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Tinearity™ G1

User Manual

ENGLISH

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CE 2862

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The User Manual

The Tinearity™ G1 device is designed to relieve and treat the symptoms of tinnitus. The device can be used at home, at work, and in public environments.

This user manual provides instructions on how to use and maintain your new Tinearity™ G1 device.

Please carefully read this manual to learn how to use the device. Pay attention to all warnings as indicated in this manual. If you have any questions, please contact your country's representative.

Warning symbols used in this manual

⚠ **WARNING** Indicates a potentially hazardous situation which, if not avoided, could result in injury.

⚠ **CAUTION** Indicates a potentially hazardous situation which, if not avoided, could result in damage to environment or properties.

Note Indicating useful information about the safe use of the device.

Contents

1. Introduction

Model REF: 6000, Tinearity™ G1

Name and address to the manufacturer

Circius Pharma AB
Södra Långebergsgatan 34-36
436 32 Askim
Sweden

2. Intended use

Tinearity G1 is a device that generate white noise to relieve and treat patients suffering from tinnitus. The target population is adult population over 18 years of age.

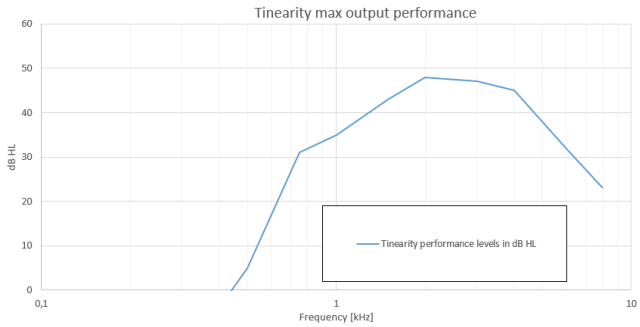
Note The patient is the intended operator of the device.

3. Indications for use

3.1. Intended medical indication

Tinearity G1 is intended to treat and relieve Tinnitus in users with normal hearing or mild hearing loss. Tinearity G1 have a performance output as shown in diagram 1. Users is recommended to get help from an audiologist to establish their audiogram.

Diagram 1. Maximum output performance



The recommended treatment time is 8 hours per day for 6-24 months.

3.2. Contraindications

Users with moderate and severe hearing loss is contraindicated, i.e., hearing threshold level above 40dB HL.
The device is NOT intended for users suffering from moderate and severe hearing loss or hyperacusis.

3.3. Possible side effects

The adapter consists of a plastic holder and medical tape. The tape has an acrylic adhesive that adheres the adapter to the user's skin. Irritation may occur behind the ear when replacing the disposable adapter.

White noise may result in worsening tinnitus symptoms. Bone conducted sound may result in headache, nausea and/or dizziness. If any of this occurs, stop using the device and consult your healthcare professional.

3.4. Useful life / service life

The device and charger have a useful lifespan of 24 months, starting from the delivery date. The expiry date of the adapter is indicated on the label.

3.5. Suitability of the treatment

The treatment can require involvement of healthcare professional, if the healthcare professional require information regarding the suitability of the treatment, further information can be obtained by contacting the manufacturer.

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4. System overview

Your Tinearity™ G1 device is designed to relief and treat tinnitus symptoms by generating white noise that is transmitted to the inner ear via the skull. This method enables treatment without obstructing your ear canal. You can use your Tinearity™ G1 device throughout the day, including during sleep.

⚠ **CAUTION** The sound generator shall never be cleaned or submerged in or under water or other liquids.

4.1. Packaging content

- Tinearity G1 Sound Generator, one pair (2pcs)
- Tinearity G1 Adapters (62pcs)
- Tinearity G1 Charger
- USB cable

☛ **Note** The Power supply for connection of the charger to the wall socket is not included in the packaging, see section technical data.

⚠ **WARNING** The Tinearity G1 device include small parts that may be an asphyxiation risk for small children. Always keep the charger station, the sound generator and the adapter out of reach for children.

