

APEX LOCATOR

User Manual





Table of Contents

	Introduction	2				
1.	Indications for use					
2.	Contraindications					
3.	Warnings	3				
4.	Precautions	3				
5.	Adverse Reactions	3				
6.	Step-by-Step Instructions	4				
	6.1. Installing the Batteries	4				
	6.2. Cable connection test	4				
	6.3. Getting Started	4				
	6.4. Apex localization	5				
	6.5. Audio feedback	8				
	6.6. Demo Mode	8				
	6.7. Automatic Shutdown	8				
7.	Installing / Replacing the Batteries	9				
8.	Maintenance, cleaning and sterilization					
	8.1. General	10				
	8.2. Disinfection and sterilization procedure	10				
9.	Troubleshooting	11				
10.	Warranty	12				
11.	Disclaimer					
12.	Certification					
13.	European Authorized Representative					
14.	Technical Specifications14					
15.	Standard symbols14					
16.	Packaging Box Content	15				

ANNEX

Electromagnetic Compatibility16	16
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FOR DENTAL USE ONLY

DIRECTIONS FOR USE

Introduction

Congratulations, you have made a good choice with **NovApex**. Ergonomic user-friendly design of **NovApex** makes it a choice of preference in modern dental clinic.

Utilizing the advantages of well proven patented technology, **NovApex** is a precise, userfriendly, affordable apex locator suitable both for skilled endodontic experts and for general practitioners performing root canal treatments. Custom color graphic display of **NovApex** helps to achieve optimal performance during working length determination.



NovApex Apex Locator

1. Indications for use

NovApex is an electronic device used for apex localization and working length determination during root canal treatment. The device enables to obtain correct results in canals with various conditions - drv and wet.

2. Contraindications

NovApex is not recommended for use in patients that have a pacemaker or other implanted electrical devices.

3. Warnings



igta This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

⚠️ 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.

Luse 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.



A Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of NovApex, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4 Precautions

- Do not use NovApex near devices emitting electromagnetic noise such as fluorescent lamps, film viewers, ultrasonic devices, etc. Cellular phones, remote controls or other devices generating electromagnetic waves may cause abnormal operation of **NovApex**. Such devices should be turned off.
- During device operation protect NovApex from occasional spillage of liquids.
- Do not use NovApex in presence of flammable materials.
- **NovApex** should be used with the manufacturer's original accessories only.
- In order to prevent infectious agent transmission it is highly recommended to use a rubber dam system during the endodontic procedure.
- To ensure that short circuits do not impair the measurements, be particularly careful with patients fitted with metallic crowns, bridges or large metallic fillings (avoid any contact of the file or the Lip Clip with metals).
- High concentrations of sodium hypochlorite may result in a lower accuracy of the measurements. For working length determination, we recommend to use sodium hypochlorite solution at maximum 3% concentration.
- Make sure that the canal is wet enough to ensure reliability of the measurement.
- Ensure that the file does not touch other instruments.

- Avoid excessive liquids inside the tooth cavity to prevent overflow and incorrect measurements.
- Teeth with open apices may give imprecise results.
- Apex locator may not be able to provide correct measurements in all conditions. In any case, it is recommended to take an X-Ray prior to device use and to compare the results obtained by both methods.
- For your own safety, please use personal protection gear (gloves, mask).

5. Adverse Reactions

None.

6. Step-by-Step Instructions

6.1 Installing the Batteries

Before the first use of **NovApex** install the batteries as explained in section 7.

6.2 Cable connection test

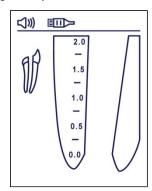
Connection test feature is included in **NovApex** in order to check the cables:

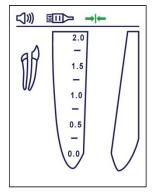
- Insert the Measurement cable with attached Lip Clip and File Clip into the device receptacle.
- Verify that the File Clip contact and the Lip Clip are clean and make connection between them.
- "Connection" symbol relations should appear on the status bar of the display indicating proper electrical connection (Pic. 1).
- If the symbol is does not appear, the Measurement cable or the File Clip should be replaced.
- <u>Note:</u> Measurement cable with attached Lip Clip and File Clip constitute Applied Parts of the device.

