

For professional use. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

#### USER QUALIFICATION

The handheld ThermoGlide must be used by a physician or by medical personnel under the supervision of a physician. The user must have received sufficient training in clinical procedures. *Medical* does not discuss or provide an explanation of clinical procedures.

CAUTION: Read all warnings and cautions provided in these instructions before using the ThermoGlide device.

#### DESCRIPTION

The handheld ThermoGlide device is used to treat human tissue lesions. It is a type B thermal coagulator which is a compact, portable, battery-powered device which can be used in hospital and non-hospital professional healthcare locations.

The ThermoGlide, which is reusable and provided non-sterile, is designed to perform low-power destruction of human cervical or other tissue with high temperatures by tissue contact with an electrically heated probe tip.

#### **Heated Probe Tip**

The ThermoGlide probe tip contains a heating element which is heated to approximately 100°C (212°F) for the destruction of human tissue. The probe tip should only be applied to tissue that is intended to be ablated and care should be taken to avoid touching any other tissue with the heated probe tip.

The ThermoGlide probe shaft is not intended to deliver heat. The probe shaft has a maximum temperature of 43°C (109°F). Contact with the probe shaft should be avoided during the procedure.

#### INDICATIONS

The ThermoGlide is intended for the destruction of human tissue with high temperatures by tissue contact with an electrically heated probe.



Figure 1: The ThermoGlide device design.

## HOW SUPPLIED

The following components are included with the ThermoGlide device, see Figure 1:

- ThermoGlide Device
- Two Probes: 19mm flat, 19mm nipple, or 16mm flat (preference *specified at time of order*)
- Two Removable Lithium-Ion Battery Packs
- Instructions for Use
- Charging Base with A/C adapter and Universal Plugs
- Hard Case

No other accessories are compatible with the ThermoGlide device.



**Figure 2:** The ThermoGlide is battery operated and is designed to be portable.

#### CONTRAINDICATIONS

The user should be familiar with the use of electrical surgical instruments and should take precautions accordingly.

#### WARNINGS AND PRECAUTIONS:

- Proper surgical procedures and techniques are the responsibility of the medical professional. Each practitioner must determine the appropriate use of this device for each patient based on medical training, experience, the type of procedure employed, and the benefits and risks associated with device use.
- Always have spare ThermoGlide probes available in order to replace the equipment in case of a malfunction or break.
- Dispose of expired ThermoGlide handles and probes according to national and local regulations and guidelines for electrical medical equipment.
- Temperatures at the probe's distal tip may be hot enough to damage tissue.
- Do not use excessive force or in a manner not consistent with normal instrumentation use.
- Although the ThermoGlide complies with IEC 60601-1-2:2007 standard for electromagnetic compliance (EMC) for the home healthcare environment, the device may emit electromagnetic radiation that may affect the performance of other electrically powered equipment, or the performance of the device may be affected by electromagnetic radiation from other electrically powered equipment in the vicinity.
- The ThermoGlide batteries should only be connected to the provided recharging base.
- In some circumstances, potential exists for alternate site burns at points of skin contact (e.g. between the legs or on the external labia and inner vagina).
- To avoid burn, always remove the probe from the handle prior to cleaning.
- The ThermoGlide device and accessories have not been tested for magnetic resonance imaging (MRI) safety. Avoid use near MRI equipment.
- The ThermoGlide device contains a lithium-ion battery pack. Please observe the following practices:
  - Do not place the device on or near fires, heaters, other high temperature locations, or apply heat directly to the unit or battery pack.
  - Do not pierce the unit or battery pack with any sharp objects, strike the unit or battery pack with a hammer, tools, or heavy objects, step on the unit or battery pack or otherwise damage the unit or battery pack.
  - Do not subject the unit to strong impacts or shocks.
  - Do not expose the unit or battery to water or any other types of liquid or allow the battery to get wet.

 Do not leave the unit or battery in direct sunlight and avoid storing in vehicles in extremely hot weather.
 Doing so may cause the battery to generate heat, rupture, or ignite. Using the battery in this manner may result in a loss of performance and short battery life.

#### SERVICE AND MAINTENANCE

There are no serviceable parts. If any failure has developed, contact the manufacturer to purchase a replacement part or system. No modifications of this equipment are allowed.

The ThermoGlide handle, charging base, and power supply are reusable and should be routinely cleaned with a clean damp cloth or with an anti-microbial wipe.

WARNING: Do not submerge the ThermoGlide handle, battery charger, or battery in fluid of any type. It may short the electronics and cause an electrical shock to the user.

#### **REQUIRED EQUIPMENT**

Before using the ThermoGlide, the following equipment should be accessible:

- Battery Pre-charged, full charge is recommended but not required.
- ThermoGlide Device Probes (Sterilized or High-Level Disinfection)

#### HANDLING AND PREPARATION

#### Inspection Before Each Use

Before each use, perform the following:

#### General Inspection:

- Inspect for visible damage of the ThermoGlide handle, battery, and probes and all its connections.
- Make sure that no parts are missing or loose.
- Make sure that connecting elements between instruments function properly.
- Verify that the ThermoGlide and accessories are in good working order by following the "Activating the Unit" steps outlined in the following section.

# WARNING: Examine all accessories and connections to the ThermoGlide before use. Ensure that the accessories function as intended. Improper connection may result in accessory malfunction.

• If the battery is not already installed, insert a charged battery into the handle of the unit. The battery can only be inserted

in a single orientation. Push the battery into place until the locking tabs snap; these tabs lock the battery into the handle.

**NOTE:** The battery is removed by compressing the two locking tabs on the sides near the battery base releasing the lock and, while firmly holding the unit head, pulling the battery down and out of the handle.

#### DIRECTIONS FOR USE

Read all instructions before use.



Figure 3: Activation Button and Indicator Lights

Activation (ON/OFF) Button: Press once to turn unit on. The activation button will illuminate green and one of the blue lights flashes to indicate unit is turned on. White illumination LED's on front of unit will also turn on.

Press a second time to begin treatment cycle. Probe tip will heat and timer lights will indicate progress of treatment cycle. The unit will shut itself off after the treatment cycle completes.

Press a third time to shut unit off if needed.

# **NOTE:** There is no need to continuously depress the activation button.

**Timer Lights:** When the activation button is pressed a second time, the lights will all illuminate blue. After each ¼ of the treatment cycle is completed one light will turn off. An audio sound is also given to indicate cycle count down. When all timer lights are turned off the treatment cycle is complete and the unit shuts itself off.

**Low Battery Indicator:** When the battery reaches its low threshold, this indicator will illuminate. Replace the battery with a fully charged battery after completing the current procedure.

Activating the Unit



Figure 4: Insertion of the treatment probe to the mating connector

**Step 1:** Insert the desired treatment probe (19mm flat, 19mm nipple, or 16mm flat) connector into the mating connector at the front of the unit. Ensure that the probe is tightly inserted. If the probe is not securely connected,

inserted improperly, missing, or is broken when the ON/OFF button is pressed, the ThermoGlide will power on briefly, flash all lights three times, then shut itself off.

Step 2: Turn ON the ThermoGlide by pressing the ON/OFF

button located on the handle, one time, and verify that the green LED is on. The white illumination LED's on the front of the unit will also turn on, and one blue light will flash showing unit is ready for placement (tip not heated yet).



**Step 3:** When the probe has been placed against the tissue needing treatment, press the ON/OFF button a second time to start the procedure. Four blue timer LEDs will flash sequentially from left to right for a few



seconds indicating that the probe tip is heating. When the blue timer LEDs turn solid and a single audible beep is heard, the treatment cycle is running. The blue timer LEDs turn off with an audible beep, one at a time, after each 1/4 of the procedure has finished. When all four (4) blue timer LEDs are turned off a longer audible beep is heard, the unit is no longer applying heat. It has commenced its cool down cycle. Once the cool down cycle is complete, the front white LED lights will turn off, and the probe may then be removed from the treatment area. If a second treatment area is needed, repeat the above steps before removing the probe.

