FRONT PAGE

Tinearity™ G1

User Manual

Model REF: 6103, Tinearity™ G1

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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.

Note The patient is the intended operator of the device.

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 the Tinearity™ G1 device and the nearby surroundings.

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

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1 INDICATIONS FOR USE

1.1 Indication for use

Tinearity G1 is intended to generate noise of sufficient intensity and bandwidth to mask ringing in the ears or internal head noise to provide relief for patients with normal hearing in the home healthcare environment. The device is for prescription use only. The target population is adult population over 18 years of age.

Tinearity G1 is applied on intact skin at the mastoid bone and transfers sound through bone conduction to the cochlea. Hearing health care professional shall be consulted for diagnosis, fitting of devices, and follow-up care.

1.2 Contraindications

The device is NOT intended for users suffering from hearing loss or hyperacusis.

1.3 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.

1.4 Useful life / service life

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

2 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 must never be cleaned or immersed underwater or in other liquids.

2.1 Packaging content

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

Note A power supply to connect the charger to a wall outlet is not included, see section 12.

⚠ **WARNING** The Tinearity™ G1 device contains small parts that may pose a choking hazard to small children. Always keep the charger station, the sound generator, and the adapter out of reach of children.

⚠ **WARNING** The USB cable included in the packaging may pose a choking hazard and should be kept away from children.

3 TINEARITY™ G1 DESCRIPTION

Figure 1. Device overview.

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

The sound generator works within the frequency of 700 Hz-10kHz with a maximum output level of 48 dB 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 grade 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 must never be cleaned or immersed underwater or in other liquids.

4 DEVICE DESCRIPTION

4.1 Sound generator

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

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

☛ **Note** For explanation of the symbols, see section 15.

Figure 2. Sound generator

4.2 Adapter

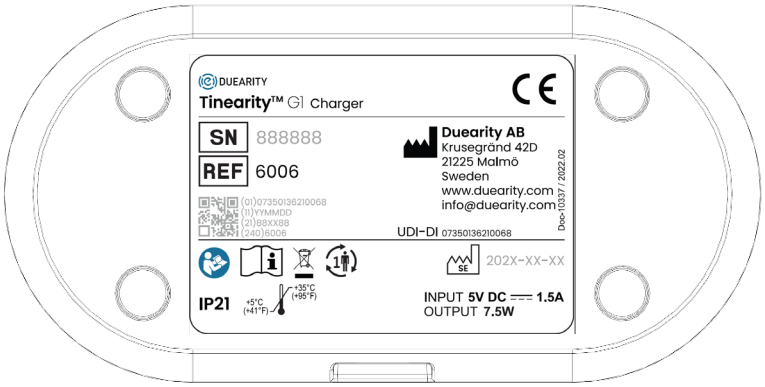
The adapter transmits the vibrations generated by the sound generator to the inner ear through the skull.

Figure 3. Illustration of Adapter.

4.3 Charger

The charger is used to charge the sound generators. Safety information is 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 contains electrical parts and shall be disposed of as electrical waste.

4.4 Packaging labels

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.

Figure 5. Example of Primary package label Sound Generator.

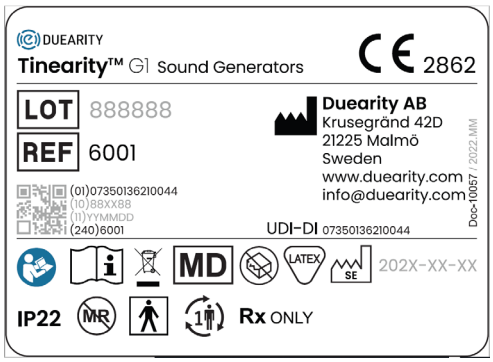


Figure 6. Example of Primary package label Adapter.