⚠ **WARNING** The USB cable is included in the packaging and might pose a risk of choking, keep away from small children.

5. Tinearity G1 description

Figure 1. Device overview.

Tinearity™ G1 comprises three components: (1) the sound generator, (2) adapters and (3) a charger (including a USB cable for connection to a power supply). The sound generator is attached to the skin behind the ear by means of the adapter.

The sound generator works within the frequency span of 700 Hz-10Khz with a maximum output level of 48dB HL. The sound generator is supplied in pairs, with the intention of being used behind both ears.

The adapter consists of a plastic holder compatible with the sound generator and a medical tape which adheres to the skin. The adapter should be disposed daily or after each treatment.

The sound generator uses a rechargeable battery as a power source. Recharge the two sound generators simultaneously by using the charger plate and the separate USB cable for connection to a compatible power supply.

The Tinearity™ G1 sound generator and adapter can be used at any time during the day & night.

⚠ **CAUTION** The sound generator shall never be cleaned or submerged in or under water or other liquids.

6. Device description

6.1. Sound generator

The sound generator converts white noise into vibrations. It is powered by a rechargeable lithium-ion battery.

Figure 2. Sound generator

⚠ **CAUTION** The sound generator contains electrical parts and should be disposed of as electrical waste.

☛ **Note** For explanation of the symbols, see section 17.

6.2. Adapter

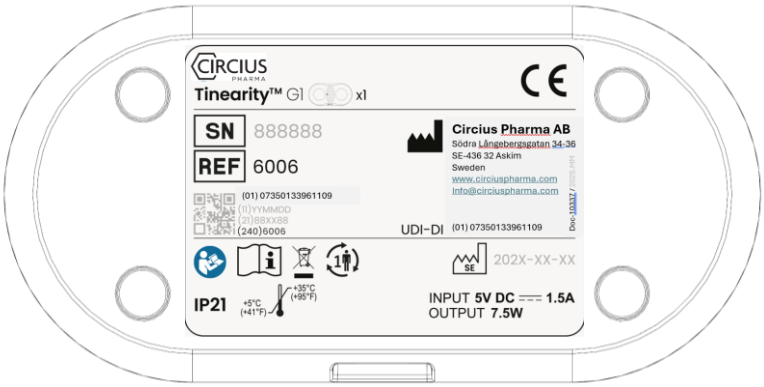
The adapter transmits the vibrations generated by the sound generator to the inner ear through the skull.

Figure 3. Illustration of Adapter.

6.3. Charger

The charger is used for charging the sound generator. Safety information marked on the underside of the charger.

Figure 4. Charger device label



⚠ **WARNING** The connecting cable is included in the packaging and might pose a risk of choking, keep away from small children.

⚠ **CAUTION** The sound generator contain electrical parts and shall be disposed as electrical waste.

6.4. Packaging material

The Tinearity G1 system is delivered in one box. The box includes packages for adapters and sound generators. Each packaging level has its own label as illustrated in figure 5-8 below. The adapters are also distributed separately, in a customer package.

Figure 5. Primary package label Sound Generator.

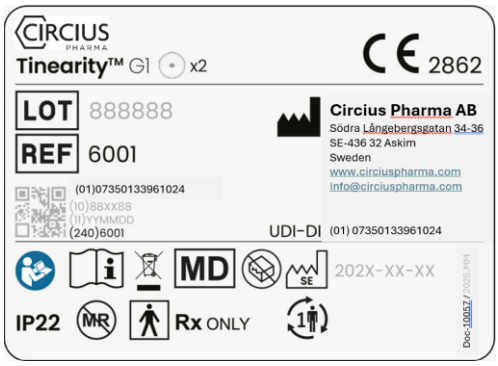


Figure 6. Primary package label Adapter.