WARNING: Do not touch the active (heated) probe tip, as it may potentially cause burned tissue damage. The unit checks the functionality of each probe during heat-up mode. If the probe is unable to reach and maintain sufficient

temperature the unit will flash the blue timer LEDs three (3) times and then shut off the unit. If this occurs, the probe or battery may be faulty and need replacing. The following actions should be taken:

- 1) Replace the probe with a new one
- 2) Replace the battery
- 3) Reactivate the unit.

If the unit gives you the same message a second time and the battery appears charged, the probe has exceeded its useful life and is no longer functional.

The treatment cycle for the ThermoGlide device is a warm-up time of ~8 seconds, a treatment time of 20 seconds of constant heat at  $100^{\circ}C$  ( $212^{\circ}F$ ), and cool down ~10 seconds.

**NOTE:** The probe is intended to be applied to tissue prior to being heated.

**NOTE:** The ThermoGlide device is capable of performing 30-60 procedures per battery charge. When the battery is low, a yellow LED indicator will illuminate. The battery in the unit should be replaced with a charged battery soon after the low battery indicator is illuminated. If the yellow LED illuminates during a procedure, the procedure in process should be completed first. Once completed, replace the battery.

**NOTE:** With continued use after the low battery LED is illuminated the unit will go into a 'sleep mode' turning off to protect the battery from being overly discharged. Over-discharge of the battery could reduce the life of the battery. Recharge or put in a charged battery to get out of 'sleep mode'.

# **Recharging the Batteries**

- The batteries should only be recharged when the battery and charger are dry.
- Plug the charger into an A/C outlet.

**NOTE:** The charger can be plugged into an A/C power outlet of 100 – 240 VAC, 50/60 Hz, with the proper country adapter. (see TABLE 1)

- The charger LED will turn green.
- Place the battery into the charging adapter, plug charger into charging adapter. The charger LED should turn red if it needs charging.
- A completely discharged battery should fully recharge in about three (3) hours.
- When the battery is fully charged, the charger LED will turn green.



Figure 5: ThermoGlide Battery charging

• Remove the battery from the charger adapter and disconnect the charger from the A/C outlet when the battery has been fully charged.

**NOTE:** The battery will <u>not</u> be damaged by leaving the battery in the charger after the battery is fully charged making overnight charging convenient.

 The ThermoGlide batteries are Lithium ion batteries and cannot be charged while connected to the ThermoGlide handle. The ThermoGlide handle cannot be connected to supply mains.

# PATIENT PREPARATIONS

The patient should be prepared according to clinic protocol for the appropriate type of procedure.

# COMPLICATIONS

The following complications may occur during or following the use of the device:

- Infection
- Pain
- Tissue burn

# CLEANING AND INSPECTION

The ThermoGlide handle and probes are reusable and require specialized cleaning after each use. The probe must undergo cleaning and either high-level disinfection or sterilization (per hospital or clinical requirements) prior to use. Follow the proper cleaning instructions for cleaning the device using the following procedure:

#### Handle and Battery Cleaning Procedure:

- Disassemble the ThermoGlide into three separate parts (handle, battery, and probe).
- Thoroughly wipe all surfaces of the ThermoGlide handle and battery with a mild cleaning solution (i.e. 70% isopropyl alcohol) or disinfectant and damp cloth. The cleaning solution or disinfectant should not be applied directly to the unit. Pour/spray the cleaning solution or disinfectant onto a cloth and ensure that the cloth is evenly damp prior to cleaning the unit.

• Do not allow fluids to enter the device. Do not sterilize the ThermoGlide handle or battery.

# Probe Cleaning Procedure:

The probes require specialized cleaning after each use to remove all visible soil. After cleaning, additional sterilization or high level disinfection (HLD) processing must be completed before each individual use of the probe, see below for directions.

- If possible, initiate instrument cleaning within 30 minutes following use.
- Place silicone cap on probe connector.

# CAUTION: Only use a soft brush or cloth to manually remove impurities; never use abrasive materials as they may damage the probes.

- Perform the <u>final</u> instrument rinse with clean water (i.e. Reverse Osmosis/ De-ionized (RO/DI) water) that does not contribute to device staining or contamination.
- If an alkaline based detergent is used during the cleaning process, a neutralization solution may be used to remove alkaline-based residues and deposits. Follow the manufacturer's recommendations.

## Manual Cleaning\*

Equipment: Personal protective equipment, enzymatic detergent, brush/cloth, running water

- Place silicone cap on probe connector.
- Rinse probe shaft using cool running water to remove gross soil. A soft bristled brush or cloth may be used to aid in the removal of soil. Run water over shaft, crevices, hard to reach areas until water runs clear.
- Prepare an enzymatic detergent such as Enzol<sup>®</sup> per manufacturer's recommendations. Fully immerse the probe in the prepared detergent. Allow probe to soak for a minimum of one (1) minute.
- Following the soak time, while still immersed, use a soft bristled brush or cloth to thoroughly clean the probe. Pay particular attention to hard-to-reach areas.
- Remove the probe from the detergent solution and rinse with running water.
- Visually inspect each probe for visible soil. If soil remains, repeat the cleaning procedure outlined above.

\* The manufacturer validated the manual cleaning method using an independent accredited test laboratory and has the data on file. The validation was accomplished using Enzol® as the enzymatic detergent. The use of an automated cleaning system was not validated by manufacturer, and the use of such a system is at the risk and discretion of the user.

## Drying

Ensure the probes are free from residual moisture prior to sterilization. If moisture remains on the probe, dry using a clean lint-free cloth and/or filtered pressurized air.

# WARNING: Failure to properly clean and dry the probes may lead to inadequate sterilization or a reduction in instrument life.

# **Probe Sterilization**

- Sterilize probes in sterilization trays/pouch and containers. Disposable sterilization packages may also be used.
- Place silicone cap on probe connector.

sterilization parameters is recommended:

- Insert probe(s) into sterilization tray/pouch following sterilizer manufacturer guidelines for appropriate tray/pouch and packaging instructions.
- Ensure that all surfaces will be exposed to the sterilizing agent. Ensure that probes do not contact each other if multiple probes are packaged together.
- Control the water purity dedicated to steam production to prevent damage to the instruments.
- Sterilization temperatures higher than 121°C (250°F) may damage the instruments.

To achieve a sterility assurance level of 10<sup>-6</sup>, use of the following

Gravity Steam Sterilization Method*	Minimum Temperature	Time	Min. Drying time**
Crowity Stoom	121 °C	30	30
Gravity Steall	(250 °F)	min	min

\* The manufacturer validated this sterilization cycle using an independent accredited test laboratory and has the data on file. The validation was accomplished with probes individually double pouched and placed on edge in the sterilizer. Other sterilization cycles may be suitable; however, individuals or hospitals not using the recommended method are advised to validate an alternative method using appropriate laboratory techniques. Steam sterilization will reduce the useful life of the probe.

\*\* The manufacturer validated this dry time using probes individually double pouched, weighing approximately 17g (0.6 oz.). Longer dry times may be required for instrument trays exceeding this weight.

# Probe High Level Disinfection (HLD)\*

Materials (not provided):

- A High Level Disinfectant, such as Cidex<sup>®</sup>, in a basin large enough for submerging the probe.
- Tongs
- Pure water (boiled) at room temperature.
- Sterile cloths for drying and storage.

