![FHC logo]
**FHC**
*Neural microTargeting™ Worldwide*

# Guideline 4000™ 5.0

Directions For Use

L011-85 (Rev D0, 2019-08-15)

Contains directions for the following products:
MT-LPP, C0215, C0216, C0217, C0218, C0234, C0237
Storage: C0226
Country Specific Cables: 66-EL-LC-XXX



**Guideline 5**

www.fh-co.com

# Table of Contents

## Indications for Use

The Guideline 4000™ 5.0 is intended to record and stimulate electrophysiological activity, as well as aid in the accurate placement of electrodes and other instruments.

## Intended Use

The microTargeting™ Guideline 5 system is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist to accurately position depth electrodes during functional neurosurgical procedures.

## Applicable Standards

The Guideline 5 system complies with the following safety and performance standards:

- IEC 60601-1:2006 +A12:2014
  Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (the Guideline 5 is a Class 1 medical device with type BF applied parts)

  - Collateral Standards:

    - IEC 60601-1-2:2014 Ed.4
      Electromagnetic Compatibility – Requirements and Tests
      The Guideline 5 is classified as CISPR 11 Class A equipment

    - IEC 60601-1-6:2010 + AMD1:2013
      Usability

  - Particular Standards:

    - IEC 60601-2-26:2012
      Particular Requirements for the Safety of Electroencephalographs

    - IEC 60601-2-40:2016
      Particular Requirements for the Safety of Electromyographs and Evoked Response Equipment

## Symbol Key

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| ⚠ | WARNING / Caution, consult instructions for important cautionary information. | 🏭 | Medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEc and 98/79/EC. |
| 📖 | Consult the instructions for use. | ☎ | Telephone number. |
| Rx Only | **Caution**-Federal Law (USA) restricts this device to sale by or on the order of a physician. | EC REP | Authorized Representative in the European Community. |
| ! USA | In reference to "Rx only" symbol; this applies to USA audiences only. | CE 0413 | European Conformity. This device fully complies with MDD Directive 93/42/EEC and legal responsibilities as a manufacturer are with FHC, Inc., 1201 Main Street, Bowdoin, ME 04287 USA. |
| REF | Indicates the catalog number so that the medical device can be identified. | | |
| SN | Indicates the serial number so that a specific medical device can be identified. | +43°C/+109°F 5°C/+41°F | Indicates the temperature limits to which the device can be exposed. |
| MODEL | Indicates the model number so that the model of the medical device can be identified. | 95% / 5% | Range of humidity to which medical device can be exposed. |
| 〰 | Date when the medical device was manufactured. | 1060 hPa / 500 hPa | Range of atmospheric pressure to which medical device can be exposed. |
| 🗑 | Instructions for end of life disposal. | | |

### Unit Symbol Key

| Symbol | Description | Symbol | Description |
|---|---|---|---|
| ▌ | Main Power Switch, On | ⊙ | Motor Connection |
| ● | Main Power Switch, Off | ▭ | Remote Control Connection |
| ⊟ | TCP/IP Data Streaming Connection | 1 | Head Box 1 Connection |
| ▭ | Guideline 5 PC Data Connection | 2 | Head Box 2 Connection |
| | | IOIOI | Analog/Digital Synchronization Unit Connection |

Guideline 4000™, microTargeting™, STar™ and WayPoint™ are trademarks of FHC, Inc.

## Environmental Limits for Storage, Handling and Use

- **Temperature Limits:** 5℃ (41°F) to 43℃ (109°F)
- **Humidity Limits:**
  - **Storage and Handling:** 5% to 95% relative humidity, non-condensing
  - **During Use:** 35% to 95% relative humidity, non-condensing
- **Atmospheric Pressure Limits:** 50kPa to 106kPa, Altitude ≤ 2km
- The Guideline 5 is intended to be used in a professional health care operating room environment. Care must be taken to curtail electrical charge buildup resulting from the presence of flammable gases and medical instrumentation.
- Do not drop the Guideline 5 or any of its components and accessories.

⚠ **WARNING:** Do not expose the Guideline 5 to humidity greater than 95%.

⚠ **WARNING:** Do not store the Guideline 5 near or expose it to strong magnetic fields.

⚠ **WARNING:** Do not use the Guideline 5 in the presence of flammable gas mixtures.

⚠ **WARNING:** Do not expose Guideline 5 to x-ray radiation.

## System Maintenance and Repair

### Cleaning

FHC recommends the following manual cleaning protocol:
Following use, wipe all components of the Guideline 5 system lightly with a dry cloth. If necessary, slightly moisten the cloth with a standard hospital disinfectant and wipe any surfaces suspected of contamination. Neither the Guideline 5 nor any of its components and accessories should be subjected to sterilization.

⚠ **WARNING:** Do not allow any liquid to contact any Guideline 5 components.

⚠ **WARNING:** Do not attempt to sterilize the interface(s), motor unit, or the hand-held remote control.

⚠ **WARNING:** Clean the Guideline 5 using a cloth that has been slightly dampened with disinfectant if biological contamination is observed or suspected.

### Routine Maintenance

- All Guideline 5 system components and accessories, including cables, should be visually inspected for physical damage prior to each use. If any component shows wear or damage that could interfere with proper function, please contact FHC for repair or replacement.
- The Guideline 5 notebook computer runs on the Windows™ 10 Pro 64-bit operating system. If the computer is going to be connected to a hospital network, other information technology devices, or the Internet, then Windows, anti-virus software, and other installed programs should be allowed to periodically (monthly) download and install updates and security patches.
- Data files recorded by the Guideline 5 system are large and may fill up the available storage space on the notebook computer. The Guideline 5 application will provide a warning when the remaining storage on the computer starts to get low. It is the user's responsibility to archive saved patient data and move it off the Guideline 5 computer when prompted to do so. Note that the Guideline 5 encrypts sensitive patient information to protect patient privacy on all such files.

⚠ **WARNING:** Do not install third-party software onto the Guideline 5 notebook computer unless authorized to do so by an FHC factory-authorized representative.

⚠ **WARNING:** Connecting the Guideline 5 to IT networks, including other equipment, could result in previously unidentified risk to patients, operators, or third parties. It is the owner's responsibility to identify, analyze, evaluate and control these risks. Any changes to such a network could introduce new risks that require additional analysis.

## Periodic Preventive Maintenance

To ensure continued reliable operation, FHC requires that a comprehensive functional and safety inspection of the Guideline 5 system be preformed annually by an authorized FHC In-Service Engineer. FHC can provide this service on-site and offers annual service contracts that include all recommended periodic preventive maintenance, access to any available software upgrades and full coverage of any qualifying repair charges. Contact FHC for details and pricing options.

⚠ WARNING: The Guideline 5 must be serviced and inspected annually by an authorized FHC representative.

⚠ WARNING: DANGER high voltage, do not disassemble.

⚠ WARNING: No user-serviceable parts inside; do not remove external panels. Contact FHC if unauthorized disassembly is suspected.

## Repair and Warranty

All FHC products are unconditionally guaranteed against defects in workmanship for one year from the date of shipment provided they have been exposed to normal and proper use. Should service or repair be required, please contact FHC at 1-800-326-2905 (US & Canada) or +1-207-666-8190 for instructions.

With proper maintenance and use, the Guideline 5 system has been designed to operate reliably for many years. However, after a service life of 5 years, repair issues may arise due to the lack of third-party software support and obsolescence of components. In such scenarios, FHC will make a best-effort attempt to provide needed repairs but cannot guarantee success.

⚠ WARNING: Discontinue use of the Guideline 5 should any erratic function or damage become evident.

## 🗑 End-of-life System Disposal

Return the Guideline 5 system, including all components and accessories, to FHC for environmentally conscious end-of-life disposal once it is no longer in use. Please contact a FHC factory-authorized representative to arrange a return.

## Installation and Training

Included with the sale of every Guideline 5 system is on-site delivery, installation and training by an FHC In-Service Engineer. This will include functional and safety verification and up to one day of operator training on the proper use of the Guideline 5 system. After the training, the password required to log into the Guideline 5 computer will be provided and recorded by the In-Service Engineer on page 7.

While all information required to safely and effectively use the Guideline 5 system is contained within this document, FHC strongly recommends that all system operators receive in-person training from an FHC In-Service Engineer or other knowledgeable user in advance of using the system intraoperatively. In the event of staffing changes, or any time additional product training is desired, please contact FHC at 1-800-326-2905 (US & Canada) or +1-207-666-8190 to make arrangements.

⚠ WARNING: The Guideline 5 must be installed by an FHC-authorized representative.

⚠ WARNING: The Guideline 5 must be operated by a person who has read and understood the directions for use (DFU).

⚠ WARNING: The Guideline 5 components and accessories should not be used adjacent to or stacked with other equipment. Where such an arrangement is necessary, the system should be observed to verify normal operation prior to use.

⚠ WARNING: The Guideline 5 should not be used with high-frequency surgical equipment. Always remove any electrodes prior to using such equipment. Failure to do so could result in burns at the electrode site and possible damage to the Guideline 5.

⚠ WARNING: Potentially hazardous interactions between the Guideline 5 and other connected equipment may occur.

⚠ WARNING: Operation of the Guideline 5 in close proximity to shortwave or microwave therapy equipment may produce instability in the system.

