

RomiApex™ A-15

APEX LOCATOR User Manual



FORUMTEC
Dental Solutions & Beyond

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FOR DENTAL USE ONLY

Introduction

Congratulations on the purchase of your RomiApex™ A-15 Apex Locator.

The RomiApex™ A-15 Apex Locator is a battery operated portable device which uses the frequency dependent impedance method and proprietary algorithms to determine the position of the apical foramen.

Utilizing the advantages of its well proven patented technology, RomiApex™ A-15 offers the operator performing root canal treatments an accurate, reliable and user-friendly apex locator. Custom color graphic display of RomiApex™ A-15 helps to achieve optimal endodontic performance required during your root canal treatments.



RomiApex™ A-15 Apex Locator





1. Indications for use

RomiApex™ A-15 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 – dry and wet.

2. Contraindications

RomiApex™ A-15 is not recommended for use in patients that have a pacemaker or other implanted electrical devices.

3. Warnings

-  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.
-  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.
-  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 RomiApex™ A-15, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

4. Precautions

- Do not use RomiApex™ A-15 near devices emitting electromagnetic noise such as x-ray viewer with fluorescent lamps, film viewers, ultrasonic devices, etc.
- Cellular wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones, and their base stations etc. can affect RomiApex™ A-15 and should be kept at least at a distance of 30 cm (12 inches) to any part of the device.
- During device operation protect RomiApex™ A-15 from occasional spillage of liquids.
- Do not use RomiApex™ A-15 in presence of flammable materials.
- RomiApex™ A-15 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. Package Contents

Check the contents of the package before use:

- 1 RomiApex™ A-15
- 1 Cradle
- 1 AAA 1.5V Alkaline Battery
- 1 Measuring cable
- 2 File clips
- 5 Lip clips
- 1 Touch probe
- 1 Screwdriver (for battery compartment)
- 1 User Manual



1 - Measuring cable



2 – File clips



5 - Lip clips



1 – Touch Probe

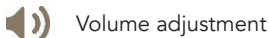
7. Getting Started

7.1 General

There are two buttons on the front panel:



On/Off



Volume adjustment

The measuring cable receptacle is located on the left side of the device.



The battery compartment is located on back of the device.

The RomiApex™ A-15 may be placed in or out of the cradle.

The lip clip, the touch probe and the file clip should be sterilized before use. Please refer to ***“Maintenance, Cleaning and Sterilization”*** section 9 (page 17) for further information regarding maintenance of the RomiApex™ A-15.

7.2 Installing / Replacing the Battery

The RomiApex™ A-15 is powered by a standard AAA size 1.5V alkaline battery (included).

-  Prior to battery replacement the device must be turned off.
-  Before replacing the battery the measuring cable should be disconnected from the patient and removed from the RomiApex™ A-15 device.

7.2.1 To install/replace the battery, unscrew and remove the battery compartment cover on the back of the device (Fig. 1a). Remove the old battery (if one is present) using the built-in cloth strip; insert the new battery following polarity indications marked inside the battery compartment, (Fig. 1b), replace cover and tighten screw.

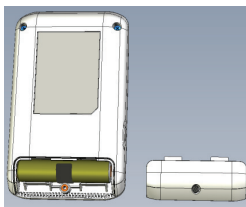


Fig. 1a

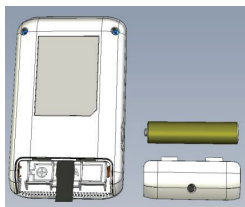


Fig. 1b

7.2.2 When the battery level is low, the flashing Low Battery indicator will appear on the screen (Fig.2). RomiApex™ A-15 will continue normal operation even with a low battery, but the battery should be replaced before it loses all power.

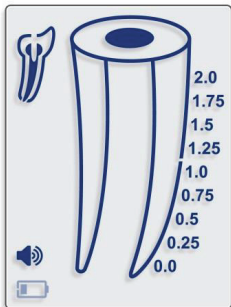


Fig. 2

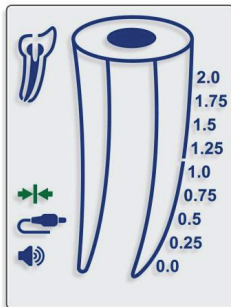


Fig. 3

7.3 Cable connection test

Prior to each use, the RomiApex™ A-15 should be checked for functionality. The RomiApex™ A-15 has a connection test feature in order to check the cables.

- 7.3.1 Connect the measuring cable with attached Lip Clip and File Clip into the device receptacle. Touch file clip contact to the lip clip.
- 7.3.2 "Connection" icon →↔← should appear on the display, indicating proper connection (Fig. 3).
- 7.3.3 If the symbol does not appear, the measuring cable or file clip should be replaced.