**Disinfection Procedure:** 

- 1. Ensure minimum effective concentration (MEC) of the glutaraldehyde following manufacturer's guidelines.
- 2. Place silicone cap on probe connector.
- Immerse the end of the heating tip of the probe into a cup of disinfectant solution approximately ~5 inches (12cm) deep
- Allow the probe to soak in glutaraldehyde following manufacturer's guidelines (i.e., 20 minutes at room temperature (20°C) for Cidex<sup>®</sup>).
- 5. Thoroughly rinse the probe(s) in pure water agitating and allowing them to set for a minimum of 5 minutes.
- 6. Repeat the previous rinsing step (5) two more times for a total of 3 rinses using a fresh batch of pure water each time.
- 7. Dry with a sterile lint-free cloth.
- 8. Store in a sterile lint-free cloth until next use.

\* The manufacturer validated the High-Level Disinfection cleaning method using an independent accredited test laboratory and has the data on file. The validation was accomplished using Cidex<sup>®</sup> as the disinfectant.

# INSPECTION

*The manufacturer* recommends that the ThermoGlide handle and probes be inspected on a monthly basis for visible damage. The following concerns should be immediately addressed:

- Signs of deterioration or obvious damage to the unit
- Signs of damage to any connector
- Accumulation of lint or debris on or around the unit

In each case, discontinue using the unit. If the unit is damaged externally or has a damaged connector, please contact the manufacturer. If the unit has accumulated dust or debris, follow the cleaning procedure to remove the debris.

CAUTION: Do NOT reuse probes for more than one hundred and twenty (120) disinfection cycles. Do NOT reuse probes for more than six (6) sterilization cycles.

# TROUBLESHOOOTING

The manufacturer has no user-adjustable controls or diagnostic tests. If the unit fails to respond as expected, try the following steps before contacting manufacturer.

- If the ThermoGlide will not turn on, please verify that the battery is fully charged and that the probe is properly connected and not faulty.
- 2. To determine whether the handle or probe are faulty, turn on the ThermoGlide unit with a probe. If the probe is faulty, the ThermoGlide will flash all four (4) blue LEDs

indicating a non-functional probe. If this fails to happen, then turn on the ThermoGlide unit again WITHOUT a probe. The ThermoGlide will flash all four (4) blue LEDs indicating absence of a probe. If this fails to occur, either the battery or the ThermoGlide is faulty.

## **DEVICE DISPOSAL:**

When the ThermoGlide handle, probe, battery, or power supply no longer are functional, or show signs of wear and damage, they should be disposed of in the same manner as electrical waste.

To order additional devices/ accessories, or replacement accessories go to info@mobileodt.com

## WARRANTY AND RETURN POLICY

The warranty period for the ThermoGlide is two (2) years from the date of shipment.

The manufacturer warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service for the period(s) set forth below.

The manufacturer's obligation under this warranty is limited to the repair or replacement, as its sole option, of any product, or part thereof, which has been returned to it or its Distributor within the applicable time period shown below, after delivery of the product to the original purchaser, and which examination discloses, to manufacturer satisfaction, that the product is indeed, defective.

This warranty does not apply to any product, or part thereof, which has been repaired or altered outside the manufacturer's factory in a way so as, in the manufacturer's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

This warranty is in lieu of all other warranties, express or implied, including without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of the manufacturer.

The manufacturer neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of the manufacturer's products.

Notwithstanding any other provision herein or in any other document or communication, the manufacturer's liability with respect to this agreement and products sold hereunder shall be limited to the aggregate purchase price for the goods sold by the manufacturer to the customer.

The manufacturer disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Utah, United States of America (USA). The sole forum for resolving disputes arising under or relating in any way to this warranty is the 3<sup>rd</sup> District Court of Utah, USA.

The manufacturer, its dealers, and representatives reserve the right to make changes in equipment built and/or sold by them at any time without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.

## **TECHNICAL ASSISTANCE:**

For Technical Assistance, please send an e-mail to support at <a href="mailto:support@mobileodt.com">support@mobileodt.com</a>.

#### **TECHNICAL SPECIFICATIONS**

All specifications are nominal and subject to change without notice. A specification referred to as "typical" is within  $\pm 20\%$  of a stated value at room temperature ( $25^{\circ}C/77^{\circ}F$ ) and utilizing a sufficiently charged battery pack.

TABLE 1: Device Parameters					
Power Parameters					
Power Supply:	11.1 VDC				
	Rechargeable Lithium-Ion				
Battery Pack:	3-cell 2AH Battery Pack				
	BMS overcharge protection				
	100 – 240 VAC, 1.0A, 50-60Hz Input				
Battery Charger:	12.6VDC, 1.8 amp, Output				
	Charge Time: Two(2) hours				
Full-Charge Activation:	Until low-battery indicator illuminates				
Power Output:	30 Watts				
Treatment (Duty) Cycle	~8 seconds of heat up, 20 seconds of therapy at 100°C,				
Treatment (Duty) Cycle	and ~10 seconds of cool down				
Dimensions and Weight					
Width:	1.5 inches (4 cm)				
Height:	8 inches (20 cm)				
Depth:	2 inches (5 cm)				
Weight:	11 oz (240 g) -				
Operating Conditions					
Ambient Temperature:	16° to 45°C				
Relative Humidity:	0% to 80% non-condensing				
Transport and Storage					
Ambient Temperature:	-5° to 45°C				
Relative Humidity:	0% to 80% non-condensing				
General Info					
Type B Applied Parts					
IP21 Pating	Solid particle protection: Level 2 (>12.5mm)				
	Liquid ingress protection: Level 1 (dripping water)				

#### Electromagnetic Compatibility Guidance (in accordance with EN/IEC 60601-1-2:2015)

TABLE 2: Manufacturer'	s Declaration – El	ectromagnet	ic Emissions					
The ThermoGlide is intended for use in the electromagnetic environment specified below. The customer or the user of the ThermoGlide should ensure that it is used in such an environment.								
Emissions Test	Compliand	e	EMC Enviro	onment Co	ompliance			
RF Emission Group 1		The ThermoGlide uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any						
CISPR 11	Gloup 1		interference in nearby electronic equipment.					
RF Emission	Class B							
CISPR 11								
Harmonic Emissions -	-IEC Not Applic	C Not Applicable		The ThermoGlide is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply betwork that supplies buildings used for domestic purposes.				
61000-3-2	Not Applie	Not Applicable						
Voltage Fluctuation	&		paone iow voltage power supply network that supplies bandings used for domestic purposes.					
Flicker –	Not Applic	able						
IEC 61000-3-3								
TABLE 3: Manufacturer'	's Declaration – El	ectromagnet	tic Immunity					
The ThermoGlide is inter	nded for use in the	electromagn	etic environn	nent specif	ied below. The	e customer or the user of the Therr	moGlide should ensure that it is used in such an environment.	
Immunity Test		IEC 60601	Test Level	Complia	nce Level	Electromagnetic Environment	- Guidance	
IEC 61000-4-2 - Electros	static discharge	±8kV conta	±8kV contact ±8kV co		ntact	Floor should be wood, concre	ete, or ceramic tile. If floors are covered with a synthetic	
(ESD)		±2,±4,±8,±	±15kV air ±2,±4,±8		,±15kV air	material, the relative humidity	should be at least 30%.	
IEC 61000-4-4 -	Electrical fast	Not Applic	t Applicable Not Ap		licable	Not applicable		
transient/burst		Not Applica			icable	Not applicable		
IEC 61000-4-5 - Surge		Not Applica	able	ole Not Applicable		Not applicable		
IEC 61000-4-8 - Power fr	requency	Not Applic	able Not Appli		licable	able Not applicable		
(50/60Hz) magnetic field	b	NOT Applica	able Not Applic		icable			
IEC 61000-4-11 - Volta	age dips, short							
interruptions and voltage	ge variations on	Not Applicable		Not Applicable		Not applicable		
power supply input lines	S							
<b>NOTE:</b> $U_T$ is the a.c. m	ains voltage prior	to applicatio	n of the test l	evel.				
TABLE 4: Manufacturer'	's Declaration – El	ectromagnet	tic Immunity					
The ThermoGlide is inter	nded for use in the	electromagn	etic environn	nent specif	fied below. The	e customer or the user of the Ther	moGlide should assure that it is used in such an environment.	
IMMUNITY Test IEC 60601 test level Compliance Level		Electromagnetic Environment – Guidance						
Conducted RF Not applicable Not applicable IEC 61000-4-6			Portable and mobile RF communications equipment should be used no closer to any part of the ThermoGlide including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.					
					Recommend	led separation distance		
	2.14	2.11						
Radiated RF EM	3 V/M	3 V/m			E 00.1411		5 000 MU + 2 2 CU	
IFC 61000-4-3	2 7GHz 10				FOR SU IVIHZ			
.2001000 + 0	2.7 5112					a = 1.1/VP	a = 2.33 VP	

