NEUROMARK RF CONSOLE INSTRUCTIONS FOR USE

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

1 | INDICATIONS FOR USE

The NEUROMARK System is indicated for use in otorhinolaryngology (ENT) surgery for creation of radiofrequency (RF) lesions through destruction of soft tissue to disrupt posterior nasal nerves in patients with chronic rhinitis.

2 | DEVICE DESCRIPTION

The NEUROMARK System is composed of the NEUROMARK Device and the NEUROMARK RF Console.

NEUROMARK RF Console

The NEUROMARK Console (Figure 1) is designed for use with the NEUROMARK Device only, and is connected via a flexible interface cable. Consult the NEUROMARK Device IFU for guidance on performing the NEUROMARK procedure.

The NEUROMARK Console delivers, monitors and controls RF energy to the Device. The Console includes a Graphical User Interface (GUI) which provides operational instructions for the procedure, directs the user to select nasal cavities for treatment, indicates when the device is in contact with tissue and ready to start treatment, provides status of therapy and indicates when the procedure is complete. The NEUROMARK Console works in conjunction with software.

The user initiates RF energy delivery by either selecting “Start Treatment” on the touchscreen or pressing the activation button on the NEUROMARK Device for 2 seconds. The Power Delivery Indicator LED, located on the front panel of the Console, illuminates whenever RF power is delivered. During RF power delivery, alerts are conveyed to the operator through an on-screen message along with an audible tone.

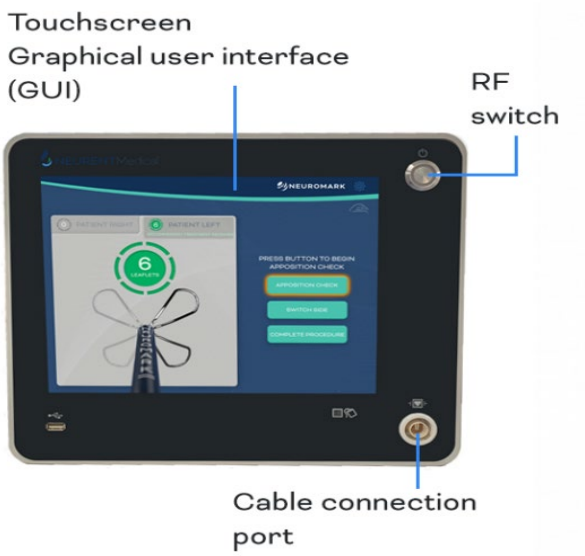


Figure 1: NEUROMARK Console/GUI

Frequently Used Functions

- The nasal cavity displayed will be as per the user Default Start Cavity preference. To change sides:
  - Press the device button once to toggle to “Switch Side” and then hold the device button for 1 second to confirm the selection;
  - or select “Switch Side” on the touchscreen;
  - or select the “PATIENT RIGHT” or “PATIENT LEFT” tab on the touchscreen;

  The chosen side will be displayed on the touchscreen.
- Select “Apposition Check” on the touchscreen or press the device button for 1 second to start the apposition check.
- Press the Console RF ON/OFF button or select “Start Treatment” on the touchscreen to start treatment (activate delivery of RF energy).
- Following an initial treatment cycle (after RF energy delivery cycle has stopped):
  - To add another treatment in the same nasal cavity, move the NEUROMARK device to the next treatment area and repeat the Apposition Check and Start Treatment steps.
  - Use the device button or touchscreen options to switch side and treat the other nasal cavity.
  - Select “Complete Procedure” on the touchscreen to finalize the procedure.

The NEUROMARK System consists of the following:

Description	Model Number
Console	010-00089-000
Mains Power Cord (US)	610-00001-000
Interface Cable for the NEUROMARK Device	600-00594-000
NEUROMARK Device	NMK00301
Roller Stand (includes Mounting Bracket)	FLP-0001-61 or NR-0003-60
Roller Stand Basket	RS-0001-24
Roller Stand Handle	RS-0004-18
Desktop Stand (optional alternative to Roller Stand, Basket & Handle)	FS-006-01

4 | CONTRAINDICATIONS

None.