Note: Measurement cable with attached lip clip and file clip constitute Applied Parts of the device.

7.4 Device operation

⚠ Do not use this unit with patients who have a pacemaker, as its effect has not been evaluated.

- 7.4.1 Place rubber dam prior to beginning endodontic treatment.
- 7.4.2 Obtain an initial radiograph and measure the distance between a reference point (i.e. incisal edge, peak of the cusp, etc.) to the image of the anatomical apex for the canal you will be working on. Subtract 0.5mm to establish your TEMPORARY working length.
- 7.4.3 **Preflare** the canal to partially remove canal contents and establish patency to your TEMPORARY working length.
- 7.4.4 To ensure proper measurements, verify that the canal is not completely dry or calcified. If needed, fill the canal with an electrolytic solution (i.e. Sodium Hypochlorite, Saline, etc.).

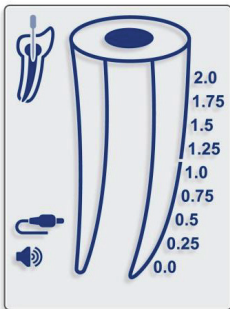






Fig. 4

- 7.4.5 Depending on the size of the canal, insert a #15 hand K-file or other appropriate file into the canal.
- 7.4.6 Press the On-Off  button to turn the device on. The initial image appears on the display.
- 7.4.7 Before connecting the measurement cable with attached lip clip and file clip to the patient, plug measurement cable into the device receptacle and make sure that the cable icon appears on the display (Fig. 4).
- 7.4.8 Put the lip clip onto the patient's lip.
- 7.4.9 Connect the file clip to the file. The RomiApex™ A-15 will automatically detect that root canal measurement has started. If the electrical contact is good and the conductivity of the root canal is sufficient, the file icon inside the small tooth image will stop blinking and a double beep audio signal will sound.
-  If there are no beeps, stop measurements, clean the file clip and the file, irrigate the canal, if required, and resume measurements.
-  Make sure that irrigation solutions, blood or saliva don't fill the access cavity. Dry the cavity if required before performing measurements.
- 7.4.10 Movement of the file inside the canal is reflected by the DOWN (Fig. 5) and UP (Fig. 6) arrows on the screen.

7.4.11 Continue to advance the file moving it smoothly in a watch-winding motion. As the instrument progresses toward the foramen, color segments inside the root canal image accompanied by audio signals with varied frequency will indicate the file's progress. Numerical readings 2.0, 1.75, 1.5, 1.25, 1.0, 0.75, 0.5, 0.25, 0.0 (Foramen) or OVER appear under the tooth icon (Figs. 7-11).

 Erratic movement of the file may cause unstable readings.

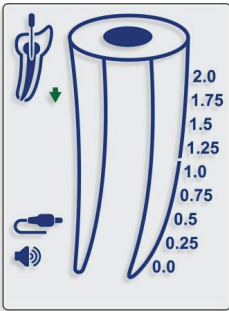


Fig. 5

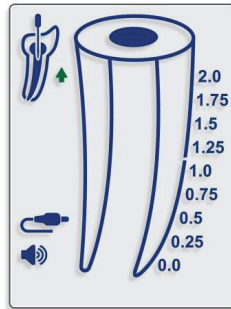


Fig. 6

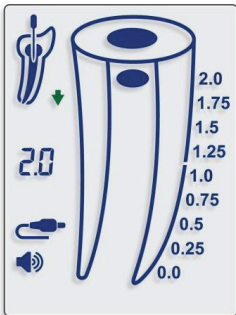


Fig. 7

Median Zone (Blue)

Beginning of the Apical Zone (Blue)

Mid Apical Zone (Green)

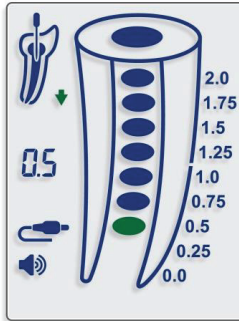
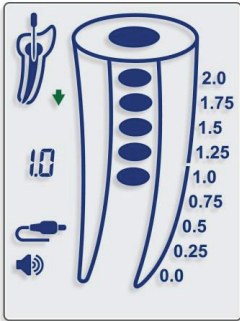


Fig. 8

Fig. 8

7.4.12 Reaching the apical foramen (0.0) is indicated by a red color segment inside the root canal image (Fig. 10) and a constant audio tone.

