FHC

Neural microTargeting™ Worldwide

UE Interface

Directions For Use - Supplementary Information

L011-85-01 (Rev F0, 2019-12-10)

Contains directions for the following products:
MT-LPP, C0219, C0221, C0222, C0236, C0230,
C0231, C0232, C0233

Guideline 5

www.fh-co.com

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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.

Symbol Key

⚠	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.	+43°C +109°F / 5°C +41°F	Indicates the temperature limits to which the device can be exposed.
SN	Indicates the serial number so that a specific medical device can be identified.	95% / 0%	Range of humidity to which medical device can be exposed.
LOT	Indicates the batch code so that the batch or lot can be identified.	1060 hPa / 500 hPa	Range of atmospheric pressure to which medical device can be exposed.
MODEL	Indicates the model number so that the model of the medical device can be identified.	STERILE EO	Indicates a medical device that has been sterilized using ethylene oxide.
🏭	Date when the medical device was manufactured.	②STERILIZE	Indicates a medical device that is not to be resterilized.
⧗	Indicates the date after which the medical device is not to be used.	②	Do not re-use; Intended for one use on a single patient, during a single procedure.
🚫	Indicates a medical device that should not be used if the package has been damaged or opened.	🗑	Instructions for end of life disposal.

Unit Symbol Key

👁	WARNING: Read usage instructions.	▦	Head Box Connection
🧍	Type BF Applied part		

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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.

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.

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.

UE Interface Overview

The UE Interface (C0219), UE being short for µE electrode or microelectrode, is a core component of the MT-Guideline 5 system; it is not a stand-alone device. The 3m Digital Interface Cable (C0221) provides an entirely digital connection to the Guideline 5's Main Processing Unit. The UE Interface provides 8 channels of recording and stimulating capability designed for the recording of single and multi-unit activity within the brain. The UE Interface has been optimized for connection to FHC's Differential microTargeting Electrodes.
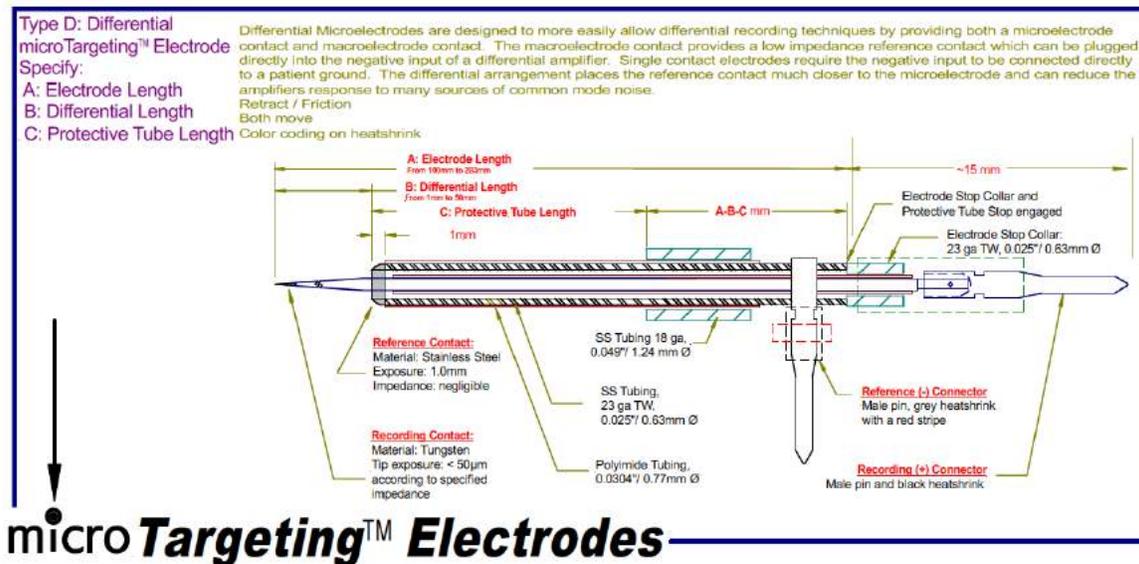
⚠ **WARNING:** Use of non-supported electrodes can result in poor quality recordings, incorrect stimulation, inaccurate targeting, or patient injury.

⚠ⓧ **WARNING:** Electrodes and microelectrode cables are intended for one use on a single patient, during a single procedure. Do not attempt to sterilize and reuse.

🗑 Dispose of electrodes according to hospital protocol.

⚠ **WARNING:** Remove patient leads if engaging defibrillation.

⚠ **WARNING:** Do not allow the Interface to get wet.

The UE Interface is designed to be located immediately outside the sterile field, putting it closer to the patient and significantly reducing the effects of environmental noise. The Pole Mount Clamp (C0233) allows the UE Interface to be mounted vertically on an IV pole. Alternately, the interface may be placed on any horizontal surface. Care should be taken when positioning the interface to ensure it is stable and outside the sterile field. The interface should not be placed on the floor, nor be allowed to hang from the patient leads.

Pre-sterile patient leads connect the UE Interface directly to the microelectrodes and are available in both 1.5 (C0231, C0232) and 3m lengths (C0230). Where practical, use of the 1.5m leads is preferable as the shorter lead length will help to reduce both low-frequency noise artifacts caused by swaying leads and microphonic feedback caused by acoustic vibrations.

Stimulation is controlled through a hand-held Remote Control (C0222), allowing the operator to closely monitor the patient during stimulation. Status indicator lights on the interface will indicate which channels are actively recording 🟢 (green), stimulating 🟠 (orange), or inactive ⚫ (dark).

The UE Interface features numerous advanced and innovative capabilities:

- The UE Interface features 8 independent channels; all inputs are fully differential with a common patient reference connection required. All inputs are high-impedance, low-leakage, and fully isolated, making them ideally suited for extracellular metal microelectrode recording.

- Amplification, signal conditioning, and digitization of the recorded signal is performed entirely within the UE Interface. Signals traveling from the UE Interface to the Guideline 5 system are immune from degradation.

- The digitized signal has 17 bits of resolution and a 32-kHz sample rate for high-fidelity microelectrode recordings.

- In addition to differentially recording single unit activity between the micro- and macro-contacts of the differential electrodes, the UE Interface simultaneously acquires Local Field Potentials (LFPs) present at the macro-contact at a sample rate of 1.0 kHz and provides an independent data stream of this activity to the Guideline 5 system. This is two streams of data for every electrode and channel utilized.

- Driven shield technology is employed by the UE Interface on the patient leads to further reduce electrical noise and the capacitive loading effects commonly associated with coaxial shielding.

- The UE Interface can measure the impedance associated with the microelectrode contact as well as that of the macro-electrode contact. Electrode impedances may be measured simultaneously on all connected electrodes. Fully adjustable measurement parameters allow user selection of the desired measurement frequency and duration. The UE Interface has been designed to minimize the effect of impedance checks on the microelectrodes impedance by keeping the measurement current around 1 μA. One has to keep in mind that given the non-linear properties of the electrode tissue interface, the displayed electrode impedance strongly depends on the measurement current. Other recording systems or instruments may use a lower current to measure impedance. Typically, at 1 μA the electrode impedance is half the one measured using 100 nA.

- The UE Interface is capable of both constant current and constant voltage electrical stimulation through both electrode contacts. Micro-stimulation is delivered through the microelectrode contact with a maximum intensity of ±100 μA / ±10V. Macro-stimulation is delivered through the macro-electrode contact with a maximum intensity of ±10 mA / ±10V.

- Channels not involved in stimulation continue to record activity. Adaptive stimulus artifact suppression filters minimize stimulus artifacts present on these recordings.

- The UE Interface boasts an independent stimulation circuit for every channel, supporting complex multi-channel stimulation protocols, including current steering.

- An independent circuit within the UE Interface monitors the peak stimulus voltage delivered by every channel and displays this read-back voltage on screen throughout the stimulation.

