in dental training (dental school or dental assistance training) working under the supervision of a dental professional.

NOTICE

To avoid misinterpretation of the user guide instructions: No person is authorized to provide any information that deviates from the information provided in this user guide.

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General Information

Product Description

The Midmark™ High-Resolution Sprayer is a battery operated scanning spray delivery system used to add scanning spray to the oral anatomy. The system consists of four user parts; the sprayer body, removable sprayer tips, replaceable scanning spray bottle, and a commercially-available 9-volt alkaline battery.

Principles of Operation

The operator of the Midmark High-Resolution Sprayer applies a scanning spray to the patient's teeth, preparation area, or oral anatomy by compressing the trigger of the sprayer to release a dusting of True Definition High-Resolution Scanning Spray (powder). Use of the scanning spray better enables the Midmark True Definition Scanner to capture high-resolution images.

Indication(s)

The Midmark High-Resolution Sprayer delivers powder to the oral anatomy to facilitate the capture of high-resolution images from the Midmark True Definition Scanner.

Contraindication(s)

The product is not intended for uses outside its labeled indication(s) for use.

Intended User Profile: Job Type, Training and Experience

Dental/Orthodontic professionals and their assistants or hygienists are the primary users. It is expected that these users will have had training and clinical experience with common dental hand tools, prevention of cross-contamination, and disinfection procedures and will be trained on the care, maintenance and usage of the Midmark High-Resolution Sprayer.

The sales force and trainers are secondary users. It is expected that any secondary users using the product in-vivo will have had appropriate training for such (e.g., they were previously dental assistants/hygienists). They are expected to have training in prevention of cross-contamination and disinfection procedures.

Other users may include individuals in dental training (dental school or dental assistance training) working under the supervision of a dental professional.



United States Federal law restricts this device to sale by or on the order of a licensed dentist or physician; sale by or on the order of any other person is prohibited.

Safety Information

Please read, understand and follow all safety information contained in these instructions prior to and during the use of this Midmark™ High-Resolution Sprayer. Retain these instructions for future reference.

WARNING

Indicates a potentially hazardous situation that if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation that if not avoided, may result in minor or moderate injury.

NOTICE

Indicates a potentially hazardous situation that if not avoided, may result in device damage/property damage.

Warnings, Cautions and Notices

WARNING

To reduce the risks associated with inhalation, ingestion or choking:

- Ensure that the sprayer tip is securely attached to the sprayer body before use.
- When in use, always keep the device upright when applying scanning spray. Excessive scanning spray may be dispersed if the sprayer is inverted.
- Use suction to reduce the amount of possible airborne spray.

To reduce the risks associated with cross contamination:

- Always follow the cleaning and disinfecting procedures for the sprayer tip before each use.
- Always clean and disinfect the sprayer body, including the trigger, after each patient.
- Wear gloves when changing or capping the Midmark™ High-Resolution Scanning Spray.
- Avoid touching the exposed interior of the scanning spray bottle, and bottle cap when not connected to the sprayer.

No modification of this equipment is allowed!

CAUTION

To reduce the risks associated with exacerbating periodontal disease:

- Weigh the risks/benefits of initiating crown and bridge work in patients with poor oral hygiene or periodontal disease.

To reduce the risks associated with cuts or abrasions:

- Do not modify the sprayer tip.
- Inspect the sprayer housing and tips before each use. Replace damaged tips.
- Do not use the sprayer if the housing is cracked.




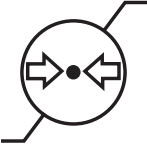



To reduce the risks associated with environmental contamination:

- Follow applicable regulations when disposing of all electronic circuits, batteries and related parts.

NOTICE

To avoid reduced performance and damage to the sprayer:

- After use, do not lay the sprayer on its side with the scanning spray bottle attached as this may allow scanning spray to clog the manifold.
- Other than replacing the sprayer tip and the battery, do not attempt to service this device.
- Do not shake or tap the sprayer while the scanning spray is attached.
- Do not turn the sprayer upside down. To redirect spray, rotate the sprayer tip.
- Use only Midmark High-Resolution Scanning Spray, catalog number 68960.
- Do not submerge the sprayer.
- Do not spray or pour liquids on the sprayer.
- Do not use abrasive detergents, cleaners or cloths on the sprayer body.
- Remove the battery if the sprayer is not likely to be used for some time.