5 | POTENTIAL ADVERSE EFFECTS

Potential adverse effects related to the use of RF energy on tissue in the nasal airway may include temporary pain/discomfort, infection, minor nasal bleeding, delayed onset (2-4 weeks post procedure) epistaxis requiring operative intervention*, mucosal trauma, mucosal perforation, superficial burns, temporary headache, scar formation with increased obstruction, cosmetic deformity, sensory (olfactory) changes at treatment site, septal perforation, worsened eustachian tube function, bone necrosis, atrophic rhinitis, or dry nose.

* Patients with a history of hypertension and patients on anticoagulants may be at a higher risk to experience post procedure epistaxis.

6 | WARNINGS

- The safe and effective operation of the NEUROMARK Console relies on factors within the operator's control. It is essential that users of the NEUROMARK System are properly trained. It's essential to thoroughly read and comprehend the operating instructions provided with the NEUROMARK Console before use and to adhere to all contraindications, warnings, and precautions outlined in these instructions. Neglecting to do so could result in device malfunction and/or patient complications.
- Fire Hazard: Avoid use in the vicinity of flammable anesthetics, other flammable gases, near flammable fluids like skin prepping agents and tinctures. Also, keep away from flammable objects and oxidizing agents. Always adhere to appropriate fire safety measures.
- Fire Hazard: Avoid using in oxygen-enriched atmospheres, nitrous oxide (N_2O) atmospheres, or where other oxidizing agents are present.
- Risk of RF Burns: Avoid turning on RF power while touching any electrodes.
- Risk of RF Burns to the Patient: During an RF procedure with the NEUROMARK System, ensure the patient does not touch grounded metal objects like the surgical table frame or instrument table. It is advisable to use antistatic sheeting.
- Risk of RF Burns to the Patient: Prevent skin-to-skin contact, such as between the patient's arms and body, by using dry gauze or other suitable measures.
- Risk of RF Burns: Console or cable failure may lead to unintended increases in output power.
- Exercise caution to prevent ignition of endogenous gases.
- RF energy may cause unintended neuromuscular stimulation during ablation. Take appropriate precautions including continuously monitoring of the patient during treatment to minimize the risk of patient injury.
- Interference with Other Equipment: Only use approved devices and cabling. Using devices or cabling not specifically approved by Neurent Medical for use with the

NEUROMARK Console may increase electromagnetic emissions or decrease electromagnetic immunity.

- Interference with Other Equipment: The use of electrosurgical generators on patients with internal or external pacemakers, implantable defibrillators, or monitoring equipment may be affected. Seek qualified advice as necessary to minimize the risk of injury from implanted device malfunction.
- Interference with Other Equipment: When using electrosurgical generators on patients with conductive implants, there's a risk of heating the implants and harming tissue. Seek qualified advice to reduce this risk.
- Interference with Other Equipment: RF output may interfere with other medical equipment's electrical functions. If you suspect interference with equipment outside the NEUROMARK System, relocate it and its cables away from the NEUROMARK System.
- Risk of Electric Shock: To prevent electric shock, only connect the NEUROMARK Console to a mains supply with protective earth. Avoid using extension cords or adapters. Regularly inspect the mains power cord assembly for any signs of damaged insulation or connectors.
- Risk of Electric Shock: Modification of this equipment is strictly prohibited.
- Risk of Electric Shock: Do not use the NEUROMARK Console with a multiple portable socket outlet.
- Proper Device Use: Do not use the device if the display area is damaged, cracked or broken. Return the unit to the manufacturer.
- Proper Device Use: Before use, inspect the Interface Cable for any damage. If damaged, do not operate the device. Return the unit to the manufacturer.
- Proper Device Use: If you do not hear audible tones for each press of the touchscreen or device button, do not operate the device even after increasing the audio volume.
- Proper Device Use: Observe the LCD, LEDs, and audible tones during Power-On-Self-Test (POST) before using the device.
- Proper Device Use: Use the device only in the configuration specified in this document.
- Storage: Ensure that both the Console and Interface Cable are stored at the same temperature and comply with the environmental specifications outlined in this document.
- Avoid simultaneous contact with both the Console and the patient.
- Do not initiate the Console with a USB device installed in the front panel USB port.
- Non-Sterile: Keep the Console, Stand, and Interface Cable outside the sterile field as they are non-sterile. Do not try to sterilize the Console, Stand, or Interface Cable.

