

INSTRUCTIONS FOR USE

For use by qualified professionals only

Endocator®

Protected by US Patent 10,959,620.
Multiple worldwide patents pending.



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Rx ONLY

407736-I-V-ENG (1)



IMPORTANT!

Please read entire manual before using this product for the first time.

TABLE OF CONTENTS

INTRODUCTION	3
Welcome to Endocator	3
Contents of Endocator Box	4
Indications for Use	4
Intended Users and Target Patient Groups	4
Contraindications	4
Adverse Reactions	4
REGISTER YOUR ENDOCATOR	4
WARNINGS & PRECAUTIONS	5-6
SYMBOL IDENTIFICATION	7
SETTING UP ENDOCATOR	8
ENDOCATOR OPERATION	9
Charging the Device	9
Endocator Test Swaps	10
Testing with Endocator	10-12
Other Endocator Operations	13
Maintenance	14
Care of the Device	14
Cleaning Endocator	14
ACCESSORIES	15
DISPOSAL	15
TECHNICAL DATA	16
TROUBLESHOOTING GUIDE	17-18
VISTAAPLEX TERMS & CONDITIONS OF WARRANTY	19
RETURN POLICY	20
ADDITIONAL INFORMATION	21-25
NOTES	26-27

INTRODUCTION

Welcome to Endocator

Congratulations on your decision to incorporate Endocator into your practice. It is the first and only chairside device that enhances root canal treatment by delivering an adjunctive canal cleanliness score in 10 seconds.

Endocator works by detecting trace amounts of adenosine triphosphate (ATP) and other biomarkers inside of a root canal. Low levels of ATP correlate to low levels of cellular debris within the root canal.

Contents of Endocator Box

Endocator is composed of the following:

- (1) Endocator Device
- (1) USB Wall Charger
- (1) USB Cable
- (1) IFU
- (1) Quick Start Guide

** Test swabs sold separately.*

NOTE: All components are non-sterile.



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Indications for Use

Endocator is an adjunctive device that helps detect residual organic debris, including bacteria, within the root canal during endodontic treatment prior to obturation.

Intended Users and Target Patient Groups

Endocator is intended for use by qualified dental professionals only to be used during endodontic procedures.

Contraindications

Endocator should not be used for any application outside its indications for use.



Warnings

This system has been designed and manufactured to assure personal safety. Please read all safety and operating instructions carefully before use. Handle system with care at all times.



Precautions

Endocator swabs are single use only.

Adverse Reactions

There are no known adverse reactions.

REGISTER YOUR ENDOCATOR

Thank you for investing in precision endodontic care with Endocator. Registering your product takes just a moment—simply scan the QR code. When you register, you'll gain access to:

- Exclusive Updates – Stay informed about the latest product advancements and accessories.
- Educational Resources – Receive training tips, clinical insights, and step-by-step guides to maximize your results.
- Streamlined Support – Enjoy faster service and personalized assistance whenever you need it.

**Please scan the
QR code below
to register your
Endocator**



WARNINGS & PRECAUTIONS

















PLEASE NOTE: Prior to start-up of the device, please read these instructions carefully. As with all technical devices, the proper function and safe operation of this device depends on the user's compliance with the standard safety procedures as well as the specific safety recommendations presented in these Operating Instructions.

1. **CAUTION:** Federal law restricts this device to sale by or on the order of a dental professional, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device. The manufacturer assumes no liability for any damage arising from any other or improper use of this device.
2. Endocator is an adjunctive device. Endocator is not a diagnostic device. Regardless of Endocator results, use your clinical judgment to determine the best course of action for treatment.
3. Endocator test swabs (packaged and sold separately) are single use and must be tested within 3 minutes of activation before the reaction degrades, which will result in artificially low scores.
4. Do not use products that are past the expiry date. Expired products may not yield accurate results (the expiry date is printed on the bottom of the aluminum bag holding the swab devices).
5. Wherever possible, use up all swabs from a single bag that has been opened before opening a second bag. For long term storage, close the aluminum bag and store it in a refrigerated environment (2°C to 8°C (35.6°F to 46.4°F)) for up to 30 days. For short term storage, closed bags can be left out at room temperature for up to 14 days. High temperatures may cause performance to degrade.
6. Do not subject the test swabs to direct sunlight for long periods of time. Strong light may cause product performance to decrease.
7. Do not drop the tests swabs as damage to the inner seals may occur, causing leaking or decreased performance.
8. Do not use test swabs that are visibly damaged, including leaking.
9. Do not consume and void contact with fluid in case of leaking test swabs.