Table 1: Explanation of Safety/Regulatory Related Symbols	
	<p>Refer to Instruction Manual. Follow instructions for use.</p>
	<p>Attention, consult instructions for use.</p>
<p>ETL CLASSIFIED</p> 	<p>Conforms to AAMI Std ES60601-1 Certified to CSA Std C22.2 No. 60601-1</p>
	<p>Indicates the range of atmospheric pressure to which the medical device can be safely exposed.</p>
	<p>Indicates the temperature limits to which the medical device can be safely exposed.</p>
	<p>Type B Applied Part</p>
	<p>Manufacturer</p>

Warranty

Midmark™ warrants this product will be free from defects in material and manufacture. Please refer to your Purchase and Sales agreement for full warranty terms. MIDMARK MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is defective within the warranty period, your exclusive remedy and Midmark's sole obligation shall be repair or replacement of the Midmark product.

Catalog Numbers

Midmark™ High-Resolution Sprayer – 68904

Midmark™ High-Resolution Sprayer Tips – 68912

Midmark™ High-Resolution Scanning Spray – 68960

Midmark High-Resolution Sprayer Components

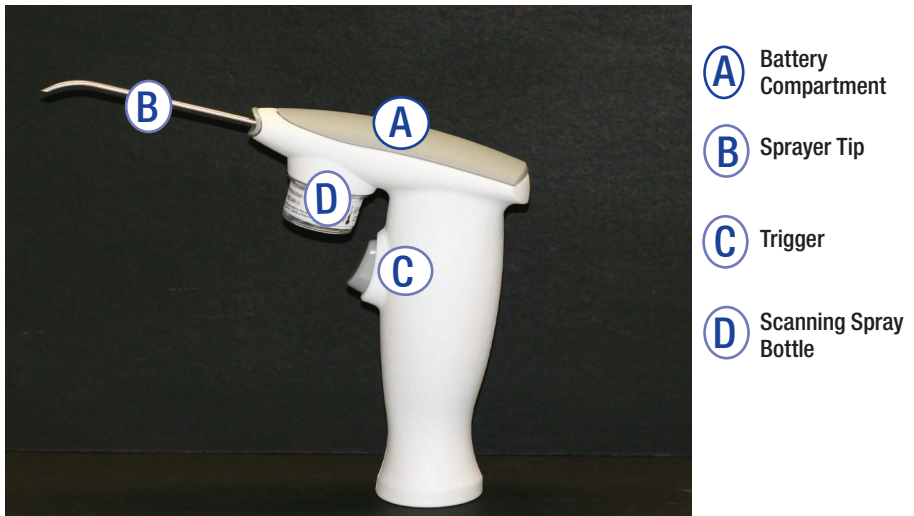


Figure 1: Sprayer components

The Midmark High-Resolution Sprayer is a stand-alone alkaline battery-powered device. You can remove the sprayer tip, replace the battery and the scanning spray bottle, but otherwise the sprayer is NOT a user-serviceable device.

First Use of the Midmark High-Resolution Sprayer

- The sprayer system is made up of four parts: the sprayer body, sprayer tip, scanning spray bottle, and a commercially-available alkaline 9-volt battery.
- Before using the sprayer for the first time, it will need to be assembled.

CAUTION

To reduce the risks associated with cuts or abrasions:

- Do not modify the sprayer tip.
- Inspect the sprayer housing and tips before each use.
- Replace damaged tips.
- Do not use if sprayer housing is cracked.

NOTICE

To avoid reduced performance and damage to the sprayer:

Other than replacing the sprayer tip, battery and scanning spray bottle, do not attempt to service this device.

How to Install or Replace the Battery

Remove the sprayer tip and scanning spray bottle from the sprayer.

1. Place the sprayer on a solid surface, and using a small, flathead screwdriver, loosen the screw from the battery compartment.

The screw is located on the back of the sprayer near the top of the handle, as shown below.