B01s       A01       at       Where P is the maximum angutg over rating of the transmitter in with a condition in the intervent (M)       Find project from the eff transmitter in with a conditioned in partice (M) according to the transmitter in with a conditioned in partice (M) according to the transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmitter in with a conditioned in partice (M)       Find project from the eff transmiter (M)       Find project from the eff tranam	ABLE 4: Manufactur	rer's Declaration	- Electromagnetic immunity	-					
165       modulations and entropy and consequence data set in the recommended approximation addeministration and entropy and extromagnetic data survey is should be less involved with the following symbol:         Ended and Mitub       Ended and Mitub       Ended and Mitub       Modulation       Modulation       Modulation       Modulation       Modulation         106       300.300       TETRA ADD       Public modulation 181:       1.8       0.3       27         200       400.4707       entropy of ent		80% AM a	at	Where P is	the maximum c	output power rating of the t	ransmitter in watts (W	) according to the transmitter	
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$ \begin{array}{  c    \hline  c    \hline $				than the co	ompliance level	in each frequency range <sup>b</sup> .	Interference may occu	r in the vicinity of equipment	
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Test       Frequency       Book (Mth2)       Service       Modulation       Moduation       Modulation	Enclosure Port Immu	nity to RF wirele:	ss communication equipment						
(MHz)         Join (MHz)         Join (MHz)         Join (MHz)         Join (MHz)         Multice (MHz)	Test Frequency	Band (MHz)	Sanuica	Modulatio	n	Maximum Power (W)	Distance (m)	Immunity Test Level	
385       380-30       TETRA 400       Puise modulation 12Hz       1.4       0.3       27         10       0.3       28       0.3       28       0.3       28         10       0.4       0.4       0.3       28       0.3       28         10       0.4       0.4       0.3       28       0.3       28         10       0.4       0.4       0.3       28       0.3       28         10       0.4       0.4       0.3       28       0.3       28         10       0.4       0.4       0.3       28       0.3       28         120       0.3       0.3       28       0.3       28       0.3       28         120       0.3       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       28       0.3       0.3	(MHz)	Bullu (IVIH2)	Service	Wodulatio	"	waximum Power (W)	Distance (m)	(V/m)	
as0       430-470       GMR 540, FSC 600       FM 15 Mit served       2       0.3       28         710       700	385	380-390	TETRA 400	Pulse mod	ulation 18Hz	1.8	0.3	27	
Construction       Construction <t< td=""><td>450</td><td>430-470</td><td>GMRS 460 ERS 460</td><td>FM ± 5 k</td><td>Hz deviation</td><td>2</td><td>0.3</td><td>28</td></t<>	450	430-470	GMRS 460 ERS 460	FM ± 5 k	Hz deviation	2	0.3	28	
710       70 - 787       It TE Band 13, 17       Pulse modulation 217H       0.2       0.3       9         780       780       600 960       900 950, 157 No. 70.4       90.0 950, 150 No. 70.4       90.0 No. 70.4	150	100 170		1kHz sine		1	0.0	20	
745       704       701       THE and 13, 17       Pulse modulation 2174:       0.2       0.3       9         810       800-960       CSM       800/000,TTRA       90,000       28       0.3       28         930       100       100,000,000       800,100       114       2       0.3       28         930       1000,000,000       114,000       800,000,000       114       2       0.3       28         9300       1000,000,000,000,000,000,000,000,000,00	710	_							
Product       CSM       S00/900,TETNA       Pulse modulation 15Hz       2       0.3       28         870       800-460       S00,DES20,CDMA       850,1T       Pulse modulation 11Hz       2       0.3       28         1200       1300,SSM 1000,DEC1,TET Band       Pulse modulation 217Hz       2       0.3       28         1210       1300,SSM 1000,DEC1,TET Band       Pulse modulation 217Hz       2       0.3       28         1230       1300,SSM 1000,DEC1,TET Band       Pulse modulation 217Hz       2       0.3       28         1340       1300,SSM 1000,DEC1,TET Band       Pulse modulation 217Hz       0.2       0.3       9         5400       5100-SS00       WCA 802.11 a/n       Pulse modulation 217Hz       0.2       0.3       9         DT21       T. RED Missions mon role optical missions. Recromangetic instructures, objects, and Pulse       Nord 800 MHz, the higher frequency cange optics.         DT21       T. RED Missions MMz, the higher frequency cange optics.       Nord 800 MHz, the higher frequency cange optics.         T22       T. RED Missions MMz, the higher frequency cange optics.       Nord 800 MHz, the messure diff bit messare diff bit	745	704-787	LTE Band 13, 17	Pulse mod	ulation 217Hz	0.2	0.3	9	
3.00       800 960       SM	780								
8/0       800 Hold       800 LDNR	810		GSM 800/900,TET	RA					
340       and so that is a second seco	870	800-960	800, IDEN820, CDMA 850, I	IE Pulse mod	ulation 18Hz	2	0.3	28	
12.42       1700-1990       GSMB00_CDMA (1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1, 1	930		Band S						
1453       1/10/19/0       130/05/30/10/05/20/11/12 Band       Pulse modulation 21/Hz       2       0.3       28         2450       2400-2570       Biletroom, VU-N, 802.11 b/fn       Pulse modulation 21/Hz       2       0.3       28         250       5100-5800       WLAN 802.11 a/n       Pulse modulation 21/Hz       0.2       0.3       9         250       5100-5800       WLAN 802.11 a/n       Pulse modulation 21/Hz       0.2       0.3       9         7878       5100-5800       WLAN 802.11 a/n       Pulse modulation 21/Hz       0.2       0.3       9         7878       5100-5800       WLAN 802.11 a/n       Pulse modulation 21/Hz       0.2       0.3       9         7878       7578       These guidelines may not opply in all structures, subjects, and people.       11/Hz       1	1720	1700 1000	GSM1800,CDMA	nd Dulas mad		2	0.0	20	
13/0       Libration       Libration       Libration       Pulse modulation 217Hz       2       0.3       28         2540       \$100-5800       WLAN 802.11 a/n       Pulse modulation 217Hz       0.2       0.3       9         7575       NOTE 1: At 80 MHz the higher frequency range opplies.       0.2       0.3       9         NOTE 1: At 80 MHz and 800 MHz, the higher frequency range opplies.       0.2       0.3       9         NOTE 2: The guidelines may on a topy in all structures. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and propies.         ** Field strengths from fixed transmitters, sub as a stations for radio (callular/cordetss) lelephones and land moble callo, AM and FM radio broadcast, and TV broadcast cannee to premare in the location in which the To area this electronagnetic level blow, the Thermofolde.         * Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 v/m.       TABLE 5: Recommended segaration distanced between portable and moble radio. MA and FM radio broadcast, and TV broadcast cannee to be electronagnetic instand a minimal a minima a minimum distance between portable and moble radio and broadcast.       The measures myle and electronagnetic evolution and reflection from structures, objects, and propies         10       TABLE 5: Recommended segaration distance between portable and moble are communications equipment (transmitter) and the Thermofolde as necommended below, according to the maximum output power of the communications equipment and the Thermofolde.       B00 MHz to 2.5 GHz <td>1845</td> <td>1700-1990</td> <td>1900,GSM1900,DECI,LIE Ba</td> <td>ind Pulse mod</td> <td>ulation 21/Hz</td> <td>2</td> <td>0.3</td> <td>28</td>	1845	1700-1990	1900,GSM1900,DECI,LIE Ba	ind Pulse mod	ulation 21/Hz	2	0.3	28	
2450       2400-2570       microautry routing, such 10 g/m1       Pulse modulation 217Hz       2       0.3       28         2340       500       \$100-5800       WLAN 802.11 a/n       Pulse modulation 217Hz       0.2       0.3       9         5785       NOTE 1: At 00 MHz and 800 MHz, the higher frequency range opplies.       0.2       0.3       9         7815       At 00 MHz and 800 MHz, the higher frequency range opplies.       0.4	1910		1,3,4,23, UIVII3	/n			+		
Set the set of the set	2450	2400-2570	BILLELOULI, WLAN, 802.11 D/g	Pulse mod	ulation 217Hz	2	0.3	28	