10. Do not touch any of the parts inside the test swabs, particularly the absorbent fiber, with a finger or other object before use. Touching these parts may contaminate the sample causing inaccurate readings.
11. Keep Endocator in upright position when performing a test, and do not move the device until the test completes.
12. Remove the test swab after completion of test. Keeping swab in the Endocator during storage may lead to leaking and damage.
13. Condensation resulting from the Endocator device being transferred from a cold to a warm environment may be a potential risk. Never begin operating the device until it has reached the ambient temperature.
14. Do not push or rub the display panel with hard or sharp objects. Injury or failure may occur.
15. The charger must be accessible at all times. Do not use the charger for any use other than charging of the Endocator handpiece. Disconnect the handpiece from the mains by unplugging the charger from the electrical outlet.
16. Use only the charger (AC adapter plug) which is provided with the device. The use of any other charger can result in damage to the battery.
17. The batteries are not user replaceable. When needed, the device should be returned to VistaApex for replacement. Replacement of lithium batteries by inadequately trained personnel could result in a hazard.
18. There are no user-serviceable items in the handpiece or charger. Do NOT attempt to service the battery - the battery is NOT replaceable by the user. No modification of this equipment is allowed.
19. Use only components and accessories listed in the Operating Instructions associated with the device. Failure to do so will void the warranty, may decrease the system performance, and may lead to unsafe operation.
20. Connect this equipment only to a properly grounded or earthed power supply.
21. In order to avoid electric shock, do not introduce any objects into the device or remove the device enclosure.
22. Should you have any reason to suspect the safety of the device to be compromised, the device must be taken out of operation and labeled accordingly to prevent third parties from inadvertently using a possibly defective device.
23. Do not autoclave Endocator device or Test Swabs.

SYMBOL IDENTIFICATION

Description for additional symbols.

	Serial Number		Consult instructions for use
	Manufacturer		Temperature Limitation
	Manufacturing Date		Humidity Limitation
	Keep Dry		Pressure Limitation
	Part Number		Batch Code / Lot Number
	Warning / Caution		Do not use if seal or packaging is compromised
RxOnly	CAUTION: U.S. federal law restricts this device to sale by or on the order of a dental professional.		Fragile, handle with care
	Do not reuse		Keep away from sunlight
	This symbol refers to the special disposal of electrical and electronic devices in EU countries. Please do not discard this device in household garbage. Check the proper means of disposal in your country at your community recycling, waste center or at your dealer. Take care to dispose of properly.		

SETTING UP ENDOCATOR

Components

- 1 Endocator Device (1)
- 2 Endocator Test Swabs (20 pack; packaged and sold separately)
- 3 Wall Charger (1)
- 4 USB Cable (1)



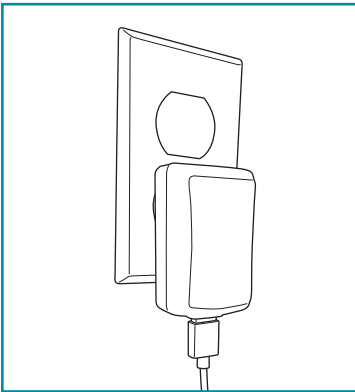
ENDOCATOR OPERATION

Charging the Device

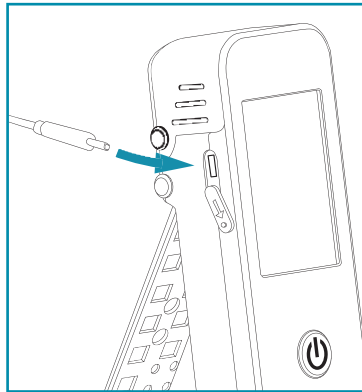
Endocator runs on an internal lithium-ion battery (note – the battery is NOT replaceable by the user). Charge the device completely prior to first use.

USB port is for charging only, do not connect it to any other equipment.

- 1.** Connect USB cable to power adapter.
Plug the power adapter into the wall outlet.



- 2.** Connect the USB cable to the Endocator charging port.
Charge the device as needed when low battery is indicated.