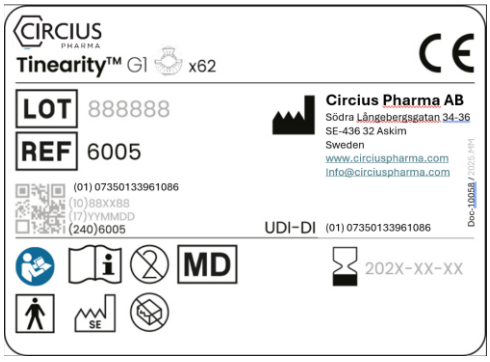


Figure 7. Customer label Tinearity System.

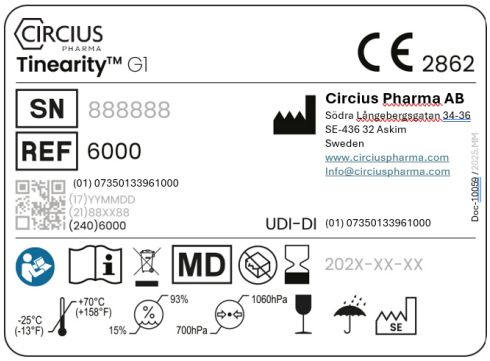
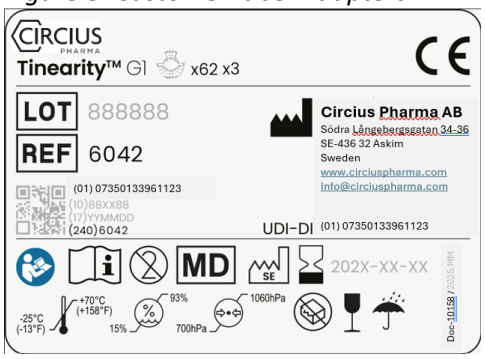


Figure 8. Customer label Adapters



Note for explanation of the symbols see section 17 “Description of symbols used in this user manual”.

7. Preparation before first use

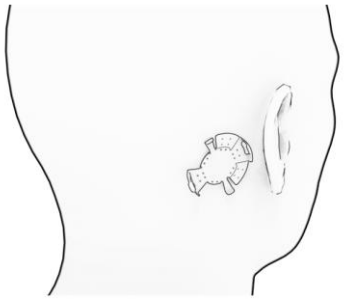
- Unpack the parts and inspect for any signs of damage, then follow the cleaning instructions for the sound generator and charger in sections 10.2 and 10.3.
- Check the safety-related labeling on the Tinearity G1 devices for legibility.
- Make sure that the power supply (not supplied in the package) for connecting the charger into the wall outlet has the following performance:
  - USB-A port, 5V DC, min 1000mA, Max 1500mA
  - Double insulated ⧈
  - CE marked
- Fully charge the sound generators using the supplied charger, see section charging the batteries / sound generator, see section 11.

8. Preparation before every use

8.1. Skin hygiene

The skin behind the ear must be clean, dry and free from hair.
If needed, remove any excess hair to ensure an adequately sized contact area.

Clean the skin with mild soap and let it dry completely before you apply the adapter.
Figure 9.



8.2. Sound generator and Adapter

Visually inspect the sound generator and adapter for any damage, prior to use.

⚠ **WARNING** If covers are damaged or any parts are loose, do not use the device.

Clean the sound generator according to section 10.

8.3. Charger

Place the device on a flat surface.

⚠ **WARNING** Check the cable and connections for pinching or damage. Pets and pests may damage the insulation of the cables. Do not use damaged cables.

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9. Operating instructions user

9.1. Applying the adapter

1) Locate the area for application of the adapter behind the ear. To maximize the performance of your treatment, ensure that the adapter is positioned over the mastoid bone and orientated as illustrated in the figure below. Make sure that the area is free from hair.

Figure 10. Correct application: the soft part is applied closest to the ear.

