

LF Interface

Directions For Use - Supplementary Information

L011-85-02 (Rev C0, 2019-02-01)

Contains directions for the following products:
MT-LPP, C0220, C0221, C0222, C0233



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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
	Caution-Federal Law (USA) restricts this device to sale by or on the order of a physician.		Authorized Representative in the European Community.
	In reference to "Rx only" symbol; this applies to USA audiences only.		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.
	Indicates the catalog number so that the medical device can be identified.		Indicates the temperature limits to which the device can be exposed.
	Indicates the serial number so that a specific medical device can be identified.		Range of humidity to which medical device can be exposed.
	Indicates the batch code so that the batch or lot can be identified.		Range of atmospheric pressure to which medical device can be exposed.
	Indicates the model number so that the model of the medical device can be identified.		Instructions for end of life disposal.
	Date when the medical device was manufactured.		
Unit Symbol Key			
	WARNING: Read usage instructions.		Head Box Connection
	Type BF Applied Part		

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

Periodic Preventive Maintenance

To ensure continued reliable operation, FHC requires that a comprehensive functional and safety inspection of the Guideline 5 system be performed 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.

LF Interface overview

The LF Interface (C0220), LF being short for Low Frequency signal, is an accessory 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 LF Interface provides 8 channels of recording and stimulating capability designed to interface with electrodes suitable for the recording of neural field potentials. The Guideline 5 Main Processing Unit can also connect to two LF Interfaces simultaneously for a maximum of 16 LF channels. Alternately, the LF Interface may be used in conjunction with a UE Interface where needed.

There are two basic modes of operation for the LF Interface. Based on the procedure setup in the Guideline application,

- **LF Signal Recording:** the LF Interface can be configured for generic LF electrode recording. It is optimized for recording from larger surface area electrodes, such as those designed to sense field potentials (EEG, ECoG). Standard 1.5mm touch-proof connectors on the LF front panel provide the connection point for generic LF electrodes.
- **DBS Lead Recording and Stimulating:** Alternately, when configured for DBS Lead recording and stimulating, a high-density connector allows for convenient connection to the sterile DBS trailing cable for use in intraoperative DBS procedures.

Like the UE Interface, the LF Interface is intended to be located immediately outside the sterile field, when used intraoperatively, putting it closer to the patient and significantly reducing the effects of environmental noise. The Pole Mount Clamp (C0233) allows the LF 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 remains outside the sterile field. The interface should not be placed on the floor, nor allowed to hang from the patient leads.

The LF Interface features many advanced and innovative capabilities:

- 8 independent channels; all inputs are single-ended with a common patient reference and ground connection. All inputs are high impedance, low leakage, and fully isolated, making them well suited for recording from a variety of electrode types.
- Amplification, signal conditioning, and digitization of the recorded signal are performed entirely within the LF Interface. Signals traveling from the LF Interface to the Guideline 5 system are immune to further noise pick-up.
- The LF Interface can measure the impedance of all electrode contacts connected to it. Electrode impedances may be measured simultaneously on all connected electrodes. Adjustable measurement parameters allow user selection of the desired measurement frequency and duration.
- When connected to a DBS Lead, the LF Interface is capable of both constant current and constant voltage electrical stimulation with a maximum intensity of ± 10 mA / ± 10 V.
- Channels not involved in DBS stimulation continue to record LFP activity, while adaptive stimulus artifact suppression minimizes stimulus artifacts present on these recordings.
- The LF Interface boasts an independent stimulation circuit for every channel, supporting complex multi-channel DBS stimulation protocols, including current steering. Continuous monitoring of peak stimulus voltage delivered by every channel is displayed 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 LF Interface features prior use.



WARNING: Use of non-supported electrodes can result in poor quality recordings, incorrect stimulation, inaccurate targeting, or patient injury.



WARNING: Remove patient leads if engaging defibrillation.



WARNING: Do not allow the Interface to get wet.

Specifications

C0220 - LF Interface

Dimensions: 12.5 cm Width, 4.5 cm Height, 23 cm Length

Weight: <1 kg

Mounting: Pole mount, table mount

Channels: 8x

Connectors: Input – 1.5mm Touch-proof 8x or micro-HDMI high density, Output – 26 pos. Centronics F

Patient Lead Cable Length: <= 1.5 meters recommended



WARNING: Use of longer than recommended patient lead cables could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Guideline 5 and possibly result in improper operation

Isolation: Type BF medical Isolation

Inputs: Single ended inputs with common reference and ground

Input Impedance: 100 M Ω typ.