Monitor your battery charge level:



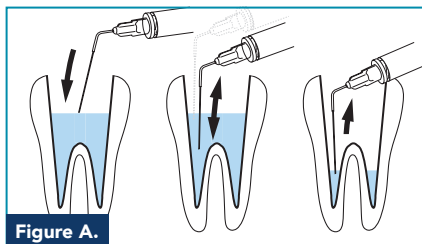
NOTE: Endocator will automatically turn off after extended period.
Turn off Endocator when not in use.

Endocator Test Swabs

When opening a new bag of swabs, record the date where indicated on the label. Remove an Endocator Test Swab from the refrigerator and allow it to warm up to room temperature. Always reclose bags after removing a swab. Wherever possible, use up all swabs from a single bag that has been opened before opening a second bag. For long term storage, close the aluminum bag and store it in a refrigerated environment (2°C to 8°C (35.6°F to 46.4°F)) for up to 30 days. For short term storage, closed bags can be left out at room temperature for up to 14 days. High temperatures may cause performance to degrade. Do not subject the test swabs to direct sunlight for long periods of time. Strong light may cause product performance to decrease.

Testing with Endocator

1. Turn on the Endocator by holding down the button located on the bottom center of the unit. Remove any used test swabs from Endocator for startup initialization.
2. Aspirate the canals to remove irrigants.
3. Fill a new 1.2-3mL syringe with approximately 1mL of sterile water. Use a new 27-30ga tip. Bend the tip as needed with the inner cap of the syringe and take care not to let the new tip contact any surfaces that may be contaminated (i.e. gloves).
4. Rinse the root canal to near working length with the ~1mL of water to further remove any trace irrigants. After rinsing, leave the canals and approximately half of the tooth chamber filled with water (approximately 50 uL). For anterior teeth and broken-down teeth it may be helpful to leave a small amount of fluid in the syringe (approximately 50uL) to help eject the sample into the Endotester.
5. Using the now-empty syringe, insert the tip into the apical third of the canal [See Figure A]. Gently pump the tip up and down inside each canal 2-3 times to agitate the water and facilitate the removal of debris from the canal walls. Aspirate the sample:
 - Aspirate the sample by pulling all fluid from the chamber and approximately half of each canal.



- If bleeding is present in a canal, skip testing that canal or wait until bleeding is controlled and rinse with NaOCl and water before performing testing with Endocator.

6. Remove the swab from the tube by the orange handle. Take care not to let the swab touch any surfaces that may be contaminated.

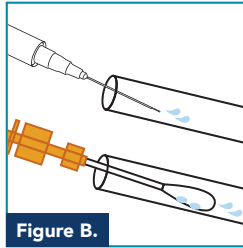


Figure B.
Use absorbant tip of the test swab to soak up the sample.

Inject the solution onto the plastic test tube wall near the top. Use the

absorbent tip to soak up the sample from the tube wall [See Figure B]. Press down firmly on the top of the tester to collapse the colored top into the test tube, ensuring that the orange swab handle is flush with the plastic tube [See Figure C].

7. Flick, shake, or tap the tester tube against the table to ensure that the solution settles at the bottom of the test tube and the powder is completely dissolved into the solution [See Figure D]. This may take 10 seconds of agitation, avoid shaking up and down as the sample may eject from the reaction chamber.

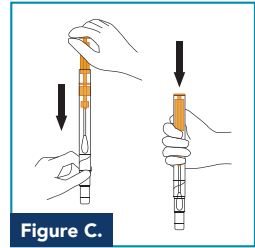


Figure C.
Insert swab into tester.

8. Open the Endocator lid and insert the test swab, ensuring that it is fully seated [See Figure E].

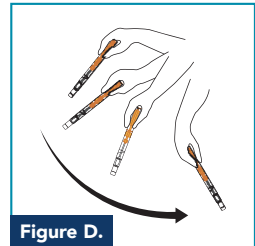


Figure D.
Flick, shake, or tap the tester tube against the table.

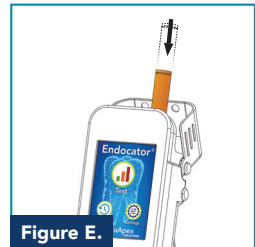


Figure E.
Insert the test swab into the device.