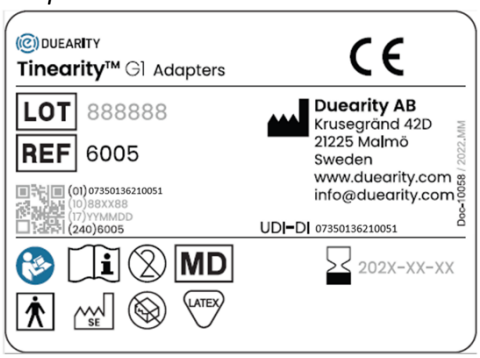


Figure 7. Example of Customer label Tinearity™ G1 System.

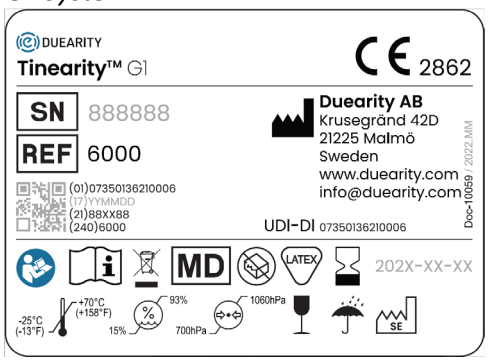
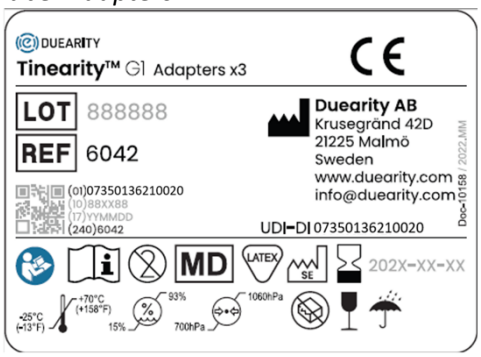


Figure 8. Example of Customer package label Adapters



Note for explanation of the symbols see section 15.

5 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 8.
- Check the safety-related labeling on the Tinearity™ G1 device for legibility.
- Make sure that the power supply (not provided in the package) connecting the charger to the wall outlet has the following performance:
    - USB-A port, 5V DC, min 1000mA, Max 1500mA
    - Double insulated
- Fully charge the sound generators using the supplied charger, see section 9.

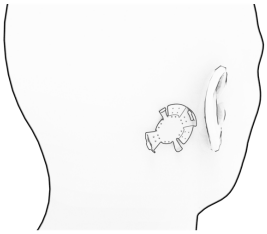
6 PREPARATION BEFORE EVERY USE

6.1 Skin hygiene

The skin behind the ear must be clean, dry, intact, 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.



6.2 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 8.

6.3 Charger

Place the device on a flat surface.

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

7 OPERATING INSTRUCTIONS USER

7.1 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.

√

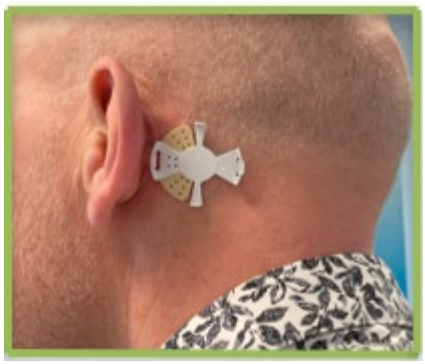


Figure 11. In-correct application; rotate the adapter approx. 90 degrees relative to your skull. X

Note Transmitting sound via bone conduction is most effective if the adapter is attached to the thinnest part of the skin.

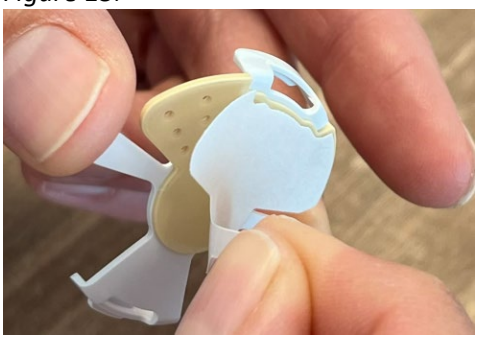
Note The curve of the adapter is designed to match the curve behind the ear, therefore ensure the adapter is rotated as shown for a proper fit.