12-00 5783       100-5800       WLAN 802.11 a/n       Pulse modulation 217Hz       0.2       0.3       9         5783       NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.         NOTE 2: These quidelines may not apply in all situations. Electromagnetic prographics is affected by absorption and reflection from structures, objects, and people.         - Field strengths from fixed transmitters, such as base stations for radio (cellular/cordiess) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed above, the ThermoGilde should be observed to verify normal operation. If abnormal performance is observed, additional distance distance accuracy in the IntermoGilde.         * Over the frequency range 150 Hz to 80 MHz, field strengths should be tess than 3 V/m         That E s. Recommended sparation distance distance portable and mobile RF communications equipment and the ThermoGilde can help prevent electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ThermoGilde can help prevent electromagnetic transmitters and the Distance distance according to Thermonications equipment.         Rated maximum output power of transmitter m transmitter m watch and according to Thermonications environment and the frequency of transmitter m transmitter m watch with a distance distance according to Thermonications equipment.         Both is to 80 MHz       0.117m       0.233m         0.1       N/A       0.37m       0.73m         0.1       N/A       0.37	5240	1	ALID 2450, LIE Dallu 7						
2020       1000 MONITOR 10 min       1000 Monitor 10 min       0.0       9         2783       1100 Monitor 10 min       1000 Monitor 10 min       0.0       9         NOTE 1: At 80 MM to ad 80 MM k, the higher frequency range applies.       Norman in the set of the	5500	5100-5800	WI AN 802 11 a/n	Pulse mod	ulation 217Hz	0.2	03	9	
Arrow Internet in the index and show that, the higher frequency range applies.       Internet int	5785	5100 5800	WEAN 002.11 0/11	i uise mou		0.2	0.0		
NOTE 1:       At 80 MHz, the higher frequency range applies.         NOTE 2:       These guidelines any not apply in all structions. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.         * Field strengths from fixed transmitters, such as base stations for radio (cellular/cordiess) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength is hould be absorption and reflection fixed but the term collide strengths. Note the term collide strengths in the object strengths in the object strengths of the term collide strengths in the strength strength strength strength strength strengths should be observed to verify normal operation. If abnormal	5765								
<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, and electromagnetic site survey should be considered. If the measured field strength should be lised and above, the ThermoGilde above, the ThermoGilde. <sup>b</sup> Over the frequency rage 150 kt/z to 80 MHz; field strength should be less than 3 /m <b>TABLE 5: Recommended separation distance between portable and mobile RF communications equipment and the ThermoGilde The ThermoGilde Is intended for use in an electromagnetic environment in which radio fields RF distances are controlled. The ThermoGilde Is intended for use in an electromagnetic environment in which radio radios equipment and the results of the communications equipment and the ThermoGilde as recommended below, according to the maximum output power of the communications equipment and the transmitter in transmitter in the assert of the communications equipment and the transmitter in transmitter in the assert of the communications equipment in which radio radio and and in the maximum output power of the communications equipment in a sint and the radio of the assert of the transmitter in the trasmitter in the trasmitter in the trasmitter in the transmitter i</b>	NOTE 1: At 80 MHz NOTE 2: These guid	z and 800 MHz, th delines may not a	ne higher frequency range applies. pply in all situations. Electromagne	tic propagation is	affected by abs	orption and reflection from	structures, objects, and	d people.	
The backgrown of the prevent of the	<sup>a</sup> Field strengths from	n fived transmitte	ars such as hase stations for radio	(cellular/cordless	) telenhones an	d land mobile radio. AM ar	nd FM radio broadcast	and TV broadcast cannot be	
strength in the location in which the ThermoGilde is used seared: the applicable BF compliance level above, the ThermoGilde should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ThermoGilde.       IntermoGilde should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ThermoGilde.         TABLE 5: Recommended separation distanced between portable and mobile RF communications equipment and the ThermoGilde. The customer or the user of the ThermoGilde can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment.         Table 5: Recommended separation distanced between portable and mobile RF communications equipment and the ThermoGilde. The customer or the user of the ThermoGilde can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment.         Table Site of the communications equipment.         Note the maximum output power of the communications equipment.         Note the maximum output power of the communications equipment and the thermoGilde should be observed to verify normal operation. If abnormal the transmitter maters are controlled. The customer of the customications equipment the transmitter maters and and the transmitter maters andite and matere (transmitter the equation applicable to	nredicted theoretical	lly with accuracy	To assess the electromagnetic envi	ronment due to fi	yed RF transmit	ters an electromagnetic sit	e survey should be con	sidered. If the measured field	
performance is observed, additional measures may be necessary, such as reorienting or relocating the ThermoGilde.         * Over the frequency range 150 kHz, field strengths should be less than 3 V/m         TABLE 5: Recommended separation distanced between portable and mobile KF communications equipment and the ThermoGilde. The ustomer or the user of the ThermoGilde can help prevent electromagnetic interference by maintaining an imimum distance between portable and mobile KF communications equipment (transmitters) and the ThermoGilde as recommended below, according to the maximum output power of the communications equipment         Rated maximum output power of the communications equipment       Separation distance according to frequency of transmitter m         150 kHz to 80 MHz       all 0.117m       0.233m         0.01       N/A       0.137m       0.74m         1       N/A       0.37m       0.74m         10       N/A       1.17m       2.33m         10       N/A       1.0       Recommended separation distance of In meters (m) can be estimated using the equation ap	strength in the location	on in which the T	hermoGlide is used exceeds the ap	plicable RF compli	iance level abov	e. the ThermoGlide should	be observed to verify r	normal operation. If abnormal	
b         Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $3\sqrt{m}$ TABLE 5: Recommended separation distanced between portable and mobile RF communications equipment and the ThermoGilde is intended for use in an electromagnetic environment in which realisted RF disturbances are controlled. The customer or the user of the ThermoGilde as recommended below, according to the maximum output power of the communications equipment.           Separation distanced between portable and mobile RF communications equipment (transmitters) and the ThermoGilde as recommended below, according to the maximum output power of the communications equipment.           Separation distance according to frequency of transmitter m           Rated maximum output power of the communications equipment.           Separation distance according to frequency of transmitter m           A separation distance of the communications equipment.           Separation distance of the down the transmitter maximum output power rot						-,			
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The ThermoGlide is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ThermoGlide can help prevent detectoragnetic interference by maintaining distance between portable and mobile RF communications equipment (transmitters) and the ThermoGlide can help prevent detectoragnetic interference by maintaining distance between portable and mobile RF communications equipment (transmitters) and the ThermoGlide can help prevent detectoragnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ThermoGlide can help prevent detectoragnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ThermoGlide can help prevent detectoragnetic interference by maintaining and the ThermoGlide can help prevent detectoragnetic interference by maintaining and the ThermoGlide can help prevent detectoragnetic interference by maintaining and the ThermoGlide can help prevent detectoragnetic interference by maintaining and the ThermoGlide can help prevent detectoragnetic interference by an inter	<sup>b</sup> Over the frequency	rved, additional m range 150 kHz to	neasures may be necessary, such as 80 MHz, field strengths should be	s reorienting or rel less than 3 V/m	locating the The	rmoGlide.			
electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ThermoGilde as recommended below, according to the maximum output power of the communications equipment          Rated maximum output power of the communications equipment       Separation distance according to frequency of transmitter m         10       N/A       0.117m       0.233m         0.01       N/A       0.37m       0.74m         1       N/A       0.37m       0.74m         10       N/A       3.70m       7.37m         10       N/A       3.70m       2.33m         10       N/A       1.17m       2.33m         10       N/A       3.70m       7.37m         11.7m       2.33m       1.17m       2.33m         10       N/A       1.17m       2.33m         10       N/A       1.17m       2.31m         10       N/A       1.17m       2.33m         100       N/A       1.17m       2.31m         101       N/A       1.17m       2.31m         102       N/A       1.17m       2.31m         103       N/A       1.17m       2.31m         104       N/A       1.17m       2.31m         105	<sup>b</sup> Over the frequency TABLE 5: Recommen	rved, additional m range 150 kHz to ded separation d	Neasures may be necessary, such as 80 MHz, field strengths should be listanced between portable and metable and	reorienting or rel less than 3 V/m obile RF communi	locating the The	rmoGlide.	_		
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Rated maximum output power of transmitter W150 kHz to 80 MHz d = $[\frac{3.5}{V_1}]\sqrt{P}$ 80 MHz to 800 MHz d = $1.17\sqrt{P}$ 800 MHz to 2.5 GHz0.01N/A0.117m0.233m0.1N/A0.37m0.74m1N/A1.17m2.33m10N/A3.70m7.37m100N/A1.17m2.33mFor transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter multicature.NOTE 1:At 80 MHz at 0.80 MHz, the separation distance for the higher frequency range appliesNOTE 1:At 80 MHz at 0.80 MHz, the separation distance for the higher frequency range appliesNOTE 1:At 80 MHz at 0.80 MHz, the separation distance for the higher frequency range appliesSymbolDescriptionSymbolSymbolSerial NumberSerial NumberIthium-ion Battery EnclosedRe OnlyCAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.ExpertAuthorized Representative in the European CommunityImage: Representative in the European CommunityNMRI Unsafe: Keep away from magnetic resonance imaging (MRI) equipmentIP21IP21ILiquid ingress protection: Level 1 (dripping water)	<sup>b</sup> Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t	rved, additional m range 150 kHz to <b>ded separation d</b> ntended for use i rference by main the maximum out	Peasures may be necessary, such as 80 MHz, field strengths should be <b>listanced between portable and m</b> n an electromagnetic environment ntaining a minimum distance betwu put power of the communications	s reorienting or rel less than 3 V/m obile RF commun in which radiated een portable and equipment	locating the The ications equipm RF disturbances mobile RF com	rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr	ner or the user of the T ansmitters) and the Ti	ThermoGlide can help prevent hermoGlide as recommended	
transmitter W150 KH2 to 800 MH2 d = $[\frac{3}{2}, \frac{1}{1}]\sqrt{P}$ 80 MHz to 800 MHz d = 1.17 $\sqrt{P}$ 800 MHz to 2.5 GH20.01N/A0.117m0.233m0.1N/A0.37m0.74m1N/A1.17m2.33m10N/A3.70m7.37m10N/A1.17m2.33m10N/A1.17m2.33m10N/A1.17m2.33m10N/A1.17m2.33m10N/A1.17m2.33m10N/A1.17m2.33m10N/A1.17m2.33m10N/A1.17m2.33m10N/A1.17m2.33m10N/A1.17m2.33m10N/A1.17m2.33m100N/A1.17m2.33m101N/A1.17m2.33m102N/A1.17m2.33m103N/A1.17m2.33m104N/A1.17m2.33m105Iterasmiter varef of the higher frequency range appliesNorating to the transmiter manufacturer.NOTE 1:At 80 MHz to 800 MHz, the separation distance for the higher frequency range appliesWarning, ElectricityNOTE 2:These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.SymbolDescriptionSymbolDescriptionSymbolCauton, See Instructions for UseMSolAttention, See I	b Over the frequency b Over the frequency TABLE 5: Recommen The ThermoGlide is in electromagnetic inte below, according to t	rved, additional m range 150 kHz to <b>ded separation d</b> ntended for use i rference by main the maximum out	neasures may be necessary, such as 80 MHz, field strengths should be <b>listanced between portable and m</b> n an electromagnetic environment ntaining a minimum distance betwi put power of the communications Separation distance according to f	reorienting or rel less than 3 V/m obile RF commun in which radiated een portable and equipment requency of trans	locating the The ications equipm RF disturbances mobile RF com smitter m	rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr	ner or the user of the T ansmitters) and the Ti	ThermoGlide can help prevent hermoGlide as recommended	
W $d = [\frac{N-1}{V_1}\sqrt{P}$ $d = 1.17\sqrt{P}$ $d = 2.33\sqrt{P}$ 0.01N/A0.117m0.233m0.1N/A0.37m0.74m1N/A1.17m2.33m10N/A3.70m7.37m100N/A3.70m7.37m100N/A11.7m2.3.3mFor transmitters rated at a maximum output power not listed above, the recommended separation distance of in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.NOTE 1:At 80 MHz and 800 MHz, the separation distance for the higher frequency range appliesNOTE 2:These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.SymbolDescriptionSymbolDescriptionSymbolDescriptionSymbolSerial NumberIthium-Ion Battery EnclosedRx OnlyCAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.Manufacturer & date of manufacturing order of a physician.ExpMit Unsafe: Level 2 (>12.5mm) Liquid ingress protection: Level 2 (>12.5mm) Liquid ingress protection: Level 1 (dripping water)Solid particle protection: Level 1 (dripping water)	<sup>b</sup> Over the frequency <sup>b</sup> Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t <b>Rated maximum outp</b>	rved, additional m range 150 kHz to ded separation d ntended for use i rference by main the maximum out put power of	Neasures may be necessary, such as 80 MHz, field strengths should be <b>listanced between portable and m</b> an an electromagnetic environment itaining a minimum distance betw. put power of the communications Separation distance according to f	reorienting or rel less than 3 V/m obile RF commun in which radiated een portable and equipment requency of trans	locating the The ications equipm RF disturbance: mobile RF com mitter m	rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr	ner or the user of the T ansmitters) and the Ti	ThermoGlide can help prevent hermoGlide as recommended	
V1     0.23 m       0.01     N/A     0.117m     0.233m       0.1     N/A     0.37m     0.74m       1     N/A     1.17m     2.33m       10     N/A     3.70m     7.37m       100     N/A     3.70m     7.37m       100     N/A     1.1.7m     2.33m       100     N/A     3.70m     7.37m       100     N/A     3.70m     7.37m       100     N/A     1.7m     23.3m       For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.       NOTE 1:     At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies       NOTE 2:     These guidelines may not apply in all situations. Electromagnetic propagation is diffected by absorption and reflection from structures, objects, and people.       THELE 6: Symbols and marking       Symbol     Description     Symbol       Symbol     Attention, See Instructions for Use     M       Symbol     Attention, See Instructions for Use     Manufacturer & date of manufacturing       SN     Serial Number     III hum-Ion Battery Enclosed       SN     CAUTIO	<sup>b</sup> Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t <b>Rated maximum out</b> transmitter	rved, additional m range 150 kHz to ded separation d ntended for use ii rference by main the maximum out put power of	easures may be necessary, such as 80 MHz, field strengths should be listanced between portable and m an electromagnetic environment itaining a minimum distance betw. put power of the communications Separation distance according to f 150 kHz to 80 MHz 35	reorienting or rei less than 3 V/m obile RF communi in which radiated een portable and equipment requency of trans	locating the The ications equipm RF disturbance: mobile RF com mitter m MHz	rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz	ner or the user of the T ansmitters) and the Ti	ThermoGlide can help prevent hermoGlide as recommended	