9. Press the "Test" button and an estimated Endoscore will appear after 5 seconds and final results will display after 10 seconds [See Figure D]. While waiting, dry the canals with paper points to confirm that there is no bleeding from the canals as blood will result in a higher Endoscore.
10. The results will be displayed as an Endoscore ranging from 1-100. Lower scores indicate lower levels of bioburden inside the root canal. Higher scores suggest the presence of higher levels of cellular debris, indicating the need for further cleaning before completing the case. Endocator is adjunctive, providing data to combine with your clinical experience to make the best judgement of canal cleanliness prior to obturation. VistaApex recommends the following guidelines based on the Endoscore:
 - a. **1-25 Low Bioburden**
 - b. **26-50 Medium Bioburden**
 - c. **51-100 High Bioburden**
11. If further irrigation is performed and re-testing is desired, repeat steps 3-9 and press "Test Now" on the Results screen to test the new sample. The previous test results will be shown at the top stating "Previous Endoscore:".
12. When first learning to use Endocator, it may be beneficial to take a test after instrumentation prior to irrigation, followed by the post-irrigation test to observe the change.
13. After testing is completed, return to the Home Screen by pressing "Back", or power off the Endocator by pressing and holding the Power Button until the unit beeps and turns off.

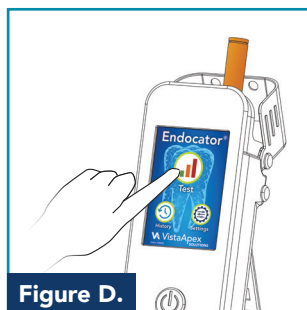


Figure D.

Press the Test button to obtain your Endoscore.

Other Endocator Operations

1. History

- To view history of all tests, press the "History" button on the home screen.
- Historical test data is shown correlated to date and time. Individual tests can be deleted by selecting one or more test results and pressing "Delete".
- Note:** Ensure the correct date and time is set on the device prior to first use.
- Press "Back" to exit the History screen.

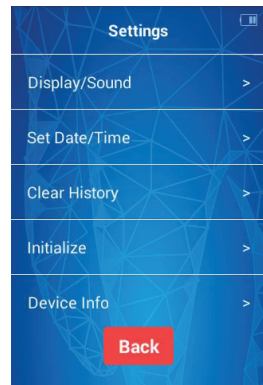


History	
2025-07-19 09:15:05	18
2025-07-19 09:14:33	15
2025-07-19 09:14:14	93
2025-07-19 09:13:55	60
2025-07-19 09:13:22	93
2025-07-16 04:06:15	12
2025-07-16 04:05:24	65
2025-07-16 04:05:05	94

Navigation buttons: < Delete Back >

2. Settings

- Display/Sound - Device timeout for auto shut-off can be adjusted by entering the time in minutes. Enter the desired timeout, then press the "Back" button. Likewise, choose whether to toggle sound on or off.
- Set Date/Time - Set the device date and time. For each field, enter the desired information. When complete, press the "Back" button.
- Clear History - All historical test data can be cleared at once by pressing "Clear History", or exit by pressing the "Back" button.
- Initialize - The device can be reinitialized to zero-out the measurement with no swab inserted. Initialization is also performed each time the device is powered on.
- Device Info - This screen shows model, serial number, and firmware revision information that may be useful for customer service. To exit, press the "Back" button.
- Developer Options - This settings menu is locked from access, it is used by the manufacturer for production and service work.



Settings	
Display/Sound	>
Set Date/Time	>
Clear History	>
Initialize	>
Device Info	>

Back button

Maintenance

Endocator is maintenance-free. No periodic maintenance is required.

Care of the Device

Use only the charger included with the product. The use of other chargers may damage the battery cells or result in inadequate charge. Do not immerse the device in water or incinerate. Follow all precautions and warnings from this instructions for use.

Cleaning Endocator

The device may be wiped down with a standard disinfectant wipe. Quaternary ammonium compound products are recommended (containing 20% alcohol or less). Wipe, do not spray, solution onto the unit. Prevent liquids from entering openings on the device. Never spray disinfectant directly onto the device. Do not autoclave.



CAUTION

DO NOT spray devices with any liquids as it may damage the circuitry and outer housing. DO NOT allow liquid to collect in the USB charger or USB receptacle on the rear of the handpiece or come in contact with the connectors as it may damage the circuitry and functionality.

ACCESSORIES

Accessory	Mfg SKU
Endocator® Test Swabs 20pk	407731
1.2cc Luer-Lock Syringes 100pk	316002
30ga Vista-Probe™ 1" Bendable Irrigating Tips 100pk	315630
27ga Appli-Vac™ 1" Irrigating Tips 100pk	315527
Clear Pre-Bent Elasti-Vac™ Evacuation Tips 50pk	406151

DISPOSAL



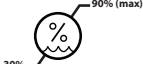




Disposal of Unit

U.S. - Dispose of the system components in accordance with state and local laws.