- A hand-held remote control allows the operator to control the delivery of stimulus and to smoothly ramp the intensity up or down while closely monitoring the patient for associated efficacy and side effects.
- An automated power-on self-test provides the operator with a quick and reliable way to verify the proper and safe functioning of all UE Interface features prior use.

Specifications

C0219 - UE Interface

Dimensions: 12.5 cm Width, 4.5 cm Height, 23 cm Length
Weight: <1 kg
Mounting: Pole mount, table mount
Channels: 8x with independent status indicators and stimulation circuits
Connectors: Input – proprietary 8x, Output – 26 pos. Centronics F
Isolation: Type BF medical Isolation
Inputs: Differential inputs, common reference, driven shielding on (+) & (-)
Input Impedance: 100 MΩ
CMRR, typical: -90 dB @ 60Hz with adaptive suppressor and notch filter engaged
Data Acquisition (per channel):

- Gain: variable (5.94x to 214x)
- MER Digitization: 32 kHz @ 17 bits
- LFP Digitization: 1 kHz @ 24 bits
- AC/DC coupled user selectable
- Analog Filter Stage: optional, gain 3x 250Hz to 8Khz 2nd order bandpass

		Analog Filter Off: (DC Coupled)			Analog Filter On: (DC Coupled)		
		Range	Resolution	Noise Floor	Range	Resolution	Noise Floor
		mV	µV	µV RMS	mV	µV	µV RMS
Fixed Gain	1	±421	10.3	105	±140	3.4	41
	2	±337	5.1	59	±112	1.7	30
	4	±168	2.6	42	±56	0.9	27
	6	±112	1.7	38	±37	0.6	27
	8	±84	1.3	37	±28	0.4	26
	12	±56	0.9	35	±19	0.3	25

* Noise floor results with 100kΩ load, 1.5m lead, line noise filter enabled & bandpass filter at 200Hz to 16kHz

Stimulation (per channel):

- Constant Voltage or Constant Current operation
- Stimulus Tone – configurable
- Compliance voltage: ±14V in Constant Current Mode
- Multi-source stimulation
- Stimulus Generation:
    - Mono-phasic / bi-phasic
    - Dual polarity
    - Pulse width: 47.5 µs to 3.4 ms
    - Pulse Frequency: 1 Hz to 300 Hz
    - Max duty cycle: 50%
    - Fixed duration: 0.5s to 60s

- Micro-stimulation:
    - src: (+), ret: (REF)
    - ±10V or ±100 µA max amplitude
- Macro-stimulation:
    - src: (-), ret: (REF)/(-)/(-)(-)…
    - ±10V or ±10 mA max amplitude
    - Pulse rise time: 10%-90% full amplitude in less than 10µS with a 10kOhm load
    - Multiple returns possible / source
- Impedance Check:
    - 8x simultaneous measurement – optional
    - Measurement current <= ±1µA micro, <= ±100µA macro
    - Micro/macro-contact measurement
    - Measurement Frequency: user selectable from 220Hz or 1.0kHz
    - Measurement Duration: user selectable from 1s to 10s
    - Range: Macro 100-10kΩ, Micro 10kΩ-5MΩ
    - Measurement Accuracy: ±10%

C0221 – Digital Interface Cable
Length: 3-meters
Weight: 0.3 kg
Connectors: M-M 26 pos. Centronics
Specifications: Latching, shielded, bidirectional with dual ferrite suppression

C0222 – Remote Control
Dimensions: Length-20cm, Width-6cm, Height-5cm
Weight < 0.5kg
Cord Length: 3-meters
Dual Mode: Stimulation Control when stimulation dialog is open, motor control otherwise
Safety Cover for activation of stimulus.

C0230 – 3m Patient Lead
C0231 – 1.5m Patient Lead
C0232 – 1.5m Patient Lead (Special Use)
Length: 3 meters / 1.5 meters
For Single Use Only, do not re-sterilize
Pre-sterile, sterilization method – EtO
Configuration: Dual, shielded Coaxial, 3.5mm OD
Interface Connector: proprietary, 6-pin
Electrode Connectors:

- Color coded: red – macro, black – micro
- Gold plated, 0.9mm IDx 3.5mm deep (C0230, C0231)
- 0.9mm ID x 3.5mm dp (C0230, C0231)
- Alligator Clips (C0232)
- Insertion/Extraction force: <500g

Reference Connector: Green, mini-alligator clip
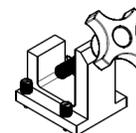Color Coded Flags: White, Blue, Green, Red, Yellow

C0233 – Interface Pole Mount Clamp
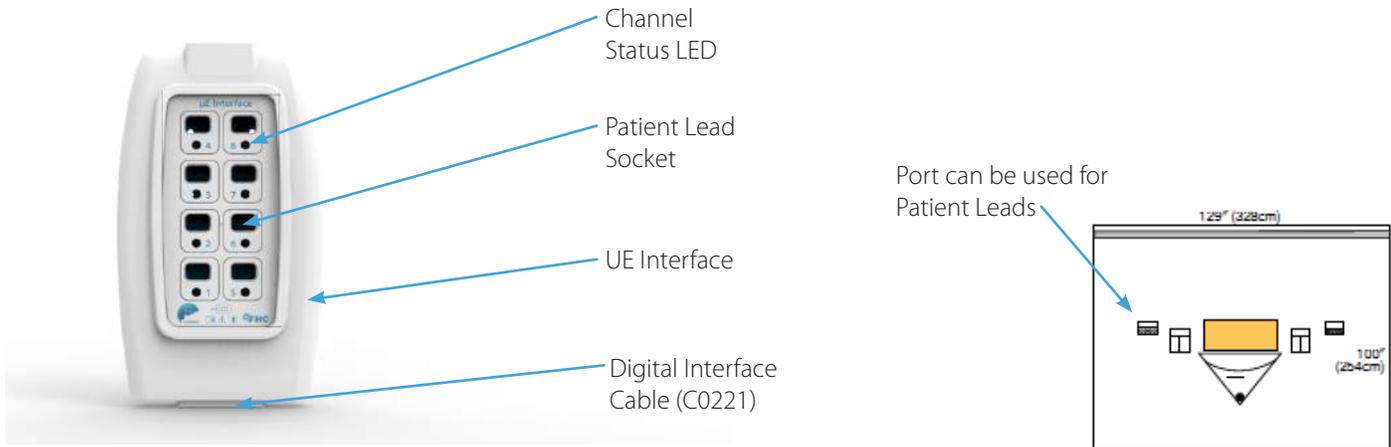Dimensions: 10cm x 10cm x 5.1 cm including knob
Weight: 0.25kg
Material: Anodized Aluminum

Illustrative Procedure

Preoperative Setup

Channel Status LED

Patient Lead Socket

Port can be used for Patient Leads

UE Interface

Digital Interface Cable (C0221)

Position the UE Interface

The UE Interface should be placed immediately outside the sterile field around the patient's head. Care should be taken to ensure that the patient leads can comfortably reach from the electrodes to the UE Interface. Ideally, the interface can be mounted to an IV pole, such as one being used to hold up an edge of the sterile field drape. Such sterile isolation drapes will often have a port that the leads can pass through. Alternately, the patient leads will need to be routed around the edge of the drape.

⚠ **WARNING:** Secure Interface module in place. Failure to secure the Interface module in place could lead to serious patient injury.

Connect the UE Interface to the Guideline 5

Connect the Digital Interface Cable between the UE Interface and the Guideline 5 MPU. The interface cable should be connected to interface port 1, or if multiple interfaces are being used, port 1 or 2. Note that the Guideline 5 can handle two UE Interfaces with the addition of a 2nd Interface processing card (C0218) for a total channel capacity of sixteen.

