

RomiPointer™ Implant Detector

User Manual



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FOR DENTAL USE ONLY

Congratulations, you have made a good choice with RomiPointer™ Implant Detector – innovative device for precise localization of implants buried under gum tissue. Ergonomic user-friendly design of Implant Detector makes it a choice of preference in modern dental clinic.

Utilizing the advanced technology, Implant Detector is a precise, user-friendly, affordable device suitable both for skilled implantologists and for general practitioners working with implants.



**RomiPointer™
Implant Detector**

Pic.1

1. Indications for use

RomiPointer™ Implant Detector is an electronic device used for localization of implants covered by gum tissue during two-stage implantology. The device enables to obtain good results with various implant systems.

2. Contraindications

RomiPointer™ Implant Detector is not recommended for use in patients or by personnel having 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.

4. Precautions

- Do not use RomiPointer™ Implant Detector 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 Implant Detector. Such devices should be turned off.
- During device operation protect Implant Detector from occasional spillage of liquids.
- Do not use Implant Detector in presence of flammable materials.
- Implant Detector should be used with the manufacturer's original accessories only.
- In order to prevent infectious agent transmission, the sensor should be changed or sterilized between patients.
- Presence of metallic bodies near the sensor may distort device indication. Avoid presence of metallic items in the vicinity of the sensor during device operation.
- For your own safety, please use personal protection gear (gloves, mask).
- Implant Detector should be stored at normal environmental conditions:
 - Temperature: +10 °C to +60 °C (+50 °F to +140 °F).
 - Relative humidity: 10% to 90%, non-condensing.

5. Adverse Reactions

None.

6. Step-by-Step Instructions

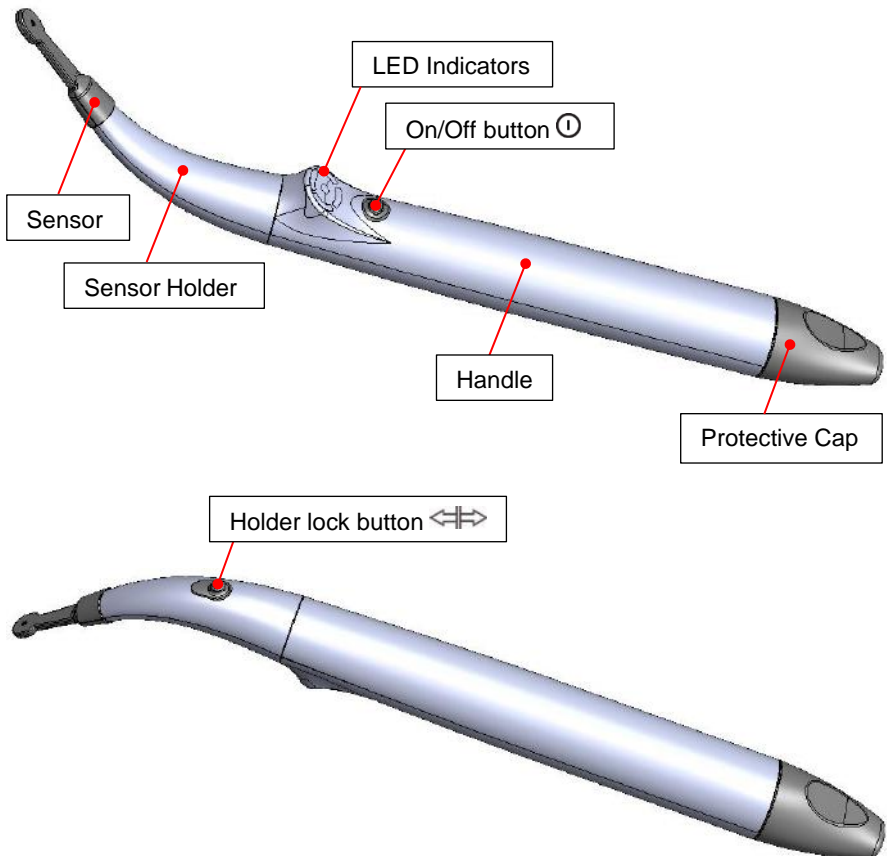
6.1. Packaging Box Content

Check the content of the packaging box before use:

- RomiPointer™ Implant Detector - 1 pc.
- AA alkaline battery - 1 pc.
- Sensor holder - 2 pcs.
- Sensor - 5 pcs.
- User Manual - 1 pc.