Foramen (red)

OVER (Red)

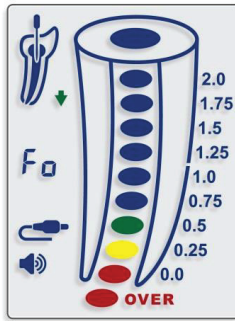
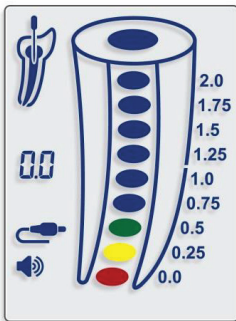


Fig. 10

Fig. 11



The red OVER indication accompanied by frequent beeps indicates that the file tip have progressed beyond the foramen into the periapical region - 'Foramen over-instrumentation' (Fig. 11).

- 7.4.13 The file clip may be disconnected from the file and connected back during measurement without affecting normal device operation (for instance, when the file is changed to a larger number during root canal treatment or when another canal should be measured). In such cases the device detects automatically that the new measurement is initiated, the electrical contact and conductivity of the root canal are checked again and two beeps are sounded.

Note: The RomiApex™ A-15 operates completely automatically. No manual adjustments are required. The RomiApex™ A-15 enables accurate localization of apical foramen independently of root canal conditions (dry, wet, with blood, pulp). In case of very dry canal or previous obturation (retreatment cases) you may use irrigation solution such as Sodium Hypochlorite, Saline, etc. to provide a conductive electrical environment.

7.5 Completion of the measurements


- 7.5.1 Before unplugging the Measurement cable from the device receptacle, disconnect the lip clip and the file clip from the patient.
- 7.5.2 Move the file stopper to the selected reference point on the tooth.
- 7.5.3 Gently remove the file from the canal and measure the apical length between the stopper and the file tip.

7.5.4 To determine the working length for canal shaping, it is recommended to subtract 0.5mm from the measured apical length.


7.6 Audio feedback

The RomiApex™ A-15 is equipped with an audio indicator which is activated in parallel with progression of the file. This function enables monitoring of the file progression within the canal in the apical zone even without seeing the display.

The volume can be adjusted to one of the four levels: mute, low, normal and high.

The adjustment is performed by successive pressings of the volume key  .





7.7 Automatic Shutdown

The RomiApex™ A-15 automatically shuts off after 5 minutes without use. In order to prolong the battery life, after completing the measurements, it is recommend switching the device off by pressing the On/Off key  .

8. Demo mode

The built-in Demo mode is available to demonstrate operation of the device.

8.1. Disconnect the measuring cable from the device and turn the device off.

- 8.2. To start **Demo** mode, press and hold the On/Off key  for about 1 sec. until the second beep sounds and “**Demo**” indication appears on the screen.
- 8.3. During **Demo** cycle the operating sequence of the device is shown on the screen.
Press On/Off key  to pause the simulation; press On/Off key  again to resume.
- 8.4. When **Demo** cycle is completed, it is repeated automatically until interrupted by the operator.
- 8.5. To exit **Demo** mode press and hold the On/Off key  for about 1 sec. until a beep sounds.

Note: If measuring cable is inserted into the device receptacle during Demo cycle, RomiApex™ A-15 exits Demo mode and switches automatically to regular operation mode.

9. Maintenance, Cleaning and Sterilization

9.1. 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 before the first use and between treatments. Please follow “Disinfection and sterilization procedure” described in next section.

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



The measuring cable should not be autoclaved.



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





9.2. Disinfection and sterilization procedure

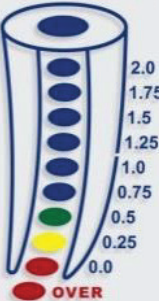
#	Operation	Instructions	Details and Warnings
1	Preparation at the point of use prior to processing	No particular requirements	
2	Preparation for decontamination/ preparation before cleaning	No particular requirements	
3	Cleaning: Automated	The accessories are not intended for automated cleaning.	
4	Cleaning: Manual	Clean the accessories with an appropriate brush or towel soaked in a disinfectant solution.	<ul style="list-style-type: none"> - The file clip should be pressed and released several times during cleaning to assure all debris is removed. - After cleaning, there should be no visible debris on the accessories.
5	Disinfection	Soak the accessories in a disinfectant solution that contains a proteolytic enzyme if possible. Rinse accessories thoroughly in running water.	<ul style="list-style-type: none"> - Follow manufacturer's instructions on the disinfectant (concentration, immersion time, etc.). - Do not use disinfectant containing aldehyde, phenol or any products which may damage the items.