Perform the Power-On Self-Test

Prior to connecting any patient leads to the interface, Start the Guideline 5 system (Refer to L011-85). When the Guideline 5 system detects the presence of the UE Interface, it will prompt the operator to perform the power on self-test. As the self-test involves stimulation voltages being present on the UE Interfaces Patient Lead sockets, make sure that there are no patient leads connected for the self-test. If preferred, the self-test may be skipped. Click **Yes** to perform the self-test, it will take less than 10 seconds to complete.

Review the results of the self-test if desired. The self-test will verify safety and functionality of the impedance check and stimulator circuitry. The stimulator will be tested in all combinations of micro-stimulation, macro-stimulation, constant current mode and constant voltage mode. In the unlikely event that an issue is detected during the self-test, do not use the UE Interface. Contact FHC technical support for troubleshooting assistance.

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

Map Channels and Connect the Patient Leads

This procedure resumes once the microelectrodes have been inserted.

Connecting an electrode to the Guideline 5 system is a two-step process: connect the Patient Lead from the electrode to the UE Interface and 'map' that connection in the Guideline application. While these steps may be performed in any order, to avoid the risk of making an error, they should both be completed for every electrode before moving on to the next one.

Mapping the Electrode: The Guideline application presents a Ben-gun array diagram within the PreOp screen for mapping,. As shown below, Channel 1 has been mapped to the Center track of the array. When an UE Interface channel is mapped to an electrode track within the array, the status LED for that channel will turn green on the UE Interface, indicating that channel is now active.

Connecting the Patient Lead: Maintaining sterile protocols, peel open the Patient Lead pouch. Connect the lead contacts to the electrode as shown: black to black for the microelectrode contact, red to grey/red for the macro-electrode contact, and connect the patient reference alligator clip to the insertion tube or any other suitable patient reference source. Being careful not to touch the non-sterile UE Interface (or handing off to a non-sterile assistant), plug the opposite end of the lead into the proper channel of the Interface. It will be the one with the green status LED.
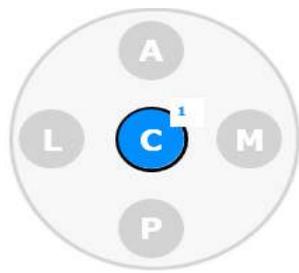
For C0230/C0231 Configuration

⚠ **WARNING:** Do not apply bends in lead cable. Failure to keep lead cable as straight as possible may degrade noise immunity.

⚠ **WARNING:** Conductive parts of electrodes or electrode cables which are connected to the Guideline 4000 5.0, whether applied to the patient or not, should not be connected to nor allowed to contact other conductive parts, including earth. Patient reference connector(s) should never be connected directly to earth.

⚠ **WARNING:** Electrodes and electrode cables should be connected one at a time. Be careful to assign electrode tracks and electrode contacts correctly.

⚠ **WARNING:** Route electrode lead cables carefully to avoid a tripping hazard or possible contamination of the sterile field.

Repeat the above procedure for all electrodes that will be used during the recording pass. For an additional level of assurance, colored stickers are provided with the Patient Leads. Selecting a different color for every Patient Lead used, attach a colored sticker near both ends of the lead. These color codes can be matched to the colors used within the Guideline Application to represent that channel.
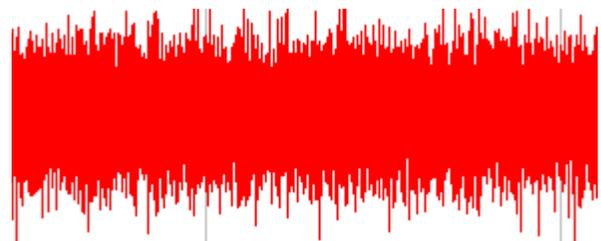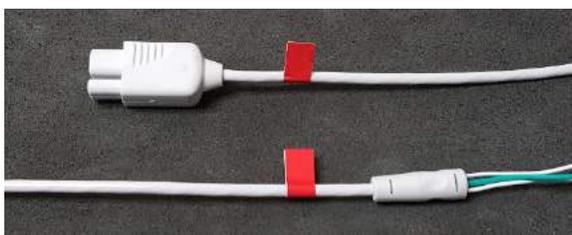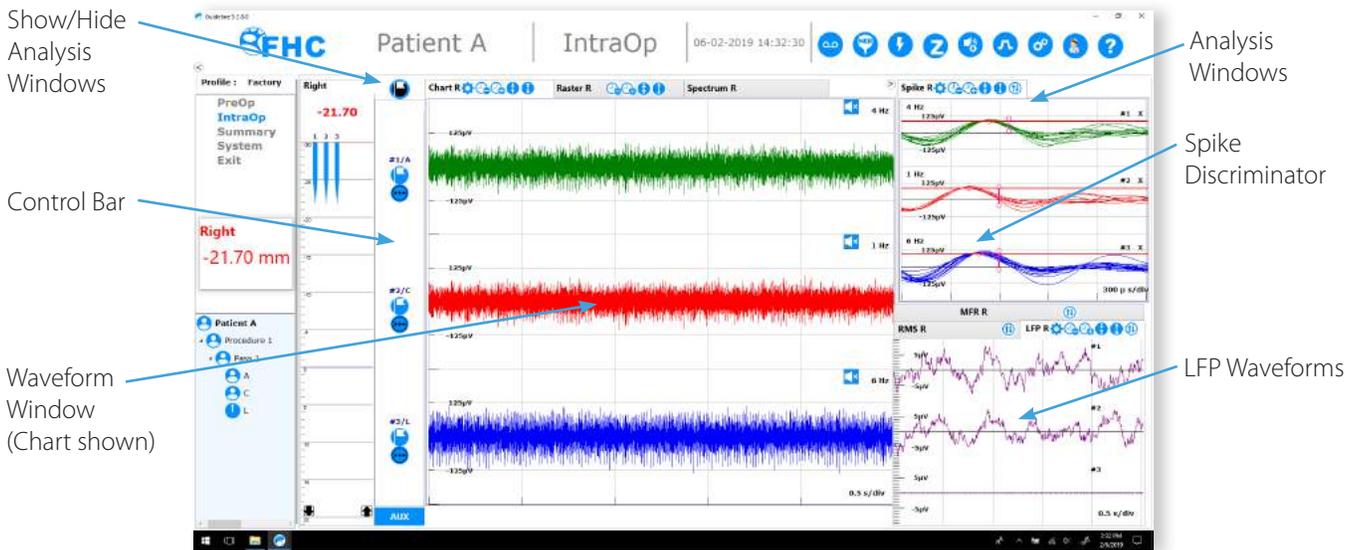

Associating a color with each channel/track/electrode in this manner can be very helpful with correctly identifying channels throughout the procedure.

Aux Channels

If any channels of the UE Interface will be used to acquire signals from other types of electrodes or sensors, those channels will need to be mapped as AUX channels by pressing the AUX button. Any channels not mapped to a microelectrode track in the Ben-Gun array or assigned as Auxiliary channels will remain disabled.

IntraOperative Set-up and Use

Once all the electrode channels have been mapped and the Patient Leads have been connected, select IntraOp from the Main Menu to begin the procedure.

Show/Hide Analysis Windows

Control Bar

Waveform Window (Chart shown)

Analysis Windows

Spike Discriminator

LFP Waveforms

Recording

A review of the recording options and system configurations will be provided. Typically, the preferred settings will be stored in a user profile and need not be reviewed or adjusted during the procedure unless special circumstances require it.

Signal Processing

A simplified block diagram of the MER signal acquisition chain in the UE Interface is shown below. The dynamic range of the processing chain is ±2.5V.
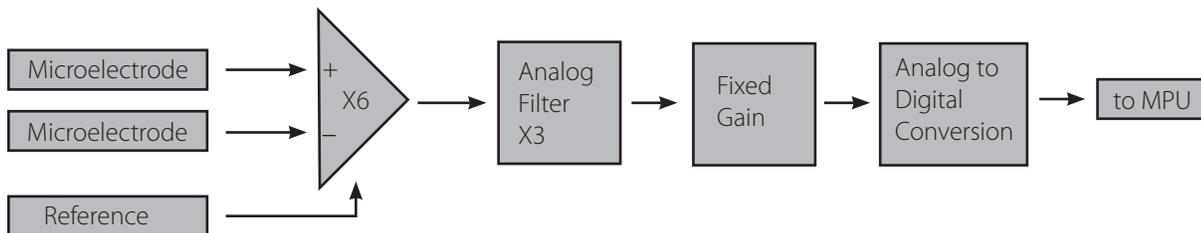
The first stage is an instrumentation amplifier with a fixed gain of 5.94.