Password Reminder: _____

Training Log:

| Trained Operator | Training date | Trainer |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |

## System Overview

The Guideline 5 system has been designed to record electrophysiological biosignals derived from electrodes to assist neurophysiologists and/or neurosurgeons during intraoperative procedures, such as the accurate placement of DBS electrodes within the brain. The wide range of input configurations possible with the Guideline 5 make it suitable for amplifying, conditioning, filtering, analyzing, and archiving the biosignals received from various types of electrodes and electrode recording methodologies:

- **MER** - extracellular microelectrode recording with high impedance metal microelectrodes inserted into the brain for acquiring and analyzing single and multi-unit action potentials.

- **LFP** - local field potentials can be acquired simultaneously with MER activity through the macrocontact of a differential microelectrode or directly from the contacts of a DBS electrode for verifying placement.

- **ECoG** - electrocorticography strips and arrays for acquiring cortical field potentials directly from the surface of the brain.

- **SEEG** - stereoelectroencephalography through depth electrodes, for recording field potentials from specific areas of the brain, often used for locating epileptogenic zone.

- **EEG** - electroencephalography for recording field potentials from the brain typically using non-invasive surface electrodes. Acquired biosignals are suitable for a variety of purposes including Evoked Potentials.

- **EMG** - surface electromyography for non-invasively recording electric potentials generated by muscle cells through the skin.

- **Microelectrode Neurography** - for the intramuscular recording of activity using a needle (microneurography) electrode.

- **General Purpose Analog Inputs** - configurable for a large variety of biosignal transducers such as accelerometers.

- **General Purpose Digital Inputs** - capable of serving as digital triggers or for the accurate capture of timestamps and digital words frequently required during investigational studies. These digital inputs are earth referenced and not suitable for direct connection to the patient.

⚠ WARNING: The Guideline 5 does no analysis, diagnosis, or monitoring for undesirable or dangerous physiological conditions.

⚠ WARNING: The Guideline 5 issues no alarms should undesirable or dangerous medical conditions arise.

⚠ WARNING: Do not use the Guideline 5 system or any part of it as a diagnostic instrument.

⚠ WARNING: The use of accessories, electrodes, and cables other than those specified or provided by FHC could result in increased electromagnetic emissions or the decreased electromagnetic immunity of the Guideline 5 and possibly result in improper operation.

In addition to biosignal acquisition, the Guideline 5 system can be configured to provide the following features:

- A highly versatile audio monitor for MER signals.

- Integrated multi-channel stimulation capable of delivering configurable constant current pulse trains from one micro-amp to 10 milliamps in amplitude for intracranial MER and DBS electrodes.

- Integrated impedance monitoring for verifying electrode characteristics and lead connections.

- An integrated motor controller, designed to mount on FHC's STar™ Drive (or microTargeting Drive) micropositioner for accurate depth positioning of intercranial depth electrodes.

- A multi-function, ergonomic, hand-held remote control for accessing commonly used functionality associated with stimulation and depth control.

- A sophisticated power-on self-test.

- An intuitive and easy-to-learn user interface.

- A compact and clean design that minimizes cable clutter, OR footprint size, and setup complexity.

- A host of patient-isolated, configurable digital and analog outputs are provided for integration with legacy systems and other data processing equipment.

- Ethernet streaming of electrophysiological data to custom analysis applications and/or other devices, such as the WayPoint™ Navigator's Intra-Op module.

- Pre-sterile, disposable patient leads utilizing driven shield technology to minimize artifact pickup in the noisy OR environment.

- A transport and storage case suitable as carry-on luggage is provided to facilitate ease of travel and safe storage of the Guideline 5 system.

The Guideline 5 connects to the electrodes via an Interface which is designed to be located just outside the sterile field (where required). The Interface connects to the Guideline 5 system via a 3-meter digital cable. Interfaces can be pole mounted or placed on any appropriate surface. All acquired signals are amplified, conditioned, isolated, and digitized entirely within the Interface. The Guideline 5 Interface is capable of independent recording and stimulation from as many as eight channels. The Guideline 5, with the addition of an optional second signal processing card, is capable of simultaneously supporting two Interfaces for a maximum channel count of 16 channels. This, in addition to the two general purpose analog inputs and thirty-four digital inputs provided with the optional Synchronization I/O Unit, gives the Guideline 5 enough signal acquisition capability for even the most demanding research applications. All data acquired by the Guideline 5 is time-synchronized and can be recorded in its entirety for offline review and analysis.

There are two different models of Guideline 5 Interface, both optimized for different kinds of electrodes:

**UE Interface (C0219):**
The UE Interface records high frequency (up to 16 kHz) biosignals and is optimized for the recording of single units within the brain using differential microelectrodes. Pre-sterile patient leads are available in 1.5m and 3m lengths. The Interface provides eight channels of differential inputs all sharing a patient common connection. It is capable of simultaneous acquisition of both high and low-frequency activity (spikes and LFPs) from each channel. All channels are equipped with an independent stimulation circuit enabling micro-stimulation as well as complex multi-channel macro-stimulation protocols.
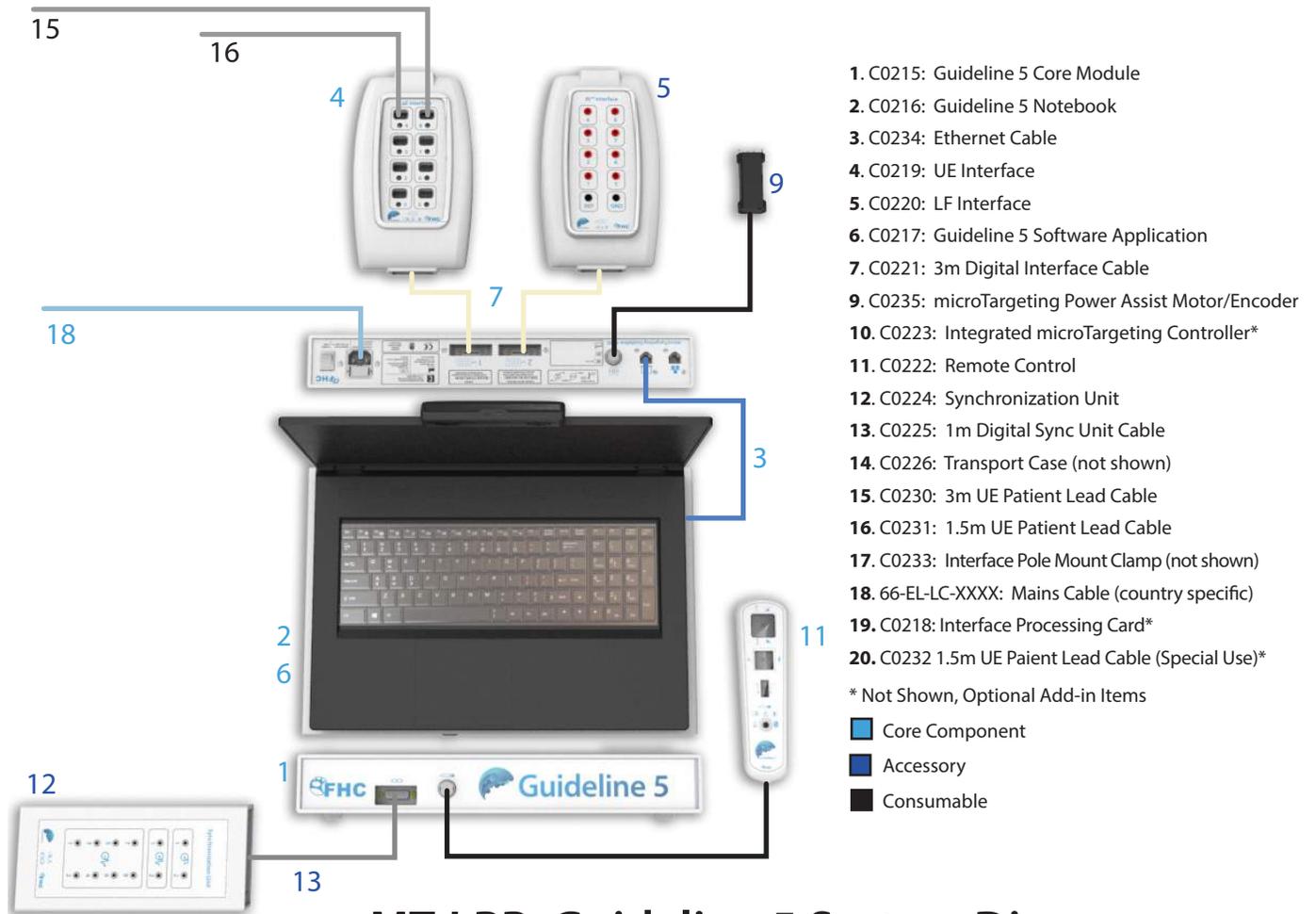
**LF Interface (C0220):**
The LF Interface is optimized for capturing low-frequency biosignals (bandwidths from DC to 1 kHz). Patient-connected electrodes or sensors utilizing 1.5mm touch-proof connectors can be directly connected to the LF Interface. Eight channels of single-ended inputs sharing a common reference and patient common connection are provided. A high-density connector allows for the direct connection of externalized DBS leads through a manufacturer-specific trialing cable. All channels are equipped with an independent stimulation circuit, enabling complex multi-channel stimulation protocols where appropriate.

