



ROMET®
GENESIS

**OPERATING
INSTRUCTIONS
MODEL # R600**

Digital Technology



Registered with
the USA FDA
Registration
Number:
3007615474.

EU Rep Name
Europe Cert
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Alsstr.97
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Monchenglad
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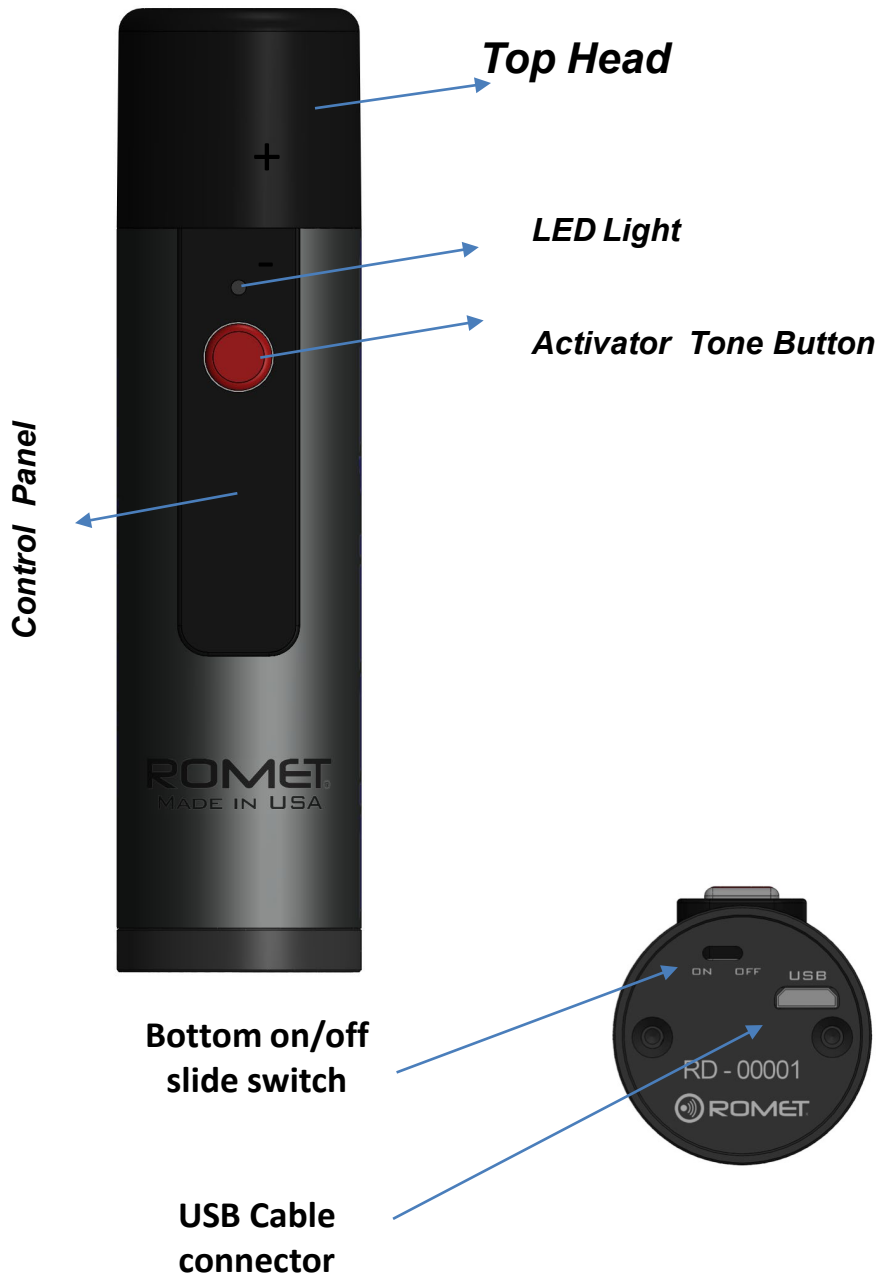
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Key components



OVERVIEWS

What is the Romet Genesis?

The Romet Genesis is a digital electro-larynx device designed and manufactured using the most current digital technologies to assist Laryngectomees to communicate. Romet Genesis is a **CLASS I** medical device.

The General principle of operation for all electro larynxes is manufactured by Fountain Head Marketing Inc. in San Antonio, Texas USA.