This is followed by an analog filter stage. The analog filter stage may be bypassed entirely from the signal processing dialog. The gain of the analog filter stage is shown below.
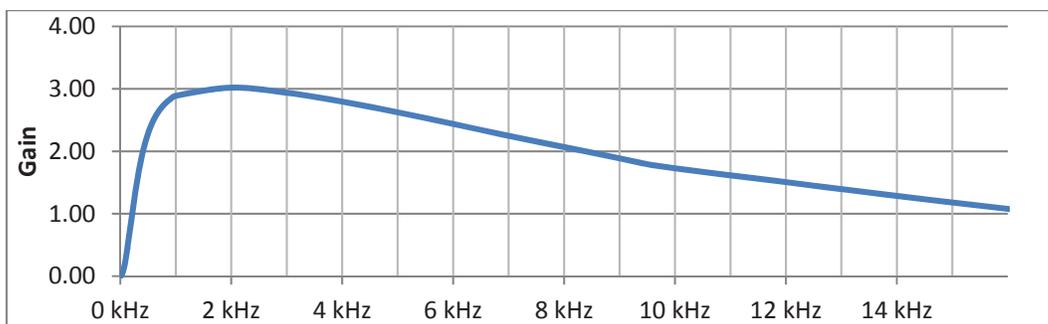
As can be seen, the analog stage applies a gain of approximately 3x in the frequency band where most of the MER signal will be present. An important aspect of the analog stage is that it removes any low frequency, or DC, components from the signal. It is a well-known phenomenon that metal microelectrodes will develop a DC voltage, often in the 100s of millivolts range at the electrode tissue interface. The analog filter, when enabled, eliminates this DC offset from the signal, enabling significantly higher levels of gain to be applied. This stage has been designed to optimize microelectrode recording performance and should be enabled when the channel is connected to a microelectrode.

The fixed gain stage can be controlled from the Signal Processing dialog. Gain options are 1, 2, 3, 4, 6, 8, and 12x. The signal-to-noise ratio of the system will improve the higher the gain is set. However, larger signals may require reduced gain to avoid saturation of the amplifier. For single and multi-unit extracellular recording, a gain of 12x may safely be used in most cases without worrying about saturation effects.

The LFP signal chain is depicted below:
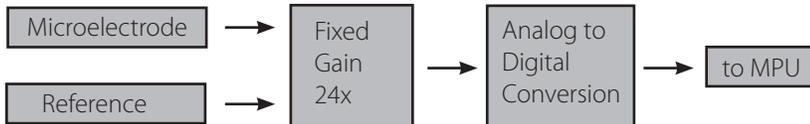
The LFP voltages present are amplified by a gain of 24x prior to digitization at 1000 samples per second with 24 bits of resolution.

Recommended Settings (MER)

- Signal processing settings may be made on a channel by channel basis or globally. To select one or more channels, click on their corresponding track in the Ben-Gun array diagram(s). Any changes made will affect only highlighted channels. Alternately, settings for all channels may be made by pressing the appropriate selection button underneath the Ben-Gun arrays. When selecting multiple channels, only those settings that are changed by the user will be updated.

- **Fixed Gain:** Select the amount of fixed gain desired. Note that the Guideline application will always show waveform amplitudes as those present at the input. It can be counterintuitive to increase the system gain only to see the amplitude of the noise band decrease. This is a result of the improved noise performance associated with higher gains. The visible amplitude of the signal displayed on screen will not visibly change when adjusting fixed gain. Note that changes made to the fixed gain during MER recording will affect the congruency of the collected data.

- **Analog Filter:** Check this box to enable the analog filter stage when doing MER recording. This box may be unchecked in situations where accurate amplitudes are critical (the analog stage's gain is frequency dependent) or where the DC component of the signal is needed.

- **Band-pass Filter:** Two sliders may be adjusted to set the low cut-off and high cut-off frequencies of the digital band-pass filter. Typical settings depend on preference, but 300Hz to 7500Hz is a recommended starting point as this provides a good balance between preserving spikes and eliminating noise. This filter is applied in software. It should be noted that the data saved by the Guideline system will be saved prior to the application of the digital band-pass filter. This allows users to review either the raw (unfiltered) data or apply different filter settings to the saved data offline. Any signals seen on-screen and/or played by the audio monitor of the Guideline system will be affected by the band-pass filter.

- **Adaptive Line Noise Suppressor:** The adaptive line noise suppression filter maintains and continuously updates a model of line-related signal artifact present on the incoming signal by successively averaging the incoming signal received over every line cycle. Portions of the signal that do not repeat every line cycle will be averaged out by this process. When the adaptive line noise suppressor is enabled, the modeled line-related artifact is subtracted from the incoming signal leaving just the line artifact free signal. The slider may be adjusted to control the rate at which the line noise model can adapt to changing line noise conditions. A high to mid-range setting is usually best. While the shielding inherent to the Guideline 5 is very effective at controlling line noise, there is often a significant amount of line noise present on the patient. This can be minimized by earthing the patient. The reference connection made by the UE Interface is isolated and does not serve this purpose. There are really no scenarios where one would not want the line noise suppressor enabled. This filter can be disabled temporarily to monitor the amount of line noise with which it is contending. In extreme situations, line noise can cause the system to saturate and a lower fixed gain setting or improved patient grounding may be necessary, a condition hard to diagnose with the filter enabled.

- **Adaptive Stimulus Artifact Suppressor:** The stimulus artifact filter works on the same principle as the line noise suppressor. Instead of being synchronized with the mains, though, it is synchronized with the stimulus pulse train. When enabled, this filter is only active in situations where stimulus is being applied by the Guideline system and channels uninvolved with the stimulus continue to record activity. In cases where the stimulus amplitude is large, the inputs of recording channels may saturate. The adaptive stimulus filter will not be able to recover the signal in these cases and a lower gain may be required to prevent saturation. If saturation is prevented, the stimulus artifact filter can significantly improve recordings made during stimulation.

- **Notch Filter:** Select the mains frequency for your location and enable the notch filter if desired. This will enable a digital filter to help eliminate noise specifically at line frequency if it is a problem.

- **Enable LFP:** The acquisition of LFP data from the macro-contact can be enabled or disabled by this check box. When disabled, data saved by the Guideline 5 will not include LFP data and functionality related to LFP data will be disabled.

- **Enable LFP Band-pass 1-200Hz:** When enabled, a digital IIR low pass filter with a cut-off frequency of 200 Hz will be engaged to reduce high frequency noise.

Waveform Window

The waveform window is the primary display of recorded activity. There are two modes of operation shown below. Chart mode provides a view of the microelectrode recording and Spectrum provides a spectrogram of the LFP recording. A pair of tabs along the top border are used to switch back and forth between the two. The Display page of the control panel provides further configuration options for these windows.

The Chart display shows the MER waveform recorded by the microelectrodes. The amplitude of this waveform, as indicated by the scale along the left, is referred to the input of the UE Interface. Changes to the gain of the system are automatically compensated for and will not result in the waveform getting larger or smaller on screen (except to the extent that lower gains will typically have a higher amount of noise). To change the size of the waveform displayed, the zoom controls, and not the gain, should be adjusted. Data from channels can overlap with neighboring channels above or below when a large amount of zoom is employed or a large number of channels are active.