7 | PRECAUTIONS

- To avoid damage to the Console, mount the Console on the Roller or Desktop Stand prior to use.
- Only activate RF energy delivery once the NEUROMARK Device is correctly positioned in the patient's nasal cavity.
- Do not remove the cover of the Console to avoid the risk of electrical shock. For servicing, contact the manufacturer.
- Continuous activation of the device button is not necessary to deliver RF energy. Always monitor the activation indicator or tone during RF output to ascertain the delivery state.
- The activation tone and light (backup RF ON/OFF indicator) are important safety features. Do not disable the activation tone and do not block the activation light.
- Avoid wrapping cabling around metal objects, as doing so may induce hazardous currents.
- Regularly inspect electrosurgical cables and the NEUROMARK Device for any damage to the insulation.
- Use only the recommended cabling with the Console.
- Use smoke plume extraction to minimize the risk of surgical smoke inhalation by operator.
- Refer to the Instructions for Use (IFU) for the corresponding parts for guidance on connecting and disconnecting detachable components.
- Exercise caution to prevent the ignition of endogenous gases.
- Special precautions regarding EMC are necessary for the Console, and it must be installed and put into service according to the EMC information provided in this IFU.
- The operation of electronic equipment, including portable and mobile RF communications equipment, can impact the functioning of the Console. It is advisable to avoid operating non-essential equipment near the Console. If interference is suspected, relocate the responsible equipment and associated cables away from the Console.
- The emissions characteristics of this equipment are suitable for use in industrial areas and hospitals (CISPR 11 class A). However, if used in a residential environment (where CISPR 11 class B is typically required), this

equipment might not provide sufficient protection to RF communication services. User may need to

- take mitigation measures, such as relocating or reorienting the equipment.
- Avoid using the Console adjacent to or stacked with other equipment outside of its pre-set configuration. If the Console must be operated in such a configuration, observe the Console to verify normal operation.
- When using the Console and physiological monitoring equipment simultaneously on the same patient, ensure that any monitoring electrodes are positioned as far as possible from the surgical electrodes. Avoid using needle monitoring electrodes. It is recommended to use monitoring systems that incorporate high-frequency current limiting devices in all cases.
- If the Console is stored in an environment outside of room temperature, allow for an acclimation period of at least 2 hours before use.
- Ensure that all cabling is positioned at least one inch away from the Console's touchscreen during Console operation.
- Only use the power cord that is supplied with the Console.
- The Console is not designated for use with a Neutral Electrode.

8 | ROLLER STAND SETUP

PRECAUTION: To avoid damage to the Console, mount the Console on the Roller or Desktop Stand prior to use.