2) Hold the adapter by its 'wings.'

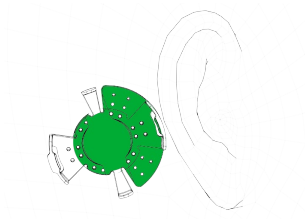
Figure 12.

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

Figure 13.



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



⚠ **WARNING** Risk of skin damage**.** Only use the adapter provided by Duearity and according to this manual.

7.2 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.

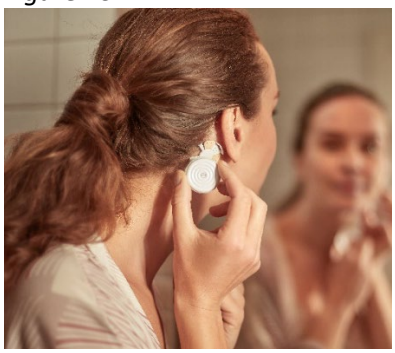


Figure 16.

7.3 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.

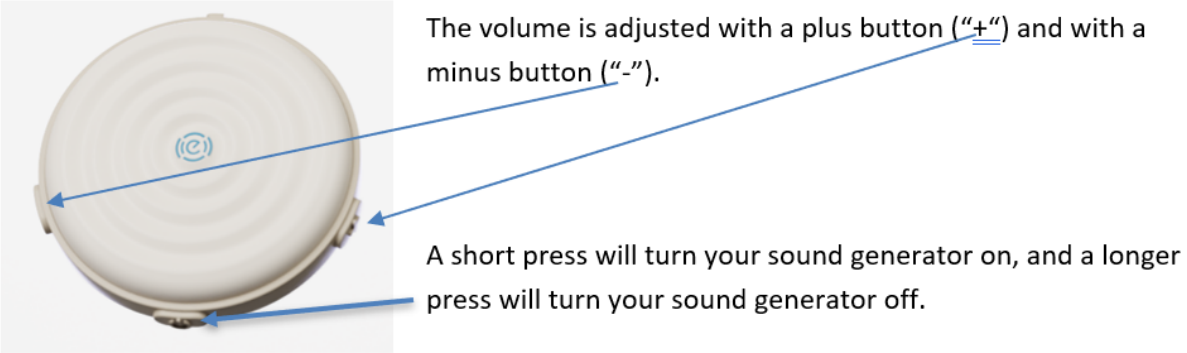
Figure 17.

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

7.4 Adjust the volume

Adjust the volume according to the prescription from your healthcare professional. 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.



7.5 Treatment

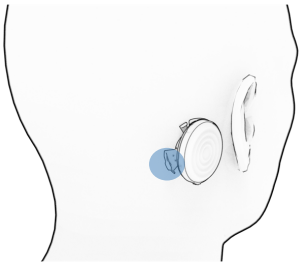
Follow the recommendations of your healthcare professional.

⚠ **WARNING** Risk of hearing damage. If you experience **discomfort** or if your tinnitus worsens, stop treatment immediately and contact a healthcare professional**.**

7.6 Remove the sound generator

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

Figure 19.



⚠ **CAUTION** To avoid damage to the device, charge the device after each use.

7.7 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.

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

☛ **Note** Dispose the adapter after each use.

8 MAINTENANCE

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

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

8.1 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.

8.2 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 should never be cleaned or submerged underwater or in any other liquids.
⚠ **CAUTION** The charger should never be cleaned underwater or in any other liquids.