Once the digitized biosignals leave the Interface(s), further signal processing is performed by the Guideline 5's Main Processing Unit before being sent via Ethernet connection to the Guideline 5 Notebook PC and Guideline 5 Software application for filtering, display, analysis, and archival. An integrated TCP/IP Server feature allows processed data from the Guideline 5 to be streamed to additional equipment in pseudo-real-time. All acquired data is archived in raw format, allowing filters to be fine-tuned and analyses to be honed during offline playback.

The Guideline 5 system has been designed to facilitate and simplify the intraoperative monitoring of electrodes. It is capable of being set up and initialized quickly, with minimal cables and clutter, and can provide up to 16 channels of simultaneous recording and/or stimulating capability. The Guideline 5 system can connect to two Interfaces simultaneously, for a total of 16 channels.

## System Components and Connections



**1.** C0215:  Guideline 5 Core Module

**2.** C0216:  Guideline 5 Notebook

**3.** C0234:  Ethernet Cable

**4.** C0219:  UE Interface

**5.** C0220:  LF Interface

**6.** C0217:  Guideline 5 Software Application

**7.** C0221:  3m Digital Interface Cable

**9.** C0235:  microTargeting Power Assist Motor/Encoder

**10.** C0223:  Integrated microTargeting Controller*

**11.** C0222:  Remote Control

**12.** C0224:  Synchronization Unit

**13.** C0225:  1m Digital Sync Unit Cable

**14.** C0226:  Transport Case (not shown)

**15.** C0230:  3m UE Patient Lead Cable

**16.** C0231:  1.5m UE Patient Lead Cable

**17.** C0233:  Interface Pole Mount Clamp (not shown)

**18.** 66-EL-LC-XXXX:  Mains Cable (country specific)

**19.** C0218: Interface Processing Card*

**20.** C0232 1.5m UE Paient Lead Cable (Special Use)*

\* Not Shown, Optional Add-in Items

⬜ Core Component

🟦 Accessory

⬛ Consumable

# MT-LPP: Guideline 5 System Diagram

## Detailed Instructions for Use

The Guideline 5 system has been designed to be expandable and modular to meet a variety of needs and use scenarios. The directions for use for the Guideline 5 system are split into seven documents as explained below. Please refer to the appropriate directions for use when looking for specific information. Additional printed or digital copies of all directions for use for the Guideline 5 system may be obtained free of charge either online at www.fh-co.com or by calling 1-800-326-2905.

**L011-85 Guideline 5 System Directions for Use (this document)**
Provides high-level information regarding the use of the Guideline 5 system in general and details core components and procedures common to all use scenarios.

- C0215: Guideline 5 Main Unit
- C0216: Guideline 5 Notebook PC
- C0234: Ethernet Cable
- C0217: Guideline 5 Application
- C0218: 2nd Interface PCB
- C0226: Transport Case
- C0237: High Performance Speaker
- 66-EL-LC-XXX: Mains Cable (country specific)

### L011-85-01 UE Interface

Provides instructions for recording and stimulating using depth microelectrodes. Details procedures and functionality of the Guideline 5 system supporting target localization for placement of DBS leads or ablation electrodes.

- C0219: UE Interface
- C0221: 3m Digital Interface Cable
- C0222: Remote Control
- C0230: 3m UE Patient Lead
- C0231: 1.5m UE Patient Lead
- C0232: 1.5m Patient Lead (Special Use)
- C0233: Interface Pole Mount Clamp

### L011-85-02 LF Interface

Provides instructions for recording and stimulating using low-frequency electrodes.

- C0220: LF Interface
- C0221: 3m Digital Interface Cable
- C0233: Interface Pole Mount Clamp

### L011-85-03 Integrated microTargeting Controller

Provides detailed instructions and procedures for utilizing the integrated microTargeting Controller and motor for power-assisted remote control of microelectrode depth.

- C0235: microTargetign Power Assist Motor/Encoder
- C0223: Integrated microTargeting Controller Card
- C0222: Remote Control
- 66-DA-SD: Sterile Drape Sleeves

### L011-85-04 Synchronization I/O Unit

Provides instructions for the use of the Synchronization I/O unit to interface the Guideline 5 system with other equipment.

- C0224: Synchronization Unit
- C0225: 1m Digital Sync Cable

### L011-85-05 microTargeting Electrode Lead Cable

Provides instructions for the both the 3m and the 1.5m Electrode Lead Cable.

- C0230: 3m Patient Lead
- C0231: 1.5m Patient Lead
- C0232: 1.5m Patient Lead (Special Use)

### L011-85-06 microTargeting Guideline 5 Remote Control

Provides instructions for the Guideline 5 Remote Control.

- C0222: Remote Control

## Specifications

### C0215 - Guideline 5 Main Processing Unit (MPU)

Dimensions: ~ 41 cm Width, ~ 6 cm Height, ~ 11 cm Length
Weight: <3 kg
Power Requirements: 100-240 VAC, 50/60 Hz, 2A
Fuses: 2x 250V 2A Type T H
Interface Capacity: 1 or 2* x 8 channels, can handle any combination of interfaces
       * 2nd interface connectivity requires installation of optional C0218 Interface PCB
TCP/IP Connectivity: Required client IPv4 Address – 192.168.0.XXX (XXX >= 010)
Data Streaming Protocol: Details available on request, contact FHC. Example Matlab® script provided.

### C0216 - Guideline 5 Notebook Computer Minimum Specifications

Dimensions: <42cm x <28cm x <3cm
Weight: <3.5 kg with power supply
Power Requirements: 100-240 VAC, 50/60 Hz, 2.5A
Specifications: Core i7 Intel processor, 15.6" diagonal display, 1920x1080 Resolution, 500GB SSD Hard Drive, 1TB Storage Drive, External monitor support (HDMI), Win 10 Pro 64-bit Operating System, 8GB Ram, Touch-screen, Track-pad, microphone, 3x USB, Wired Ethernet jack.
Full Drive Encryption will be enabled by request.

### C0234 - Ethernet Cable

Length: 30 cm
Configuration: straight to right angle RJ-45 dual RFI suppression ferrites

### C0218 - Second Interface PCB

Optional Internal Add-on, installation by authorized FHC representative only, provides connectivity for second interface. No specifications provided, internal component.

### C0226 - Transport Case

Dimensions: <25cm x 46cm x 50cm
Construction: Soft case with internal frame & padding, roller wheels and extendable handle
Specifications: Weight (empty) < 3.2kg, (fully loaded) < 12.5kg

### C0237 – High Performance Speaker

Dimensions: <21cm x 7cm x 3cm
Weight: 210g
Connection: USB/3.5mm stereo
Controls: Volume, power, LED power indicator

### 66-EL-LC-XXX - Mains Cable (country specific)

Length: 3 m (10')
Configuration: Country specific mains plug to IEC320 C13
Grade: Medical, shielded

### C0217 - Guideline 5 Software

The Guideline 5 application version number will be displayed within the introductory splash screen, on the title bar, and is also available within the system/maintenance section.

The Guideline 5 application can be configured for numerous languages. During installation and training, FHC will configure the application based on the native language of the territory where it will be used or the operator's preferences. Please contact FHC for assistance if a language change is desired.

Note: The Guideline 5 application is capable of operating in 'Demo' mode where a sample waveform will be presented in place of that coming from any connected interface hardware. This mode can be helpful for training new operators on the use of the system. Please contact FHC for assistance if use of the demo mode is desired.

## Illustrative Procedure

## Preoperative Setup

### Set-up of the Guideline 5

- Remove the Guideline 5 system components from the Transport case (C0226).

- Visually inspect all components for signs of damage which may affect functionality.

- Place the Guideline 5 MPU (C0215) on a surgical table of appropriate height with the Guideline 5 logo facing the operator and oriented away from the patient. Ensure that the side and bottom vents are not obstructed and that access to both the power switch and the line cord power entry are not blocked or obstructed.

- Set the Notebook PC (C0216) on top of the MPU and open the lid.

- Clip the Speaker (C0237) to the top of the PC screen and plug both the USB and 3.5mm stereo phono plugs into the PC.

- If connecting the Guideline 5 to an external monitor, plug in the HDMI cord prior to starting the PC.

- Plug the MPU and the PC into the mains using the (66-EL-LC-XXX) mains cord provided. Ensure the cord is routed safely along the floor to the desired mains outlet.

- Connect the PC to MPU with the Ethernet cable (C0234).
- Power on the PC and log into Windows under the Guideline 5 account using the password provided during training. If the password is forgotten, see the reminder in the training log earlier in this manual or contact FHC Technical Support.
- Connect all other equipment: Interface(s), Remote Control, Sync I/O, etc., to the MPU. See appropriate equipment DFU supplements for instructions on the proper connection of peripherals.

⚠ **WARNING:** Only the remote control, draped motor, and the electrode lead cables should be used within the patient environment. No other part of the system should enter the patient environment or the sterile field.

⚠ **WARNING:** Route component and accessory cables carefully to avoid creating a tripping hazard.

⚠ **WARNING:** Do not block the fan vents or intake air vents of the Guideline 5. Do not remove the 4 rubber feet, as this will cause the vents on the bottom of the MPU to become blocked.

⚠ **WARNING:** Assemble the Guideline 5 and related equipment on a level, stable surface only. Do not move the Guideline 5 during a procedure. If used on a wheeled work surface, lock the wheels to prevent movement.