Setup Instruction	Roller Stand
Assembling the Mounting Bracket	• Follow the Roller Stand Instructions for Use for mounting bracket assembly instructions.
Preparing the Stand for Use	• Lock the stand wheels prior to mounting. Depress the tab on the wheels to lock. To unlock the wheels, flick the tab up on both wheels. When locking the stand wheels, ensure that one locked wheel is positioned under the handle and in line with the stand pole to prevent unintended movement. • Do NOT adjust the position of the mounting brackets on the Stand. • Ensure the shelf surface is clear of items.
Preparing the Console for Use	• Inspect the Console for any signs of physical damage to the display, metal trim, or rear panel. Also ensure that all Console labels are present and legible. If any physical damage is found, DO NOT USE THE CONSOLE. CONTACT manufacturer for a replacement. Manufacturer must approve all returns. • Inspect the power cord(s) for damage.
Mounting the Console	• The Console shall be placed on a mounting Stand using the provided mounting bracket. Do NOT use the Console without mounting on a compatible Stand. If the Stand has not been assembled yet, follow the Stand Instructions for Use for assembly instructions. • Ensure nothing is connected to the Console prior to mounting. • Lift the Console such that the Console mounting holes are level with the holes in the Stand mounting bracket. • Use the four (4) screws provided with the Stand to attach the Console to the mounting bracket. Ensure the Console is secure. • Do NOT adjust the position of the mounting brackets on the Stand. • Do NOT obstruct the vents underneath the Console. Under continuous use for extended periods of time, it is normal for the outer housing to be warm to the touch.

9 | DESKTOP STAND SETUP (OPTIONAL ALTERNATIVE TO ROLLER STAND)

PRECAUTION: To avoid damage to the Console, mount the Console on the Roller or Desktop Stand prior to use.

Setup Instruction	Desktop Stand (OPTIONAL alternative to Roller Stand)
Preparing the Console for Use	• Inspect the Console for any signs of physical damage to the display, metal trim, or rear panel. Also ensure that all Console labels are present and legible. If any physical damage is found, DO NOT USE THE CONSOLE. CONTACT manufacturer for a replacement. Manufacturer must approve all returns. • Inspect the power cord(s) for damage.

Setup Instruction	Desktop Stand (OPTIONAL alternative to Roller Stand)
Mounting the Console	• Ensure nothing is connected to the Console prior to mounting. • Follow the Desktop Stand assembly instructions provided with the Desktop Stand. • Ensure the Console is secure.

10 | DIRECTIONS FOR USE

The safe and effective operation of the NEUROMARK Console relies on factors within the operator's control. It is essential that users of the NEUROMARK System are properly trained. It's essential to thoroughly read and comprehend the operating instructions provided with the NEUROMARK Console before use and to adhere to all contraindications, warnings, and precautions outlined in these instructions. Neglecting to do so could result in device malfunction and/or patient complications.

11 | POWERING ON THE CONSOLE

- Connect the RF power cord to the AC Power Inlet on the Console and plug the other end into a wall outlet. Position the Console so that the power supply connection is easily accessible for disconnecting power from the Console.
- Locate the AC Mains Switch on the rear panel of the Console. Flip the switch to **I** to turn on the Console. During startup, the LCD, LEDs, and audible alarm will cycle and should be observed before using the Console.

12 | STARTING A NEUROMARK PROCEDURE

- Consult the NEUROMARK Device IFU to prepare for an ablation procedure.
- Follow the on-screen instructions displayed on the Console to initiate a procedure.

13 | ADJUSTING CONSOLE SETTINGS

To access Console Settings, select the Settings icon located at the top right corner of the Console touchscreen when RF energy delivery is not active.

- To change the DEFAULT START CAVITY, tick RIGHT or LEFT.
- To change the DEFAULT INFO DISPLAY, tick ON or OFF.
- Adjust the audible tone volume using the slider below SYSTEM VOLUME.
- Adjust the display brightness using the slider below DISPLAY BRIGHTNESS.
- Adjust the Date and Time using the up and down arrows.
- To update the software, insert the USB key into the front panel USB port, and then select the "Update" button and follow the instructions onscreen.
- To calibrate the touchscreen, press CALIBRATE (below TOUCHSCREEN) and follow the on-screen instructions. If the touchscreen is misaligned, power cycle the unit (OFF-ON) and hold the touchscreen for 2 seconds after "NEUROMARK" appears on the splash screen.
- To download therapy logs, insert a USB key into the front panel USB port, and then select "Download Logs" and follow the instructions onscreen.