The Spectrum display shows the results of a Fourier Transform performed continuously on the LFP data with frequency shown along the vertical axis. This is a heat map-like display. The color bars on the right indicate the color coding scheme employed. The color encoding utilized is dynamic and will change automatically to maximize the dynamic range of the data presented.
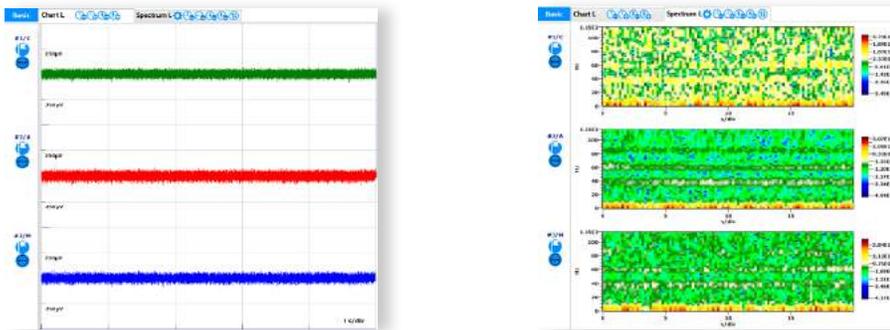
Controls located within the tabs are used to control the appearance of the displayed data. These will apply to all active channels.

 Horizontal (Time) scale zoom: The scroll or sweep rate may be slowed down (-) or sped up (+) as desired.

 Vertical (Amplitude) scale zoom: The vertical scaling can be decreased (-) or increased (+) as desired to maximize waveform resolution in the space available.

 Similar controls for channel specific adjustments can be found within the options menu on the Control Bar.

Also within the options menu, a floating focus window can be launched to provide a simultaneous view of all pertinent data from any channel of interest.
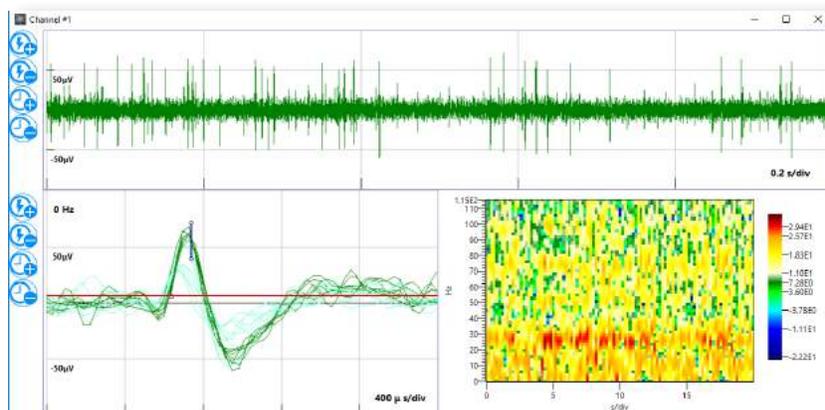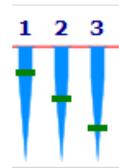
Events

Events are an important concept in the Guideline Application. An event is any item of interest that occurs during a procedure. Events corresponding to impedance checks and stimulation will be automatically generated by the Guideline system. Events related to neural activity must be created by the user as activity of interest occurs. A user-created event may correspond to anything of interest such as a well isolated neuron, a distinctive firing pattern, or a high amount of beta wave activity on the LFP signal. An event may also be created as a means of storing comments; both audio and text notes can be stored as events. Finally, at any point where the neurophysiologist feels confident about which neural structure they are in, an event can be easily created to capture that information. Events can be quickly and easily classified according to the neural structure with which they are associated. The Guideline displays event-related information in many ways throughout the application. These displays are designed to provide visual summaries of the entire recording pass and document/highlight anything of significance for later review.

When an event is generated, if the Guideline system is actively recording, a timestamp will be saved to the data to mark the events location for quick access.

All events, regardless of what they represent, can be viewed and edited from the event dialog shown below:

Within the IntraOp screen, events will be shown on the Depth View Panel to indicate the track, depth, and classification associated with them, as seen to the right. These markers may be clicked on at any time to bring up that event within the Event Viewer.

The hierarchical procedure representation also displays any events created. These can also be selected to bring up the corresponding event for review.

 The Event button is used to create an event at any point during the procedure. Clicking on any one of these buttons will bring up a classification menu to select the appropriate neuron classification. If unsure, UDTM for undetermined (color code: gray) may be selected. Events may also be classified from within the event dialog or from the Summary, Raster screen at any time.

 There is one event button located in the top Mode Control options within the IntraOp Status Bar. This button will create an event associated with all active channels. Event buttons located in the Control Bar along the left edge of the Waveform Window will create channel specific events.

Creating events when there is a signal of interest allows the operator to quickly and easily review that data within the Summary screens and will provide a useful record of the signals which were of interest when determining the final lead location. All recorded events may be reviewed from the Summary, Rasters screen and they appear in numerous reports.

Analysis Windows

The Analysis Windows can be displayed on screen or hidden with the Basic/Advanced button at the top of the Control Bar. When displayed, they will appear on the right side of the screen. The border between the Analysis Windows and the Waveform Window can be dragged to adjust the allotment of space given to both windows. There are four different analyses available in the Analysis Windows, any two of which can be viewed simultaneously in a top and bottom pane. The analyses can be moved between the upper and lower panes with the Up/Down arrow buttons.

Spike Analysis

The Spike Analysis Window can contain multiple waveforms simultaneously. To bring a waveform into the Spike Analysis Window, drag it from the Waveform Window into the Spike Analysis Window. The x in the upper right corner next to the channel number may be used to remove a waveform from the spike analysis window.