CMRR, typical: -90 dB

Data Acquisition (per channel):

- Gain: User adjustable from 1x, 2x, 4x, 6x, 12x, 24x
- Greater than 1 μ V resolution RTI
- Noise: < 6 μ V RMS 1Hz - 1kHz with inputs tied to REF & GND
- DC Coupled Inputs
- Digital Resolution: 24 bits over \pm 2.5V dynamic range
- Sample rate / channel with simultaneous use of UE Interface: 1000Hz
- Sample rate / channel when the LF is used in DBS mode: 2000Hz, 1000Hz, 500Hz, 250Hz
- Sample rate / channel otherwise is user selectable from: 16kHz, 8kHz, 4kHz, 2kHz, 1kHz, 500Hz, 250Hz
- Continuously adjustable band pass filters (software for visualization only) 0Hz – $\frac{1}{4}$ sample rate
- Adaptive line noise suppressor and mains frequency notch filter

Stimulation (per channel) Available in DBS Mode Only:

- Constant Voltage or Constant Current operation
- Stimulus Tone – configurable
- Compliance voltage: \pm 14V (constant current mode), \pm 10V (constant voltage mode)
- Maximum current: \pm 10mA per channel
- Multi-source / multi-return capable
- Stimulus artifact suppression, recoding on channels not involved in stimulation
- Stimulus Generation:
 - Mono-phasic / bi-phasic
 - Dual polarity
 - Pulse width: 47.5 μ s to 3.4 ms
 - Pulse Frequency: 1 Hz to 300 Hz
 - Max duty cycle: 50%
 - Fixed duration: 0.5s to 60s
- Impedance Check:
 - 8x simultaneous measurement – optional
 - Measurement current < 100 μ Ap-p per channel
 - Measurement Frequency: user selectable from 200Hz to 1000Hz
 - Measurement Duration: user selectable from 1s to 10s

- Measurement Range: 100Ω - 10kΩ
- Measurement Accuracy: ±10% of nominal measurement

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



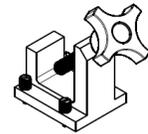
C0222 - Remote Control

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



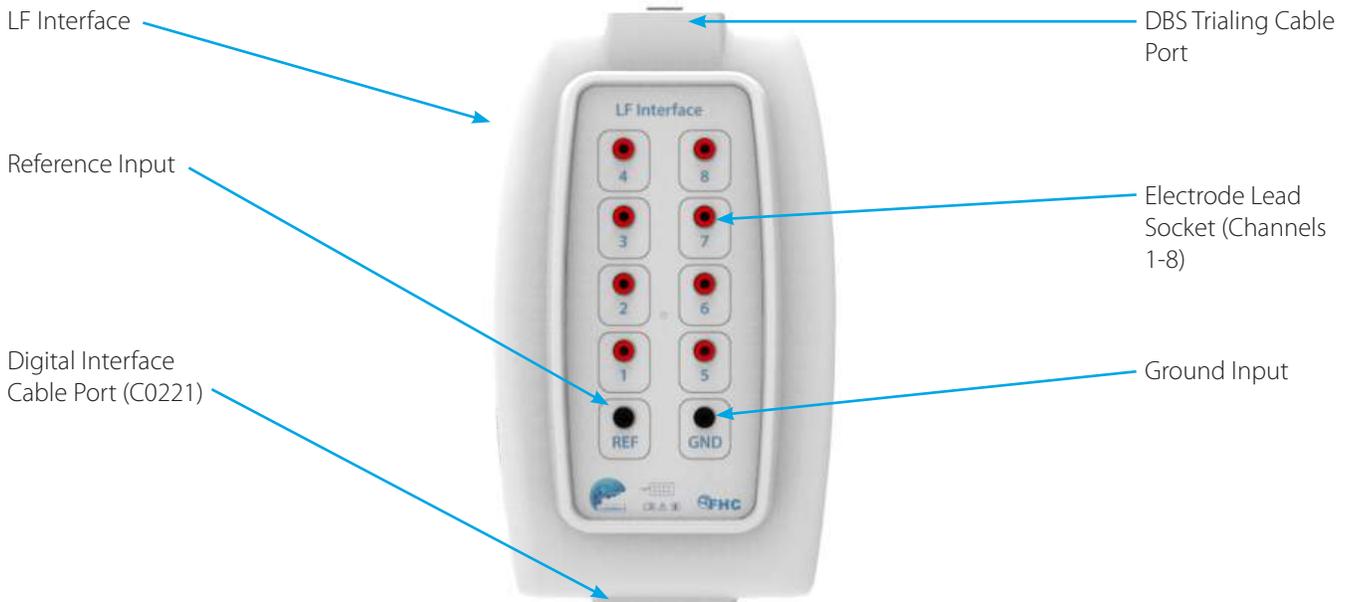
C0233 - Interface Pole Mount Clamp

Dimensions: 10cm x 10cm x 5.1 cm including knob
 Weight: 0.25kg
 Material: Anodized Aluminum