14 | SHUTDOWN PROCEDURE

- Turn off the mains power using the AC Mains Switch located on the rear panel of the Console. Flip the switch to the "O" position to power off. Confirm that the LCD is also turned off.
- Disconnect the Console power cord from the mains outlet and from the AC Power Inlet on the Console.

15 | CONSOLE CLEANING AND DISINFECTION INSTRUCTIONS

- Clean the Console surfaces and cables using a solution of 70% isopropyl alcohol (IPA) and a damp cloth. Note that the Console cannot be sterilized. Take care to not allow fluids to enter the chassis.

- Avoid spraying or pouring liquids directly onto the Console.
- Allow flammable cleaning or disinfecting agents, solvents, or adhesives to evaporate before use. Prefer non-flammable agents for cleaning and disinfection whenever possible.

16 | CONSOLE MAINTENANCE SCHEDULE

The Console verifies calibration integrity during Power-On Self-Test (POST). No maintenance is required.

17 | DISPOSAL INSTRUCTIONS

Do not dispose of it. Return to the manufacturer.

18 | USER INTERFACE

Front Panel Controls and Connections	
1. Touchscreen Window: Displays messages and enables the Operator to interact with the device via the touchscreen. In the event of a system fault, the Console will enter a Fault state. To attempt recovery from a system fault, power to the system must be cycled (OFF-ON). **2.** Backup RF ON/OFF Indicator: An LED surrounding the RF ON/OFF button indicates whether RF is being delivered. The indicator is illuminated blue during RF delivery and turned off when RF is not being delivered. **3.** Backup RF ON/OFF Button: This button toggles the RF output on if the system is in Measure Mode, and off if the system is in RF Delivery Mode. **4.** RF Output Connection: This is a patient-isolated connection used for attaching the Console Interface Cable. **5.** Front USB Port: This port allows for a USB flash drive to be connected to the front panel for updating software and downloading logs. ***CAUTION:*** *Only use USB memory devices in the front panel USB port.*	 *Figure 2: Front Panel Controls and Connections*

Rear Panel Controls and Connections	
1. Fuse Drawer: This compartment houses the fuse and accommodates AC input voltages ranging from 100-240 V. 2. AC Mains Switch: This switch controls the AC power input. 3. AC Power Inlet: The AC power cord is connected to the inlet to supply power to the system. 4. Equipotential Ground Connection: This connector is linked to the chassis/earth ground and is designated for earth reference connection in environments utilizing equipotential ground cabling. 5. Device Label: This label displays the unit's model number and serial number. 6. Foot-switch Connection: This port is currently not in use. 7. Back USB Port: This port enables connection of a USB flash drive to the rear panel for software updates and log downloads. However, the Front USB Port is the primary mode of access. *CAUTION: Use only USB memory devices in the front panel USB port.*	 *Figure 3: Rear Panel Controls and Connections*

19 | TECHNICAL SPECIFICATIONS

System Classification

The NEUROMARK System is classified according to IEC 60601-1 as illustrated in the table below.

Item	System Classification
Protection against Electric Shock	Class I
Applied Part: NEUROMARK Device (FS-004-01 or NMK00301)	Type-CF defibrillator proof
Mode of Operation	Continuous
Ingress Protection	IPX0
Methods of Sterilization	NEUROMARK Console: N/A NEUROMARK Device: Ethylene oxide (EO)
Suitability for Use in an Oxygen Rich Environment	Not suitable

Compliant Standards

- IEC 60601-1: 2005 (Third Edition) + CORR. 1: 2006 + CORR. 2: 2007 + A: 2012
- IEC 60601-2-2: 2017 (Sixth Edition)
- IEC 62304: 2015 (Edition 1.1)
- IEC 60601-1-2: 2014 (Fourth Edition)

- IEC 60601-1-6: 2010, AMD1: 2013 (Edition 3.1)
- IEC 62366-1: 2015 (First Edition)

Impedance Measurement

- Range: 40 to 2000 ohms with 1 ohm resolution.
- Low Power Impedance Measurement delivers less than 10.0 milliwatts averaged over any 1-second period.
- Low Power Impedance Measurement operates at the same frequency as the RF output.
- During Low Power Impedance Measurement, the RF load received no more than 25 volts RMS (VRMS).
- Low Power Impedance Measurement provides impedance readings at least once every 0.1 second.