Even when a waveform is not being displayed within the Spike Analysis Window, discrimination will continue to be performed using the last set parameters.
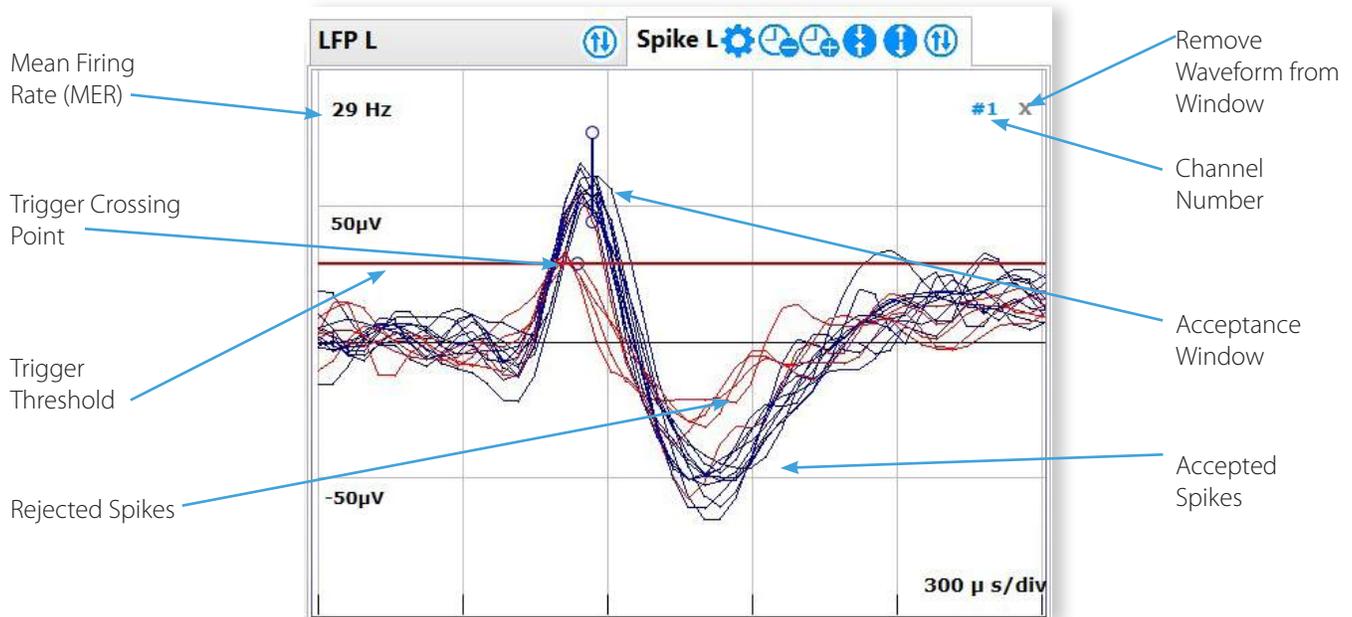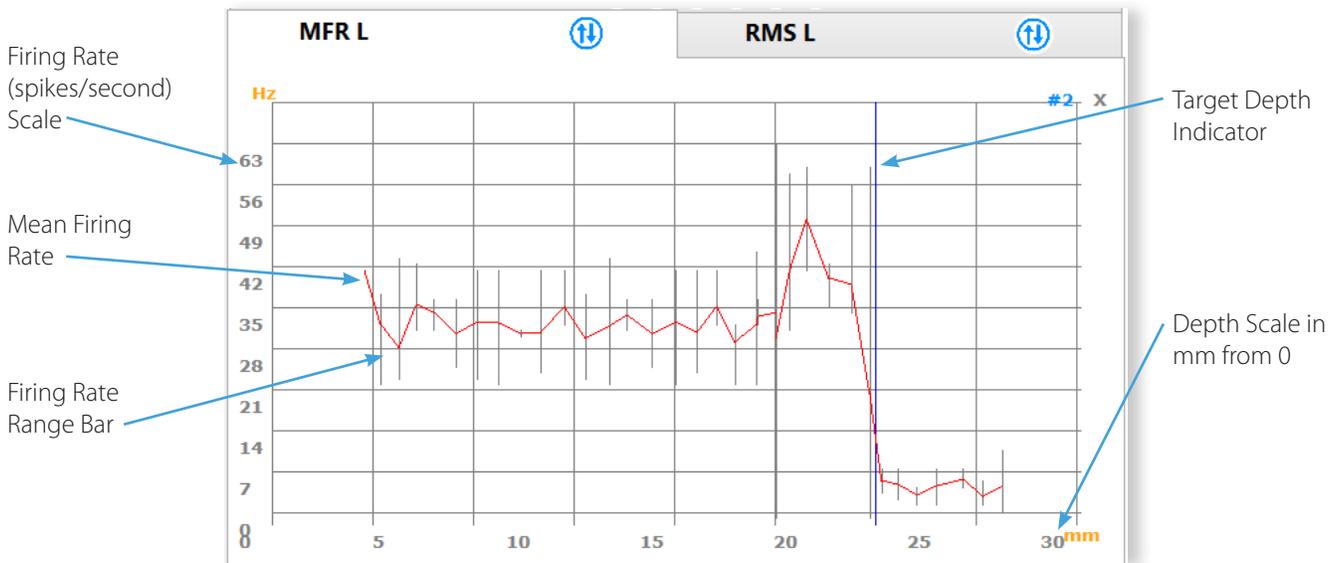

There are two methods of spike discrimination available: window discrimination (shown above) and level discrimination. A trigger threshold level, represented by the red line, can be dragged up or down within the window. When the MER waveform crosses the trigger threshold level, a spike will be displayed. The trigger threshold may be set above or below zero. The trigger crossing point, represented by the little circle on the trigger line, is used to set the amount of pre-trigger waveform to display. It may be dragged left or right along the trigger threshold line to center the spikes within the window. Triggered waveforms will be aligned such that they cross the trigger threshold at the crossing point.

Any waveforms that pass through the acceptance window will be counted as spikes. Using level discrimination, any waveforms that enter and leave the acceptance zone defined by the two levels from the level closest to zero will be counted. Accepted spikes will be displayed in a different color than rejected spikes. Colors may be set in the control panel's display window.

The handles on the upper and lower endpoints of the window may be dragged to adjust the window size. Similarly, the window itself may be dragged to any location desired so long as it remains to the right of the trigger crossing. Note that it is possible using the amplitude/time zoom controls to adjust the spike discrimination window so that the trigger line or the discrimination window is not visible. If this happens, press the gear icon to recenter the window on screen or zoom back out to locate them.

There are a few things that depend on the spike discriminator being set properly to detect spikes: the MFR chart plots the mean firing rate for the waveform as determined by the spike discriminator; some advanced audio modes only play portions of the waveform that cross the trigger line or were accepted as spikes; finally, data streaming of spike waveforms depends on the proper detection of spikes as well.

MFR (Mean Firing Rate) Chart

Firing Rate (spikes/second) Scale

Mean Firing Rate

Firing Rate Range Bar

Target Depth Indicator

Depth Scale in mm from 0

Like the Spike Discriminator, multiple channels can be dragged into the MFR analysis window. Charts for all MER channels are updated continuously, regardless of whether the MFR chart is currently being displayed.

The MFR Chart plots the mean firing rate of the waveform as a function of depth. A new point will be generated any time the electrode remains at the same depth for more than a second. The firing rate from the spike discriminator is updated once per second. These updates are averaged by the MFR chart; the MFR line will cross through every depth at the average value of all firing rates seen while at that depth. Range bars are displayed to indicate the largest and smallest firing rate observed.

The MFR chart is a useful analysis tool for locating the borders of neural structures (such as the STN) when the average firing rate of neighboring structures differs.