That digital electro-larynx produces mechanical vibrations with a low sound frequency between 60-195 Hz. When the top head of the unit is pressed to the neck or side of the face , these vibrations create vibrations in the oral cavity replicating the human voice. The combination of starting and stopping the sound vibrations and oral articulation with use of tongue creates comprehensible human speech.

Box Contents

- Romet Genesis digital electrolarynx device;
- USB charging cable;
- USB International charger 5V 2A; w/ EU Wall adapter
- "Romet" safety lanyard;
- Romet Genesis User manual;
- Romet Genesis **2-year from date of purchase Conditional Warranty card.**

In the presentation box, you will find everything you need to start using the device and begin speaking

GETTING STARTED

Basic use - The battery of this medical device has been partially pre-charged by the battery manufacturer. To Begin speaking, locate the slide switch on the bottom of the device. Slide the switch from **OFF to ON**. After pushing the activator button on the control panel, if the LED lights **Green**, then you will know that the battery is fully charged; if the LED lights **RED**, the battery is **NOT sufficiently charged** and is **LOW**. The device should be charged as soon as possible. Battery Charging instructions see section **11 (a)** within this manual.

After pushing the activator button, you will be able to begin speaking by following instructions which are detailed later in this Manual.

The Digital Genesis Model is economical. The patient is not able to alter either the Volume or the pitch values.

If you wish to have a digital electronic larynx with pitch / volume control, we suggest you try **model R700 Clarity** which enables **full control** of the variables.

Finding the sweet spot

A sweet spot is a place where you feel the vibrations from the electro larynx transmit through your neck tissue and into your oral cavity with the most clarity. The easiest way to find your sweet spot is to tightly press the electro larynx on your neck in different positions and actuate the sound by moving your mouth and using your tongue to articulate word sounds. What you are looking for is the place on your neck that transmits sound the best. While looking for a sweet spot, aim to transmit sound through your neck tissue and out your oral cavity (mouth). Take your time finding your sweet spot. This is the most crucial part of learning how to use an electrolarynx. Finding just the right place will set you up for success. Each patient's sweet spot is in a different location due to degrees of surgery and radiation treatments.

First Words

After you have located your “sweet spot”, you can start making some basic sounds. Focus on single vowels first. Over-articulate every sound with your mouth until you feel comfortable with all the vowels. After that, you can start practicing short words. Slowly work your way up to sentences and conversation.

Expectations

Learning to speak with an electro larynx device is not easy. Think of it as learning to play a musical instrument. It will take time, practice, and patience. In some cases, talking can be achieved in a month, in other cases it can take only 3 days.

BATTERY

Check the battery level when the device is first turned ON. If the battery is sufficiently charged the LED will light **GREEN**. If the battery is **LOW** the LED will light **RED**. While you are speaking the LED will shine the appropriate color depending upon the level the battery is currently charged. Once plugged in, the **Red** LED on the button panel will “breathe” (slowly light up to full brightness then slowly dim until fully off). When the device is fully charged, the LED on the button panel will turn **Solid Green**. The device will charge no matter what position the main power switch is in. Note: The device will not work while charging. This is a safety measure that protects the device from any damage.

Charging the Battery

Charging the device is required when the LED on the panel turns red after the activator button has been pushed (**meaning the battery level is below 100%**). When the activator tone button is pressed or when the device is initially turned on and **red LED flashes** (meaning the battery is **less than 100%**), the battery needs to be charged prior to extensive speaking. Charging is carried out with the charger included in the box. Plug the provided micro-USB cable into the Micro-USB port on the bottom of the device, then plug the opposite end of the cable into the electrical wall socket. Please use care when inserting the USB micro-cable into the receptacle located on the bottom of the unit. Gently insert the micro-USB into the socket to activate the charging function. Do not try to force the micro-USB into the receptacle. **The red LED** on the button panel will then “breathe” (slowly light up to full brightness then slowly dim until fully off). When the device is **fully charged, the LED on the button panel will turn green and stay lit**. Note: The **device will not operate while charging**. This is a safety measure that protects the device from any electrical damage. The device will charge no matter what position the main power switch is in on or off.

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Technical specifications

General:	
Adjustable tone	No
Adjustable volume	No
PCB Design Frequency	140 Hz
Device Output Frequency	1,072 Hz
Standard Volume	67 dB
Speech buttons	1
Setting button	n/a
Speech time	Up to 30 hours
Charging time from 0 to 45%	60 min with Romet charger
Charging time from 0 to 100%	3h 15min with Romet charger
Connector	Micro USB
USB Charging	Battery Charging Specification 1.2
Input power:	5V 1.5A max.

