FHC
Neural microTargeting™ Worldwide

Guideline 5

FHC's Next Generation Neuromodulation System

Performance – Intuitive, Integrated & Individualized

*Interfaces include clamp to mount on customer-supplied IV pole

Guideline 5 Application

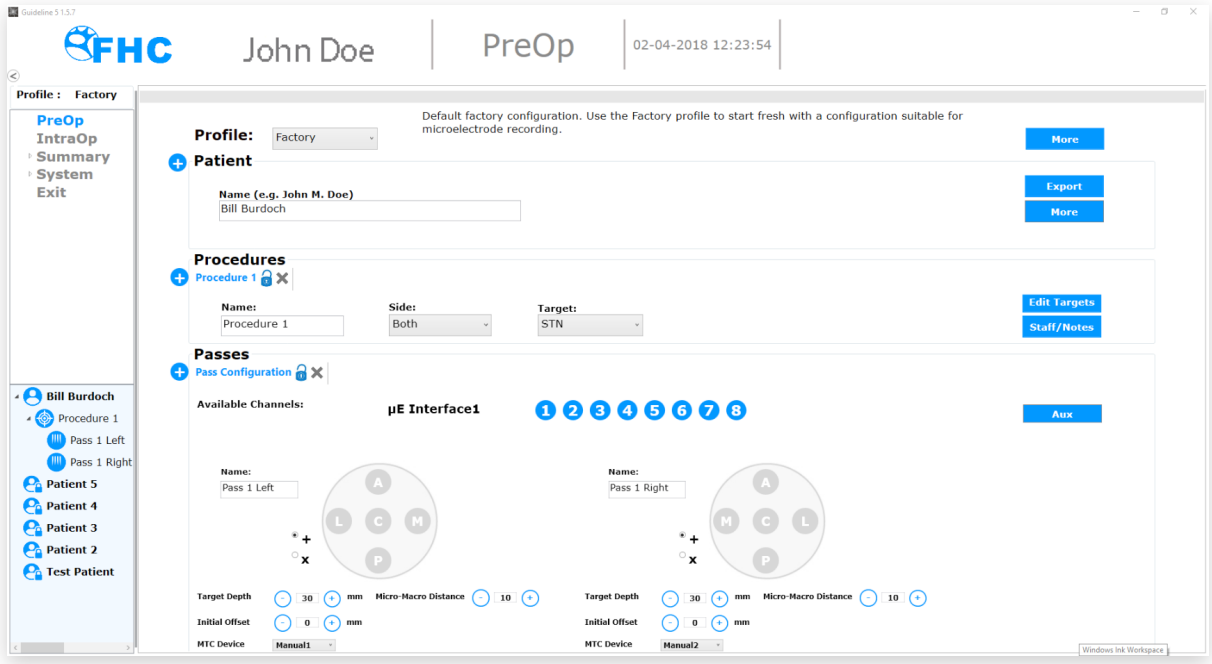
The Guideline 5 application provides all the tools needed to configure, acquire, classify and analyze your neuromodulation data:

- Streamlined user interface for intuitive ease of use and quick start
- Touch-screen and multi-monitor support
- Continuous or on-demand capture of all acquired signals
- Simplified pre-operative setup
- Quick access to pop-out channel analysis windows with trace, spike and time-frequency analysis
- Adaptive line noise suppression
- Continuously adjustable band-pass filtering

- Manual threshold triggering, dual level and window spike discrimination
- Recorded neuron classification and event marking with pre- and post- event recordings
- Mean firing rate vs. depth track analysis
- RMS amplitude vs. depth track analysis
- LFP waveform and spectrogram analysis vs. time

- Integrated drive control and depth monitoring
- Simultaneous bilateral procedure support
- Simultaneous multi-channel stimulation with custom pulse train support
- Full procedure reporting
- Archive data to patient archive files (.glr) with option to anonymize PHI data.
- Matlab support for access to data files and data streaming

The Guideline 5 application is included with system purchase for use on the provided laptop. Additional copies for off-line analysis on other computers is available for additional cost.



High Performance Notebook PC

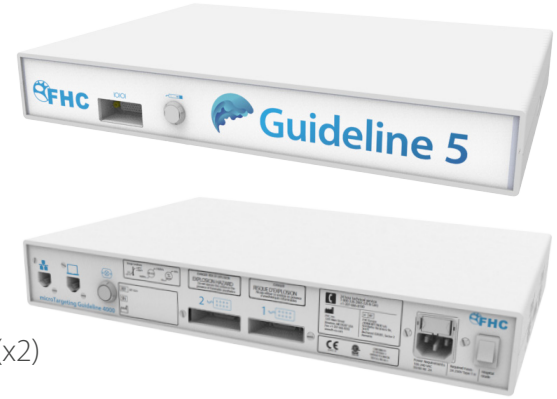
The Guideline 5 application runs on a Windows laptop that connects to the Guideline 5 core module via an ethernet cable.