Disposal of Accessories

Do not dispose Endocator accessories with household waste. Follow your office protocol for disposal of regulated waste.

TECHNICAL DATA

TECHNICAL INFORMATION	ENDOCATOR		
Charger	Input: 90-264 V, 50-60 Hz		
	Nominal Consumption: 0.5 A max		
	Output: 5.0 V, 2.0 A max		
	Manufacturer: GlobTek INC.		
	Model: GTM46101-1005-USB		
	Dimensions without blade or cable (LxWxH): 41mm x 71mm x 31.5mm		
	Weight: 50g		
Device	Classification: Protection class II, 		
	Input: 5.0 V, 2.0 A max		
	Battery: 3.65V nominal, 5000 mAh Li-Ion 18.25 Wh		
	Battery Pack Manufacturer: EVE Energy Co., Ltd.		
	Battery Pack Model: INR21700/50E		
	Dimensions (LxWxH): 180mm x 26mm x 28mm		
	Intermittent Operation: The device has been designed solely for short-term operation. Typical operating time at room temperature (23°C): 10 min.		
Operating Conditions	Run Time: 10 hrs. fully charged		
	Time to Charge Depleted Battery: Approx. 7 hrs.		
Transport and Storage Conditions	Temperature: 10°C - 40°C (59°F - 104°F) 	Relative Humidity: 30% - 90% (non condensing) 	Atmospheric Pressure: 697hPa - 1013hPa 
	Temperature: -20°C - 40°C (-4°F - 104°F) 	Relative Humidity: 30% - 90% (non condensing) 	Atmospheric Pressure: 500hPa - 1400hPa 

TROUBLESHOOTING GUIDE

If the suggested solutions do not rectify the problem, please call VistaApex +1-877-418-4782 (Toll Free).

PROBLEM	POSSIBLE CAUSES	ACTION
The powder won't dissolve when mixing the Endocator swab	<i>Test swab is not warmed up</i>	Dissolution of the powder may take a little bit longer so continue monitoring the powder. Ensure the swab is at room temperature before use.
	<i>Test swab is not agitated enough</i>	Tap test swab 3-4 times to ensure the enzyme is completely dissolved
Not enough sample to test	<i>Narrow single rooted canal or broken-down tooth</i>	When sampling, leave additional ~50 ul of water in the syringe to ensure sample is expressed into the test tube
High Endoscores from apical fluid	<i>Blood, purulent exudate, apical fluid are in the sample. Note you can use a paper point to confirm apical contamination after testing.</i>	Control apical discharge, reclean, and retest. Also you can skip the weeping canal during testing.
Blood in the chamber	<i>Perforation, strip perf, etc.</i>	Samples with blood will have high Endoscores and will need to be sealed before testing
Saliva in the sample	<i>Broken teeth, missing walls, etc.</i>	Make sure to rebuild any walls and have good isolation prior to testing
Can I test just one canal?	<i>Selective retreat, etc.</i>	While most users prefer to test all canals at once it is possible to test individual canals

Consistently high Endoscores	<i>Sampling too close to the apex and aspirating apical fluid</i>	Sample no more than halfway down the canal
	<i>Not enough activation or NaOCl</i>	More irrigation time, activation, higher concentration of NaOCl, and Ca(OH) ₂ have been shown to reduce Endoscores
Consistently low Endoscores	<i>NaOCl contamination</i>	Aspirate NaOCl and rinse canal with 1ml of sterile water before testing with Endocator
	<i>Lack of agitation of canal walls</i>	Pump the 30-gauge syringe up and down to agitate the canal walls
Difficulty getting the sample onto the swab	<i>Expressing sample onto the absorbent swab instead of inside of the test tube</i>	Express the sample onto the inner plastic of the sample tube, and then use the absorbent swab to soak up the sample
Endocator won't turn on	<i>An old swab in the Endocator or batteries not charged</i>	Make sure the unit is charged, and any old swabs are removed from Endocator during calibration
Test won't start	<i>Lid is open or incorrect swab is inserted.</i>	Check for error message on screen. The test will not proceed if the lid is open or a swab from another manufacturer is used
Endocator is not responding, or screen is blank	<i>Software malfunction</i>	Use the power button to turn off and turn back on the device to reboot it
Any other Endocator device related issues	<i>Malfunction or damage</i>	Contact VistaApex for further troubleshooting or to start an RMA for repair

VISTAAPEX TERMS & CONDITIONS OF WARRANTY

The operator assumes all risk and liability for damages arising out of the improper use of VistaApex's product. In the event of a defect in material or workmanship, VistaApex's liability is limited, at VistaApex's option, to replacement of the defective product, or part thereof, or reimbursement of the actual cost of the defective product. In order to take advantage of this limited warranty, the defective product must be returned to VistaApex.