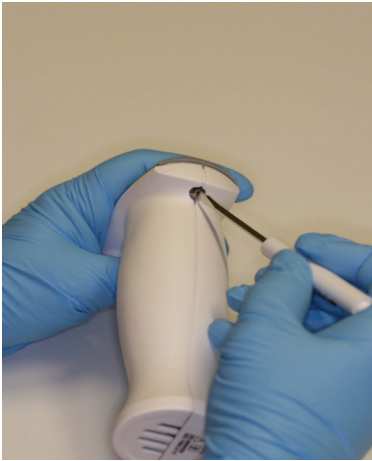


Figure 2: Loosen screw from battery compartment

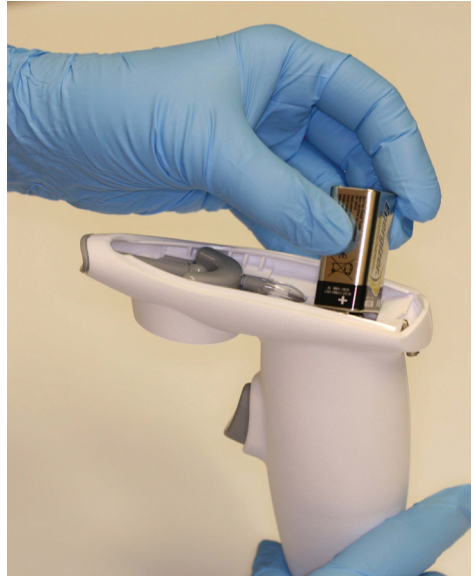


Figure 3: Place 9-volt alkaline battery into compartment

NOTICE

When loosened, the screw does not come all the way out of the sprayer.

2. Remove the battery compartment cover.
3. Remove and properly dispose of the battery.
4. Place a new 9-volt alkaline battery into the battery compartment. Follow the markings for positive and negative orientation.
5. Replace the battery compartment cover. Be sure to hold the sprayer unit upside down and on a solid surface as you tighten the screw. To make screw alignment easier, push down the cover and hold it in place. Install the screw firmly, but do not over-tighten.
6. Carefully re-insert the sprayer tip. **DO NOT** push the tip into the sprayer slot with excessive force. When the sprayer tip is properly in place, it should not be loose, but should be easy to remove by hand.

How to Install or Replace the Scanning Spray Bottle

1. The scanning spray bottle screws into the sprayer body as shown.



Figure 4: Install Scanning Spray Bottle

2. When it is time to replace the scanning spray bottle, remove the bottle by unscrewing it from the body.

⚠ WARNING

To reduce the risks associated with cross contamination:

- Avoid touching the exposed interior of the scanning spray bottle and bottle cap, when not connected to the sprayer.
- Wear gloves when changing or capping the Midmark™ High-Resolution Scanning Spray.

NOTICE

- To maintain the quality of the scanning spray, remove the bottle from the sprayer when the sprayer is not being used and re-attach the bottle's cover.
- Store the Midmark High-Resolution Scanning Spray in a cool, dry place with storage conditions of (10-27 °C/0-80 °F). Do not refrigerate.

NOTICE

To avoid reduced performance and damage to the sprayer:

- Remove the scanning spray and replace the lid after use.
- After use, do not lay the sprayer on its side with the scanning spray bottle attached as this will allow scanning spray to clog the manifold.
- A clogged manifold can result in damage to the sprayer.
- Do not shake or tap the sprayer while the scanning spray is attached.
- Do not turn the sprayer upside down. To redirect spray, rotate the sprayer tip.

How to Unclog the Manifold

1. Remove the sprayer tip and scanning spray container from the sprayer.
2. Use an air syringe placed into the hole that holds the sprayer tip. Blow dry air through the sprayer body to clear any powder clogging the manifold.
3. Use the brushes provided in the Midmark High-Resolution Sprayer kit to clear any scanning spray from the sprayer tip or replace with a new disinfected sprayer tip.

Cleaning and Disinfection

The stainless steel sprayer tip must be cleaned and disinfected before each use. The sprayer tip easily slides into and out of the body of the sprayer.

Cleaning Procedure for the Sprayer Tip

1. Submerge the tip in an enzymatic detergent safe for use with metal devices.
Prepare the detergent according to the manufacturer instructions.
Soak the sprayer tip for five (5) minutes.
2. Scrub the tip with a soft bristle brush.
Agitate the sprayer tip while scrubbing.
Use a small brush to scrub the lumen for one (1) minute.
3. Rinse in warm (38 to 49 °C / 100 to 120 °F) tap water for at least thirty (30) seconds.
4. Place the sprayer tip into a bath containing warm (38 to 49 °C / 100 to 120 °F) water and agitate by hand for one (1) minute. Repeat this process two (2) additional times.
5. Ultrasonically clean the sprayer tip for ten (10) minutes in a neutral pH detergent.
Prepare the detergent according to the manufacturer's recommendations.
6. Rinse the sprayer tip with clean tap water for at least one (1) minute.
7. Dry the exterior with a clean, lint free cloth.
8. Repeat this cleaning procedure if the sprayer tip appears to be soiled after the initial cleaning.

Disinfection Procedures for the Sprayer Tip

1. Clean the tip as described above.
2. Pre-vacuum autoclave with minimum cycle parameters of three (3) minute exposure time at (132 °C + 3 °C / 270 °F + 37 °F) followed by a two (2) minute dry time is required. Please note that individual autoclaves and loading conditions vary and it is the responsibility of the user to ensure proper processing through the use of appropriate biological indicators.
3. If the interior of the sprayer tip is wet, the sprayer could clog.
Dry the lumen of the sprayer tip with compressed air before use (38 to 49 °C / 100 to 120 °F).