#	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 devices in sterilization pouches.	<ul style="list-style-type: none"> - Check the expiration date of the pouch given by the manufacturer to determine the shelf life. - Use packaging which is resistant up to a temperature of 141°C (286°F).
9	Sterilization	<ul style="list-style-type: none"> - Steam sterilization at 135°C (275°F) for 10 minutes in table top, N-type autoclave. - Drying time after sterilization – 30 minutes. 	<ul style="list-style-type: none"> - Follow maintenance and operation procedures of the autoclave provided by the manufacturer. - The only sterilization parameters to be used are those that have been provided in this Manual.
10	Storage	Keep devices in sterilization packaging in a dry and clean environment.	Sterility cannot be guaranteed if packaging is open or damaged (check the packaging before using the instruments).

10. Troubleshooting Guide

Problem	Possible Solution
Blank screen after use	<ul style="list-style-type: none">- The device automatically shuts down after 5 minutes without use - press the On-Off button to turn the device on.- Battery is completely dead – replace with fresh battery - ensure the battery is installed with proper polarity. Realign if necessary.- Device has malfunctioned – contact your supplier.
Display showing no progression of the file towards the apical area/ foramen	<ul style="list-style-type: none">- If already in use, this may indicate a poor connection - check all connections and ensure lip clip is contacting the oral mucosa and file clip is clean and free of debris- Fill the canal with an electrolytic solution, if required (i.e. Sodium Hypochlorite, Saline, etc.).- The endodontic file is not touching the internal canal walls - replace the file using a larger diameter file.- If the behavior persists, the measuring cable or file clip may need to be replaced and/or the device should be sent in for service – contact your supplier.

Problem	Possible Solution
<p>The cable icon does not appear </p>	<ul style="list-style-type: none"> - Make sure the measuring cable is properly connected. - If the behavior persists, the measuring cable may need to be replaced and/or the device should be sent in for service – contact your supplier.
<p>The File icon keeps blinking </p>	<ul style="list-style-type: none"> - The file clip is not properly connected with the endodontic file. - Check all connections and ensure lip clip is contacting the oral mucosa and file clip is clean and free of debris. - If the behavior persists, the measuring cable may need to be replaced and/or the device should be sent in for service – contact your supplier.
<p>The connection icon  does not appear when touching the file clip and the lip clip</p>	<ul style="list-style-type: none"> - Try connecting another file clip to the measuring cable. - If the behavior persists, the measuring cable may need to be replaced and/or the device should be sent in for service – contact your supplier.
<p>The OVER  OVER indication appears accompanied by frequent audio beeps</p>	<ul style="list-style-type: none"> - The file tip has progressed beyond the apical foramen – move the file back until the OVER indication disappears.
<p>No audio tones</p>	<ul style="list-style-type: none"> - The volume was adjusted to “mute” - press the volume key until the desired volume level is reached. - Device has malfunctioned - contact your supplier.

Problem	Possible Cause	Solution	
<p>1. File position indication is unstable, erratic results.</p> 	<p>Is second electrode (lip clip) making good contact with mucosa?</p>	<p>Make sure the lip clip makes good contact with the oral mucosa</p>	
	<p>Is the file clip dirty?</p>	<p>Clean the file clip with Ethanol 70-80% vol.</p>	
	<p>Is blood or other fluids overflowing the access cavity of the tooth?</p>	<p>If blood or other fluids are overflowing the access cavity they may create a conductive path outside the canal and cause incorrect measurements ("OVER" indication, unstable readings, etc.). Check the rubber dam isolation, <u>use OraSeal® Caulking or Putty to repair rubber dam leaks. You may use ViscoStat® or Astrigedent® for control the gingival tissue bleeding.</u> Clean and dry the pulp chamber and tooth crown thoroughly.</p>	
	<p>2. Measurements are too short or too long; poor accuracy.</p>	<p>Is the canal filled with blood, or chemical solutions?</p>	<p>The canal length indicator may suddenly swing when it breaks the surface of fluids inside the canal, but it will return to normal as the file is advanced toward the apex.</p>
		<p>Is the tooth surface covered with tooth debris, smear layer or chemical solutions?</p>	<p>Clean entire tooth surface.</p>
	<p>Is the file touching the gingival tissue?</p>	<p>This might lead to incorrect readings or cause the canal length indicator suddenly to jump all the way to the "OVER" position.</p>	

Problem	Possible Cause	Solution
	Is there vital inflamed pulp tissue left inside the canal?	If a large amount of vital inflamed pulp tissue is left inside the canal, particularly in wide canals such as upper incisors and canines, it may cause incorrect measurements.
	Is the file touching metal prosthesis or filling?	Touching a metal prosthesis or filling with the file may create a conductive path outside the canal and cause incorrect measurements ("OVER" indication, unstable readings, etc.)
	Are proximal surfaces infected with caries?	Deep caries may create a conductive path outside the canal and cause incorrect measurements ("OVER" indication, unstable readings, etc.)
	Are there external resorption or is the tooth fractured?	The canal length indicator may jump to "OVER" position when it reaches a resorption area or a fractured root tooth.
	Does a broken crown cause incorrect measurements?	Build up an insulating barrier to isolate the file from the crown.
	Is there a lesion at the apex?	A chronic lesion can destroy the apical foramen through resorption and cause incorrect measurements.
	Is the file clip holder broken or dirty?	Is the file clip holder broken or dirty?