6.2. Implant Detector outlook

General view of Implant Detector is shown on Pic. 2.



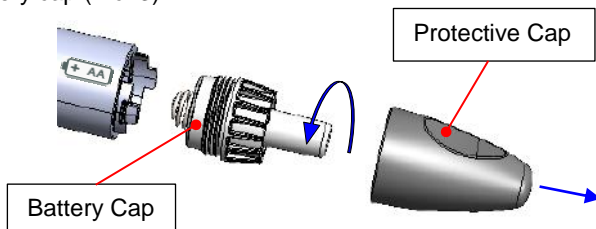
Pic 22

6.3. Installing / Replacing the Battery

Implant Detector is powered by one 1.5V AA alkaline primary battery.

⚠️ Prior to battery replacement the device must be turned off.

6.3.1. To install / replace the battery, remove the protective cap and unscrew the battery cap (Pic. 3).



Pic. 3

- Remove old battery from the battery compartment
- Insert new battery into the battery compartment according to the marking on the device as shown on Pic 4.



Pic. 4

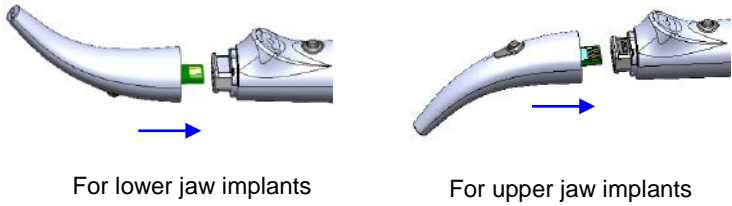
⚠️ Take care for correct polarity during battery insertion ("+" must be towards the inner part of the battery compartment). Implant Detector is protected against incorrect battery polarity. In case of polarity error, remove the battery and reinsert it correctly.

- Screw in the battery cap and close the protective cap until click.


6.4. Getting Started

⚠️ Prior the first use and between the patients, the device and sensor holder should be cleaned and disinfected using wipes moisturized by disinfectant. The sensor should be cleaned and autoclaved as described in §7.

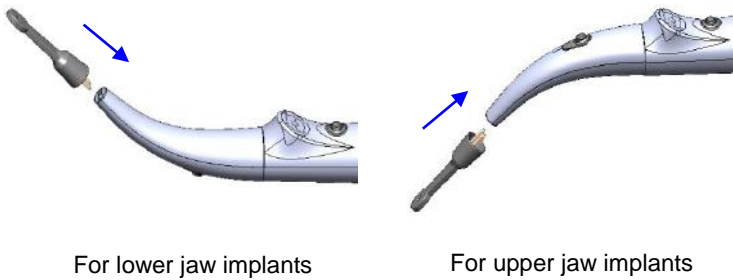
6.4.1. Gently attach the sensor holder to the device as shown on Pic. 5.



Pic. 5

- To remove the sensor holder press the holder lock button  and gently pull the holder from the device.

6.4.2. Insert the sensor into the holder until stop as shown on Pic. 6.



Pic. 6

6.4.3. Correct device configurations are shown on Pic. 7.




Device configuration for lower jaw implants



Device configuration for upper jaw implants

Pic. 7

- 6.4.4. Turn the device on by pressing the  button. One short beep indicates that audio feedback is enabled. To disable the audio feedback hold the button pressed for about 1 sec.



Take care that no metallic object will be closer than 10 cm to the sensor.

- 6.4.5. Battery check-up.

After turning the device on, the battery status is checked. If the battery is depleted, or flat, 4 segments are flashing red 3 times accompanied by 3 beeps.

- In case of depleted battery the device may continue normal operation before the battery is replaced.
- In case of flat battery the device turns off and cannot operate before battery replacement.

- 6.4.6. Self-test and calibration.


Before starting device operation the self-test is performed.

- If sensor holder is not properly connected to the device or sensor is not inserted into the holder, the error is indicated by running red segment. After 10 sec. the device turns off automatically.