6.3 Getting Started

Prior the first use, it is recommended to sterilize the Lip Clip, the File Clip and the Touch Probe. Please refer to section 8 for further information regarding **NovApex** maintenance.

- 6.3.1 Turn the device on by pressing ^(U) (On/Off) button. The main screen is displayed. Status bar with sound level, cable connection and battery indicators is located in the upper part of the display.
- 6.3.2 Before connecting the Measurement cable with attached Lip Clip and File Clip to the patient, plug the Measurement cable into the device receptacle and make sure that the cable icon appears on the status bar of the display (Pic. 2).





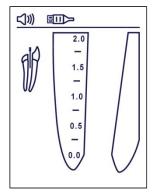


- 6.3.3 Attach the Lip Clip to the patient.
- 6.3.4 Gently insert endodontic file into the root canal and connect the File Clip to the file (to ensure precise measurements the file size should be adjusted to the canal diameter).

Alternatively, use the Touch Probe to provide electrical contact with the endodontic file.

6.3.5 The file image inside the small tooth icon will appear accompanied by a double beep signal (Pic. 3). Absence of file image and of audio signal indicates a faulty connection. In such case disconnect the Measurement cable from the patient, check cable connections, clean File Clip/Touch Probe contact, moisten the canal, if necessary, and start again.

No other adjustments are necessary before starting measurements.

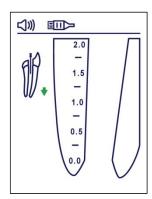


Pic. 3

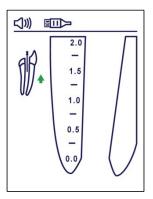
6.4 Apex localization

6.4.1 Coronal and Medial Zone

Slowly move the file forward inside the root canal. The progression of the file inside the canal is reflected on the screen by green arrows Down and Up (Pic. 4 and Pic. 5).



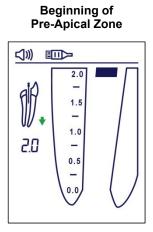




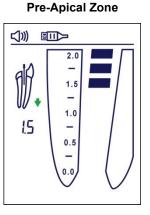
Pic. 5

Along the pre-apical zone a zoomed view of file progression in the canal is shown on the enlarged root image in the right side of the display, and numerical values from 2.0 to 1.25 appear on the left side of the display under the tooth image (Pic. 6 and Pic. 7).

NovApex provides audio feedback of file progression as a series of progressive rate beeps.







Pic. 7

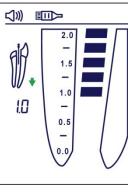
6.4.2 Apical Zone

File position in the Apical Zone is visually indicated by color segments inside the root canal image and numerical readings 1.0, 0.75, 0.5, 0.25 and 0.0 appearing under the tooth image in the left part of the display (Pic. 8 and Pic. 9).

File progression in the apical zone is accompanied by a series of beeps with variable rate. When the apical position is reached (read bar at the mark "**0.0**"), solid tone is emitted (Pic. 10).

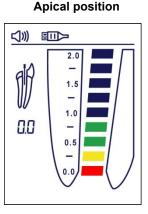
The apical position indicated by **NovApex** corresponds to file tip position at minor apical foramen.

Beginning of the Apical Zone



Mid-Apical Zone

✓)») EII> ↓ 2.0 − 1.5 − 1.5 − 1.0 0.5 − 0.0 0.0



Pic. 8



Pic. 10

6.4.3 Over-instrumentation

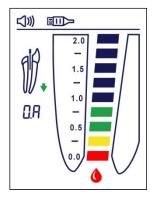
A red "**Blood drop**" icon and warning sound indicate that the file has passed the apex. "**O.A**" reading appears in the left part of the screen under the tooth image (Pic. 11).

To return to the apical position, gently retreat the file until the "Blood drop" disappears and "**0.0**" indication returns.