RF Output

Frequency: 465.1 kHz ± 3%
Waveform: Quasi-sinusoidal voltage waveform with harmonic content less than -15 dBc
Maximum power: 40 VA (applicable to an impedance range of 40 ohms to 2000 ohms)

Outside this range, the Console adjusts the available power to adhere to specified voltage and current limits. The applied part of patient circuit is not referenced to earth at high frequency.

The maximum output of 40 VA is restricted by:

- Maximum Voltage: 130 VRMS
- Maximum Current: 1.0 ARMS
- Phase Angle: Ranges from -30º (capacitive) to +30º (inductive)

Measurement Accuracy (at time of manufacture)

Power:
Impedance = 40 to 99 ohms ± 10% or ± 1 watt, whichever is greater
Impedance = 100 to 500 ohms ± 5% or ± 0.2 watt, whichever is greater
Impedance = 501 to 1000 ohms ± 8% or ± 1 watt, whichever is greater
Impedance = 1000 to 2000 ohms ± 15% or ± 1 watt, whichever is greater

Impedance:
40 to 99 ohms ± 10% or ± 5 ohms, whichever is greater
100 to 1000 ohms ± 8%
1000 to 2000 ohms ± 15%

Hardware Shutdown Limits

Measured RF Power:
> 40 watts

Mechanical Specifications

Size: 336 mm x 282 mm x 103 mm
Weight: 17 lb. (7.7 kg) maximum (Console only)
Moisture protection rating: IPX0 (ordinary, per IEC 60601-1)

Environmental Specifications

- Operating Temperature: 10 °C to 40 °C

- Operating Relative Humidity: 30% to 70% non-condensing
- Transport and Storage Temperature: -20 °C to 60 °C
- Transport and Storage Relative Humidity: 20% to 95% non-condensing
- Altitude: Up to 3000 m
- All system components must undergo a two-hour acclimation period at 25 °C ±3 °C before use following exposure to the storage environment.

Fuses

Replace mains fuses as indicated with: 5 A / 250 V, High breaking capacity, T-lag, 5X20 mm.
When replacing fuses, ensure the integrity of the new fuses by inspecting for any damage that could affect their function. Use a precision slot drive screwdriver to remove the fuse drawer. Replace the fuses and then close the fuse drawer.

Line Input Ratings

The Console operates from an AC power source ranging from 100 to 240 volts AC, at 50/60 Hz, drawing a maximum current of 2.5 amps.

Rated Accessory Voltage

The rated voltage for the Interface Cable and NEUROMARK Device is 130 volts RMS (VRMS).

Output Power Graphs

Power cannot be delivered below 40 ohms of impedance.