Endocator is warranted to be free from defects under normal usage conditions for 3 years from its date of delivery. There is no warranty, expressed or implied, on the Endocator Test Swabs. There is no warranty, expressed or implied, of merchantability or fitness. The manufacturer's sole obligation under this warranty is to opt to either repair or replace the defective part of the product. If service must be performed to correct a defect, then the manufacturer will provide the service at its factory according to the mutual agreement made in advance. The manufacturer and its distributors will not accept the return of product unless the return is authorized and shipped in accordance with the distributor's instructions. Contact the local representative of the distributor from which the product was purchased for shipping instructions, a return authorization number, and an ARS shipping label.

There is no warranty, remedy or condition, expressed or implied, except as provided herein. The warranty and remedies contained herein are made by the manufacturer to the first buyer for dental use and are in lieu of all other agreements (expressed or implied), liabilities or remedies for breach of warranty. VistaApex shall not be liable for consequential or incidental damages. No person or distributor is authorized to modify the terms of this warranty.

This warranty is void if any defect is caused by conditions beyond the manufacturer's control, including acts of God, damage resulting from mishandling, neglect, misuse, improper maintenance, accident or alteration/repair by anyone other than the manufacturer. The buyer assumes all liability for any damage caused by improper use of the product. The manufacturer assumes no liability for the user's failure to follow the instructions contained in this manual.

RETURN POLICY

VistaApex will accept for return previously purchased merchandise which is suitable for resale or that which was shipped in error by VistaApex. Merchandise suitable for resale requires current labeling and unopened non-soiled packaging.

All returns must have prior approval and must be shipped "prepaid" along with a return authorization form and a copy of the original invoice. Any products returned that are discontinued, dated, damaged, or opened could be denied credit or assessed a higher return fee.

Merchandise returned for credit must be received by VistaApex within 60 days of the original invoice date. Returns made within 30 days will be subject to a 10% restocking fee. Any returns made 31-60 days after the original invoice date will be subject to a 20% restocking fee.

RESTOCKING POLICY

30 days	10%
31-60 days	20%
60+ days	Not Returnable

Equipment cannot be returned without written authorization from VistaApex. Any equipment returned within 30 days from the date of the original shipment from VistaApex may not be assessed a restocking fee as long as the merchandise has current labeling and unopened non-soiled packaging. Unopened equipment returned within 31 to 60 days from the date of the original shipment from VistaApex requires a restocking fee of 25% of the purchase price, including shipping and handling charges. Any equipment returned 60 days after the date of original shipment from VistaApex will not be restockable for credit. Installation, if required, must be initiated with an outside party, and is the sole responsibility of the customer.

- Special orders are not suitable for resale and therefore not returnable for credit.
- Claims for lost or damaged shipments should be filed immediately with the carrier.
- Claims for overage, shortage, and/or internal damage must be made to VistaApex within 10 days of receipt of goods.

ADDITIONAL INFORMATION



EMC COMPATIBILITY:

- EMC requirements have to be considered, and Endocator must be installed and used accordingly with the specific EMC information provided in the accompany documents.
- The device complies with the EMC (Electromagnetic Compatibility) according to IEC 60601-1-2. Radio transmitting equipment, cellular phones etc. shall not be used in close proximity of the unit as they could influence the performance of the system.
- Read carefully the indications relevant to the EMC in the dedicated appendix EMC COMPATIBILITY of this manual.



PROTECTION AGAINST EXPLOSIONS:

The device **MUST NOT** be used in the presence of flammable or potentially explosive gases or vapors that might catch fire and cause damage. In case these materials have to be used let the vapors completely disperse before turning on the device.