RMS (Root Mean Square Noise Floor) Chart

The RMS Chart functions identically to the MFR Chart, except that it plots the calculated RMS value of the waveform, which is recalculated once per second. This is a measure of the noise floor seen, which like firing rate, can be a good indicator of the borders of neural structures.
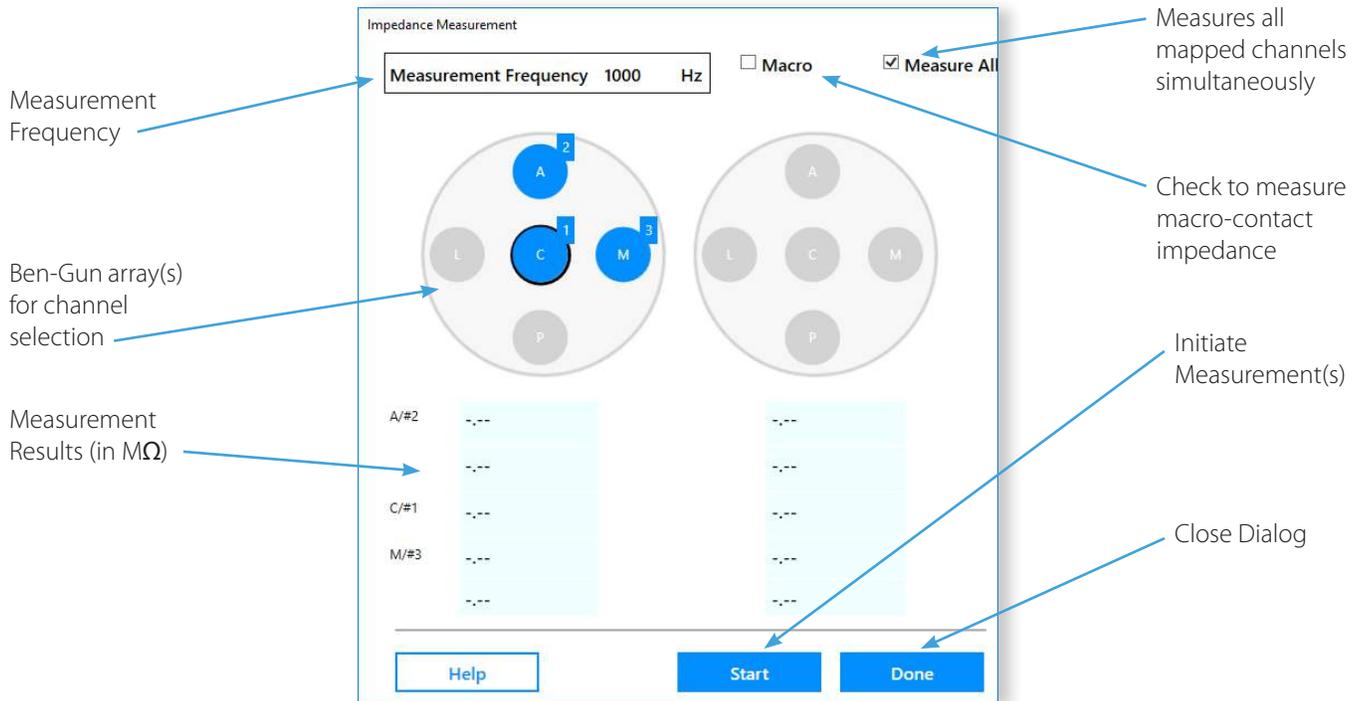
LFP
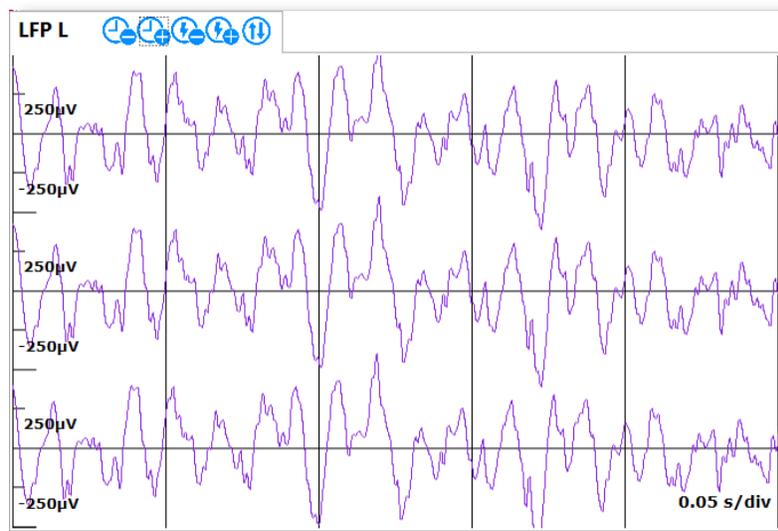
The LFP Waveform window shows the LFP waveforms acquired with every active channel. This is the waveform used to generate the LFP Spectrograms of the Main waveform window. Unlike the other analysis windows, channels do not need to be dragged into this analysis. It will automatically display the LFP activity detected by all active MER channels with LFP acquisition enabled.

Z Impedance Check

To perform an Impedance Check on any electrode contact connected to the UE Interface, press the Z button (the letter Z is commonly used to represent impedance) located in the Mode Control Buttons within the IntraOp Status Bar. This will launch the Impedance Check dialog shown below. The impedance measurement circuitry of the UE Interface has been designed to safely measure the electrode impedances in-vivo.

Measurement Frequency

Ben-Gun array(s) for channel selection

Measurement Results (in MΩ)

Measures all mapped channels simultaneously

Check to measure macro-contact impedance

Initiate Measurement(s)

Close Dialog

Once the measurement is initiated, a tone will sound to indicate that the measurement is underway. The duration of the measurement cycle can be set within the control panel. Longer cycles will be more accurate, however, improvements are minimal beyond a duration of two seconds. Once the measurement is made, the results will be shown in the dialog box.

It is possible to measure the impedances of all electrodes simultaneously rather than sequentially. There is no loss of accuracy associated with this. Micro and macro-impedances must be measured separately. While the impedance dialog box is open, the status LEDs on the UE Interface for all channels selected for measurement will turn orange.

Events will be automatically created for all impedance measurement results, though this behavior can be disabled or modified within the control panel.

FHC recommends a measurement frequency of 1000 Hz for microelectrodes and 220Hz for macro-electrodes as these settings are well matched to the spectral content of the signals obtained from these types of electrodes.

⚡ Stimulation

The Guideline 5 UE Interface features an independent stimulation circuit for every channel. There are two basic modes of operation: micro-stimulation and macro-stimulation. When micro-stimulation is selected, the stimulation contact will be the microelectrode contact. In macro-stimulation mode, the macro-contact will be utilized. Micro-stimulation currents are limited to ±100µA, while macro-stimulation currents can range up to ±10mA maximum.

In addition to the micro/macro-stimulation range setting, the stimulation circuits can be placed in Constant Voltage mode or Constant Current mode. Constant Voltage mode will deliver pulses at the selected voltage, regardless of the load impedance. This means that the amount of current delivered may vary based on the electrode contact impedance. In Constant Current mode, the amount of current is fixed, while the actual voltage delivered will vary to compensate for the electrode contact's impedance. In Constant Current mode, the compliance voltage of the stimulator is ±14V.

- **Stimulator Safety:**
  A review of literature regarding long-term stimulation of neural tissue with DBS-sized and larger electrode contacts (geometric surface area of approximately 6 mm2 and larger) reveals that charge densities above 30 µC/cm2/phase may lead to neural tissue damage. The Guideline 4000 5.0 is capable of producing charge densities that exceed 30µC/cm2/phase.

⚠ **WARNING:** Stimulation charge densities may be high enough to cause tissue damage. Follow the recommendations provided by the manufacturer of the electrodes used to determine safe limits for stimulation intensities.

The use of biphasic, charge-balanced pulses with short pulse durations (< 120 µS) can help to minimize the risk of tissue damage occurring. Closely monitor the patient when applying stimulation and discontinue immediately if adverse side effects are observed.

⚠ **WARNING:** Do not attempt to use the Guideline 4000 5.0 stimulator to create lesions.

⚠ **WARNING:** Patients with existing implanted electronic devices should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.

⚠ **WARNING: Avoid trans-thoracic stimulation.**
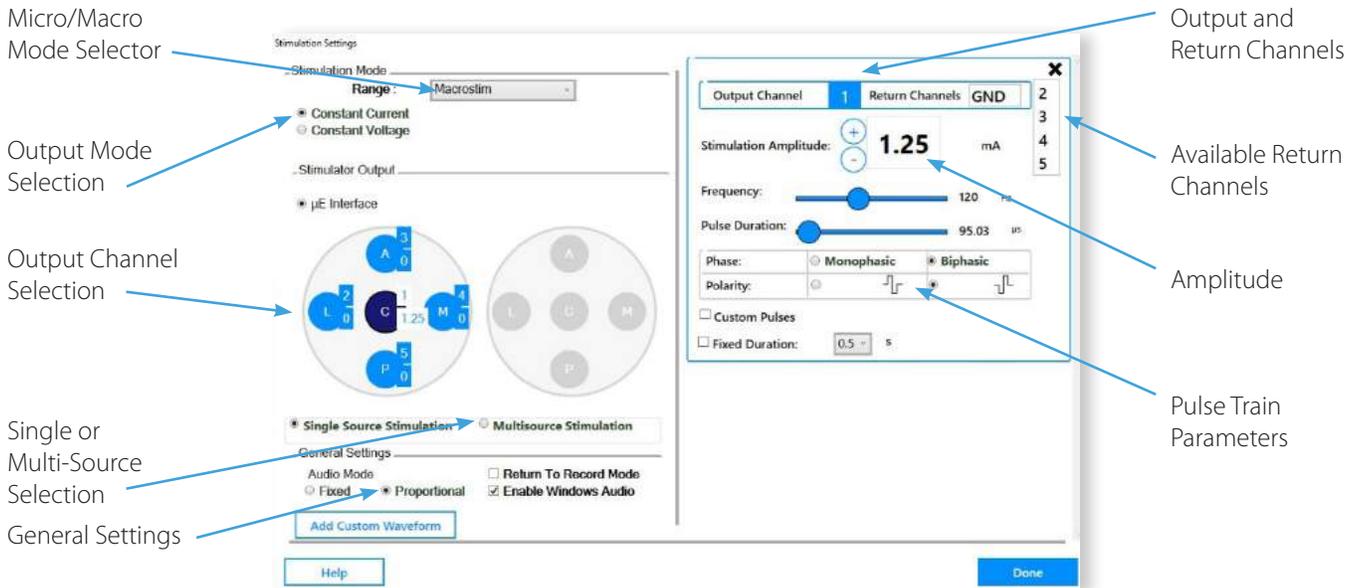
Select the stimulation source(s):

Once you have selected the proper range and mode for the stimulator, select one or more channels to be the stimulation source by clicking on them in the Ben-Gun array diagram. Once selected as a stimulation source, the channel will turn dark blue. In the above figure, the Center (C) track corresponding to channel 1 has be selected as the source channel for the stimulation. The blue boxes beside the channels indicate the channel number and the peak stimulation amplitude that will result when stimulation is applied, 1.25mA shown.