√

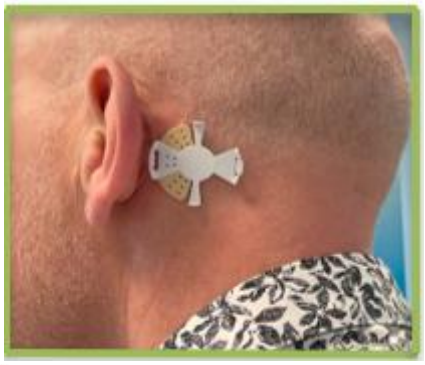


Figure 11. In-correct application; rotate the adapter approx. 90 degrees relative to your skull.

X

👉 **Note** Transfer of sound/noise through Bone conduction is most effective if the adapter is attached to the skin where the tissue thickness is minimized.

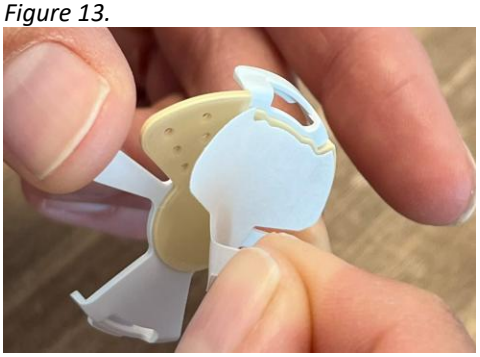
👉 **Note** The curve of the adapter is designed to match the curve behind the ear, therefore ensure the adapter is rotated as shown for a proper fit.

2) Hold the adapter by its wings.

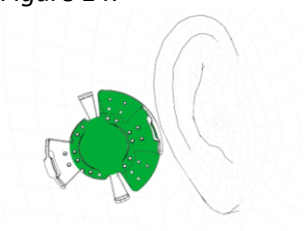
Figure 12.

3) Remove the protective film and do not touch the adhesive surface.

Figure 13.



4) Gently Press on the highlighted surface of the adapter for at least 20 seconds. *Figure 14.*



⚠ **WARNING** Risk for skin damage**.** Only use the adapter provided by Circius Pharma and according to this manual.

9.2. Connecting the Sound generator

To connect the sound generator safely and comfortably to the adapter, tilt it slightly and gently push it into the adapter until it clicks into place.

☛ **Note** The side of the sound generator marked with CE_{2862} shall be towards the adapter.

Figure 15.

Figure 16.

9.3. Turn the Sound generator on and off

Turn your sound generator on and off by pressing the “power” button. A short press turns your sound generator on, and a longer press turns your sound generator off.

Figure 17.

☛ **Note** use a short press to turn your device on, a long press will turn your device off.

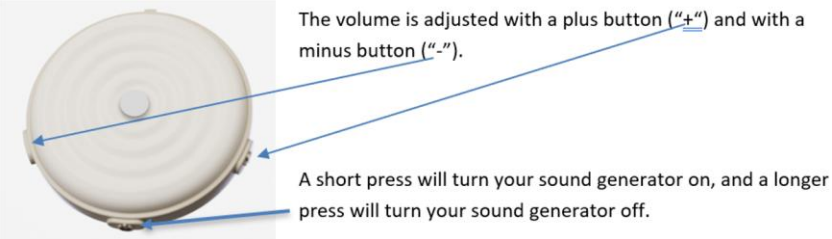
9.4. Adjust the volume

Adjust the volume until you feel a relief from your tinnitus noise.

- Increase the volume by pressing the button marked with “+”.
- Decrease the volume by pressing the button marked with “-“.

Your sound generator is by default started at mid-volume and the volume can be increased by 10 steps and decreased by 10 steps. Each step represents 2 dB HL.

Figure 18.



9.5. Treatment

Your sound generator can be used for instant relief (masking) or as the sound source during management of tinnitus (treatment).

- For masking your tinnitus, adjust the volume until you feel a relief.
- For management of tinnitus, adjust the volume just below your tinnitus sound. Use the device for 6-8h each day.

We recommend you consult a healthcare professional for individual adjustments.