⚠ **WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains power outlet with a protective earth conductor (3-pronged socket). Never use a damaged power cord or power strip.

### Start the Guideline 5 system and confirm a successful self-test, load user profile

- Toggle the main power switch to turn on the Guideline 5 MPU.
- Launch the Guideline 5 application (C0217) on the PC.
- A user Account Control Dialog will pop up – click **Yes**.
- At the splash screen, once the system has completed detecting and initializing the hardware, press any key to continue:
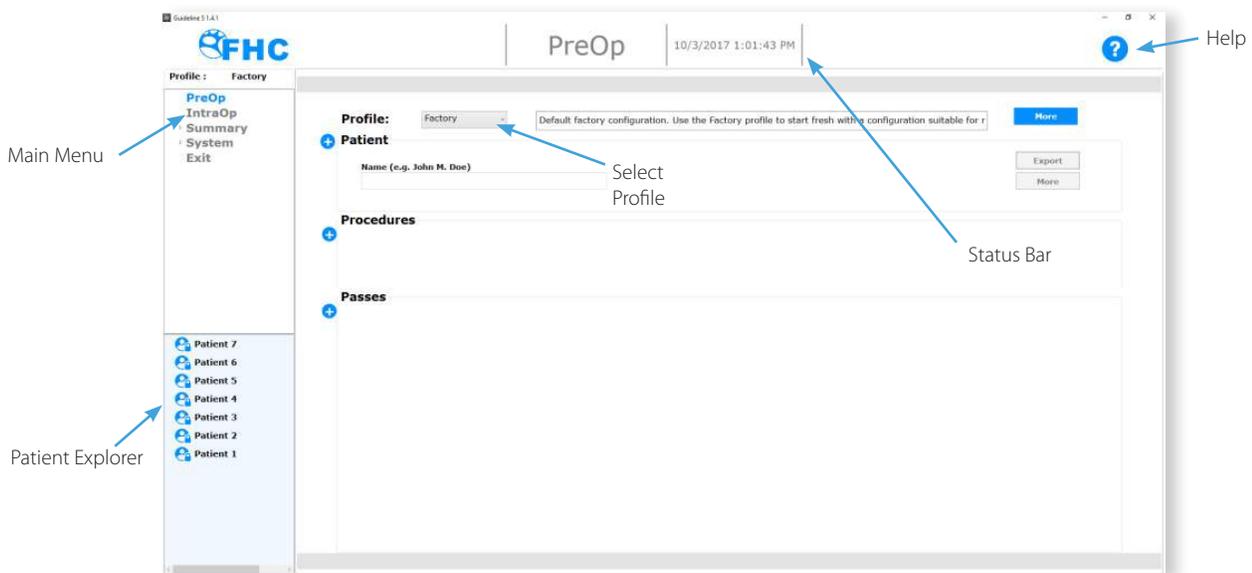
- When prompted to perform the functional verification, click **Yes**.
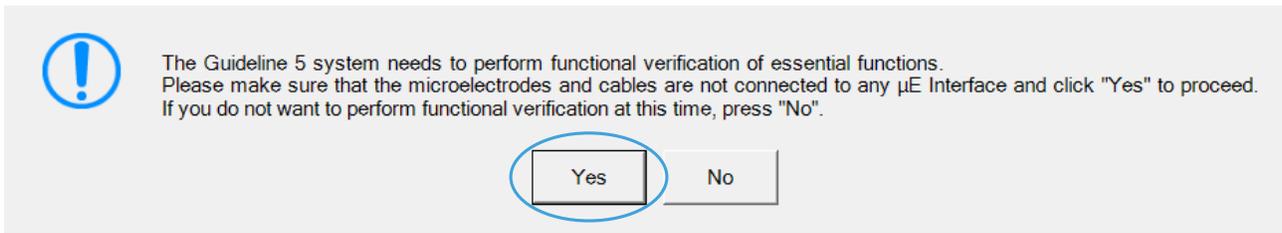


- Confirm the successful completion of the system self-test and click **Done**.

⚠ **WARNING:** Disconnect ALL patient connections when performing the system self-test.

- The Guideline 5 application will open to the PreOp screen shown below:



- **Main Menu:** Used to jump between different screens of the Application.
- **Patient Explorer:** Provides access to all archived data.
- **Help:** Most places within the Guideline 5 application provide access to context-sensitive help documentation.
- **Status Bar:** A persistent bar along the top of the screen that will display information pertaining to the procedure.
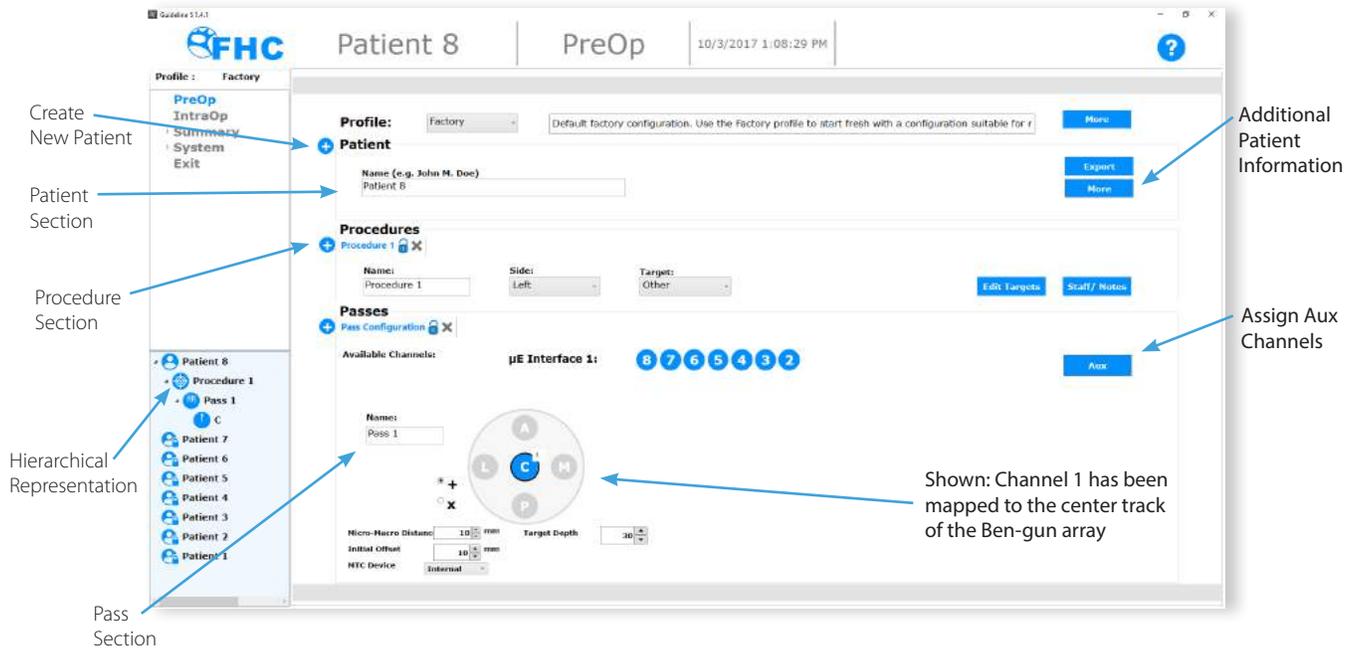
- Select the desired user profile

The Guideline 5 application makes use of user profiles. A profile contains a complete record of all the settings, configurations, and preferences chosen within the Guideline 5 system. By selecting a user profile, a user can quickly place the Guideline 5 system in a known state.

During the onsite installation and training, the FHC In-Service Engineer will help to create an appropriate Profile. Clicking on the **More** button next to the profile selection box will display a dialog box allowing users to modify their profiles and create new ones as desired.

All settings can be changed as needed from within the application at any time. Profiles may be applied at any time during use to bring the system back into a known state. The last applied profile is shown above the Main Menu.

Create a new Patient Record



- Create New Patient
- Additional Patient Information
- Patient Section
- Procedure Section
- Assign Aux Channels
- Hierarchical Representation
- Shown: Channel 1 has been mapped to the center track of the Ben-gun array
- Pass Section

- To create a new Patient record, press the (+) button next to the Patient section. Note that this action will also create a new Procedure and Pass associated with the new Patient.
- Type the patient's name in the box provided. Additional patient information may be entered by pressing the **More** button. Note that except for the name, all patient information entered will be encrypted in the patient record and only accessible from within the Guideline 5 application.

Enter Procedure information

- **Name:** The default procedure name may be overwritten if desired.
- **Side:** Enter the hemisphere associated with the procedure (Left, Right, None, or Both).

Note that a sequential procedure on the left hemisphere followed by one on the right hemisphere (or vice versa) should be entered as two separate procedures. Selecting **Both** is intended for simultaneous bilateral procedures where recordings from both hemispheres need to be available simultaneously. An option for **None** is provided for procedures not involving the use of intracranial depth electrodes.

- Select the intended target nucleus for the procedure, if desired. Additional targets may be added with the **Edit Targets** button. Default targets of STN, GPi, VIM, Other are available.
- Medical staff attending the procedure and notes pertaining to the procedure may be entered in the dialog box associated with the **Staff/Notes** button. Entry of this information is optional.