WARNING

To reduce the risks associated with cross contamination:

Always follow the cleaning and disinfecting procedures for the sprayer tip before each use.

Cleaning the Sprayer Body and Trigger

1. Apply the cleaning agent to a soft, non-abrasive cloth.
2. Wring out the cloth until damp.
3. Wipe down the sprayer with the damp cloth.
4. Rinse the cloth in clean water.
5. Wipe down the sprayer a second time.
6. Dry with a clean, non-abrasive cloth.

Approved Cleaning Agents

The following agents are approved for this purpose:

- BIREXse* (by Biotrol) or equivalent
- CaviCide AF** (by TotalCare Kerr/Metrex) or equivalent
- Warm water and mild, non-abrasive detergent

* Birex is a registered trademark of Biotrol.

** CaviCide AF is a registered trademark of Kerr/Metrex Corporation.

 **WARNING**

To reduce the risks associated with cross contamination:

Always clean and disinfect the sprayer body, including the trigger, after each patient.

NOTICE

To avoid reduced performance and damage to the sprayer:

- Never submerge the sprayer.
- Do not spray or pour liquids on the sprayer.
- Do not use abrasive detergents or cleaners or cloths on the sprayer body.

 **WARNING**

To reduce the risks associated with cross contamination:

- Avoid touching the exposed interior of the scanning spray bottle and bottle cap when not connected to the sprayer.
- Wear gloves when changing or capping the Midmark™ High-Resolution Scanning Spray.

How to Use the Sprayer

For optimal scanner performance, apply a light, consistent dusting of scanning spray to the area to be scanned. These are the recommended steps:

1. The patient may be seated upright or supine to apply the contrast scanning spray.
2. Air dry the field.
3. Position the sprayer tip approximately 2.5 cm (1 in.) above the surface of the tooth.
4. Depress the trigger on the sprayer and move in a continuous, smooth motion across the area. The trigger controls the flow rate so the further you squeeze the trigger, the greater the flow of scanning spray. It is recommended you start with a light squeeze on the trigger.
5. If you need to change the direction of the spray, for example to apply spray to a patient's upper arch, rotate the sprayer tip, not the device itself.
6. Repeat as necessary to deposit a very thin, consistent layer of scanning spray on all sides and surfaces.
7. If necessary, apply air to evenly distribute the scanning spray.
8. When the trigger is not depressed the scanning spray will not flow from the sprayer tip. To stop the flow of scanning spray, release the trigger.

Between scans, make sure you maintain the proper coating of scanning spray. Check for the following:

- Gaps in the scanning spray caused by the tongue, lips or cheek wiping it away.
- Any obstructions of the scanning field caused by scanning spray clumps, or the accumulation of fluids.
- Spots where the scanning spray pattern has worn off. This usually happens on cusps and occlusal surfaces.

If any of the above occurs, reapply the scanning spray.

NOTICE

To avoid reduced performance and damage to the sprayer:

Use only Midmark™ High-Resolution Scanning Spray, catalog number 68960.

A clogged manifold can result in damage to the sprayer:

- Do not shake or tap the sprayer while the scanning spray is attached.
- Do not lay the sprayer on its side while the scanning spray is attached.
- Do not turn the sprayer upside down while the scanning spray is attached. To redirect the spray, rotate the sprayer tip.

WARNING

To reduce the risks associated with inhalation, ingestion or choking:

- Ensure the sprayer tip is securely attached to the sprayer body before use.
- Always keep the device upright when applying scanning spray. Excessive scanning spray may be dispersed if the sprayer is inverted.
- Use suction to reduce the amount of possible airborne scanning spray.

Standards Compliance Tables

The Midmark™ High-Resolution Sprayer has been evaluated using the processes described in these standards and found to be in compliance with relevant requirements.