⚠ **WARNING** Risk of hearing damage. If you **perceive discomfort** or if your tinnitus is **getting worse**, immediately **abort** the treatment and consult a healthcare professional**.**

9.6. Remove the Sound generator

Remove the Sound generator by holding it and firmly pressing the wing handle furthest away from the ear on the adapter. The sound generator will then disconnect.

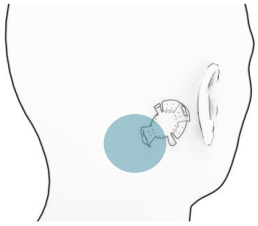
Figure 19.

⚠ **CAUTION** Risk of damage to the device, charge the transducer after each use.

9.7. Remove the adapter

Remove the adapter by slowly peeling it off the skin. The adapter is single-use only and must be disposed of after each use.

Figure 20.



⚠ **WARNING** Risk of skin damage, only use the adapter provided by Circius Pharma and according to this manual.

☛ **Note** Dispose the adapter after each use as plastic waste.

10. Maintenance

Store your Tinearity G1 device in room temperature environment protected from dust, dirt and sunlight. Before each use, clean your device as follows.

☛ **Note** Your sound generator is protected against ingress of water but is not waterproof.

10.1. Preparation for cleaning

- Separate your sound generator from the adapter.
- Make sure your sound generator is turned off.
- Remove the USB cable from the charger.

☛ **Note** the adapter is single use and shall be disposed after each use/treatment, no cleaning is needed.

10.2. Cleaning the Sound generator and the charger

Clean your sound generator and charger at least once every seven days using soft cleaning wipes on the outside. The duration of the cleaning action shall be minimum 1 minute. Make sure to reach all areas. The level of cleaning shall be as minimum equivalent to general personal grooming items. Inspect the sound generator and charger to ensure no visual contamination remains.

⚠ **CAUTION** Your sound generator is protected against ingress of water, i.e., it is designed to be used in your daily life but the sound generator is not waterproof.

⚠ **CAUTION** The sound generator shall never be cleaned or submerged in or under water or other liquids.

⚠ **CAUTION** The charger shall never be cleaned in or under water or other liquids.

11. Charging the batteries / sound generator

11.1. General information

The sound generator is powered by a rechargeable lithium battery with a maximum duration of 12 hours.

11.2. When to re-charge batteries/sound generator

Your sound generator shall be re-charged after each use.

⚠ **WARNING** The sound generator include coin cell batteries that may be corrosive if swallowed. Risk for small children. Always keep the sound generator out of reach for children. If a battery is accidentally swallowed, seek medical attention at the nearest emergency department.

11.3. How to charge the sound generator

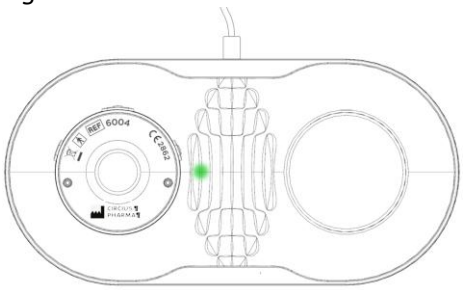
To charge the sound generator, follow below steps:

- Make sure that the Charger is placed in a room that has a temperature of maximum 35°C
- Place your sound generator(s) with the back side (indicated with the CE symbol) towards you, see figure 21.
- The blinking green light indicates that the device is charging.
- Let the sound generator(s) charge until the indicator(s) stops blinking. A complete charge cycle is approximately 6 hours. If the battery is fully discharged or if the ambient

temperature exceeds 30 degC during charging, the charging rate will be reduced, but not completely halted, to prevent battery damage or overheating.

- Your device(s) is/are now fully charged and ready for use.

Figure 21.



Note, Risk of damage to the device, charge the sound generator after each use.

12. Consumables, Service and Repair

If your Tinearity™ G1 device is not functioning properly or if you need to order additional adapters, please contact your distributor.

13. Technical description

13.1. Trouble shooting

Table 1.