0.01       N/A       0.117m       0.233m         0.1       N/A       0.37m       0.74m         1       N/A       1.17m       2.33m         10       N/A       3.70m       7.37m         100       N/A       1.17m       23.3m         100       N/A       3.70m       7.37m         100       N/A       11.7m       23.3m         100       N/A       11.7m       23.3m         100       N/A       11.7m       23.3m         For transmitters rated at a maximum output power not listed above, the recommended separation distance of in meters (m) can be estimated using the equation applicable to the frequency of the transmitter in watts (W) according to the transmitter manufacturer.         NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies         NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.         TABLE 6: Symbols and marking         Symbol       Description       Warning, Electricity         SN       Serial Number       Warning, Electricity         SN       Serial Number       Warning, Electricity         Ex Rep       Authorized Representative in the European Community	<sup>b</sup> Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t <b>Rated maximum output</b> transmitter W	rved, additional m range 150 kHz to ded separation d ntended for use ii rference by main the maximum out put power of	heasures may be necessary, such as 80 MHz, field strengths should be <b>listanced between portable and</b> m n an electromagnetic environment itaining a minimum distance betwi- put power of the communications <b>Separation distance according to f</b> 150 kHz to 80 MHz $d = [\frac{3.5}{V}]\sqrt{P}$	reorienting or rei less than 3 V/m obile RF communi in which radiated een portable and equipment requency of trans 80 MHz to 800 f d = 1	locating the The ications equipm RF disturbances mobile RF com mitter m MHz 17√P	rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz	mer or the user of the Transmitters) and the Transmitters $d=2.33\sqrt{P}$	ThermoGlide can help prevent hermoGlide as recommended	
0.1       N/A       0.37m       0.74m         1       N/A       1.17m       2.33m         10       N/A       3.70m       7.37m         100       N/A       11.7m       2.33m         100       N/A       11.7m       2.33m         For transmitter, where P is the maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the separation distance for the higher frequency range applies         NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies         NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.         TABLE 6: Symbols and marking         Symbol       Description       Symbol         Image: Symbol       Attention, See Instructions for Use       Image: Symbol         SN       Serial Number       Image: Symbol       Warning, Electricity         SN       Serial Number       Image: Symbol       Manufacturer & date of manufacturing         Image: CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.       Image: Solid particle protection:       Image: Solid particle protection:         Image: Ele Ref       Authorize	<sup>b</sup> Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t <b>Rated maximum out</b> transmitter W	rved, additional m range 150 kHz to ded separation d ntended for use ii rference by main the maximum out put power of	heasures may be necessary, such as 80 MHz, field strengths should be <b>listanced between portable and</b> m an electromagnetic environment itaining a minimum distance betwiput power of the communications <b>Separation distance according to f</b> 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	reorienting or rei less than 3 V/m obile RF communi in which radiated een portable and equipment requency of trans 80 MHz to 800 f d = 1	locating the The ications equipm RF disturbances mobile RF com mitter m MHz $17\sqrt{P}$	rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz	ther or the user of the Transmitters) and the Transmitters $d=2.33\sqrt{P}$	ThermoGlide can help prevent hermoGlide as recommended	
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10       N/A       3.70m       7.37m         100       N/A       11.7m       23.3m         For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter in watts (W) according to the transmitter manufacturer.         NOTE 1:       At 80 MHz, the separation distance for the higher frequency range applies         NOTE 2:       These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.         TABLE 6: Symbols and marking       Symbol         Symbol       Description         Symbol       Serial Number         SiN       Serial Number         Ittimum-ion Battery Enclosed         Rx Only       CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.         EC       REP         Authorized Representative in the European Community       Image: Solid particle protection: Level 2 (>12.5mm)         Liquid ingress protection:       Level 1 (dripping water)	b Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t <b>Rated maximum out</b> transmitter W 0.01 0.1	rved, additional m range 150 kHz to ded separation d ntended for use ii rference by main the maximum out put power of	heasures may be necessary, such as 180 MHz, field strengths should be <b>listanced between portable and</b> mi- n an electromagnetic environment tianing a minimum distance betwe put power of the communications <b>Separation distance according to f</b> 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$ N/A N/A	reorienting or rei less than 3 V/m obile RF communi in which radiated een portable and equipment requency of trans 80 MHz to 800 f d = 1 0.117m 0.37m	locating the The ications equipm RF disturbances mobile RF com mitter m VHz $17\sqrt{P}$	rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz 0.233m 0.74m	the root the user of the Taransmitters) and the The definition $d=2.33\sqrt{P}$	ThermoGlide can help prevent hermoGlide as recommended	
100       N/A       11.7m       23.3m         For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.         NOTE 1:       At 80 MHz and 800 MHz, the separation distance <i>for the higher frequency range applies</i> NOTE 2:       These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.         TABLE 6:       Symbol       Description         Symbol       Attention, See Instructions for Use       Marning, Electricity         SN       Serial Number       Lithium-Ion Battery Enclosed         Rx Only       CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.       Manufacturer & date of manufacturing         Image: REP       Authorized Representative in the European Community       Image: Representative in the European Community       Image: Representative in the European Community         Image: Representative in magnetic resonance imaging (MRI) equipment       Image: Lipping water)       Solid particle protection: Level 1 (dripping water)	b Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t <b>Rated maximum out</b> transmitter W 0.01 0.1 1	rved, additional m range 150 kHz to ded separation d ntended for use ii rference by main the maximum out put power of	heasures may be necessary, such as 80 MHz, field strengths should be <b>listanced between portable and</b> m n an electromagnetic environment ttaining a minimum distance betw. put power of the communications. <b>Separation distance according to f</b> 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$ N/A N/A N/A	reorienting or rei less than 3 V/m obile RF communi in which radiated een portable and equipment requency of trans 80  MHz to $800  Id = 10.117m0.37m1.17m$	locating the The ications equipm RF disturbances mobile RF com imitter m VHz $17\sqrt{P}$	rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz 0.233m 0.74m 2.33m	ther or the user of the Transmitters) and the Transmitters $d = 2.33\sqrt{P}$	ThermoGlide can help prevent hermoGlide as recommended	
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.         NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies         NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies         NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.         TABLE 6: Symbols and marking         Symbol         Symbol         OBEScription         Symbol <td>b Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t <b>Rated maximum out</b> transmitter W 0.01 0.1 1 10</td> <td>rved, additional m range 150 kHz to ded separation d ntended for use ii rference by main the maximum out put power of</td> <td>heasures may be necessary, such as 80 MHz, field strengths should be <b>listanced between portable and</b> m n an electromagnetic environment training a minimum distance betw. put power of the communications. <b>Separation distance according to f</b> 150 kHz to 80 MHz <math>d = [\frac{3.5}{V_1}]\sqrt{P}</math> N/A N/A N/A N/A N/A</td> <td>reorienting or rei less than 3 V/m obile RF communi in which radiated een portable and equipment requency of trans 80  MHz to <math>800  I d = 1 0.117m 0.37m 1.17m 3.70m</math></td> <td>locating the The ications equipm RF disturbances mobile RF com imitter m MHz 17√P</td> <td>rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz 0.233m 0.74m 2.33m 7.37m</td> <td>the user of the The ransmitters) and the The definition <math>d = 2.33\sqrt{P}</math></td> <td>ThermoGlide can help prevent hermoGlide as recommended</td>	b Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t <b>Rated maximum out</b> transmitter W 0.01 0.1 1 10	rved, additional m range 150 kHz to ded separation d ntended for use ii rference by main the maximum out put power of	heasures may be necessary, such as 80 MHz, field strengths should be <b>listanced between portable and</b> m n an electromagnetic environment training a minimum distance betw. put power of the communications. <b>Separation distance according to f</b> 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$ N/A N/A N/A N/A N/A	reorienting or rei less than 3 V/m obile RF communi in which radiated een portable and equipment requency of trans 80  MHz to $800  Id = 10.117m0.37m1.17m3.70m$	locating the The ications equipm RF disturbances mobile RF com imitter m MHz 17√P	rmoGlide. ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz 0.233m 0.74m 2.33m 7.37m	the user of the The ransmitters) and the The definition $d = 2.33\sqrt{P}$	ThermoGlide can help prevent hermoGlide as recommended	