To correct the error, turn the device off, connect the sensor holder, insert the sensor until stop and turn the device on again.

After the self-test the device performs automatic calibration.

- Running green segment indicates calibration in progress. When calibration is completed, 4 segments blink green indicating that the device is ready for operation.

Pressing the  button will restart automatic calibration cycle described above.



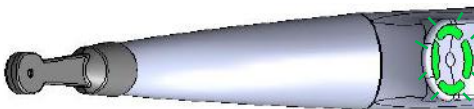
Presence of metallic objects close to the sensor during self-test and calibration may prevent correct device operation or reduce precision of implant localization.

- If calibration error is detected, it is indicated by running orange segment. After 10 sec. the device turns off automatically.

To correct calibration error, turn the device off, check proper connection of the sensor holder and of the sensor. If required, replace the sensor. Verify that there are no metallic objects in the vicinity of the sensor and turn the device on again.

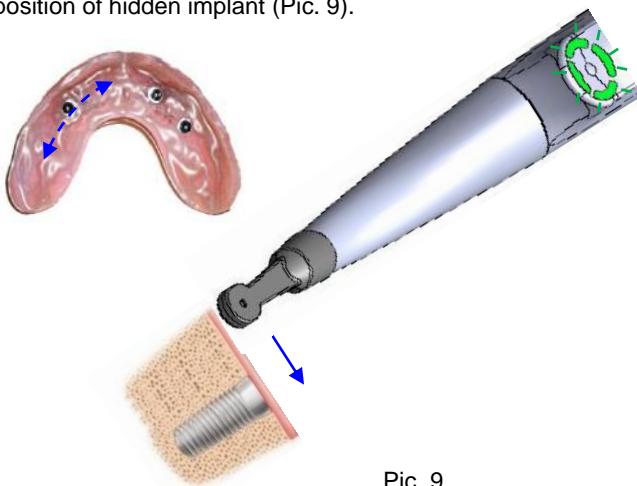
6.5. Device operation

6.5.1. When Implant Detector is ready, 4 segments blink green (Pic 8).





Pic. 8

6.5.2. Insert the device into the mouth cavity and place the sensor plane onto the gum at some distance from the estimated position of the implant. The central hole of the sensor should be approximately in the middle of the jaw ridge. Slowly move the sensor along the jaw towards estimated position of hidden implant (Pic. 9).



