



Neural microTargeting™ Worldwide

Synchronization Unit

Directions For Use - Supplementary Information

L011-85-04 (Rev C0, 2021-05-19)

Contains directions for the following products:
C0224, C0225



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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, 98/79/EC and Medical Device Regulation (EU) 2017/745.
	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.		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 Medical Device Regulation (EU) 2017/745 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 to that the batch or lot can be identified.		Date when the medical device was manufactured.
	Date when the medical device was manufactured.		Range of atmospheric pressure to which medical device can be exposed.
	Indicates Medical Device		
	Instructions for end of life disposal.		
Unit Symbol Key			
	Digital Input		Analog Output
	Analog Input		Analog/Digital Synchronization Unit Connection

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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.

System Overview

The Synchronization Unit is an optional accessory to the Guideline 5 system that provides additional analog and digital inputs and outputs.

- 2 high-speed digital inputs*
- 2 configurable analog inputs
- 8 analog outputs for MER/LFS signals
- 16 general purpose digital inputs*
- 16 general purpose digital outputs*

* Requires second Interface PCB (C0218) as digital inputs and outputs are split evenly between the cards for Interface 1 and Interface 2.

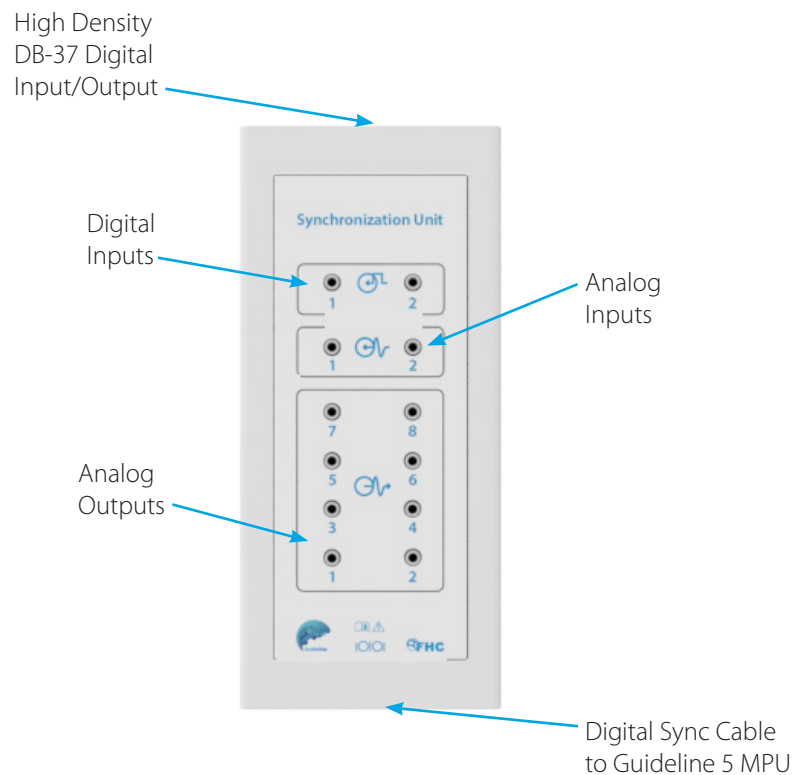
All IO signals present on the synchronization unit are earth-referenced and not suitable for direct patient connection. All analog and digital inputs are synchronized with the electrode signals acquired by the Guideline 5 and saved for offline data analysis.

Equipped with the Synchronization Unit, the GL5 is ready to handle even the most demanding research applications.

Components and Connections

Connect the Digital Sync Cable (C0225) to the bottom of the Synchronization Unit (C0224). Connect the other end of the Digital Sync Cable to the GL5 MPU.

Place the Synchronization Unit next to the Guideline 5 MPU.



Specifications

Dimension:

- Length - 23cm
- Width - 10cm
- Height - 4cm

Weight: 0.485 kg

Digital Sync Cable:

- Length 0.7m
- Connectors HD26 M-M
- Shielded with EMI suppression Ferrite

High Density DIO Connector:

- DB-37 F Connector
- DIO: TTL/CMOS, +5V, 12.44ms Timestamp resolution on rising edge
- Pins 1-8: Digital Output 1 - bits 0-7
- Pins 9-16: Digital Input 1 - bits 0-7
- Pins 20-27: Digital Output 2 - bits 0-7
- Pins 28-35: Digital Input 2 - bits 0-7
- Pins 17, 19, 36: Ground
- Pins 18, 37: Strobe 1,2 (not currently implemented)



Front Panel Connectors:

- 3.5mm Ø mono-phono jacks
- FHC Mating Cable – 3.5mm male mono-phono to BNC x 1m – 55-00-4 (not included)

High Speed Digital Inputs (1,2):

- TTL/CMOS +5V
- 31.25µs (1/32kHz) Timestamp resolution (rising edge). Synchronous to Interface inputs.