Illustrative procedure

Pre-procedure Setup



Position the LF Interface

The LF Interface is not designed to be sterilized. When used intraoperatively, the LF Interface should be placed immediately outside the sterile field around the patient's head. Care should be taken to ensure that the electrode leads or trialing cable can comfortably reach from the electrodes to the LF 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 electrode 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 LF Interface to the Guideline 5

Connect the Digital Interface Cable between the LF 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 GL5 can handle two 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 electrode leads to the interface, Start the GL5 system (Refer to L011-85). When the GL5 system detects the presence of the LF Interface, it will prompt to perform the power on self-test. As the self-test involves the presence of stimulation voltages on the LF Interface's electrode lead sockets, make sure that there are no electrode 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.

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

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

Map Channels and Connect the Electrode Leads

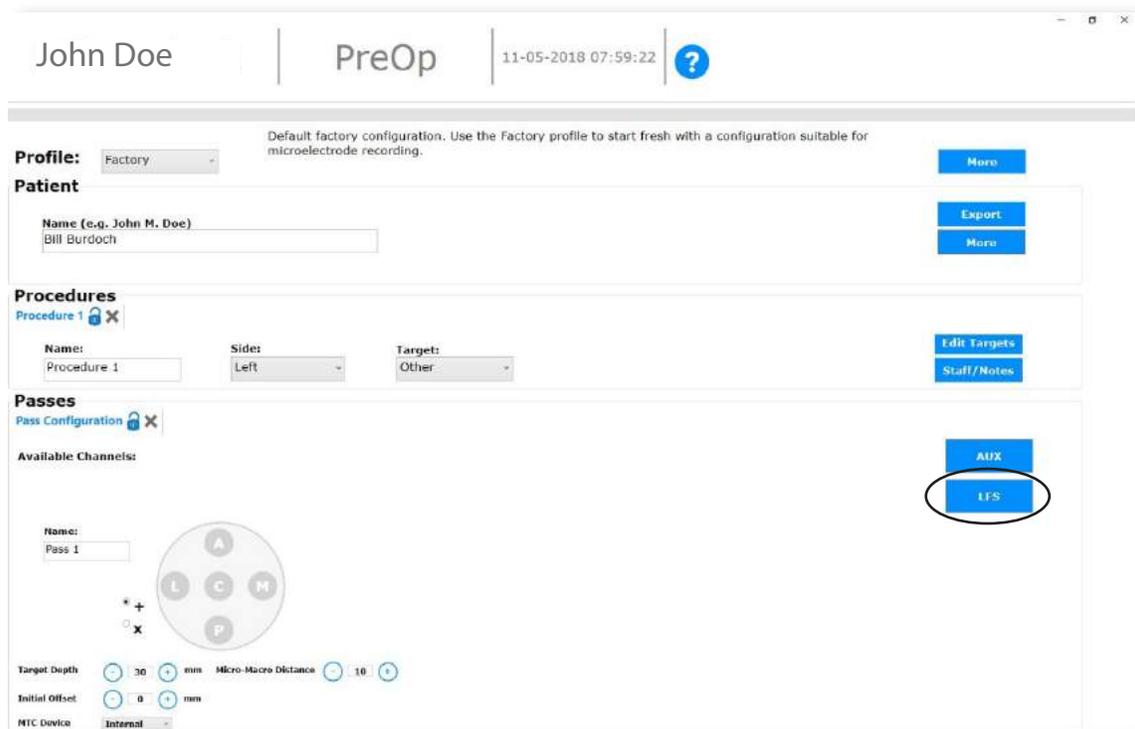
This procedure resumes once the electrode(s) are in place.