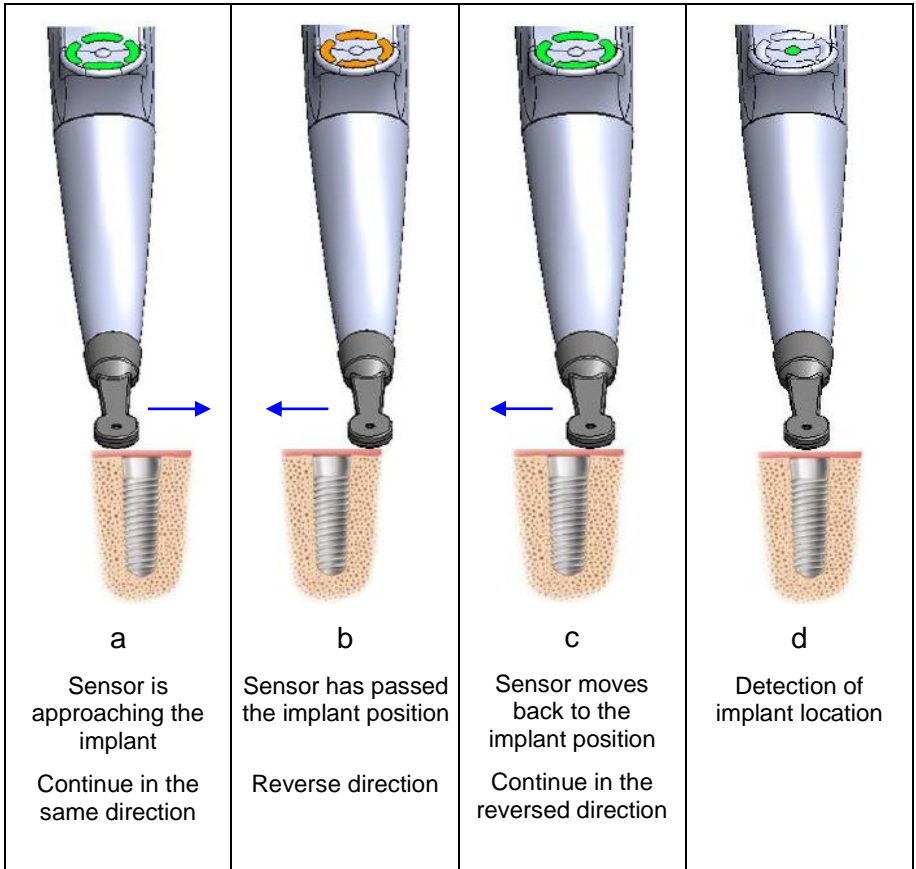
Pic. 9

-  **To ensure correct measurements, take care that the sensor plane will be always slightly pressed to the gum without gap.**
-  **Thick gum layer covering the implant may prevent correct implant localization or reduce precision.**

6.5.3. Implant localization

- When the sensor is approaching the implant, 4 segments turn steady green (Pic. 10a).
- Continue fluent movement of the sensor in the same direction without stopping until the segments turn orange indicating that the sensor has passed the implant position (Pic. 10b).
- Reverse direction and slowly move the sensor back along the same path. Four segments turn green again indicating sensor movement towards the implant (Pic. 10c). Continue sensor movement in reverse direction without stopping.

- When the sensor returns to the implant position, 4 segments turn off and the central dot turns green indicating detection of implant location (Pic. 10d). The visual indication is accompanied by solid audio signal.



Pic. 10

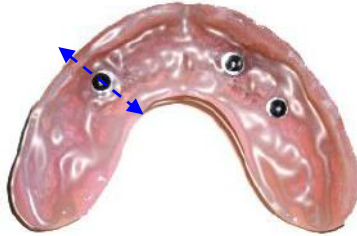
- Through the hole in the middle of the sensor mark on the gum location of the implant using dental probe.

⚠ The sensor movement should be smooth without stopping or unnecessary reversing the direction of the movement. This may cause incorrect readings.

⚠ Stopping sensor movement for more than 3 sec. before completing detection of implant location is indicated (central green dot turns on) will cause automatic reset (4 segments blink green). Implant localization should be repeated from the beginning.

6.5.4. Cross-scanning

- To improve the precision of implant localization it is possible to perform additional cross-scanning in Buccal-Lingual direction as shown schematically on Pic. 11.



Pic. 11

- After initial implant localization as shown on Pic. 10d slowly move the sensor in Buccal-Lingual direction pressing it slightly to the gum. The operating sequence is similar to the sequence described in § 6.5.3.



Presence of metal crown, abutment, tooth with large amalgam filling, metallic instrument close to the implant may prevent correct implant localization or reduce precision.

6.5.5. Localization of multiple implants

In case of multiple implants, after locating and marking the first implant continue to the estimated position of the next implant.

- Slowly move the sensor along the jaw ridge. The central dot will turn off and 4 segments will turn orange; then the segment will blink green indicating that the Implant Detector is ready for detection of the next implant.
- Perform implant localization as described in §§ 6.5.3. and 6.5.4.




Correct localization of implant position may be impossible when 2 or more implants are too close.

6.6. *Audio feedback*

Implant Detector is equipped with an audio feedback which enables monitoring of device operation additionally to visual indication. Audio feedback may be disabled as described in s. 6.4. above.


6.7. *Automatic Shutdown*

Implant Detector 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 implant localization by pressing the  button and holding it for about 1 sec.

7. Maintenance, cleaning and sterilization

7.1. 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 and disinfected after each use.


 **Use of agents other than specified in this section may cause damage to the equipment and its accessories.**

7.2. Device cleaning

Before the first use and between treatments the device should be cleaned using tissue or soft cloth impregnated with aldehyde free disinfecting and detergent solution (a bactericidal and fungicidal).

7.3. Sensor holder cleaning and disinfection

Before the first use and between treatments the sensor holder should be separated from the device, cleaned and disinfected using tissue or soft cloth impregnated with aldehyde free disinfecting and detergent solution (a bactericidal and fungicidal).