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NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.         TABLE 6: Symbol and marking         Symbol       Description         Symbol       Marring, Electricity         SN       Serial Number       Itthium-Ion Battery Enclosed         Rx Only       CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.       Image: Caution of the enclosed of the enclose	b Over the frequency b Over the frequency <b>TABLE 5: Recommen</b> The ThermoGlide is in electromagnetic inte below, according to t <b>Rated maximum out</b> transmitter W 0.01 0.1 1 10 100 For transmitters rated of the transmitter, wh	Additional m range 150 kHz to ded separation d ntended for use i rfference by main the maximum out put power of d at a maximum o here <i>P</i> is the max	the asures may be necessary, such as the NHz, field strengths should be <b>listanced between portable and m</b> in an electromagnetic environment intaining a minimum distance betwith put power of the communications. <b>Separation distance according to f</b> 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$ N/A $N/A$ N/A N/A N/A N/A N/A N/A N/A N/A M/A N/A M/A M/A M/A M/A M/A M/A M/A M/A M/A M	reorienting or rel less than 3 V/m obile RF commun in which radiated een portable and equipment requency of trans 80  MHz to $800  fd = 10.117m0.37m1.17m3.70m11.7mecommended sep-ransmitter in watt$	locating the The ications equipm RF disturbances mobile RF com mitter m MHz $17\sqrt{P}$ aration distance is (W) according	rmoGlide.  ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz 0.233m 0.74m 2.33m 7.37m 23.3m d in meters (m) can be estit to the transmitter manufac	mer or the user of the Ti ansmitters) and the Ti $d = 2.33\sqrt{P}$ mated using the equation	ThermoGlide can help prevent hermoGlide as recommended	
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Liquid ingress protection: Level 1 (dripping water)	performance is obser         b Over the frequency         TABLE 5: Recommend         The ThermoGlide is in electromagnetic interest below, according to the transmitter         W         0.01         0.1         1         10         100         For transmitters rated of the transmitter, with NOTE 1: At 80 MHz NOTE 2: These guided         TABLE 6: Symbols and Symbol         SN         Rx Only         EC REP	rved, additional m range 150 kHz to ded separation d ntended for use i rference by main the maximum out put power of put power of d at a maximum o here <i>P</i> is the max z and 800 MHz, th elines may not ap d marking Atte	heasures may be necessary, such as to 80 MHz, field strengths should be <b>istanced between portable and m</b> an electromagnetic environment intaining a minimum distance betwiput power of the communications. <b>Separation distance according to f</b> 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$ N/A $d = [\frac{3.5}{V_1}]\sqrt{P}$ N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A	reorienting or rei less than 3 V/m obile RF commun in which radiated een portable and equipment requency of trans 80 MHz to 800 f d = 1 0.117m 0.37m 1.17m 3.70m 11.7m 2.70m 11.7m ecommended sep- ransmitter in watt r frequency range ic propagation is a	locating the The ications equipm RF disturbances mobile RF com mitter m MHz $17\sqrt{P}$ aration distance is (W) according applies affected by abso Symbol Symbol i	rmoGlide.  ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz 0.233m 0.74m 2.33m 7.37m 23.3m d in meters (m) can be estit to the transmitter manufar rption and reflection from s Li Manuf	mer or the user of the Ti ansmitters) and the Ti $d = 2.33\sqrt{P}$ mated using the equation cturer. tructures, objects, and Description Warning, Electricity thium-Ion Battery Encl acturer & date of manu- Type B Applied Parts Solid particle protectic	ThermoGlide can help prevent hermoGlide as recommended	
Level 1 (dripping water)	performance is observed         b Over the frequency         TABLE 5: Recommend         The ThermoGlide is in electromagnetic interest below, according to the transmitter         W         0.01         0.1         1         100         For transmitters rated of the transmitter, with work transmitter, with wo	rved, additional m range 150 kHz to ded separation d ntended for use i rfference by main the maximum out put power of put power of d at a maximum o here <i>P</i> is the max z and 800 MHz, th elines may not ap d marking Authorized Re Geep away from n	the asures may be necessary, such as the NHz, field strengths should be <b>istanced between portable and m</b> an electromagnetic environment thatining a minimum distance betwith put power of the communications. <b>Separation distance according to f</b> 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$ N/A $d = [\frac{3.5}{V_1}]\sqrt{P}$ N/A N/A N/A N/A N/A N/A N/A N/A N/A N/A	reorienting or rel less than 3 V/m obile RF communi in which radiated een portable and equipment requency of trans 80 MHz to 800 f d = 1 0.117m 0.37m 1.17m 3.70m 11.7m commended sep- ransmitter in watt r frequency range ic propagation is a ce by or on the munity equipment	locating the The ications equipm RF disturbances mobile RF com mitter m MHz $17\sqrt{P}$ aration distance is (W) according applies iffected by abso Symbol iffected by abso Symbol $iffected by abso Symbol iffected by abso Symbol bol iffected by abso$	rmoGlide.  ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz 0.233m 0.74m 2.33m 7.37m 2.3.3m d in meters (m) can be estit to the transmitter manufar rption and reflection from s Li Manuf	mer or the user of the Ti ansmitters) and the Ti $d = 2.33\sqrt{P}$ mated using the equation cturer. tructures, objects, and Description Warning, Electricity thium-Ion Battery Encl acturer & date of manu- Type B Applied Parts Solid particle protection Level 2 (>12.5mm)	ThermoGlide can help prevent hermoGlide as recommended	
	performance is observed         b Over the frequency         TABLE 5: Recommend         The ThermoGlide is in electromagnetic interest below, according to the transmitter         W         0.01         0.1         1         100         For transmitters rated of the transmitter, with whether the second of the transmitter of the transmitter, with whether the second of the	rved, additional m range 150 kHz to ded separation d ntended for use i rfference by main the maximum out put power of put power of d at a maximum o here <i>P</i> is the max z and 800 MHz, th elines may not ap d marking Attec 10N: Federal (US) Authorized Re	heasures may be necessary, such as No MHz, field strengths should be <b>istanced between portable and m</b> na nelectromagnetic environment training a minimum distance betw. put power of the communications <b>Separation distance according to f</b> 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$ N/A N/A N/A N/A N/A N/A N/A N/A	reorienting or rel less than 3 V/m obile RF commun in which radiated een portable and equipment requency of trans 80 MHz to 800 f d = 1 0.117m 0.37m 1.17m 3.70m 11.7m eccommended sep- ransmitter in watt r frequency range ic propagation is a commended sep- ransmitter in watt	locating the The ications equipm RF disturbances mobile RF com mitter m MHz $17\sqrt{P}$ aration distance is (W) according applies iffected by abso Symbol Symbol if if if if if if if if if if	rmoGlide.  ent and the ThermoGlide s are controlled. The custor munications equipment (tr 800 MHz to 2.5 GHz 0.233m 0.74m 2.33m 7.37m 23.3m d in meters (m) can be estit to the transmitter manufar rption and reflection from s Li Manuf	ner or the user of the Tansmitters) and the Transmitters) and the Transmitters $d = 2.33\sqrt{P}$ mated using the equation of the transmitter of the transmitters of the transmitter	ThermoGlide can help prevent hermoGlide as recommended	

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