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

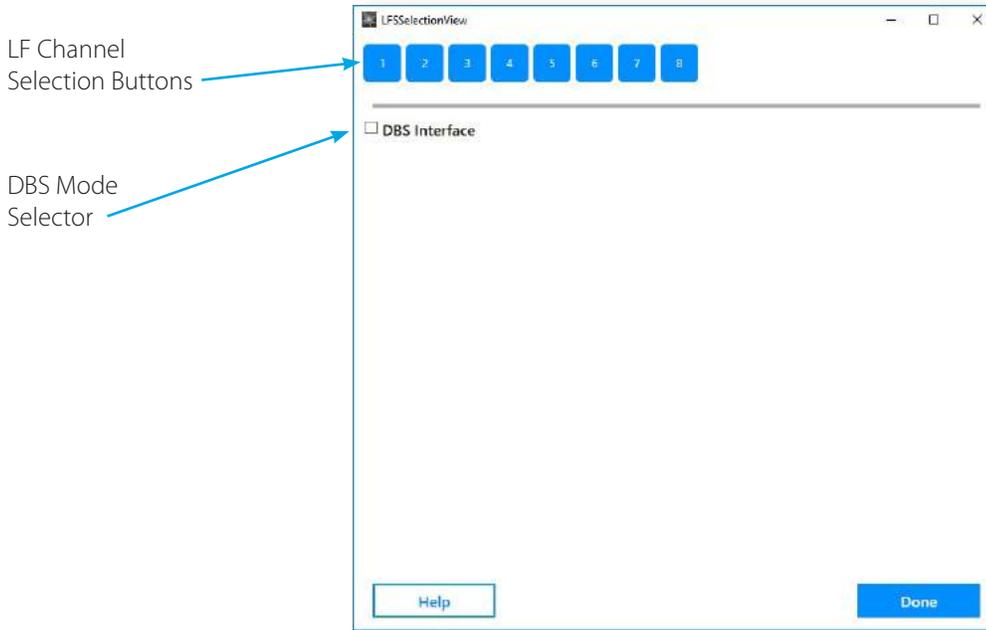
 **WARNING:** Remove patient leads if engaging defibrillation.

The PreOp screen is shown below. To access the LF Channels, click on the LF button indicated by the red oval.



LF Mode Selection

The resulting dialog is where users select which mode the LF Interface will operate in and map the LF channels to electrode contacts.

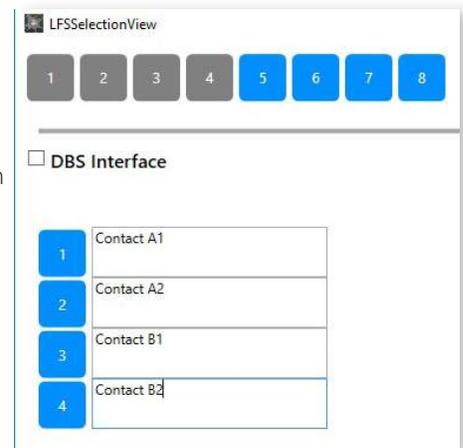


LF Interface Mode

Click on the channel numbers to activate the corresponding LF channel. In the corresponding text box, enter a name for the channel to identify which electrode contact it will be connected to. As LF channels are activated, they will become grayed out. As channels are activated and named in this fashion, connect the corresponding electrode lead to the appropriate channel input on the front panel of the LF Interface. The LF Interface accepts standard 1.5mm touch-proof connectors. When ready, click **Done** to close the LF selection dialog box and proceed to the IntraOp screen.

Reference Input: The channel 1-8 inputs on the LF are all single-ended. A common or reference electrode is required to obtain recordings. This electrode should be connected to the LF input labeled REF. The signals recorded by the Guideline will be the signals present at every channel input minus the signal present on the REF input. In this way, many noise sources common to both inputs will be eliminated from the recordings.

Ground Input: The LF Interface patient connected circuitry is isolated from earth ground for patient safety. Circuit ground is provided through the GND input to allow operators to connect the floating LF ground to patient ground. This is ideally done by connecting a patient grounding electrode to the GND input. No current will flow through this electrode. Noise performance of the LF will be improved when patient ground is connected to the GND input, though its use is not required. The GND input should not be connected directly to the earth GND, as this will effectively bypass the isolation inherent to the LF Interface.



DBS Interface Mode

If the LF is to be connected to a Deep Brain Stimulation electrode, then it is necessary to check the DBS Interface box. When checked, a pop-up message will instruct the operator to remove all connections from the front panel of the LF Interface. Connection to DBS electrodes is more easily made by connecting to the high-density connector located at the top of the LF Interface.

Note that when using the LF Interface in DBS mode, the 2D depth viewer will be active to record and allow control of the depth of the DBS electrode while recording.