Enter Pass Information

- **Available Channels:** A list of all available recording channels will be shown at the top of the Pass section. This will be determined by the type and number of interfaces connected to the Guideline 5 MPU.
- **Name:** The default pass name may be overwritten if desired.
- **Ben-gun Diagram:** Based on the Side selected for the procedure 0, 1 or 2 Ben-gun arrays will be shown with the tracks labeled (A-Anterior, P-Posterior, C-Center, M-Medial and L-Lateral).
- **(+)/(X):** The angular orientation of the Ben-gun array may be selected using the (+) or (X) radio buttons. Note that the side selected for the procedure will determine the orientation of the Lateral and Medial tracks.
- **Mapping Channels:** Available channels are mapped to available tracks by clicking first on the channel and then on the track it is to be assigned to. The touch screen may be used to drag the desired channels onto the desired track. Once a channel has been associated with a track, that track will be highlighted and the associated channel will no longer be listed in the available channels list. Note that only channels associated with a UE Interface may be mapped to tracks in a Ben-Gun Array.

- **Aux:** UE Interface channels intended to be connected to other electrodes or sensors that will not have a track location or depth associated with them may be assigned from the list of available channels by pressing the **Aux** button.

- **LF:** LF Interface channels may be assigned from the list of available channels by pressing the **LF** button.

- **Target Depth:** The depth at which the target is expected in mm. This will be determined by the electrodes, stereotactic equipment and the micropositioner used. Using the FHC microTargeting or STar Drive on any major frame with Type D differential electrodes will typically result in a target depth of 30mm. Frames with a variable distance to target or an adjustable Z-mounting stage will likely have a different distance to target.

- **Initial Offset:** If starting the pass with the micropositioner at a depth other than 0mm, enter the starting depth in mm here.

- **Micro-Macro Distance:** Enter the offset in mm between the microelectrode tip and the macrostimulation contact.

- **MicroTargeting Controller Device:** There are a number of options for controlling the depth of the electrodes during a Pass:

   - Optional Integrated microTargeting Controller (C0223). If present, this may be selected by selecting **Internal**.
   - Stand-Alone microTargeting Controller (66-EL-MS). If present and connected to the Guideline 5 PC, this may be selected by selecting **External**.
   - Manual depth control via the STar Drive/ microTargeting Drive depth knob. If no microTargeting Controller is present, electrode depth will need to be entered by the user as it changes. This option may be selected by selecting **Manual**.

- This concludes the Preoperative setup procedure for the Guideline 5. Proceed to the IntraOp screen within the Guideline 5 application by clicking IntraOp on the Main Menu.

## Intraoperative Set-up and Use

Many features and functions available on the IntraOp screen are specific to microelectrode recording. These procedures will be covered in the DFUs associated with the UE Interface.

### Intraoperative Display

The figure below shows the IntraOp screen. When the IntraOp screen is active, the Patient Explorer will only show the current patient. Various mode control option buttons will appear within the Status Bar.
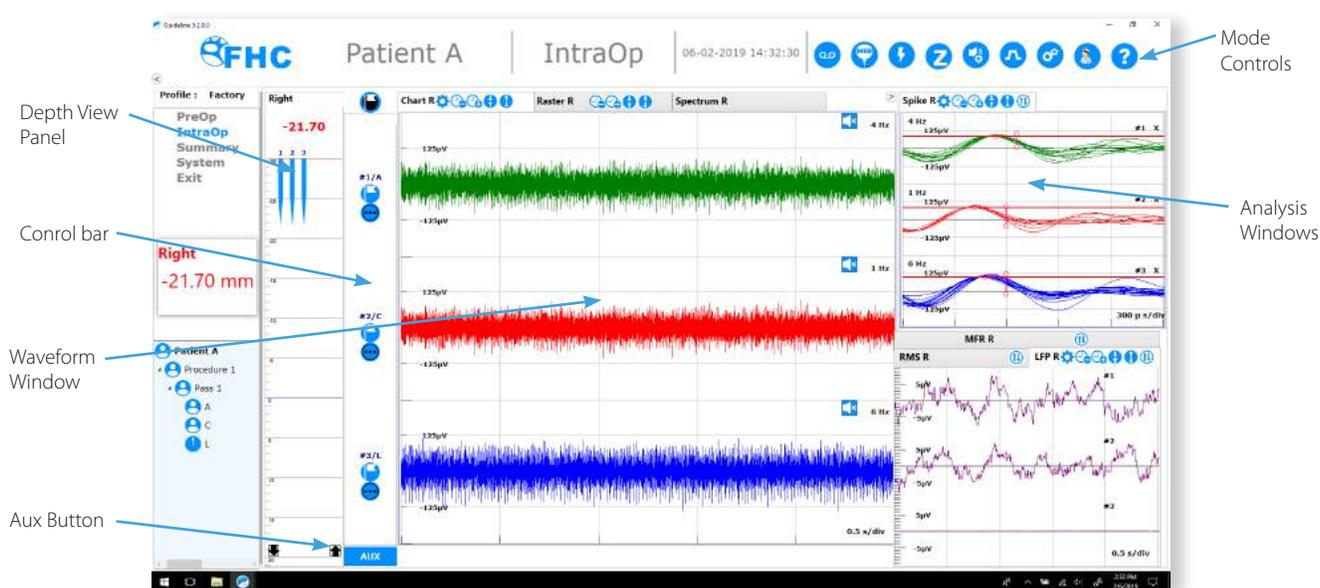


- **Depth Viewer:** The Depth View panel provides information about the current depth of the pass.

- **Control Bar:** The Control Bar provides quick access to channel-specific controls.

- **Waveform Window:** Displays the waveforms currently being recorded. Tabs at the top of the window provide access to actual waveforms recorded by the microelectrode or spectrograms of LFP activity recorded by the macrocontact. Controls along the tabs can be used for adjusting the scroll rate and amplitude of all waveforms displayed in the window.

- **Aux Button:** Pressing the Aux button will toggle a lower window pane in the waveform window dedicated to displaying waveforms not associated with microelectrodes. The height of this window pane is user-adjustable.
- **Mode Controls:** These buttons along the status bar can be used to launch various functions.

**Toggle Data Recording:** This button will be red when data is being recorded to file. While recording, waveforms associated with all channels mapped during the PreOp setup will be saved to disk. Saved data will be in raw format prior to the application of any digital filtering.

**Create an Event:** When pressed, an event will be created and saved. Events can consist of audio notes, neuron classifications, or just periodic samplings of recorded activity from one or all channels. Certain actions, such as applying stimulation or performing an impedance check, will automatically generate an associated event. Events will appear in the Patient Explorer and be shown within the Depth Viewer. All saved events will also be presented within the summary tab.

**Launch the Stimulation Dialog:** Stimulation procedures are covered in the appropriate Interface directions.

**Launch the Impedance Check Dialog:** Parameters pertaining to impedance checks may be set within the Control Panel. The Z-Check dialog provides controls to allow the impedance measurement of specific electrodes, or all electrodes simultaneously. Impedance results are automatically saved as events.

**Launch the Audio Monitoring Dialog:** From within this dialog, controls for the audio playback of recorded activity can be accessed. See the section on Audio Monitoring for details.

**Launch the Signal Processing Dialog:** Filter and gain settings can be adjusted as needed to optimize the isolation of biosignals of interest.

**Launch the Control Panel:** Various configuration settings are available from the control panel. It is divided into pages associated with settings related to specific areas of functionality.

**Launch Resident Expert:** Coming soon, the FHC Resident Expert package provides sophisticated signal analysis capabilities for automated artifact rejection, spike detection, spike discrimination, and neuron classification as well as objective analysis of waveforms recorded during motor neuron testing.

**Launch the Help dialog:** Comprehensive documentation concerning the use of the Guideline 5 system. Note that many dialogs available within the Guideline 5 application provide access to context sensitive help in addition to this general help system.

Depth Control

At the top of the panel a digital readout of the current depth is shown. Additionally, and not shown above, an independent and resizable window displaying the current depth is provided. This window will float on top of the Guideline 5 application and be visible at all times. Below the digital depth indicator is a graphical representation of the electrode pass. The side associated with the pass is shown. If the side selected for the pass was **Both,** then there will be two depth view panels shown, one associated with the left hemisphere and one with the right.

If an microTargeting Controller is present and was selected in the PreOp screen then the current depth will be automatically displayed and updated as soon as the drive is zeroed. If manual depth control was selected, a set of up/down arrows will be present next to the digital readout to allow the user to update the depth after adjusting the micropositioner.

The Depth viewer can be configured from the MTC Settings page of the Control Panel. The displayed depth can represent the distance from target (shown as negative above target and positive below), distance from zero, or distance traveled. Depth units may be displayed in mm or microns, according to preference.

The graphic depth display will run from the initial offset depth at the top to the limit depth (set from the MTC Settings

page of the Control Panel) and will indicate the expected target depth with a blue line. Any electrodes mapped to the Ben-gun array will be displayed at the current depth. The electrodes shown will thicken to indicate the current location of the macrocontact.

Any events generated during the pass will also be indicated at the appropriate depth by color-coded markers along the electrode's shaft. Clicking on these event markers will launch a dialog to provide more information about the event. These event markers can be used to provide a visual indication of the depths where various structures were encountered along the electrode track.

## Audio Monitoring

Audio Output of the Guideline 5 system is through the high performance speaker connected to the PC. Volume control is achieved through several methods: the audio monitoring controls within the Guideline 5 application, the audio volume controls of the PC, or the volume control on the top of the speaker itself.