9 CHARGING THE BATTERIES / SOUND GENERATOR

9.1 General information

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

9.2 When to re-charge batteries/sound generator

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

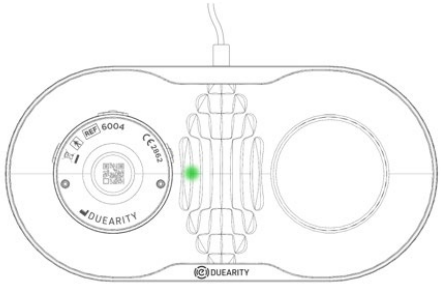
⚠ **WARNING** The sound generator includes coin cell batteries that may be corrosive if swallowed. Risk for small children. Always keep the sound generator out of reach for children. If a battery is accidentally swallowed, seek medical attention at the nearest emergency department.

9.3 How to charge the sound generator

To charge the sound generator, follow the following steps:

- Make sure that the Charger is placed in a room that has a temperature of maximum 95°F (35°C).
- Place your sound generator(s) with the front side (indicated with the Duearity symbol) facing the inductive charger, see figure 20.
- 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 completely discharged or if the ambient temperature exceeds 86°F (30°C) 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 20.



Note To avoid damage to the device, charge the sound generator after each use.

10 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.

11 TROUBLE SHOOTING

Table 1.

Symptom	Explanation	Possible Cause	Proposed action
No white noise is heard.	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 7.*4.*
No white noise is heard.	The batteries must be charged after each use.	The batteries are discharged.	Charge your sound generator, see section 9.
The sound generator falls off from the adapter.	The adapter is worn out.	The adapter is single use.	Change adapter, see section 7.*1 and 7.7.*

12 TECHNICAL AND REGULATORY INFORMATION

12.1 Technical data and regulatory information

Table 2.

Environmental conditions	Sound generator	Inductive charger
Ambient air pressure		
Operation	700 hPa to 1060 hPa	
Transport/ storage		
Ambient temperature		
Operation	+41 to +95 F	
Transport and storage	-13 to +158 F	
Ambient humidity		
Operation	RH 15% to 93%, non-condensing	
Transport and storage		
Operational altitude	Max 3000 m over sea level	
Classification		
Medical device class	EU MDR2017/745 (MDR) Class IIa, US Class II	
Applied standard	IEC 60601-1:2005+A1	IEC 62368-1:2014
Class	II	III

Environmental conditions	Sound generator	Inductive charger
Applied part category	BF	N/A
Protection of harmful ingress	IP 22	IP 21
Pollution degree	II	II
Mode of operation	Continuous use	Continuous use
Essential performance	No	No
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

12.2 Requirement for ac/ dc adapter

Table 3.

Output power voltage	5VDC
Output power	Min. 1000mA, Max 1500mA
IP class	Minimum IP 21 (NEMA 3)
Class	II (NEMA 1-15P)
Approval	Certified to IEC 62368

12.3EMC INFORMATION AND REGULATORY CLASSIFICATION

Table 4.