 **No visible impurities should remain on the sensor holder after cleaning and disinfection process.**

7.4. Disinfection and sterilization procedure for sensor

Before the first use and between treatments the Sensor should be disinfected and sterilized by autoclaving as described below:



 **The sensor is intended for 10 sterilization cycles maximum.**

#	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 sensor is not intended for automated cleaning	
4	Cleaning: Manual	Clean the sensor with an adequate brush or towel soaked in a disinfectant solution	- After cleaning no visible impurities should remain on the sensor, in particular inside and near the central hole

#	Operation	Instructions	Details and Warnings
5	Disinfection	<ul style="list-style-type: none"> - Soak the sensor in a disinfectant solution combined with proteolytic enzyme if possible - Rinse well the sensor in flowing water 	<ul style="list-style-type: none"> - 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 items
6	Drying	No particular requirements	
7	Maintenance, inspection and testing of the sensor	Visually inspect the sensor to detect possible damage to the sensor coating or to the gold plating of the contacts and the central hole	<ul style="list-style-type: none"> - Sensors with damages or scratches on the coating must be discarded - Sensors with damages to the gold plating of the contacts or of the central hole must be discarded
8	Packaging	Pack the sensor in sterilization pouches	<ul style="list-style-type: none"> - 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	<ul style="list-style-type: none"> - Steam sterilization at 134°C (273.2°F) during 18 minutes in gravity type autoclave. (Table Top, N type) 	<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 validated and provided to the user in this User Manual
10	Storage	Keep sensors in sterilization packaging in a dry and clean environment	<ul style="list-style-type: none"> - Sterility cannot be guaranteed if packaging is open or damaged (check the packaging before using the sensors)

8. Troubleshooting

Please review the suggested solutions before calling customer service.

#	Problem	Possible Cause	Solution
1	The device does not turn on by pressing  button.	<ol style="list-style-type: none">1. Button malfunction2. Flat battery.3. Electronic malfunction.	<ol style="list-style-type: none">1. Press the  button several times.2. Replace the battery.3. Contact your customer service.
2	No sound while measuring.	Audio feedback is disabled.	Turn the device Off and then turn it On. One short beep indicates that audio feedback is enabled.
3	Device cannot indicate the location of the implant.	<ol style="list-style-type: none">1. Sensor is disconnected2. Damage to the Sensor, sensor coating or sensor contacts3. Sensor holder is damaged; Bad contact4. Electronic malfunction.	<ol style="list-style-type: none">1. Turn the device Off, remove the sensor, clean contact surfaces of the sensor and reinsert it. Turn the device On again.2. Replace the Sensor.3. Replace the Sensor holder.4. Contact your customer service.

9. Warranty

Implant Detector is warranted for 24 months from the date of purchase. The accessories (sensor holder and battery) are warranted for 6 months from the date of purchase.

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. The warranty is in lieu of any other warranty expressed or implied.

Sensors are disposable and are not covered by warranty.

10. 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.

11. Certification

Implant Detector complies with IEC 60601-1:2005 (Safety) and IEC 60601-1-2:2007 (Electromagnetic compatibility) standards, including conducted and radiated immunity tests as specified for equipment of Group 1 Class B.

12. European Authorized Representative

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

Obelis s.a

Bd. Général Wahis 53

1030 Brussels, BELGIUM

Tel: +(32) 2.732.59.54

Fax: +(32) 2.732.60.03

E-Mail: mail@obelis.net

13. Technical Specifications

Implant Detector belongs to the following category of medical devices:

- Internally powered equipment
- Type B 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 transportation:
 - Temperature: -20 °C to +60 °C (0 °F to 140 °F)
 - Relative humidity: 10% to 90%, non-condensing

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

Specifications:

Dimensions: 215 x 45, dia. 21 mm
Weight: 60 gr.
Type of display: LED segments
Power source: 1 x 1.5V AA alkaline primary battery

14. Standard symbols

Device marking includes the following standard symbols:



Type B applied part



Manufacturer



Direct current



Consult instructions for use



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

Device label includes the following standard symbol:



Date of manufacture

Manufacturer

Romidan Ltd.

5 Simcha Holzberg St.,

5502213 Kiryat Ono, Israel

Email: export@romidan.com

www.romidan.com