All microelectrode channels can be monitored and controlled independently. The top row number keys on the PC keyboard can be used to quickly toggle audio output between muted and active for the channel corresponding to the number pressed (with the number 0 corresponding to channel 10). If more than 10 channels are mapped to microelectrodes, pressing shift and a number key will add 10 to the number, i.e. Shift + 1 will toggle audio on channel 11 and so on. In addition to toggling the output on the indicated channel, using the number key shortcuts mutes all other channels, allowing users to quickly listen to only the channel of immediate interest.

Generally, audio output will correspond to the waveform displayed in the waveform window on screen. However, there are a number of special audio modes that can be enabled from within the Audio Control dialog if desired:

- **Raw:** The unfiltered waveform prior to the application of the digital band-pass filters.

- **Threshold:** Only the portions of the signal whose absolute amplitude exceeds the current trigger line setting. This is a good way to eliminate the noise band from audio playback.

- **Triggered:** Only the portions of the continuous waveform appearing in the spike discrimination analysis window are played.

- **Accepted:** Only the portions of the continuous waveform appearing in the spike discrimination analysis window and meeting the level or window spike discrimination criteria are played.

- **Pulse:** Similar to Accepted, except that rather than playing the actual spike discriminated, a constant pulse is played instead.

The Audio Control dialog also provides Volume, Mute, Bass and Treble controls. Adjustments to these parameters can be applied on a channel-by-channel basis or globally by pressing the **Select All** button.

## Streaming Data

The Guideline 5 MPU is capable of streaming data to a client over an Ethernet network. This may be done wirelessly or by connecting an Ethernet cable to the network port on the back panel of the MPU. The Control Panels Data Settings page provides configuration options for this service.

- **TCP/IP Port:** When the streaming service is enabled, the Guideline 5 MPU will accept connection requests on the assigned port. This is port 2567 by default but can be changed by the user for security purposes. Note that by default, a firewall exception has been created for incoming traffic on port 2567. If changing the port number, the Windows firewall will need to be manually reconfigured to allow connections on the new port number.

- **Enable:** When checked, the Guideline 5 application will accept client connection requests and stream data to connected clients. When disabled, the Guideline streaming service is disabled.

- **Send Waveform:** The Guideline streaming service sends the current depth and mean firing rate of all microelectrode channels. When this check box is checked, streamed data will also include LFP, chart, and discriminated spike waveforms for all channels visible on screen. When unchecked, the waveform data will not be sent. Note that waveform data streamed by the streaming service may be noticeably delayed.

A sample client application in the form of a Matlab® script has been provided to demonstrate the protocol for connecting to the Guideline streaming service. In order to connect, a client application will need to know the Guideline's IP address, which is 192.168.0.2 by default, and the port number specified above.

WayPoint Navigator is one example of an application that makes use of the streaming service in order to display current electrode location and a histogram of the mean firing rate along the trajectory, all superimposed on the patient's scan imagery.

### Raster

A Raster is a short duration snippet of recorded activity centered on an event. The raster screen in IntraOp is shown below.

Rasters are shown vertically aligned by channel and horizontally aligned by the depth at which they were recorded. The duration and amplitude of the rasters can be adjusted using the controls at the top of the screen. For signals recorded with the UE Interface, it is possible to view rasters from the MER signal or the LFP signal or both.

The depth of the event rasters is shown along the left border of the screen. These are displayed from highest to lowest and evenly spaced (rasters are not spaced out to scale).

Rasters are color-coded according to the classification assigned at the time the event was created. Gray rasters correspond to the UDTM or undetermined default classification. Rasters may be classified from within the raster screen by right clicking on them and selecting the desired classification from the menu.
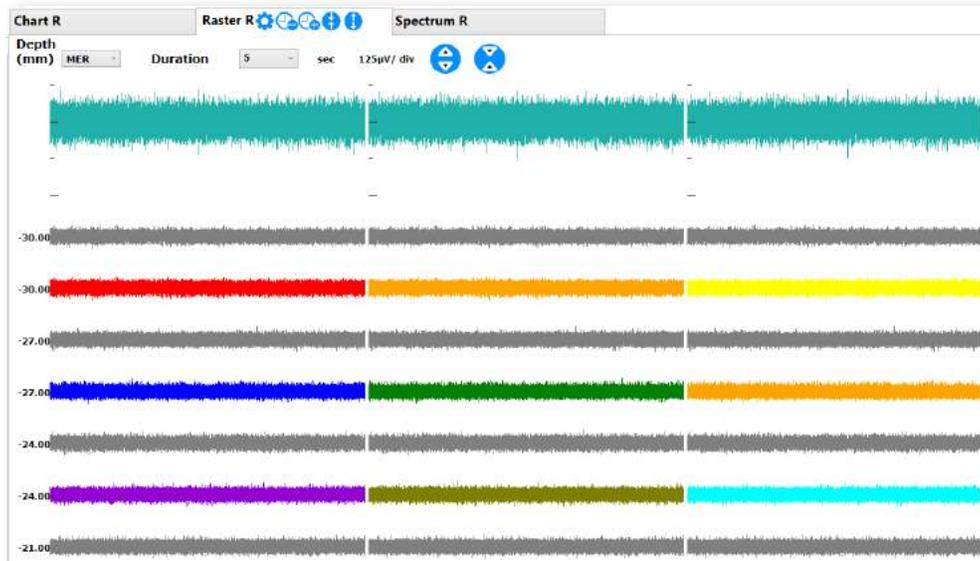


### Summary Screen

To review recorded events or saved data at any time during the procedure, select Summary from the main menu. Summary information from the recording session will only be available if data recording was enabled from the IntraOp screen. There are three options presented:
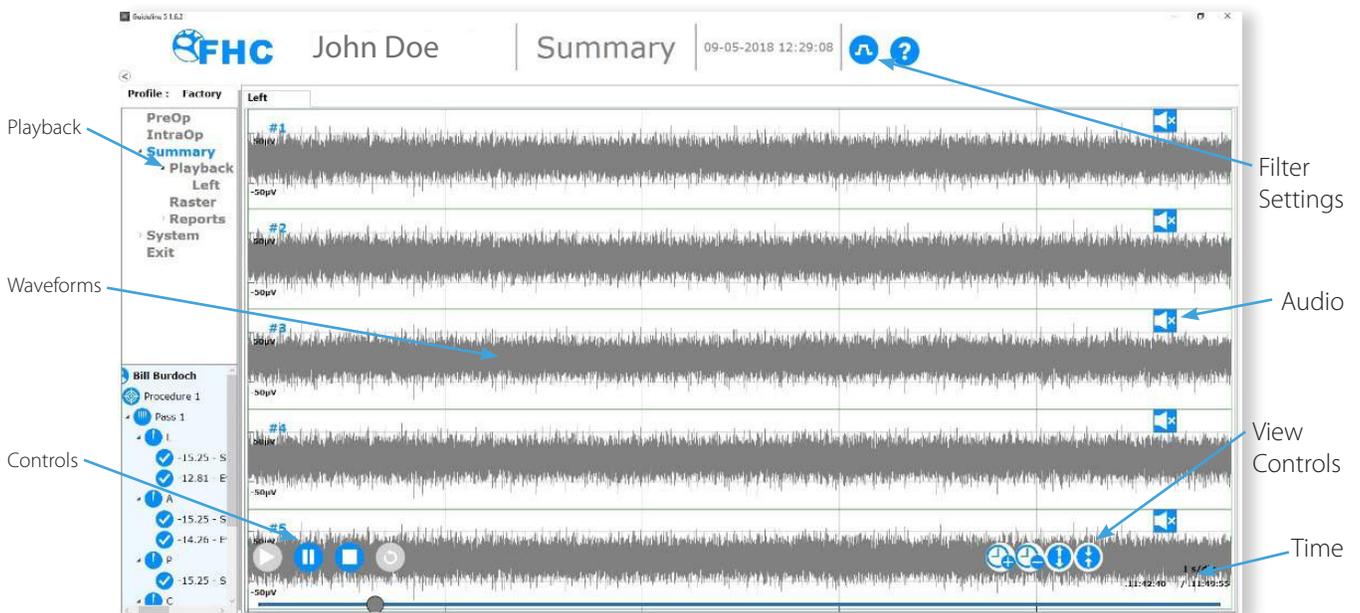
## Playback

To review MER activity recorded during the procedure, select Playback. Scrolling waveforms will be shown similarly to their original presentation on the IntraOp chart display.

**Playback:** Allows the waveforms to be paused or advanced to any point during the recording. Vertical lines will be shown over the waveforms at the timestamps corresponding to saved events.

**Filter Settings:** As data is archived in raw format, clicking on the filter settings button will allow users to adjust the filter parameters used for the playback, regardless of the filter settings active when the recording was made.