The high-density connector is designed to connect directly to the Abbott



MLTC (multi-lead trial cable) μ HDMI connector. When an 8-contact Infinity Lead is connected to the MLTC, the contacts of that lead will be automatically mapped as shown. One of the DBS contacts, typically one of the solid bands (1 or 4), should be selected to serve as the reference channel from the Reference Channel drop down menu. Select Reference Channel 1 to use DBS contact 1 (# 1/1) as the reference contact for all the others or select LF channel 5 to use the top DBS contact 4 (# 5/4) as the reference. The selected reference channel will be designated in black at the top of the dialog box. Internal switching within the LF will connect the selected channel to the reference input. The selected reference channel will be shown in black, rather than gray, at the top of the dialog. When ready, click the **Done** button.

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.



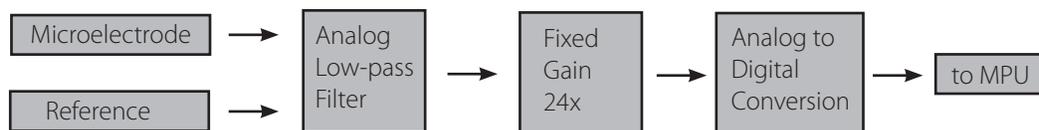
Recording

When you enter the IntraOp screen, the Guideline 5 will not be recording data that is displayed by default. Click the reel-to-reel icon in the top menu bar to engage continuous recording to disk. The icon will turn red when recording is engaged.

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.

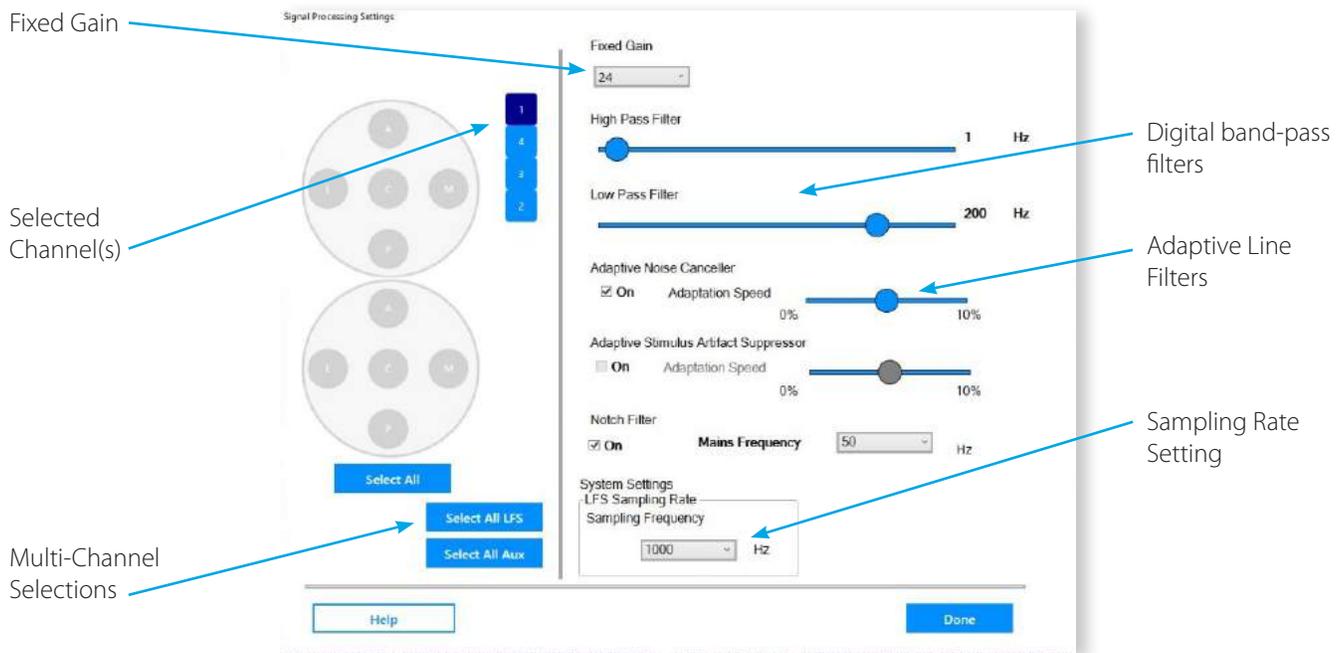
Signal Processing

A simplified block diagram of the signal acquisition chain in the LF Interface is shown below. The dynamic range of the processing chain is $\pm 2.5V$.