Electromagnetic Emissions The Tinearity™ G1 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™ G1 system should ensure that they are used in such an environment.	
Emission Tests	**Compliance**
Radiated and conducted RF emissions EN 55011/CISPR 11 FCC 47 CFR, Part 15 Subpart B FCC 47 CFR, Part 18 Subpart C	Sound Generator: Class B, Group 1 Charger: Class B, Group 2 **Electromagnetic environment - guidance** The Tinearity™ G1 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="5">Electromagnetic Immunity
The Tinearity™ G1 device is intended for use in the electromagnetic environment specified below. The user should ensure that the device is used in such an environment.</td></tr>
<tr><td rowspan="2">Immunity Tests</td><td rowspan="2">Basic EMC standard or test method</td><td colspan="3">Immunity test levels</td></tr>
<tr><td colspan="2">Professional healthcare facility environment</td><td>Home healthcare environment</td></tr>
<tr><td>Electrostatic Discharge</td><td>EN IEC 61000-4-2</td><td colspan="3">± 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>10 V/m
80 MHz - 2.7 GHz
80 % AM at 1 kHz</td></tr>
<tr><td rowspan="8">Proximity fields from RF wireless communications equipment</td><td rowspan="8">EN IEC 61000-4-3</td><td>Test frequency (MHz)</td><td>Service</td><td>Immunity Test Level (V/m)</td></tr>
<tr><td>385</td><td>TETRA 400</td><td>27</td></tr>
<tr><td>450</td><td>GMRS460, FRS460</td><td>28</td></tr>
<tr><td>710
745
780</td><td>LTE Band 13, 17</td><td>9</td></tr>
<tr><td>810
870
930</td><td>GSM 800/900, TETRA800, iDEN 820, CDMA 850, LTE Band 5</td><td>28</td></tr>
<tr><td>1720
1845
1970</td><td>GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS</td><td>28</td></tr>
<tr><td>2450</td><td>Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7</td><td>28</td></tr>
<tr><td>5240
5500
5785</td><td>WLAN 801.11 a/n</td><td>9</td></tr>
<tr><td>Electrical Fast Transient/Burst</td><td>EN IEC 61000-4-4</td><td colspan="3">±2 kV for power supply lines</td></tr>
<tr><td>Surges</td><td>EN IEC 61000-4-5</td><td colspan="3">Sound generator: Not applicable, battery-operated device
Charger: Tested through generic AC/DC adapter
Line-to-line: ±0.5 kV, ±1 kV</td></tr>
</table>

<table>
<tr><th rowspan="2">Immunity Tests</th><th rowspan="2">Basic EMC standard or test method</th><th colspan="3">Immunity test levels</th></tr>
<tr><th>Professional healthcare facility environment</th><th colspan="2">Home healthcare environment</th></tr>
<tr><td>Conducted disturbances</td><td>EN IEC 61000-4-6</td><td colspan="3">Sound generator: Not applicable, battery-operated device
Charger: Tested through generic AC/DC adapter</td></tr>
<tr><td></td><td></td><td>3 V/m
0,15 MHz – 80 MHz
6 V/m in ISM bands

80 % AM at 1 kHz</td><td colspan="2">3 V/m
0,15 MHz – 80 MHz
6 V/m in ISM and amateur radio bands
80 % AM at 1 kHz</td></tr>
<tr><td>Rated power frequency magnetic fields</td><td>EN IEC 61000-4-8</td><td colspan="3">30 A/m
50 Hz</td></tr>
<tr><td>Voltage dips</td><td>EN IEC 61000-4-11</td><td colspan="3">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°</td></tr>
<tr><td>Voltage interruptions</td><td>EN IEC 61000-4-11</td><td colspan="3">Sound generator: Not applicable, battery-operated device
Charger 0% UT, 250 cycles at 0°</td></tr>
<tr><td rowspan="4">Proximity Magnetic Fields</td><td rowspan="4">EN IEC 61000-4-39</td><td>Test Frequency</td><td>Modulation</td><td>Immunity Test Level (A/m)</td></tr>
<tr><td>30 kHz</td><td>CW</td><td>8</td></tr>
<tr><td>134,2 kHz</td><td>PM 2,1 kHz</td><td>65</td></tr>
<tr><td>13,56 MHz</td><td>PM 50 kHz</td><td>7,5</td></tr>
</table>

CW = Continuous Wave (non-modulated), PM = Pulse Modulated

13 MANUFACTURER'S WARRANTY

Duearity sound generators and chargers are covered by a limited warranty issued by the manufacturer. The warranty period is 24 months from the date of manufacture. This limited warranty covers manufacturing and material defects in the sound generator or charger itself.

Duearity intends that this device should be used only according to these instructions for use and as directed by a physician with knowledge of the device. 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.

Duearity shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from off-label use of this device. Duearity neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these devices. Federal law in the USA restricts this device to sale by or on the order of a physician.

14 IMPORTANT INFORMATION

14.1 Warnings

⚠ **WARNING** Risk of hearing damage. If you experience **discomfort** or your tinnitus worsens, stop treatment immediately and contact a healthcare professional**.**

⚠ **WARNING** Risk of electric shock. The sound generator has IP22 classification and is water resistant but not waterproof. Always remove your Sound generator before showering or bathing.