**Audio:** Clicking on the audio-enable buttons will allow audio playback of one or more waveforms.

**View Controls:** Can be used to adjust the scroll speed or amplitude of the waveforms shown.

**Time:** The time at which the signals being shown were originally recorded is shown in the lower right of the screen.

## Reports

A variety of reports are available from the Reports menu. These may be printed directly if the Guideline 5 PC has access to a printer or saved to PDF.
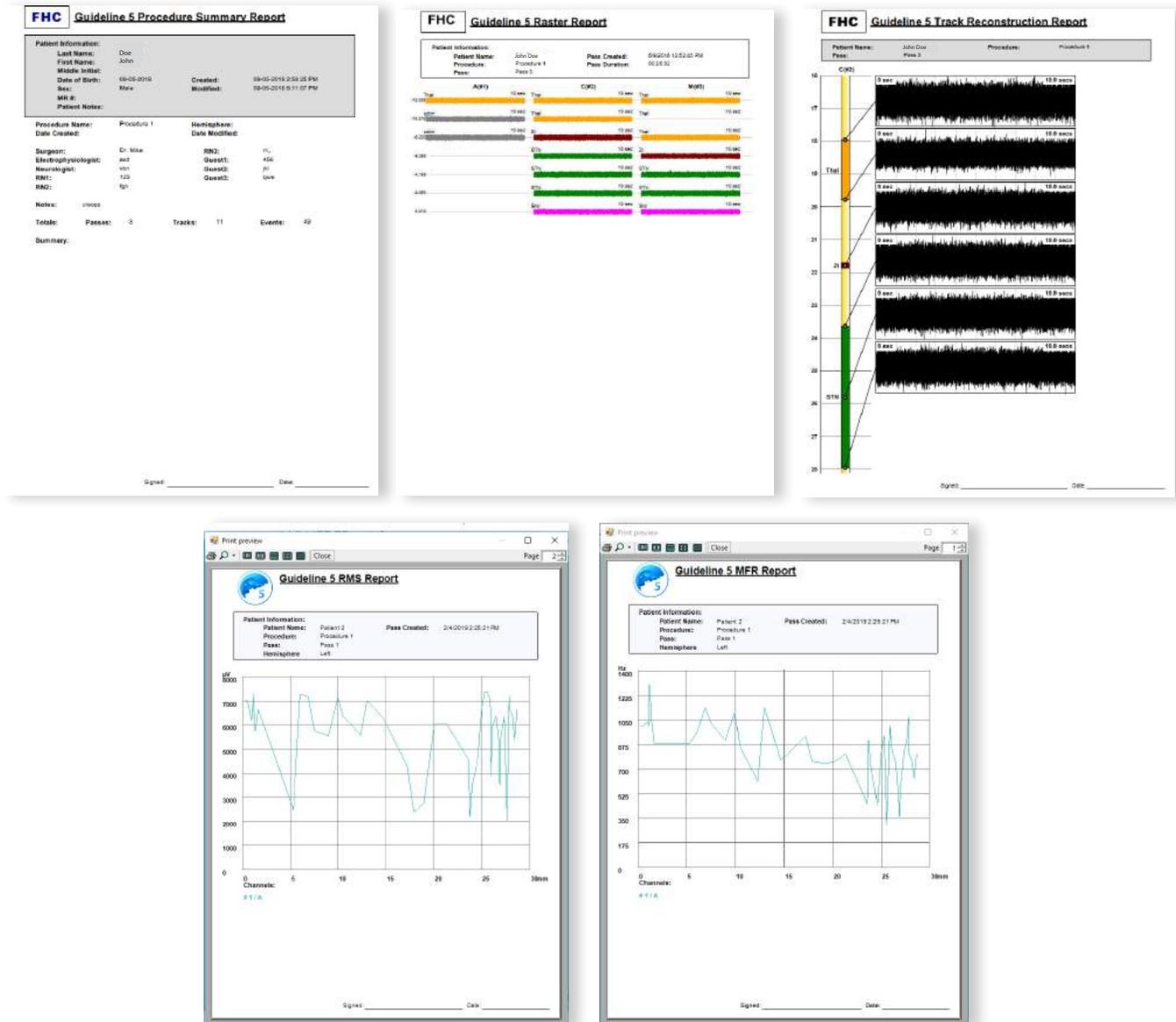
## System

### Archive

The Archive screen allows users to control and monitor the amount of available storage space available. When storage space gets low, a warning will be presented to the user when the application starts. From the archive screen, patient files can be extracted from the Guideline database and saved to a self-contained file for long-term archival off the Guideline 5 PC.
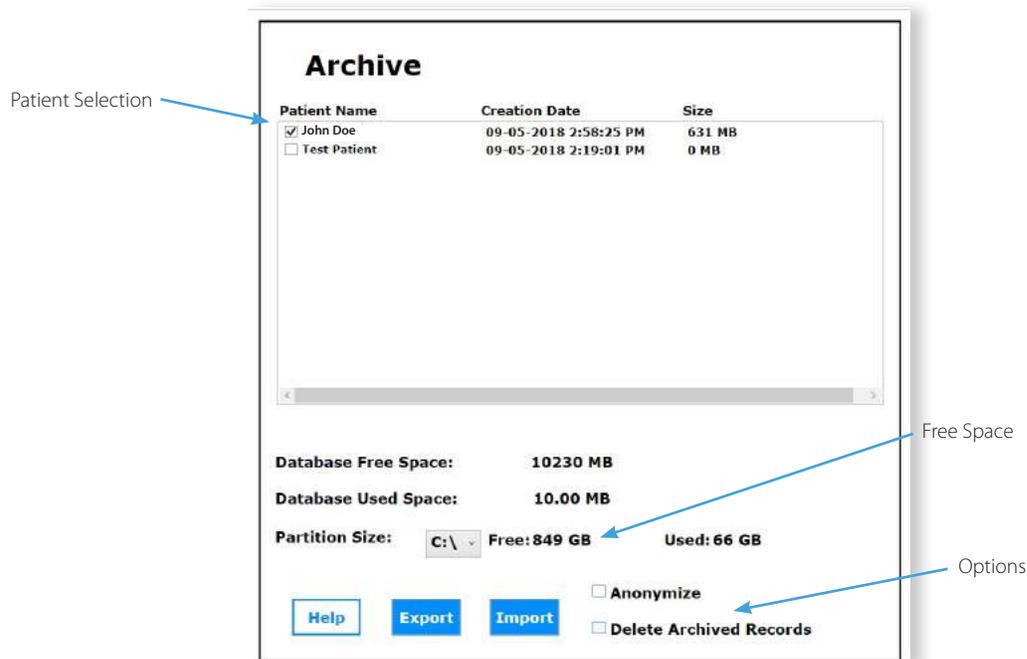


To move patient records off the Guideline 5 PC, select the files from the record list at the top of the dialog. To anonymize exported patient records for research purposes, check Anonymize. To remove the selected patient record(s) from the Guideline 5 PC select the Delete Archived Records option. You will be prompted for a location to save the archived record. This may be a network-attached storage device or removable media such as a USB Drive attached to the Guideline 5 PC.

Exported patient records may be imported back into the Guideline 5 with the Import button.

### PostOp

When the procedure is finished, selecting Exit from the main menu will exit the Guideline 5 application. Once the application has closed, the Guideline 5 PC should be shutdown like any Windows PC. Power off the Guideline 5 MPU, disconnect all cables, and return all components to the Carrying Case for storage or transport.

## Electromagnetic Emissions and Immunity

### Preventive Measures

The Guideline 5 system has been designed to record very low-level signals. This degree of sensitivity makes the system susceptible to electromagnetic disturbances of many kinds such as those generated by mobile cell phones or high frequency surgical equipment. In many cases, evidence of these disturbances will be visible as noise corrupting the signals captured by the system. When this is the case, elimination of the source of the interference during the recording session is the most effective strategy. Where this is not possible, increasing the physical separation between the Guideline 5, its components and cabling, and any likely source of interference is likely to be helpful. Some forms of electromagnetic interference can be eliminated by powering the Guideline 5 system from a dedicated mains circuit.

## Recovering from Adverse Electromagnetic Events

If problems with electromagnetic interference persist, contact FHC, Inc. technical support for on-site assistance in troubleshooting the cause(s) of the interference and implementing a solution.

The Guideline 5 system has been designed to recover automatically from many electromagnetic disturbances that are significant enough to temporarily interrupt communications with the UE or LF Interfaces or with the Sync IO module. The result of this interruption result in the waveforms provided by these components appearing to freeze on screen. The Guideline 5 will notify the user when this occurs, and automatically attempt to restore the system to normal operation.

In more severe cases, however, if the Guideline 5 system is unable to automatically recover, it will be necessary to manually restart the Guideline 5 with the following procedure:

1. Exit the Guideline 5 application by pressing the "X" on the top right of the title bar.

2. Turn off the Guideline 5 MPU using the main power switch.

3. Wait approximately 5 seconds, then turn the MPU back on.

4. Restart the Guideline 5 application by double-clicking on its icon.

5. Do not perform the power on self-test if the system is connected to any electrodes.

6. Reopen the current patient and proceed as normal.

## Recovering from a loss of mains power

In the case of a power mains loss, the Guideline 5 PC will continue to operate on battery but all other functionality will be suspended. A message will be displayed to inform the operator any time the PC switches to battery power. Restoration of the power mains will allow the Guideline 5 to return to normal operations. If power was interrupted, it will be necessary to re-zero the depth controller.

For a loss of mains power that exceeds approximately one minute, the Guideline 5 will not be able to restore normal operations automatically. A message will inform the operator to Reboot. If this occurs, exit the Guideline 5 application and restart the computer.

⚠ WARNING: Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any component, cable, or accessory of the Guideline 5 system. Otherwise, degradation of equipment performance could result.