SYSTEM MODIFICATIONS OR UPGRADES:

- Modifications or upgrades of the system can be carried out only by Inter-Med, Inc. and performed by authorized and qualified personnel, using **ONLY** genuine original spare parts of Inter-Med, Inc. Device is **NOT** serviceable by operator.
- Inter-Med, Inc. concludes that improper, unauthorized modifications or upgrades of the device, are prohibited and may result in unintended malfunctions that may cause risks and danger to patients, operators, and/or equipment. Inter-Med, Inc. assumes no responsibility and, consequently, declines all responsibility with respect to direct or indirect damages to people, the device or environment due to these reasons.
- Do not remove or attempt to remove the plastic covers of the device.
- It is strictly forbidden to attempt to repair electronic or mechanical parts by yourself.
- If you do not respect this warning you can compromise irreversibly the overall safety of the system and can be dangerous for operators, patients and environment.

GUIDANCE AND MANUFACTURER'S DECLARATION

Below cables information are provided for EMC reference.

Cable	Max. Cable Length, Shielded/unshielded		Number	Cable Classification
DC Power Line (USB Cable)	1.0m	Unshielded	1 Set	DC Power

IMPORTANT INFORMATION REGARDING ELECTRO MAGNETIC COMPATIBILITY (EMC):

This electrical medical equipment needs special precautions regarding EMC and put into service according to the EMC information provided in the user manual; The equipment conforms to this IEC 60601-1-2:2014 standard for both immunity and emissions. Nevertheless, special precautions need to be observed:

- The equipment with no ESSENTIAL PERFORMANCE is intended used in Professional healthcare facility environment except for near active HF SURGICAL EQUIPMENT and the RF shielded room of an ME SYSTEM for magnetic resonance imaging, where the intensity of EM DISTURBANCES is high.
- **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.
- The 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 30cm (12 inches) to any part of the equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment will result.
- **WARNING:** If the use location is near (e.g. less than 1.5 km from) AM, FM or TV broadcast antennas, before using this equipment, it should be observed to verify that it is operating normally to assure that the equipment remains safe

EMC COMPLIANCE TABLES

Table 1 - Emission

PHENOMENON	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
RF emissions	CISPR 11, Group 1, Class B	Professional healthcare facility environment
Harmonic distortion	IEC 61000-3-2 Class A	Professional healthcare facility environment
Voltage fluctuations and flicker	IEC 61000-3-3 Compliance	Professional healthcare facility environment

Table 2 - Enclosure Port

PHENOMENON	BASIC EMC STANDARD	IMMUNITY TEST LEVELS
		PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF EM field	IEC 61000-4-3	3 V/m 80 MHz-2.8 GHz 80% AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Refer to Table 3
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3 - Proximity Fields From RF Wireless Communications Equipment

TEST FREQUENCY (MHz)	BAND (MHz)	IMMUNITY TEST LEVELS
		PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
385	380-390	Pulse modulation 18 Hz, 27 V/m
450	430-470	FM, ± 5 kHz deviation, 1 kHz sine, 28 V/m
710	704-787	Pulse modulation 217 Hz, 9 V/m
745		
780		
810	800-960	Pulse modulation 18 Hz, 28 V/m
870		
930		
1720	1700-1990	Pulse modulation 217 Hz, 28 V/m
1845		
1970		
2450	2400-2570	Pulse modulation 217 Hz, 28 V/m
5240	5100-5800	Pulse modulation 217 Hz, 9 V/m
5500		
5785		

Table 4 - Input A.C. Power Port

PHENOMENON	BASIC EMC STANDARD	IMMUNITY TEST LEVELS
		PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Electrical fast transients/ burst	IEC 61000-4-4	$\pm 2 \text{ kV}$ 100 kHz repetition frequency
Surges line-to-line	IEC 61000-4-5	$\pm 0.5 \text{ kV}, \pm 1 \text{ kV}$
Surges line-to-ground	IEC 61000-4-5	$\pm 0.5 \text{ kV}, \pm 1 \text{ kV}, \pm 2 \text{ kV}$
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz-80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Voltage dips	IEC 61000-4-11	0% U_T ; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0% U_T ; 0.5 cycle and 70% U_T ; 25/30 cycles Single phase at 0°
Voltage interruptions	IEC 61000-4-11	0% U_T ; 250/300 cycles

Table 5 - Signal Input/Output Parts Port

PHENOMENON	BASIC EMC STANDARD	IMMUNITY TEST LEVELS
		PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V, 0.15 MHz-80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz

NOTES

[illegible]

NOTES

This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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