Analog Inputs (1,2):

- Dynamic Range:
 - Unipolar – 0 - 3.3V
 - Bipolar (AC/DC Coupled) - ± 1.6V
- Sampling:
 - User selectable (1,2,4,8,16,32 kHz)
 - 24-bit resolution
- Gain
 - 1.67x, 3.33x, 16.67x, 33.33x

Analog Outputs (1,2...8):

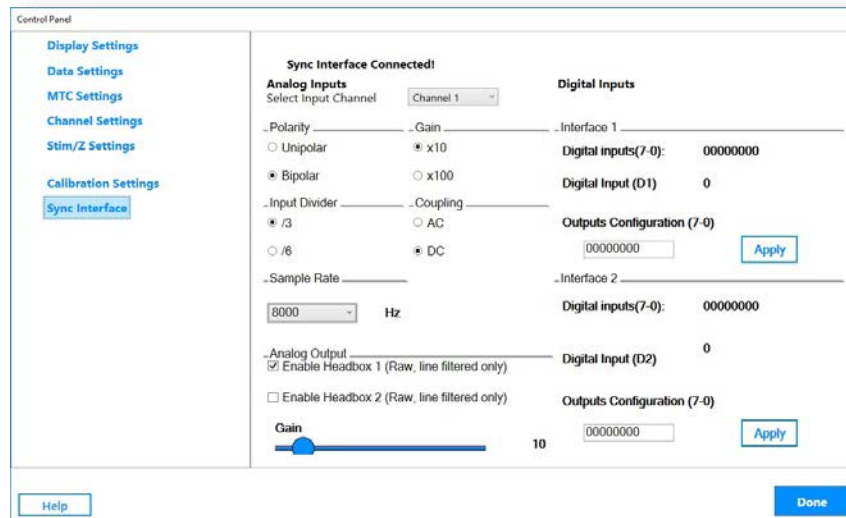
- Line level outputs
- Variable Gain 1x to 10x

Illustrative Procedure



WARNING: The auxiliary sync inputs and outputs are not isolated. Do not make direct connections between the auxiliary inputs/outputs and the patient.

Settings for the Sync Interface are located within the Settings dialog on the IntraOp screen of the Guideline application. The Sync Interface settings are shown below:



Digital Inputs



The Synchronization unit provides two high-speed digital inputs, the inputs are +5V TTL/CMOS and compatible with other similar digital equipment. The inputs are rising-edge triggered. When the inputs are driven high, a digital timestamp will be generated and saved to any ongoing data recording. The inputs are sampled at the same rate as the electrode data acquisition and timestamps generated in this way will be exactly synchronized with the recorded data.

The current state of the digital inputs can be viewed on the settings dialog as D1 and D2 for troubleshooting purposes.

These inputs are typically used to support research applications where a digital pulse is used to mark the exact moment in time that some visual, auditory, or tactile stimulation was applied within the data generated.

Note: It is possible to configure the Guideline system such that a digital input can be used to trigger stimulation. This is considered an off-label use and will require an IRB approval. Please contact FHC if interested in exploring this option for a research application.

Analog Inputs



The Synchronization unit provides two user-configurable analog inputs. The inputs have a dynamic range of 3.3V. If the inputs are configured as Unipolar, then the input range is 0-3.3V. If they are configured as bipolar, then the input range is $\pm 1.65V$. The inputs can also be AC or DC coupled as desired. Two gain options of x10 and x100 coupled with two input divider options of /3 and /6 provide four possible gain configurations. The table on page 8 summarizes these options along with the resulting dynamic range.


Input Divider	Input Gain	Uni/Bipolar	Range low (Volts)	Range High (Volts)
6	10	Unipolar	0	1.98
3	10	Unipolar	0	0.99
6	100	Unipolar	0	0.20
3	100	Unipolar	0	0.10
6	10	Bipolar	-0.99	0.99
3	10	Bipolar	-0.50	0.50
6	100	Bipolar	-0.10	0.10
3	100	Bipolar	-0.05	0.05

The sampling rate is user selectable from 32ksps, 16ksps, 8ksps, 4ksps, 2ksps, or 1ksps with a 24-bit resolution. The analog inputs are synchronized with the electrode data acquisition and will be included in any recorded data. Analog waveforms may be viewed alongside electrode-derived waveforms intraoperatively by pressing the AUX button.

Configuration controls for the analog inputs are located on the Sync Interface settings form.

These inputs are typically used to record analog signals of interest, such as data from an accelerometer or perhaps a microphone.

Analog Outputs

 The Synchronization Unit provides eight line-level analog outputs. If multiple Interfaces are present, controls within the settings dialog provide the ability to select Interface 1 or Interface 2. The analog out channel numbers correspond to the interface channel numbers. It is not possible to map signals from both interfaces to the analog outputs simultaneously. The signal present will be raw unfiltered data coming from the interface in real time. The analog outputs are audio range only and will not contain signal content below about 20Hz.

A variable gain control is provided on the settings form which can be adjusted to integer values from 1x to 10x.

High Density DIO

The Synchronization Unit features a high-density digital input/output (DIO) connector for handling bulk digital data. These inputs and outputs are all +5V TTL/CMOS compatible and are sampled or refreshed at a frequency of 80 times a second. This is fast enough for most behavioral data.

Digital Inputs:

Two 8-bit bytes can be input on the HD connector. These will be timestamped and saved to the data file, along with any recorded data. For diagnostic purposes, the current state of the digital input bytes can be viewed or monitored from the settings dialog.

These may be used for recording the results of a trial or encoding complex data into the data file.

Digital Outputs:

Two 8-bit bytes can be output on the HD connector. Data for these outputs is set from the settings dialog and will be applied when the corresponding Apply button is pressed. Please contact FHC if you have an application that requires digital outputs as our engineering staff will be able to provide customizations to tie these digital outputs to various data sources.