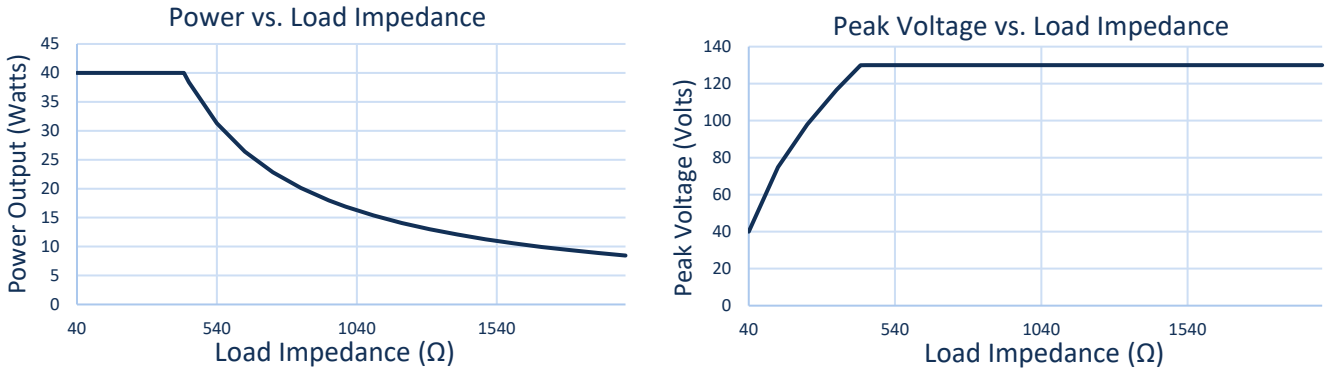


Figure 4 Output Power Graphs

Alert/Error Tones

- When an Alert indication is raised, the Console will emit the Alert Tone.
- When an Error indication is raised, the Console will emit the Error tone.
- An Alert tone consists of a single Alert Pulse.
- An Error tone consists of a single Alert Pulse repeated every 4 to 5 seconds.
- Alert Pulse volumes are always greater than 40 decibels (dBA) and less than 90 decibels (dBA).

Alert Condition Logging

The Console logs the occurrence and identity of alert conditions. The log file is maintained when the alert is acknowledged, and the system is powered down.

Fault State

If a non-recoverable fault is encountered, the Console will enter a Fault State. The Fault State will display a fault code and basic instructions to the operator. Follow the instructions provided on screen. An Error tone will play in the Fault State. Mains power to the Console must be cycle (OFF-ON) to attempt recovery from a fault.

Cybersecurity

The Console provides no remote networking connections of any kind during use or maintenance (no WIFI, Bluetooth or wired network connections are available or possible.

20 | EMC SPECIFICATIONS

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The NEUROMARK System is intended for use in the electromagnetic environment specified below. The user of the NEUROAMRK System should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The NEUROMARK System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The NEUROMARK System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class D	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Essential performance was shown to be maintained for all levels of electromagnetic immunity testing. Essential performance for this system includes accurate measurement of RF power levels.

A degradation in essential performance will generally always be prevented by an alert or error associated with that function. In the unlikely event that an alert or error does not prevent degradation of essential performance by an electromagnetic disturbance, one or more aspects of essential performance, as defined above, may be impacted.

The NEUROMARK System is intended for use in the electromagnetic environment specified below. The user of the NEUROMARK System should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, and ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines Both at 100kHz repetition frequency	± 2 kV for power supply lines ± 1 kV for input/output lines Both at 100kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.

The NEUROMARK System is intended for use in the electromagnetic environment specified below. The user of the NEUROMARK System should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Surge IEC 61000-4-5	**For power supply lines:** ±0.5kV and ±1kV line(s) to line(s) ±0.5kV, ±1kV, and ±2kV line(s) to ground For signal input/output ports: ±2kV line(s) to ground	**For power supply lines:** ±0.5kV and ±1kV line(s) to line(s) ±0.5kV, ±1kV, and ±2kV line(s) to ground For signal input/output ports: ±2kV line(s) to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT for 0.5 cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles 0% UT for 250/300 cycles	0% UT for 0.5 cycle at: 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT for 1 cycle and 70% UT for 25/30 cycles 0% UT for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Console requires continued operation during power mains interruptions, it is recommended that the Console be powered from an uninterruptible power supply.
Note: UT is the AC mains voltage prior to application of the test level.			
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V ISM bands between 0.15 MHZ and 80 MHZ 80% AM at 1 kHz	3 V 0.15 MHz – 80 MHz 6 V ISM bands between 0.15 MHZ and 80 MHZ 80% AM at 1 kHz	Portable and mobile RF communications equipment should be used no closer to any part of the System than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz Specific communication frequencies tested per table 6	3 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz Specific communication frequencies tested per table 6	Recommended separation distance: $d = [1.17] \sqrt{P}$ $d = [1.17] \sqrt{P}$ 80 MHz to 800 MHz $P = [2.33] \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range,[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: at 80 MHz and 800 MHz, 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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones, and land mobile radios, amateur radio, AM and FM radio