The LF signals are first passed through an analog RC low-pass filter with a cutoff frequency of 1066Hz. This is followed by a fixed gain stage that is controlled from the Signal Processing dialog. Gain options are 1, 2, 4, 6, 12, and 24x. The signal-to-noise ratio of the system will be better the higher the gain is set. However, larger signals may require reduced gain to avoid saturation of the amplifier. Finally, the signal is digitized at 24 bits of resolution over the $\pm 2.5V$ input window and transmitted to the GL5 MPU. The sample rate can be set from the Signal Processing dialog as follows:

If the LF Interface is being used simultaneously with an UE Interface, the sample rate will be automatically set to 1000 samples per second and will not be user adjustable. If the LF is placed in DBS Mode, the sample rate will be set to 2000 samples per second and will not be adjustable. Otherwise, the sample rate may be selected from the following options: 250, 500, 1000, 2000, 4000, 8000, 16000 samples per second per channel. Note that this setting will apply to all channels.



- **Channel Selection:** Signal processing settings may be made on a channel-by-channel basis or globally. To select one or more channels, click on their corresponding box in the left pane. Any changes made will affect only highlighted channels. Alternately, settings for all channels may be made by pressing the Select All LF button. 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 are only applied when the Signal Processing dialog is closed.
- **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 the types of electrodes and signals of interest. 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 of the Guideline system will be affected by the band-pass filter.
- **Adaptive Line Noise Canceller:** The adaptive line noise canceler 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 canceler 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. There is often a significant amount of line noise present on the patient. The effect of this noise can be minimized by grounding the patient to the GND input on the LF. There are very few scenarios where one would not want the line noise canceler enabled. It 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 canceler enabled.
- **Notch Filter:** A digital notch filter can be enabled if required to help contend with line related noise. When using the notch filter, be sure to select the appropriate mains frequency for your locale.

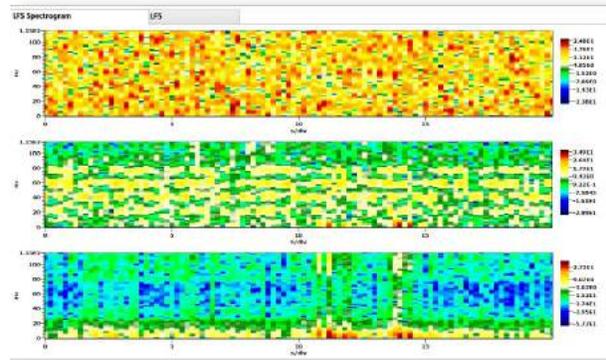
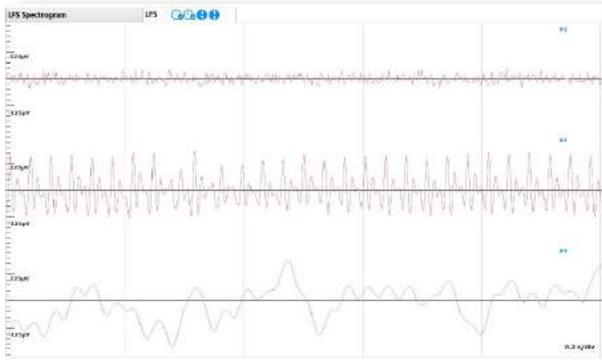
Waveform Window

The waveform window is the primary display of recorded activity. There are two modes of operation shown below. LF Mode provides a view of the signal waveform and LF Spectrogram provides a spectrogram of the LF recording. A pair of tabs along the top border are used to switch back and forth between the two display modes.

The LF display shows the waveform recorded by the electrodes. The amplitude of this waveform, as indicated by the scale along the left, is referred to the input of the LF 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, 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 Fast Fourier Transform performed continuously on the LF 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 LF tab 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.

Recording Events

An event is any item of interest that occurs during a procedure. Events corresponding to impedance checks and stimulation (if in DBS Mode) will be automatically generated by the Guideline System. Events related to recorded activity must be created by the user as activity of interest occurs. An event may also be created as a means of storing comments, both audio and text notes can be stored as events. 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.



The Event button in the top Mode Control options within the IntraOp Status Bar is used to create an event at any point during the procedure. This will create an event associated with all active channels.

Event Name →

Enter Text Notes Here →

Record an Audio Event →

Within the IntraOp screen, events will be shown on the Depth View Panel (if present) to indicate the depth associated with them. 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.

Z Impedance Check

To perform an Impedance Check on any electrode contact connected to the LF 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 LF Interface has been designed to safely measure the electrode contact impedances in vivo.