<u>Note:</u> Numerical values shown in the pre-apical and apical zones serve as a convenient reference to judge the file tip position in relation to the apex, but they do not represent the actual distance from the apex in mm.

6.4.4 Completion of the measurements

• Before unplugging the Measurement cable from the device receptacle, disconnect the Lip Clip and the File Clip from the patient.



Pic. 11

• Move the file stopper to the selected reference point on the tooth.

- Gently remove the file from the canal and measure the apical length between the stopper and the file tip.
- Determination of working length for canal shaping is a subject of dentist's professional judgment. In most cases subtraction of 0.5 mm from the measured apical length provides clinically acceptable working length. Nevertheless, in each case the dentist should define proper working length basing on his experience, apex locator readings, radiographs and other available data.

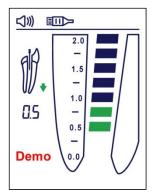
6.5 Audio feedback

 NovApex is equipped with an audio indicator which accompanies file progression within the canal in the pre-apical and apical zones. This function is activated in parallel with Apical Zoom display and enables monitoring of file advance in the apical zone, even without seeing the display. Successively pressing the volume key
 you may adjust the sound volume to one of four levels: Mute, Low, Normal and High.

6.6 Demo mode

The built-in Demo mode is available to demonstrate operation of the device and to improve the learning curve of the operator.

- 6.6.1 Disconnect the Measurement cable from the device, if connected, and turn the device on.
- 6.6.2 To start Demo Mode, press and hold the "**Mode**" button ★ for about 1 sec. until the second beep sounds and "**Demo**" indication appears on the screen (Pic. 12).
- 6.6.3 During Demo cycle the operating sequence of the device is shown on the screen. Press ★ button to pause the simulation; press ★ button again to resume.
- 6.6.4 When Demo cycle is completed, it is repeated automatically until interrupted by the operator.
- 6.6.5 To exit Demo mode press and hold the Mode button ★ for about 1 sec. until a beep sounds.





<u>Note:</u> If Measurement cable is plugged into the device receptacle during Demo cycle, **NovApex** exits Demo mode and switches automatically to regular operation mode.

6.7 Automatic Shutdown

NovApex automatically shuts down after 2 minutes without use. In order to prolong the battery life, it is recommended to switch off the device after completing the measurements by pressing the \bigcirc button.

7. Installing / Replacing the Batteries

NovApex is powered by 2 standard Lithium coin cell batteries, type CR2032.



A Prior to battery replacement the device should be turned off.

Before replacing the batteries Measurement cable should be disconnected from the patient and removed from the device.

- 7.1 To install / replace the batteries, release the screw and remove the battery compartment cover on the rear side of the device (Pic. 13a).
 - Remove old batteries from battery holders using a small screwdriver as shown in Pic 13b.
 - Insert each of the new batteries into the battery holder, slide it forward and down until it is fully seated in the holder.
 - Close the battery compartment and secure the cover with the screw.

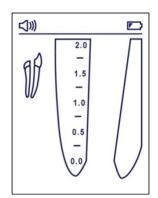
A Take care for correct polarity ("+" must be on top of the battery).





Pic. 13a

- 7.2 When the batteries are depleted, blinking "Low Battery" indicator will appear in the upper right corner of the screen (Pic.14). NovApex will continue normal operation even with low batteries, but the batteries should be replaced before it becomes flat.
- 7.3 If the batteries are flat, blinking "Low Battery" indicator will be accompanied by 3 beeps and the device turns off automatically.



Pic. 14

8. Maintenance, cleaning and sterilization

8.1 General

- The device does not contain user serviceable parts. The service and repair should be provided by factory trained service personnel only.
- All objects that were in contact with potentially infectious agents should be cleaned after each use:

Lip Clip, File Clip and Touch Probe should be disinfected and sterilized by autoclaving between treatments. Please follow "Disinfection and sterilization procedure" described in section 8.2.

Measurement cable, the device and the cradle should be cleaned using tissue or soft cloth impregnated with aldehyde free disinfecting and detergent solution (a bactericidal and fungicidal).



The Measurement cable cannot be autoclaved.

Use of agents other than specified above may cause damage to the equipment and its accessories.