To stimulate simultaneously from multiple output channels, select Multisource Stimulation below the Ben-Gun Arrays, then click on all channels wanted. Clicking a selected source channel a second time will toggle that channel back off. Note that in Multisource mode, the stimulus amplitudes must be manually adjusted for all source channels. In Single source mode, the up/down rocker switch control on the remote control may be used to increase/decrease stimulation amplitude.

**Select the stimulation return(s) for all source channels:**

For every source channel selected, a parameter entry box will appear on the right-hand side of the dialog box. The source channel will be identified by its channel number in the header of the parameter box. When multiple source channels are selected, multiple parameter boxes will be shown, with the most recently selected source channel on top.

The return channel will default to GND, or ground, which is whatever the green alligator clip(s) from the patient leads have been connected to- typically, the insertion tube(s). When the stimulator is in micro-stimulation mode, only GND may be selected as the return. In macro-stimulation mode, one may select either GND or one or more other channels from the same Ben-Gun array. It is not possible to stimulate from one hemisphere of the brain to the other. A list of all available valid return channels will be shown on the far right of the parameter box. Clicking on any one of those will select it as the return channel. It is possible to select multiple channels (not including GND) as the return for macro-stimulation. This allows the operator to better control the directionality of the stimulation. When a channel is designated as a return

channel, it will be shown in green in the Ben-Gun Array diagram. A channel may only be selected as a return for a single stimulation source. To deselect a return channel, click it a second time in the available channels listing.

Select the Desired Pulse Train Options:

Pulses may be of positive or negative polarity and either monophasic or biphasic, as depicted in the diagram to the right. Also note that for biphasic pulses, the pulse width is defined as the width of a single phase.
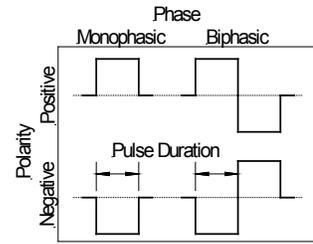
Most clinical applications will require the selection of a negative polarity pulse waveform, as this will correspond to cathodic stimulation at the source electrode contact.

When micro-stimulation is selected, only biphasic pulses are allowed, as monophasic pulses can cause accelerated degradation of the microelectrode tip. The use of charge-balanced biphasic pulses will promote the microelectrodes ability to hold its impedance following micro-stimulation.

A typical pulse train is shown to the right, where we define Pulse Period as 1/pulse frequency (in seconds) and the pulse amplitude as shown. Note that the stimulation amplitude, whether in micro-Amperes, Milli-Amperes or in Volts, refers to the peak amplitude, not the peak-to-peak value.
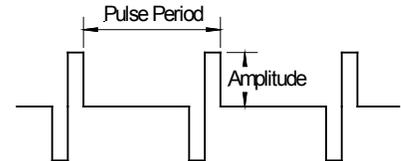
Pulse amplitudes may be controlled directly within the parameter box or by using the rocker switch on the remote control. Press upwards to continuously increase amplitude and downwards to continuously decrease it. When multiple source channels have been specified, the rocker switch does not work. Pulse amplitudes must be adjusted directly from the parameter box for every source channel present.

Understanding Biphasic Macro-stimulation:

When performing biphasic macro-stimulation, there are three possible configurations for the return channel(s):

- When the return channel is GND, the biphasic pulse will be present on the source channel. A negative polarity pulse is shown to the right.
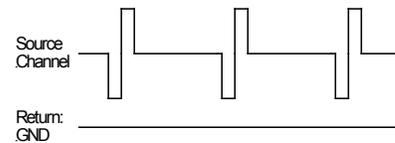
- When another channel is selected as the return, the situation changes. Only monophasic pulses will be generated and the phase selection will revert to monophasic automatically. In this case, a biphasic pulse will be split among the two channels, with the selected pulse polarity applied to the source channel and the opposite polarity to the return channel. The return pulse is applied immediately following the source pulse. This is shown to the right, again for a negative polarity pulse.
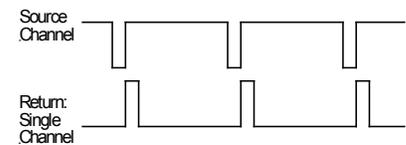
- If multiple return channels are selected, the situation is like the single channel case, except that the return pulse is applied to all channels simultaneously and the amplitude of the return pulses are all divided by the total number of channels selected. A negative polarity pulse with two return channels is shown to the right. In this case, each positive going return channel pulse train will be at one half the amplitude of the negative going pulse train at the source channel.
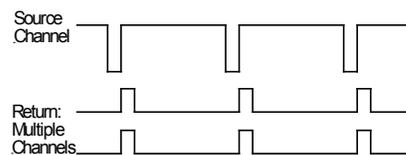
Applying Stimulation:

Stimulation may only be applied when the stimulation dialog is opened within the application, one or more source channels have been selected, and the Drive Speed Selector switch is in its lowest position, as shown in the figure. When this is the case, the stimulator is considered armed and the Apply Stimulus button will light to indicate this. Stimulus will only be applied after the Apply Stimulus button on the remote control is pressed. A flip-up safety cover is in place to prevent the accidental triggering of the stimulator. Stimulus amplitudes can be adjusted while stimulating.

NOTE: For systems with an Integrated microTargeting Controller Card installed, if the Motor Speed Select Switch is in any position other than the lowest position the Amplitude Adjustment switch will adjust the drive position, rather than the amplitude of stimulation.

By default, stimulation will be applied only while the Apply Stimulus button is depressed. If the **Fixed Duration** check box is checked, the button must only be momentarily pressed. The stimulation will be applied for the selected duration and stop automatically. Pressing the button again at any point during the fixed duration will cancel all stimulation immediately.

The Guideline 5 emits an audible tone whenever stimulus is being applied. The pitch of the tone will vary between micro-stim and macro-stim modes. This tone may be **proportional** in volume to the stimulus amplitude or of a **fixed** volume. The **Enable Windows Audio** check box can be checked to ensure that the Windows Audio controls are not

muted during stimulation, preventing the stimulus tone from being silenced.

Amplitude Adjustment

Apply Stimulus

Drive Speed Selector

Readback Voltages:

During stimulation, the Guideline 5 will continually measure the voltages present on all channels involved in the stimulation and display those values within the stimulation dialog box. The read-back display will contain the channel number, measured voltage, and the current amplitude setting (in micro-amps, Milli-amps or volts, depending on the stimulation mode). If the stimulator is in Constant Current mode and the stimulator is unable to deliver the desired amount of current because of a high electrode impedance, then a compliance warning will be shown.

For applications where it is important to record activity on a channel immediately after stimulating, the **Return to Record Mode** check box may be checked. This will result in the stimulation dialog closing automatically as soon as the stimulation is complete.

Using Custom Waveforms:

The Guideline 5 can import and apply arbitrary stimulation waveforms. This functionality is beyond the scope of this manual. Please contact FHC technical support for assistance in setting this up.