The screenshot shows the 'Impedance Measurement' dialog box. It features a control panel at the top with 'Measurement Frequency' set to 1000 Hz and 'Measurement Time' set to 2 sec. There are checkboxes for 'Macro' and 'Measure All'. Below this is a table of results for three channels. At the bottom are 'Help', 'Start', and 'Done' buttons. Blue arrows point from external labels to these elements: 'Measurement Frequency' points to the frequency field; 'Channel # Indicators' points to the channel numbers in the table; 'Measurements Results (in Ω)' points to the impedance values; 'Initiate Measurement(s)' points to the 'Start' button; and 'Close Dialog' points to the 'Done' button.

Channel #	Impedance (Ω)
2	2039.51
3	3242.62
4	8059.37

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.

When the Start button is pressed, the impedances of all electrodes will be measured simultaneously. 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 220Hz for LF electrodes. This setting is well matched to the spectral content of the signals obtained from these types of electrodes.

⚡ Stimulation

The GL5 LF Interface features an independent stimulation circuit for every channel. Stimulation is only available through the LF when it is configured in DBS Mode.

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 electrode manufacturer to determine safe limits for stimulation intensities.

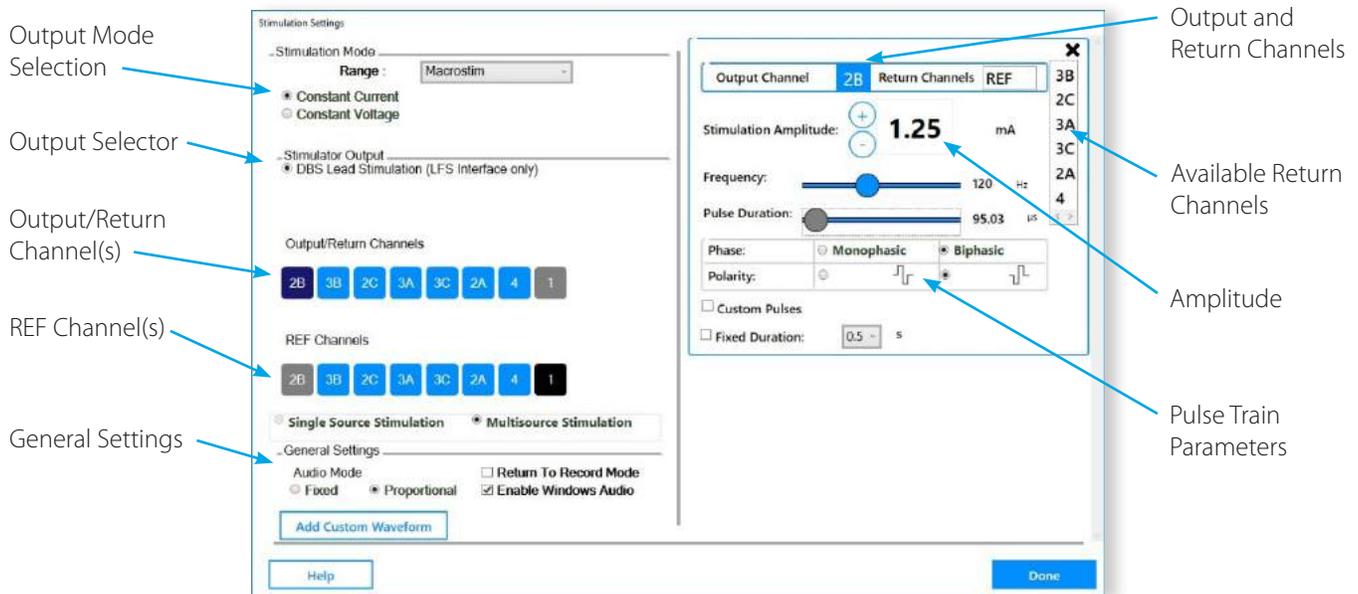
The use of biphasic, charge balanced pulses with short pulse durations (< 120 μS) can help to minimize the risk of tissue damage occurring. Closely monitor the patient when applying stimulation and discontinue immediately if adverse side effects are observed.

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

⚠ WARNING: Use caution when electrically stimulating a patient with existing implanted electronic devices.

⚠ WARNING: Avoid trans-thoracic stimulation.

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, up to a maximum of $\pm 10V$. 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 controlled up to a maximum of $\pm 10mA$, while the actual voltage delivered will vary to compensate for the electrode contact's impedance. In Constant Current mode, the actual voltage applied can go as high as $\pm 14V$. The Stimulation Settings dialog is shown below.



Stimulation Mode: When stimulating with the LF Interface, only the Macrostim range will be available. Select the stimulation mode (Constant Current or Constant Voltage) desired.