8.2	8.2 Disinfection and sterilization procedure				
#	Operation	Instructions	Details and Warnings		
1	Preparation at the point of use prior to processing	No particular requirements			
2	Preparation for decontamination/ preparation before cleaning	No particular requirements			
3	Cleaning: Automated	The accessories are not intended for automated cleaning			
4	Cleaning: Manual	Clean the accessories with an adequate brush or towel soaked in a disinfectant solution	 The File Clip should be activated during cleaning process (pressed and released several times) After cleaning no visible impurities should remain on the accessories 		
5	 Disinfection Soak the required accessories in a disinfectant solution combined with proteolytic enzyme if possible. Rinse well the accessories in flowing 		 Follow instructions given by the disinfectant manufacturer (concentration, immersion time, etc.) Do not use disinfectant solution containing aldehyde, phenol or any products which may damage the accessories 		

water

#	Operation	Instructions	Details and Warnings
6	Drying	No particular requirements	
7	Maintenance, inspection and testing of the accessories	No particular requirements	
8	Packaging	Pack the accessories in sterilization pouches	 Check the validity period of the pouch given by the manufacturer to determine the shelf life of the sterilized items Use packaging which is resistant up to a temperature of 141°C (286°F)
9	Sterilization	 Steam sterilization at 135°C (275°F) during 10 minutes in gravity type autoclave (Table Top, N type) Drying time after sterilization – 30 minutes 	 Follow maintenance and operation procedures of the autoclave provided by the manufacturer The only sterilization parameters to be used are those that have been validated and provided to the user in this User Manual
10	Storage	Keep sterilized accessories in sterilization pouches in a dry and clean environment	Sterility cannot be guaranteed if packaging is open or damaged (check the packaging before using the accessories)

9. Troubleshooting

Please review the suggested solutions before calling customer service.

#	# Problem Possible Cause Solution		Solution
1	The device does not turn on by pressing \cup button	 Malfunction of the button The batteries are flat Electronic malfunction 	 Press ^(U) button several times Replace the batteries Contact your customer service
2	The device shuts off while measuring	The batteries are flat	Replace the batteries
3	No sound while measuring	"Sound control" set at "Mute" level	Adjust the sound level by pressing ◄)) button
4	The device does not show file advance inside the canal	 Bad electrical contact Electronic malfunction 	1. Perform cable connection test as described in section 6.2

#	Problem	Possible Cause	Solution
			2. Contact your customer service
5	Incorrect measurements	 Dry/calcified canal Restoration treatment, conductive pass is blocked Blood or irrigation liquid overflow provides conductive path outside the canal Deep caries provides conductive path outside the canal Metal crown or metal filling provide conductive path outside the canal Perforation Large lateral canal 	 Irrigate the canal Remove old canal filling to open the path, irrigate the canal Dry the excessive liquid Block the external conductive path Avoid contact between the file and metal crown/filling Remove the file, close the perforation and repeat the measurement, carefully inserting the file into canal Try to continue the measurements (gently advance the file towards apex until regular readings appear)

10. Warranty

NovApex is warranted for 24 months from the date of purchase. The accessories (cables, batteries, etc.) are warranted for 6 months from the date of purchase. Within the warranty period the manufacturer undertakes, at its sole discretion, to repair or replace the faulty item without charge.

This product has been developed specifically for use in dentistry and is intended to be operated only by qualified dental professionals in accordance with the instructions contained in this manual. However, notwithstanding anything contained herein, the user shall at all times be solely responsible for determining the suitability of the product for the intended purpose and the method of its use. Any guidance on technology application offered by or on behalf of the manufacturer, whether written, verbal or by demonstration, shall not relieve the dental professional from his/her obligation to control the product and to make all professional judgments regarding its use.

Except for the warranties specifically set forth in this manual, the manufacturer provides no warranties or guarantees of any kind covering the product, expressed or implied, including, without limitation, any warranties as to merchantability or fitness for a particular purpose. Any claim for damage or breakage to the product in transit should be made to the carrier promptly upon discovery.