Symptom	Explanation	Possible Cause	Proposed action
No white noise is perceived.	The amplitude of the white noise must exceed the hearing threshold of the user.	Hearing impaired.	Increase the amplitude (turn up the volume), see section 9.4.
No white noise is perceived.	The batteries must be charged after each use.	The batteries are discharged.	Charge your sound generator, see section 11.
The sound generator falls of from the adapter.	The adapter is worn.	The adapter is single use.	Change adapter, see section 9.1 and 9.7.

13.2. Technical data

Table 2.

Environmental conditions	**Sound generator**	**Inductive charger**
Ambient air pressure		
Operation	700 hPa to 1060 hPa	
Transport/ storage		
Ambient temperature		
Operation	+5 to +35 C	
Transport and storage	-25 to +70 C	
Ambient humidity		
Operation	RH 15% to 93% , non condensing	
Transport and storage		
Operational altitude	Max 3000 m over see level	
Classification		
Medical device class	EU MDR2017/745 (MDR) Class IIa, US Class II	
Class	II	III
Applied part category	BF	Non
Protection of harmful ingress	IP 22	IP 21
Pollution degree	II	II
Mode of operation	Continous use	Continous use
Isolation from supply mains	N/A	Disconnect AD / DC adapter
Nominal voltage	3,7 VDC	5 VDC
Battery capacity	50 mAh	No battery
Battery type	Rechargeable Li-ion battery.	No battery

Requirement for AC/ DC adapter

Table 3.

Output power voltage	5VDC
Output power	Min. 1000mA, Max 1500mA
IP class	Minimum IP 21
Class	II
Approval	Certified to IEC 62368

14. EMC information

Table 4.

Electromagnetic Emissions The Tinearity system is intended for use in the electromagnetic environment associated with a Professional healthcare facility or a Home healthcare environment as specified below. The customer or the user of the Tinearity system should assure that they are used in such environment.	
Emission Tests	**Compliance**
Radiated and conducted RF emissions EN55011/CISPR 11	Sound Generator: Class B, Group 1 Charger: Class B, Group 2 **Electromagnetic environment - guidance** The Tinearity system uses RF energy only for their internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
Harmonic emissions EN IEC 61000-3-2	**Sound generator:** Not applicable, battery operated device **Charger:** Not applicable, P < 75W
Voltage fluctuations / flicker emissions EN IEC 61000-3-3	**Sound generator:** Not applicable, battery operated device **Charger:** Not applicable, P < 75W

Table 5.

<table>
<tr><td colspan="6">Electromagnetic Immunity
The Tinearity system is intended for use in the electromagnetic environment specified below. The customer or the user of Tinearity system should assure that they are used in such environment.</td></tr>
<tr><td rowspan="2">Immunity Tests</td><td rowspan="2">Basic EMC standard or test method</td><td colspan="4">Immunity test levels</td></tr>
<tr><td colspan="2">Professional healthcare facility environment</td><td colspan="2">Home healthcare environment</td></tr>
<tr><td>Electrostatic Discharge</td><td>EN IEC 61000-4-2</td><td colspan="4">± 8 kV contact
± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air</td></tr>
<tr><td>Radiated RF EM fields</td><td>EN IEC 61000-4-3</td><td colspan="2">3 V/m
80 MHz - 2.7 GHz
80 % AM at 1 kHz</td><td colspan="2">10 V/m
80 MHz - 2.7 GHz
80 % AM at 1 kHz</td></tr>
<tr><td rowspan="5">Proximity fields from RF wireless communications equipment</td><td rowspan="5">EN IEC 61000-4-3</td><td>Test frequency (MHz)</td><td colspan="2">Service</td><td>Immunity Test Level (V/m)</td></tr>
<tr><td>385</td><td colspan="2">TETRA 400</td><td>27</td></tr>
<tr><td>450</td><td colspan="2">GMRS460, FRS460</td><td>28</td></tr>
<tr><td>710
745
780</td><td colspan="2">LTE Band 13, 17</td><td>9</td></tr>
<tr><td>810
870
930</td><td colspan="2">GSM 800/900, TETRA800, iDEN 820, CDMA 850, LTE Band 5</td><td>28</td></tr>
<tr><td>1720
1845
1970</td><td colspan="2">GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS</td><td>28</td></tr>
</table>