The NEUROMARK System is intended for use in the electromagnetic environment specified below. The user of the NEUROMARK System should ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
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 in the location in which the System including cables or any of its components are used exceeds the applicable RF compliance level above, the System including cables should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the System including cables. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Guidance and Manufacturer's Declaration – Enclosure Port Immunity Levels to RF Wireless Communications Equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	GM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Console including Cables.

The Console (including cables) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Console (including cables) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Console including cables as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz d = [1.17] √P	80kHz to 800MHz d = [1.17] √P	800kHz to 2.5GHz d = [2.33] √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.7	11.7	23.3

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 80MHz and 800MHz, 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.

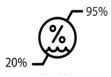
21 | GLOSSARY OF TERMS

Term	Definition
Mode	A group of states that comprise the machine steps to complete a procedure.
POST	Power On Self-Test

22 | DEFINITION OF SYMBOLS USED IN LABELING

Symbols used in the NEUROMARK System labeling are per ISO 15223-1 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements and IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Symbol	Symbol Title	Symbol Definition
	Manufacturer	Indicates the medical device manufacturer
	Catalog number	Indicates the manufacturer’s catalog number so that the medical device can be identified
	Serial number	Indicates the manufacturer’s serial number so that a specific medical device can be identified

Symbols used in the NEUROMARK System labeling are per ISO 15223-1 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements and IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance		
Symbol	**Symbol Title**	**Symbol Definition**
	Date of manufacture	Indicates the date when the medical device was manufactured
	Model number	Indicates the model number or type of a product
	Refer to instruction manual/booklet (Pantone blue)	Signifies that the instruction manual/booklet must be read
	Consult electronic instructions for use	Indicates the need for the user to consult the instructions for use
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Do not use if packaging is damaged and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Unique device identifier	Indicates a carrier that contains unique device identifier information
	Professional use only	Federal (USA) law restricts this device to sale by or on order of a physician
	Electrical hazard (Yellow)	Indicates the potential risk of electrical shock
	Fuse	To identify fuse boxes or their location
	Alternating current	Indicates on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.
	Universal Serial Bus (USB), port/plug	Identifies a port or plug as meeting the generic requirements of the Universal Serial Bus (USB); Indicates that the device is plugged into a USB port or is compatible with a USB port
	Non-ionizing electromagnetic radiation	Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or indicates equipment or systems e.g., in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed

Symbols used in the NEUROMARK System labeling are per ISO 15223-1 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements and IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance		
Symbol	**Symbol Title**	**Symbol Definition**
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed
	Keep away from rain	Indicates that the transport package shall be kept away from rain and in dry conditions
	Fragile, handle with care	Indicates that the contents of the transport package are fragile, and the package shall be handled with care
	This way up	Indicates correct upright position of the transport package.
	Stacking by limit number	Indicates that the items shall not be vertically stacked beyond the specified number, either because of the nature of the transport packaging or because of the nature of the items themselves
	Defibrillation-proof type CF applied part	Identifies a defibrillation-proof type CF applied part complying with IEC 60601-1
	Equipotentiality	Identifies the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g., for local bonding
	Protective earth protective ground	Identifies any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode
	SGS Certification Mark	Certifies that the medical device is in compliance with safety standards
	WEEE; waste electrical and electronic equipment	Indicates that separate collection for waste electric and electronic equipment (WEEE) is required

The NEUROMARK System is protected by one or more patents, available at www.neuromark.com/patents

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