The warranty is valid for normal usage conditions. Any damage caused by accident, abuse, misuse, or as a result of service or modification other than by a person authorized by the manufacturer will render the warranty void.

11. Disclaimer

The manufacturer, its representatives and its dealers shall have no liability or responsibility to customers or any other person or entity with respect to any liability, loss or damage caused or alleged to be caused directly or indirectly by equipment sold or furnished by us, including, but not limited to, any interruption of service, loss of business or anticipatory profits, or consequential damages resulting from the use or operation of the equipment.

The manufacturer reserves the right to implement changes and modifications of the product at any time, to revise this publication and to make changes in the contents hereof without obligation to notify any person of such changes, modifications or revisions.

12. Certification

NovApex complies with the following standards: IEC 60601-1 (Safety) and IEC 60601-1-2 (Electromagnetic compatibility), including conducted and radiated immunity tests as specified for equipment of Group 1 Class B.

NovApex is covered by the "CE Marking of Conformity" certificate. The device bears the following CE identification mark:



13. European Authorized Representative

European Authorized Representative who has been empowered to enter into commitments in our behalf:

CEpartner4U B.V. ESDOORNLAAN 13, 3951 DB MAARN, THE NETHERLANDS. Contact Person: Mr. Ton Pennings Tel. +31 343 442 524, Fax +31 343 442 162 Email: office@cepartner4u.com

14. Technical Specifications

NovApex electronic apex locator is a programmable electrical medical device

- Internally powered equipment
- Type BF Applied Parts
- Not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide
- Continuous operation
- Ingress of liquids not protected
- The device is intended for indoor use only
- Environmental conditions during storage/transportation:
 - Temperature: -20 °C to +60 °C (0 °F to 140 °F)
 - Relative humidity: 10% to 90%, non-condensing
 - Atmospheric pressure: 106 kPa to 19 kPa
- Environmental conditions during device usage:
 - Temperature: +10 °C to +40 °C (50 °F to 104 °F)
 - Relative humidity: 10% to 90%, non-condensing
 - Atmospheric pressure: 106 kPa to 70 kPa

NovApex is intended for use in electromagnetic environment specified for equipment of Group 1 Class B.

Specifications:

93 x 54 x 13 mm
60 gr.
Custom Color Graphic LCD
51 x 38 mm
2 x CR2032 Lithium cell batteries (6V)

15. Standard symbols

On the device label appear standard symbols as follows:



Class II equipment



Type BF Applied Parts



Direct current



Manufacturer



Consult instructions for use



<u>Recycling:</u> PLEASE DO NOT THROW AWAY! This product and all its components must be recycled through your supplier



Caution: Federal law restricts this device to sale by on the order of a physician or licensed dental practitioner.



Temperature limitation



Humidity limitation



Atmospheric pressure limitation

16. Packaging Box Content

Check the content of the packaging box before use:

• NovApex apex locator	- 1 pc.
Cradle	- 1 pc.
 Lithium coin cell 	- 2 pc. battery CR2032
Measurement cable	- 1 pc.
Lip clip	- 2 pcs.
File clip	- 2 pcs.
Touch probe	- 1 pc.
Screw driver	- 1 pc.

• User Manual - 1 pc.

ANNEX

Electromagnetic Compatibility

Notes:

- NovApex requires special precautions with regard to electromagnetic compatibility.
- It must be installed and prepared for use as described in section 6.3 "Getting Started".
- Certain types of RF wireless communication equipment such as mobile telephones are likely interfere to with **NovApex**.
- The recommended radiation levels of RF wireless communication equipment specified in this paragraph must therefore be complied with.
- NovApex must not be used near or on top of another device. If this cannot be avoided, it is necessary – before clinical use – to check the equipment for correct operation under the conditions of use.

Electromagnetic Emissions

Notes:

- **NovApex** is intended for use in the professional healthcare facility or home healthcare electromagnetic environment specified in the tables below.
- The user and/or installer of the unit must ensure that it is used in such an environment.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer's declaration: electromagnetic emissions - NovApex

NovApex is intended for use in professional healthcare facility or home healthcare electromagnetic environment specified below; The customer or the user of **NovApex** should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	NovApex uses RF energy only for its internation. 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		
Harmonic emissions IEC 61000-3-2	Complies	NovApex is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	supply network that supplies buildings used for domestic purposes.	