If the problem persists, please contact your supplier.

11. Certification

The RomiApex™ A-15 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.

The RomiApex™ A-15 is covered by the “CE Marking of Conformity” certificate. The device bears the following CE identification mark:



12. European Authorized Representative

European Authorized Representative who has been empowered to enter into commitments on 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

13. Limited Warranty

RomiApex™ A-15 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.

14. 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.

15. Technical Specifications

The RomiApex™ A-15 belongs to the following category of medical devices:

- Internally powered equipment (AAA 1.5V alkaline battery)
- Type BF applied parts
- Not suitable for use in 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 $+60^{\circ}\text{C}$ (-4 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 $+40^{\circ}\text{C}$ (50°F to 104°F)
 - Relative humidity: 10% to 90%, non-condensing
 - Atmospheric pressure: 106 kPa to 70 kPa

RomiApex™ A-15 is intended for use in electromagnetic environment specified for equipment of Group 1 Class B.

Specifications:

Dimensions:	W55 x H92 x T16 mm
Weight:	100 gr.
Type of screen:	Custom Color Graphic LCD
Screen dimensions:	51 x 38 mm
Supply:	AAA 1.5V alkaline battery

16. Standard symbols

On the device labeling appear standard symbols as follows:



Direct current



Consult instructions for use



Manufacturer



Type BF applied part



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



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



Temperature limitation



Atmospheric pressure limitation



Humidity limitation

ANNEX

Electromagnetic Compatibility

Notes:

- RomiApex™ A-15 requires special precautions with regard to electromagnetic compatibility.
- It must be installed and prepared for use as described in section 6 “Getting Started”.
- Certain types of RF wireless communication equipment such as mobile telephones are likely interfere to with RomiApex™ A-15.
- The recommended radiation levels of RF wireless communication equipment specified in this paragraph must therefore be complied with.
- RomiApex™ A-15 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:

- RomiApex™ A-15 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 - RomiApex™ A-15**

RomiApex™ A-15 is intended for use in professional healthcare facility or home healthcare electromagnetic environment specified below; The customer or the user of RomiApex™ A-15 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	RomiApex™ A-15 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	RomiApex™ A-15 is suitable for use in all establishments, including domestic establishments 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	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration: electromagnetic immunity - RomiApex™ A-15

RomiApex™ A-15 is intended for use in the electromagnetic environment specified below; The customer or the user of RomiApex™ A-15 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) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 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 transients/bursts IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Not Applicable
Surges IEC 61000-4-5	±1 kV Line-to-line ±2 kV Line-to-ground	Not Applicable	Not Applicable
Voltage dips Voltage interruptions IEC 61000-4-11	0% UT; 0,5 cycle 0% UT; 1 cycle and 70% UT; 25/30 cycles 0% UT; 250/300 cycles	Not Applicable	Not Applicable

Guidance and manufacturer's declaration: electromagnetic immunity - RomiApex™ A-15

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Immunity test	Immunity test	Immunity test	Immunity test
Rated power frequency magnetic fields IEC 61000-4-8	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 purposes, commercial or hospital, clinic environment.

Note:

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


Conducted disturbances induced by RF fields IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands 150 kHz to 80 MHz 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of RomiApex™ A-15, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.17\sqrt{P}$ $d = 1.17\sqrt{P}$ 80 MHz to 800 MHz
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Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	$d = 2.3\sqrt{P}$ 800 MHz to 2,7 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).
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Guidance and manufacturer's declaration: electromagnetic immunity - RomiApex™ A-15

RomiApex™ A-15 is intended for use in the electromagnetic environment specified below;

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Immunity test	Immunity test	Immunity test	Immunity test
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. a. Interference may occur in the vicinity of equipment marked with the following symbol: <div style="text-align: center;">  </div>

Note:

- 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 RomiApex™ A-15 is used exceeds the applicable RF compliance level above, RomiApex™ A-15 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating RomiApex™ A-15.
- 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

RomiApex™ A-15 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.

RomiApex A15 Rev. 11
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