		2450	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	28
		5240 5500 5785	WLAN 801.11 a/n	9
Surges	EN IEC 61000-4-5	**Sound generator:** Not applicable, battery operated device **Charger:** Tested through generic AC/DC adapter Line-to-line: ±0.5 kV, ±1 kV		
Conducted disturbances	EN IEC 61000-4-6	**Sound generator:** Not applicable, battery operated device **Charger:** Tested through generic AC/DC adapter		
		3 V/m 0,15 MHz – 80 MHz 6 V/m in ISM bands 80 % AM at 1 kHz	3 V/m 0,15 MHz – 80 MHz 6 V/m in ISM and amateur radio bands 80 % AM at 1 kHz	
Rated power frequency magnetic fields	EN IEC 61000-4-8	30 A/m 50 Hz		
Voltage dips	EN IEC 61000-4-11	**Sound generator:** Not applicable, battery-operated device **Charger:** Tested through generic AC/DC adapter 0% UT, 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% UT, 1 cycle at 0° 70% UT, 25 cycles at 0°		
Voltage interruptions	EN IEC 61000-4-11	**Sound generator:** Not applicable, battery-operated device **Charger** 0% UT, 250 cycles at 0°		

15. Manufacturer's warranty

Tinearity sound generators and inductive chargers are covered by a limited warranty issued by the manufacturer. The warranty period is 24 months from the date of delivery. This limited warranty covers manufacturing and material defects in the sound generator or charger itself.
Problems arising from improper handling or care, excessive use, accidents, repairs or exposure to corrosive conditions, are NOT covered by the limited warranty and may void the warranty.
The above warranty does not affect any legal rights that you might have under applicable national legislation governing the sale of consumer goods.

16. Important information

16.1. Warnings

⚠ **WARNING** Risk of hearing damage. If you **perceive discomfort** or if your tinnitus is **getting worse**, immediately **abort** the treatment and consult a healthcare professional**.**

⚠ **WARNING** Risk of electric chock. Your Sound generator has achieved IP 22 classification and is referred as water-resistant, not water-proof. Always remove your Sound generator before showering or bathing.

⚠ **WARNING** Risk of electric chock. Use cables, chargers, adapters and sound generators provided by the manufacturer, ONLY.

⚠ **WARNING** Risk of body damage. Never expose your Tinearity G1 device for extreme heat, do not dry the device in microwave or other ovens.

⚠ **WARNING** Risk of electric chock or burns,
Do not open the device
Do not use device if the enclosure or cable is damaged
Do not service or repair the device
No modification of this equipment is allowed
Only use power supply that fulfills the specification in this instruction

⚠ **WARNING** Risk of infection. This device is to be used by one user and shall not be reused by several individuals

⚠ **WARNING** Risk of fire and hazardous smoke. Do not use in an Oxygen rich environment or in areas with flammable gases.

⚠ **WARNING** Risk of affecting measurement results and treatment results. This device emits electromagnetic radiation, do not use closer than 30 cm from other medical devices.

⚠ **WARNING** Risk of hearing damage. Patient suffering from Hyperacusis (sound over sensitive) or other underlaying illnesses shall consult physician before treatment is started.

⚠ **WARNING** Risk of burn injury. Do not use during MRI (Magnetic Resonance Imaging) examination.

⚠ **WARNING** Risk for damage to your skin (irritation or redness from the use of the adapter). It is important to follow the skin hygiene guidelines. Please contact your local general practitioner if you have any concerns. Only use the adapter provided by Circius Pharma and according to this manual.