Table 2: Standards

Standard	Title	Type of Standard
ANSI/AAMI ES60601-1: 2005 CAN/CSA C22.2 No. 60601-1: 08 IEC 60601-1: 2005+ CORR. 1 (2006) + CORR. 2 (2007)	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	Product Safety
IEC 60601-1-2:2007	Medical Electrical Equipment - Part 1: General Requirements for Safety: Collateral Standard: Electromagnetic Compatibility Requirements and Tests	Electromagnetic Compatibility (EMC)

U.S. Federal Communications Commission (FCC) Requirements

The Midmark™ High-Resolution Sprayer has been tested and found to comply with the limits of electromagnetic compatibility standards for medical devices (IEC 60601-1-2), that provide reasonable protection against harmful interference in a typical medical/dental setting. The Midmark High-Resolution Sprayer may generate and radiate radio frequency energy that causes interference to other devices in the vicinity, if not used in accordance with the instructions (though there is no guarantee that interference will not occur in a particular circumstance). If interference occurs, the user is encouraged to try the following corrective measures:

- reorient or relocate the receiving device
- increase the separation between the equipment
- consult the device manufacturer or field service technician for help

Table 3: Guidance and Manufacturer's Declaration - Electromagnetic Emission

The Midmark High-Resolution Sprayer is intended for use in the electromagnetic environment specified below. The customer or the user of the Midmark High-Resolution Sprayer should ensure that they are used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The Midmark High-Resolution Sprayer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Midmark High-Resolution Sprayer is suitable for use in all establishments including domestic and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the Midmark High-Resolution Sprayer or shielding the system.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not Applicable	

Table 4: Guidance and Manufacturer's Declaration - Electromagnetic Immunity (1)


The Midmark High-Resolution Sprayer is intended for use in the electromagnetic environment specified below. The customer or the user of the Midmark High-Resolution Sprayer should ensure that they are used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 2, 4, 6 kV contact ± 2,4, 8 kV air	± 2, 4, 6 kV contact ± 2,4, 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	Not Applicable		
Surge IEC 61000-4-5	Not Applicable		
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable		
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	Not Applicable		

NOTE: U_T is the AC main voltage prior to application of the test level.

Table 5: Guidance and Manufacturer's Declaration - Electromagnetic Immunity (2)

The Midmark High-Resolution Sprayer system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that they are used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment — Guidance
Conducted RF IEC 61000-4-6	Not Applicable		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and D is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with this symbol: 
OK			

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

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, 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 Midmark High-Resolution Sprayer system is used exceeds the applicable RF compliance level above, the Midmark High-Resolution Sprayer system should be observed to verify normal operation. If abnormal performance is observed, mitigation measures - for example, reorienting or relocating the Midmark High-Resolution Sprayer system - may be necessary.

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

Table 6: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Midmark High-Resolution Sprayer

The Midmark High-Resolution Sprayer is intended for use in the electromagnetic environment specified below.

The customer or the user of the Midmark High-Resolution Sprayer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Midmark High-Resolution Sprayer 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 $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

Equipment Specifications and Classifications

Table 7: Temperatures

Operating	+10 °C to +32 °C (+50 °F to +89.6 °F)
Storage/Transport	-40 °C to +70 °C (-40 °F to +158 °F)

Table 8: Humidity

Operating	30% to 85% RH, non-condensing
Storage/Transport	10% to 100% RH

Table 9: Altitude

Operating	< 3000 m (10,000 ft)
Storage /Transport	< 12.19 km (40,000 ft)

Table 10: Atmospheric Pressure

Operating	700 - 1060 hPa
Storage/Transport	500 - 1060 hPa

Table 11: Storage for the Midmark High-Resolution Scanning Spray

Storage conditions	10 °C to 27 °C (50 °F to 80 °F)
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Table 12: Classifications

Protection against electric shock	Internally powered
Protection against harmful ingress of water or particulate matter	IPXO Ordinary protection
Mode of operation	Continuous

Troubleshooting

Possible Malfunction	Possible Solution
Sprayer not working; pump not running.	Check the battery and replace if necessary.
Scanning spray flow is low or has stopped.	Check the level of scanning spray in the scanning spray bottle. If it is low, replace with a new bottle.
Scanning spray not coming out.	<p>Check to see if the sprayer tip is clogged. If it is, clean the tip with a wire brush.</p> <p>See last item of table - "Manifold is clogged" and follow steps 1-3.</p>
Scanning spray is clumping.	Change to a new bottle of fresh scanning spray.
Manifold is clogged.	<ol style="list-style-type: none"> 1. Remove the sprayer tip and scanning spray container from the sprayer. 2. Use an air syringe placed into the hole that holds the sprayer tip. Blow dry air through the sprayer body to clear any powder clogging the manifold. 3. Use the brushes provided in the Midmark™ High-Resolution Sprayer kit to clear any scanning spray from the sprayer tip or replace with a new disinfected sprayer tip.

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Service and Support United States and Canada: (1-800-643-6275)

Service and Support Outside of the United States and Canada: Contact your local service provider



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CaviCide AF is a registered trademark of Kerr/Metrex Corporation.