Physical:	
Diameter x Length	Ø 32 x 123 mm
Weight	188 g
Body material	Premium Electroplated Aluminum
Top cap material	ABS plastic
Battery:	
Capacity	3400 mAh
Battery type	3.7V Li-Ion
Battery model	Custom Pack
Li-on Battery Cell manufacturer	LG Chemical
Battery life	More than 3 Years
Protection	Smart electronics

INFORMATION

Warnings

- Do not wash the device under running water **Do not submerge the device underwater**. This will potentially damage the electronics of the device.
- Do not try to disassemble the device under any circumstances. This will permanently void your warranty.
- Do not use any third-party chargers or charging cables. Use the original ones provided in the box. Using any other charging equipment could potentially damage the battery or the device.
- ***Do not insert any part of the electro larynx or any accessories into the stoma.***
- Do not burn or physically damage the battery.
- Do not short-circuit a cell or battery.
- Do not store cells or batteries haphazardly in a pocket, purse, box or drawer where they may short-circuit each other or be short-circuited by conductive materials such as coins or keys.
- The device contains a strong magnet that may interfere with pacemakers or other implantable devices. Consult with your physician before use.
- Please note that due to the nature of the electrolarynxes and the principle of their use, ***the device is not intended to be used by multiple people, shared use, and second-hand use.*** Due to the contact of the device to the user's neck, stoma, or other cavities - the device is **for personal use only!**
- Once a person has used the device, it should not be used by anyone else. Because of this fact, the included warranty provided by Fountain Head Marketing Inc. and . is non-transferable.

13 a Safe storage:

- Store in a dark and dry place.
- Store the device and its accessories in its original box.
- Store in temperatures between -20°C to +45°C.

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Warranty

All Romet devices come with a limited 2-year warranty from the date of purchase. The warranty period of a replacement electro-larynx or parts last as long as the remaining warranty of the original electro-larynx.

This **Limited Warranty** covers any defects in material or workmanship under normal use according to the User Manual during the specified Warranty Period.

Trying to open or repair the device; causing extensive shock damage (dropping it, hitting it against other objects, etc.); or liquid damaging it (submerging in water or other chemicals) will void your warranty.

During the Warranty Period, Romet. will repair or replace, at no charge, products or parts of a product that prove defective because of improper material or workmanship, under normal use and maintenance. **This Limited Warranty is not transferable.**

Conditions, malfunctions or damage not resulting from defects in material or workmanship.

Conditions, malfunctions or damage resulting from negligence, improper maintenance or modification.

Damaged or destroyed by natural causes including but not limited to lightning, flood, or another natural disaster - Theft or loss of the EL.

Shipping charges as well as the risk of loss or damage to the.

Please read the warranty card. To learn more about the Romet warranty, please visit <http://www.romet.us>

If you have any problems with your device, contact your local in-country distributor or contact Fountain Head Marketing Inc. directly info@romet.us

Return Your electrolarynx for repair evaluation to Fountain Heed Marketing Inc. All Postage charges must be paid in full by the sending patient and are not reimbursable. The return shipping postage charges only and no country duty charges for the return of the unit to the patient will paid by Fountain Head Marketing Inc. Only if the repair is covered by our limited warranty. *If the repair is not under warranty* an invoice will be created for the repair needed which will include return postage. All charges must be paid in full prior to repairs being completed

Information on Disposal for Users of WEEE:

This symbol on the product box and/or accompanying documents means that used electrical and electronic equipment (WEEE) should not be mixed with general household waste. For proper treatment, recovery, and recycling, please take this product(s) to designated collection points where it will be accepted free of charge. Alternatively, in some countries, you may be able to return your products to your local retailer upon the purchase of an equivalent new product. Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling. Please contact your local authority for further details of your nearest designated collection point. Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

For professional users in the European Union, if you wish to discard electrical and electronic equipment (EEE), please contact your dealer or supplier for further information.

For disposal in countries outside of the European Union: This symbol is only valid in the European Union (EU). If you wish to discard this product, please contact your local authorities or dealer and ask for the correct method of disposal.

GENESIS

*Elevated Digital
Technology*



Contact Information

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