Stimulator Output: To stimulate with the LF, select the DBS Lead Stimulation (LF Interface Only) option.

Select the stimulation source(s):

Once you have selected the proper mode for the stimulator, select one or more channels to be the stimulation source by clicking on them in the Output/Return Channels diagram. Once selected as a stimulation source, the channel will turn dark blue. In the above figure, Contact 2B has been selected as the source channel for the stimulation. To stimulate simultaneously from multiple output channels, select Multisource Stimulation below the REF Channels diagram, then click on all channels wanted. Clicking a selected source channel a second time will toggle that channel back off.

Configure the REF contact(s):

By default, the contact selected as the reference contact for recording will also be selected as the REF for stimulation. The REF Channels diagram displays the currently selected REF contact(s) in black. Contact 1 is the current REF contact in the above image. It is possible to select any other combination of contacts from this diagram by clicking on them within the REF Channels diagram. There must always be at least one REF contact selected. As source and return contacts are selected, they will be grayed out in the REF Channels diagram, indicating that contact is no longer available as a reference contact. The LF Interface will internally connect all designated REF contacts together. REF Contacts will always remain at 0V during stimulation. The REF contact(s) may be selected as a return for one or more stimulation sources.

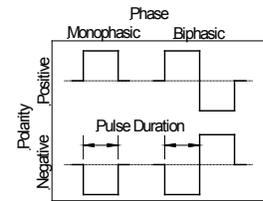
Select the stimulation return(s) for all source channels:

For every source contact selected, a parameter entry box will appear on the right-hand side of the dialog. The source contact will be identified by its contact name in the parameter box. To the right of this, the return contact will be displayed. When multiple source contacts are selected, multiple parameter boxes will be shown with the most recently selected source contact on top.

The return contact will default to REF or reference, which is all the contacts selected in the REF Channels diagram. A list of all available valid return contacts will be shown on the far right of the parameter box. Clicking on any one of those will select it as the return contact. It is possible to select multiple contacts (not including REF) as the return for a stimulation source. This allows the operator to better control the directionality of the stimulation. When a contact is designated as a return contact, it will be shown in green in the Output/Return Channels diagram and grayed out in the REF Channels diagram. With the exception of the REF contact(s), a contact may only be selected as a return for a single stimulation source. To deselect a return contact, click it a second time in the available contacts listing.

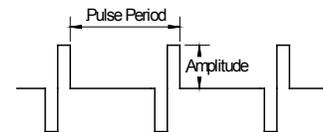
Select the Desired Pulse Train Options:

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.

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 Milli-Amperes or in Volts, refers to the peak amplitude, not the peak to peak value.

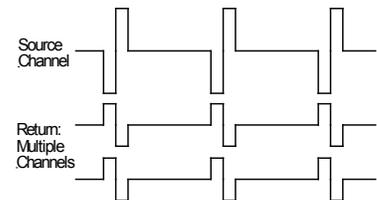
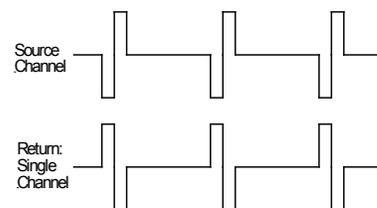
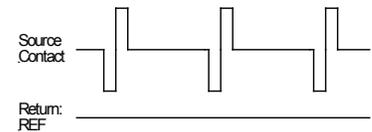


Pulse amplitudes may be controlled from within the parameter box directly or by using the rocker switch on the remote control. Press upwards to continuously increase amplitude and downwards to continuously decrease it. When multiple source channels have been specified, their amplitudes will increase or decrease at the same rate. To introduce an offset in amplitudes between two source contacts, starting values may be manually entered into the parameter boxes for all channels. This offset will be maintained when adjusting stimulation amplitudes with the remote control.

Understanding Biphasic Macro-stimulation:

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

- When the return is REF, the biphasic pulse will be present on the source contact. A negative polarity pulse is shown to the right.
- When another contact is selected as the return, biphasic pulses with opposite polarities will be applied to the source and return contacts. This is shown to the right, again for a negative polarity pulse.
- If multiple return contacts are selected, the return pulse is applied to all contacts simultaneously. In Constant Current mode, the amplitude of the return pulses is divided by the total number of return contacts selected, while in Constant Voltage mode, the amplitude on all return contacts is the same as for the source contact. A negative polarity pulse in constant current mode with two return contacts is shown to the right.



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.

Read-back 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. 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 box 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.