⚠ **WARNING** Risk for hearing damage. The Device is not to be used by persons under the age of 18 years old.

⚠ **WARNING** The Tinearity G1 device include small parts that may be an asphyxiation risk for small children. Always keep the charger, the sound generator and the adapter out of reach for children.

⚠ **WARNING** Check the cable and connections for pinching or damage. Pets and pests may damage the insulation of the cables. Do not use damaged cables.

⚠ **WARNING** The sound generator include coin cell batteries that may be corrosive if swallowed. Risk for small children. Always keep the sound generator out of reach for children. If a battery is accidentally swallowed, seek medical attention at the nearest emergency department.

⚠ **WARNING** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ **WARNING** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- ⚠ **WARNING** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the [ME EQUIPMENT or ME SYSTEM], including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- ⚠ **WARNING** Risk for hearing damage. If the Tinearity G1 device is combined with a hearing aid, the combination needs to be evaluated by a health care professional.
- ⚠ **WARNING** This device is MR unsafe. It must not be brought into an MR environment.
- ⚠ **WARNING** The sound generator contains a magnet. Caution must be taken with programmable VP/CSF shunts and active implants. Please keep the sound generator at least 10cm away from an active implant or a VP/CSF shunt, e.g., do not carry it in a breast pocket.

16.2. Caution

- ⚠ **CAUTION** The power source in your sound generator has insufficient energy to cause fire under normal conditions of use. The sound generator has not been tested for compliance with international standards concerning explosive atmospheres. It is recommended not to use your sound generator in areas with danger of explosion.
- ⚠ **CAUTION** No part of the device shall be cleaned in or under water or other liquids.
- ⚠ **CAUTION** The sound generator and the charging station contain electrical parts and shall be disposed as electrical waste.

16.3. Contacts

For assistance, if needed, in setting up, using or maintaining the Tinearity system; or to report unexpected operation or events, please find contact information, depending on your location, at www.CirciusPharma.com

If any serious incident has occurred in relation to the device it shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

17. Description of symbols used in this user manual.

Table 6.

Symbol	Title	Description
	CE mark	The device complies with all required EU regulations and directives. The four digit number indicates the identification of the notified body
	Manufacturer	The device is produced by the manufacturer whose name and address are stated next to the symbol.
	Use-by-date	Indicate the date after which the device is not to be used.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Country of manufacturer	Identifies the country of manufacture of products.
	Do not use if package is damage and consult instructions for use	Indicates that the device should not be used if the package has been damaged or opened and that the user should consult the instructions for use (user manual) for additional information.
	Fragile, handle with care	Indicates a device that can be broken or damaged if not handled carefully.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Temperature limitation	Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation	Indicates the Humidity limits to which the medical device can be safely exposed.
	Atmospheric pressure limitation	Indicates the Atmospheric pressure limits to which the medical device can be safely exposed.
	Do not re-use / Single use	Indicates a device that is intended for one single use only.

	Single patient use	Indicates a device that is intended for one patient only.
	Consult instructions for use or consult electronic instructions for use	Consult instructions for use for warnings and cautions.
	IFU	Consult instructions for use for warnings and cautions.
	Medical Device	The device is a medical device.
	Electronic waste (Weee)	Waste from electronic equipment must be handled according to local regulations.
	Type BF Applied Part	Classification of protection against electrical shock.
IP 21	IP 21	Indicates the class of protections against harmful ingress of water and objects. IP21 indicates protected from touch by fingers and objects greater than 12 millimeters and vertically falling drops.
IP 22	IP 22	Indicates the class of protections against harmful ingress of water. IP 22 protects from dripping water, from vertical direction.
	MR Unsafe	The device is not safe in MR environment, i.e., magnetic resonance imaging (magnet camera, MR-camera), and shall be removed.
Rx ONLY	Prescription device	The device is sold with prescription. Applicable for the US market.
	Distributor	Company distributing the medical device on behalf of legal manufacturer.

Name and address to the manufacturer

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