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

⚠ **WARNING** Risk of bodily injury. Never expose your Tinearity™ G1 device to extreme heat, do not dry the device in microwave ovens or other ovens.

⚠ **WARNING** Risk of electric shock or burns.
Do not open the device.
Do not use the device if the casing or cable is damaged.
Do not service or repair the device.
No modification of this equipment is permitted.
Use only power supplies as specified in this instruction.

⚠ **WARNING** Risk of infection. This device must be used by one user and should not be shared between multiple individuals.

⚠ **WARNING** Risk of fire and hazardous smoke. Do not use the device 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. Patients suffering from hyperacusis (increased sensitivity to sound) or other underlying illnesses should consult a doctor before starting treatment.

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

⚠ **WARNING** Risk of 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 doctor if you have any concerns. Only use the adapter provided by Duearity and according to this manual.

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

⚠ **WARNING** The Tinearity™ G1 device contains small parts that may pose a choking hazard to small children. Always keep the charger, the sound generator, and the adapter out of reach of children.

⚠ **WARNING** Check that the cable and connections are not pinched or damaged. Pets and pests may damage the cables' insulation. Do not use damaged cables.

⚠ **WARNING** The sound generator includes button cell batteries that may be corrosive if swallowed and pose a choking risk to small children. Always keep the sound generator out of reach of children. If a battery is accidentally swallowed, seek medical attention at the nearest emergency department.

⚠ **WARNING** The device should not be stacked on top of itself or placed near other equipment. If such use is necessary, the device and the other equipment should be observed to verify that they are operating normally.

⚠ **WARNING** Use of accessories and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or degraded performance 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 of 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.

14.2Caution

⚠ **CAUTION** The power source in your sound generator has insufficient energy to cause fire under normal conditions. The sound generator has not been tested for compliance within explosive atmospheres. It is recommended to avoid using your sound generator in areas with danger of explosion.

⚠ **CAUTION** No part of the device should be cleaned under water or in other liquids.

⚠ **CAUTION** The sound generator and the charging station contain electrical parts and should be disposed of as electrical waste.

14.3 Contacts

For assistance setting up, using, or maintaining the Tinearity™ G1 system; or to report unexpected functionality, please find contact information on the back cover of this manual.

All product complaints relating to safety, efficacy, or performance of the device shall be reported immediately to Duearity Americas Inc. by telephone, e-mail, or letter, per contact information below. All complaints shall be accompanied by the product name, model/part number (as applicable), and lot number (as applicable). The person formulating the complaint shall provide their name, address, and as many details as possible. You may contact Duearity directly according to contact details available on the back cover of this manual.

15 DESCRIPTION OF SYMBOLS USED IN THIS USER MANUAL.

Table 6.

Symbol	Title	Description
CE 2862	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 shown next to the symbol.
	Use-by-date	Indicates the date after which the device is not to be used.
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
SN	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 damaged 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 part that is intended for 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 (Instructions for use)	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	Protected from touch by fingers and objects greater than 12 millimeters, as well as from condensation.
IP 22	IP 22	Protected from touch by fingers and objects greater than 12 millimeters, as well as from water spray less than 15 degrees from vertical.
	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 by prescription. Applicable for the US market.

BACK COVER PAGE

TINEARITY™ G1 User Manual – US
Model REF: 6103, Tinearity™ G1

Name and address of the manufacturer

Duearity AB
Krusegränd 42 D
212 25 Malmö
Sweden

Name and address of the US representatives

Duearity Americas, Inc
1801 West Belle Plaine Ave, Suite 205
Chicago, IL 60613
USA

Manufactured by Tepcomp Oy for Duearity AB

Tepcomp Oy
Kaurakatu 46
20740 Åbo
Finland

www.duearity.com