Guidance and manufacturer's declaration: electromagnetic immunity - NovApex

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

Immunity test	IEC 60601-1-2 Test level	Compliance level	Electromagnetic environment - guidance	
Electrostatic discharge (ESD)	±8 kV contact	±8 kV contact	Floors should be wood, concrete or Ceramic tile. If	
IEC 61000-4-2	±15 kV air	±15 kV air	floors are covered with synthetic material, the relative humidity Should be at least 30%.	
Electrical fast transients/bursts	±2 kV for power supply lines	Not Applicable	Not Applicable	
IEC 61000-4-4	±1 kV for input/output lines			
Surges	±1 kV Line-to-line	Not Applicable	Not Applicable	
IEC 61000-4-5	±2 kV Line-to-ground			
Voltage dips	0% UT; 0,5 cycle	Not Applicable	Not Applicable	
	0% UT; 1 cycle			
	and			
	70% UT;			
	25/30 cycles			
Voltage interruptions	0% UT; 250/300 cycles			
IEC 61000-4-11				

Guidance and manufacturer's declaration: electromagnetic immunity - NovApex

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

Immunity test	Immunity test	Immunity test	Immunity test
Rated power frequency magnetic fields	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical public low-voltage power supply network that supplies buildings used for domestic
IEC 61000-4-8			purposes, commercial or hospital, clinic environment.

Note:

• UT is the a.c. mains voltage prior to application of the test level.

Conducted disturbances	3 Vrms	3 Vrms	Portable and mobile RF communications equipment	
inducted by RF fields	150 kHz to 80 MHz	150 kHz to 80 MHz	should be used no closer to any part of NovApex , including cables, than the	
	6 Vrms in ISM bands 150 kHz to 80 MHz	6 Vrms in ISM bands 150 kHz to 80 MHz	recommended separation distance calculated from the equation applicable to the frequency of the transmitter.	
IEC 61000-4-6	80% AM at 1 kHz	80% AM at 1 kHz	Recommended separation distance	
			<i>d</i> = 1.17√ <i>P</i>	
			<i>d</i> = 1.17√ <i>P</i> 80 MHz t o 800 MHz	
			$d = 2.3\sqrt{P}$ 800 MHz t o 2,7 GHz	
Radiated RF	10 V/m	10 V/m	Where <i>P is</i> the maximum output power rating of the	
IEC 61000-4-3	80 MHz to 2,7 GHz		transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).	

Guidance and manufacturer's declaration: electromagnetic immunity - NovApex

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

Immunity test	Immunity test	Immunity test	nity test Immunity test	
			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 the following symbol:	

Notes:

- 1 At 80 MHz and 800 MHz, the higher frequency range 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 and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which **NovApex** is used exceeds the applicable RF compliance level above, **NovApex** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating **NovApex**.

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

Specifications for enclosure port immunity to RF wireless communications equipment

NovApex is intended for use in an electromagnetic environment in which radiated radiofrequency disturbances are controlled.

The user and/or installer of the unit can help prevent electromagnetic interference by maintaining radiation levels of RF wireless communications equipment (emitters) within the compliance limits specified in the table below.

Recommended radiation levels of RF wireless Communications Equipment					
Frequency band	EC 60601-1-2 Test level	Compliance level	Minimum separation distance		
380 – 390 MHz	27 V/m	27 V/m	0.3 m		
430 – 470 MHz	28 V/m	28 V/m	0.3 m		
704 – 787 MHz	9 V/m	9 V/m	0.3 m		
800 – 960 MHz	28 V/m	28 V/m	0.3 m		
1,700 – 1,990 MHz	28 V/m	28 V/m	0.3 m		
2,400 – 2,570 MHz	28 V/m	28 V/m	0.3 m		
5,100 – 5,800 MHz	9 V/m	9 V/m	0.3 m		

Note:

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

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