## Declarations of Electromagnetic Compliance

⚠ **WARNING:** Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Declaration of Electromagnetic Emissions section of this document.

| Guidance and Manufacturer's Declaration - Immunity |
|---|
| The Guideline 5 is intended for use in the electromagnetic environment specified below. The user of the Guideline 5 should ensure that it is used in such an environment. |

| Immunity Test | EN/IEC 60601 Test Level | Compliance Level | Electromagnetic Environment Guidance |
|---|---|---|---|
| ESD EN/IEC 61000-4-2 | ±8 kV Contact ±15 kV Air | ±8 kV Contact ±15 kV Air | Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30% |
| EFT EN/IEC 61000-4-4 | ±2 kV 100 kHz repetition frequency | ±2 kV 100 kHz repetition frequency | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge EN/IEC 61000-4-5 | ±0.5 kV, ±1 kV Line-to-Line ±0.5 kV, ±1 kV, ±2 kV Line-to-Ground | ±0.5 kV, ±1 kV Line-to-Line ±0.5 kV, ±1 kV, ±2 kV Line-to-Ground | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage Dips/Dropout EN/IEC 61000-4-11 | 0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <br> % UT; 1 cycle <br> 70 % UT; 25/30 cycles for 50 Hz and 60Hz, respectively <br> Single phase: at 0° <br> 0 % UT; 250/300 cycle for 50 Hz and 60 Hz, respectively <br> Single phase: at 0° | 0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° <br> % UT; 1 cycle <br> 70 % UT; 25/30 cycles for 50 Hz and 60Hz, respectively <br> Single phase: at 0° <br> 0 % UT; 250/300 cycle for 50 Hz and 60 Hz, respectively <br> Single phase: at 0° | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Guideline 5 requires continued operation during power mains interruptions, it is recommended that the Guideline 5 be powered from an uninterrupted power supply or battery. |
| Power Frequency 50/60Hz Magnetic field EN/IEC 61000-4-8 | 30A/m | 30A/m | Power frequency magnetic fields should be that of a typical commercial or hospital environment. |

| Recommended Separation Distances for the Guideline 5 |
|---|

The Guideline 5 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the Guideline 5 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Guideline 5 as recommended below, according to the maximum output power of the communications equipment.

| Max Output Power (Watts) | Separation (m) 150kHz to 80MHz $D=(3.5/V1)(\sqrt{P})$ | Separation (m) 80 to 800MHz $D=(3.5/E1)(\sqrt{P})$ | Separation (m) 800MHz to 2.5GHz $D=(7/E1)(\sqrt{P})$ |
|---|---|---|---|
| 0.01 | .1166 | .1166 | .2333 |
| 0.1 | .3689 | .3689 | .7378 |
| 1 | 1.1666 | 1.1666 | 2.3333 |
| 10 | 3.6893 | 3.6893 | 7.3786 |
| 100 | 11.6666 | 11.6666 | 23.3333 |

| Guidance and Manufacturer's Declaration - Emissions |
|---|

The Guideline 5 is intended for use in the electromagnetic environment specified below. The customer or user of the Guideline 5 should ensure that it is used in such an environment.

The EMISSIONS characteristics of the Guideline 5 make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or reorienting the equipment.

| Emissions Test | Compliance | Electromagnetic Environment – Guidance |
|---|---|---|
| RF Emissions CISPR 11 | Group 1 | The Guideline 5 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. |
| Harmonics IEC 61000-3-2 | Class A | The Guideline 5 is suitable for use in all establishments, **other than** domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Flicker IEC 61000-3-3 | Complies | |
| RF Emissions CISPR 11 | Class A | |

| Immunity Test | EN/IEC 60601 Test Level | Compliance Level | Electromagnetic Environment – Guidance |
|---|---|---|---|
| Conducted RF EN/IEC 61000-4-6 Radiated RF EN/IEC 61000-4-3 | 3 V, 0.15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1 kHz 3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz | (V1)Vrms (E1)V/m | Portable and mobile communications equipment should be separated from the Guideline 5 by no less than the distances calculated/listed below: $D=(3.5/V1)(\sqrt{P})$* 0.15 MHz - 80 MHz $D=(3.5/E1)(\sqrt{P})$* 80 MHz - 2.7 GHz $D=(7/E1)(\sqrt{P})$* 80 MHz - 2.7 GHz |

*where P is the max power in watts and D is the recommended separation distance in meters.

*Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1).

*Interference may occur in the vicinity of equipment containing a transmitter.

# Software User Messages for the Guideline 5

NOTE: The text within brackets [ ] shows possible content of the message. E.g. [uE Interface or LF Interface] – depending on the type of interface, one or the other name will be used.

| Message | Description |
|---|---|
| The process Guideline 5 is already running! | Appears whenever the current process (Guideline 5) has an instance that is already running. If this occurs without the Guideline 5 application running, reboot the PC or use the Task Manager to terminate the process. |
| For optimal display settings, please change text scaling to 100%! | When text scaling is enlarged, some elements of the application will not display correctly. Set text scaling back to 100% in Windows Display Settings to resolve this. |
| Track has child events and therefore it cannot be deleted! | Appears when the track chosen to be deleted has child events. In this case the deletion cannot be performed until the events themselves have been deleted. |
| There is no recorded data to be analyzed on the current patient or no opened patient! | Appears when, upon entering summary, no patient has been opened or the current patient has no recorded data. |
| Only the channels from one UE Interface can be mapped to a hemisphere. Multiple UE Interfaces mapped to a single hemisphere are not allowed. | This message appears when the user tries to map channels from different UE Interfaces to the same hemisphere. |
| Could not open connection to server! | Appears due to software not being able to access the PC database. Ensure the SQL service on the PC is running. Please call +1-207-666-8190 (or 1-800-326-2905, toll free in US and Canada) or visit https://www.fh-co.com/tech-support. |
| Could not deserialize! [error message] | Message shown when the software unsuccessfully tries to encrypt/decrypt patient sensitive data to/from the database. |
| Expected computer IP address [IP address] differs from configured address!<br>If the IP address is not correctly set the system may not work as expected.<br>Please contact FHC, Inc. technical support for assistance.<br>Please call +1-207-666-8190 (or 1-800-326-2905, toll free in US and Canada) or visit https://www.fh-co.com/tech-support. | Message shown when the computer's network address doesn't have the same IP as the one in Guideline configuration file. This may be the result of reconfiguring the Guideline 5 PC to join a network. |
| Disk space is running out!<br>Please perform a disk cleanup to ensure sufficient storage space! | There is not enough disk space for the application to run, a minimum of 10GB is required. Move files off the Guideline 5 PC's C:/ drive to free up more space. |
| Interface: [uE Interface or LF Interface], channel [channel #] stimulation error.<br>1. Please make sure that the cable is properly connected.<br>2. Please close stimulation window, open it again and retry stimulation on this channel.<br>3. If the problem persists please contact FHC, Inc. technical support. | Message that shows up when a DC offset is detected during read-back of stimulation voltages. Once this message is triggered, the output of the channel is grounded. Closing the stimulation window and reopening it will reset the stimulator. If this message is seen again, discontinue stimulation from the channel and contact FHC technical support. |
| Interface: [uE Interface or LF Interface] failed to re-connect.<br>Please reboot the system and the software and try again. | Appears when the software repeatedly fails to reconnect with an Interface after an interruption in that connection. It will be necessary to reboot the Guideline 5 system and restart the PC in this case. |

| Message | Description |
|---|---|
| Maximum internal temperature exceeded! Current temperature: [degrees] °C | Message shown when the internal temperature of the Guideline 5 MPU is too high. Verify that the vents on the bottom and side of the MPU are clear and that the internal fans are running (they should be audible). Contact FHC technical support if this problem persists. |
| The computer switched to battery power. Please connect the external power supply! | Message shown when the computer (laptop) is disconnected from the external power supply. The performance is diminished significantly when the computer is on battery power. Reconnect the Guideline 5 PC's power connection. |
| Expected interface on port [1 or 2], none found! If you want to use the interface, please shut down the system, connect it and restart. Otherwise you can ignore this message. | Appears whenever there is an unused Interface port. Check the connections of the Digital Interface cable between the indicated MPU Interface port and the Interface. |
| Firmware version mismatch for device with serial number #[serial number]. Found version [version], expected [expected version]. Execution cannot continue! Please contact FHC, Inc. technical support for assistance. Please call +1-207-666-8190 (or 1-800-326-2905, toll free in US and Canada) or visit https://www.fh-co.com/tech-support. | Appears when the internal APM-03 firmware version is different from the required version. This may be the result of a software upgrade. Contact FHC technical support who will be able to guide you through the firmware update process. |
| Please install Adobe Acrobat Reader to open the help files! | Adobe Acrobat Reader is not installed on the computer. Help files are in PDF format and require the Acrobat reader to display properly. |
| Cannot find help file! Please contact FHC, Inc. technical support for assistance. Please call +1-207-666-8190 (or 1-800-326-2905, toll free in US and Canada) or visit https://www.fh-co.com/tech-support. | The Guideline 5 help file is missing. |
| The patient you want to import already exists. | The entered patient name or selected patient is already present in the Guideline 5 database. |
| Insufficient disk space, recording is stopped! | The Guideline 5 PC has run out of disk space and can no longer record patient data. Free up additional disk space by exporting (or deleting) patient files and moving them off of the Guideline 5 PC's C Drive. |