- HD multi-point touch screen for enhanced and intuitive ease of operation
- Windows 10 Professional 64-bit operating system

Core Module

The Guideline 5 core module provides connections, processing, patient isolation and power for all Guideline 5 components:

- Connections provided for
  - Two Guideline 5 interfaces [1,2]
  - Guideline 5 remote
  - Dual ethernet ports for Guideline laptop and data streaming
  - Optional Power assist motor [3]
  - Optional Guideline 5 synchronization unit
  - Hospital grade (NEMA 5-15P) power input
- Power: Universal input (100-240 VAC, 50/60 Hz), 2A Type TH fuses (x2)
- Physical: 41 x 28 x 6 cm, 1.5 kg



Notes

1. Support for simultaneous use of two interfaces requires optional 2nd processing card
2. Each interface connection can support both UE or LF Interfaces

Integrated microTargeting™ Controller & Power Assist Motor

The Guideline 5 microTargeting™ Controller & Power Assist Motor allows remote movement and position readout of FHC microTargeting™ STar™ Drive M/E.

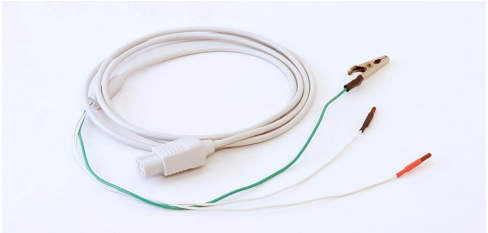
- Controller: Advance design reduces mechanical/electrical noise during movement
- Remote: Controlled using the Guideline 5 Dual Function Remote
- Cable Length: 3m
- Connections:
  - Internal microTargeting™ controller installed in Core Module by FHC personnel
  - Power Assist Motor cable plugs directly into Core Module
  - Power Assist Motor physically connects to FHC microTargeting™ STar™ Drive M/E*

* Sterile Power Assist Motor Drape Sleeve required to connect Power Assist Motor to sterile drive

UE Patient Leads

The Guideline 5 UE Patient Leads provide connections from the UE Interface to each microelectrode.

- 1.5m length reduces noise when UE interface adjacent to sterile field
- Single-use leads are provided sterile and ready to use
- Lightweight, flexible cable for easy routing
- Improved touch-proof connectors
- Includes sterile color-coded labels to simplify patient routing
- 3.0m length available for specific OR needs



UE Interface

The Guideline 5 UE Interface performs all signal processing and acquisition adjacent to the sterile field to allow for shorter patient lead length and improved noise performance.

- Eight independent channels
  - Dual Inputs
    - Microelectrode: high impedance, differential, 17-bit @32 kHz sample rate
    - Macroelectrode: differential 24-bit, 1.0 kHz
  - Constant current and constant voltage stimulation outputs
    - Microelectrode: ±100 µA / ±10V
    - Macroelectrode: ±10 mA / ±10V
  - Independent stimulation circuit for each channel supports complex multi-source stimulation protocols such as current steering
- Simultaneous MER and LFP signal acquisition on all channels
- Simultaneous low current electrode impedance check on all channels (±1 µA micro, 100µA macro)
- Utilizes low noise active shield technology
- Pole mounting option suitable for any OR setup
- Physical (without cable): 25cm x 15cm x 10cm, 1kg
- Connections:
  - Eight, 6 conductor touch-proof connectors for Guideline 5 patient leads
  - Connector for 2m cable to Core module

Synchronization Unit

The Guideline 5 Synchronization Unit provides analog and digital connections for interfacing with other recording or analysis systems.

- Two analog inputs: 24-bit, up to 32 kHz, ±1.5V
- Two digital inputs: 0-5V edge-triggered
- Eight analog outputs: 24-bit, 32 kHz, ±1.5V
- Expansion: 32 configurable digital input or output bits, 0-5V
- All connections are earth-referenced (isolated from patient)
- Physical (without cable): 25cm x 11cm x 5cm, 1kg
- Connections:
  - Front-panel connections: 1/8" bipolar tip/ring connectors
  - Expansion: DB-37 female - pin assignment available on request
  - Connector for 1m cable to core module

LF Interface

The Guideline 5 LF Interface is for recording LFP, EEG and ECoG signals from a variety of electrode types, including some DBS leads for intra-operative LFP analysis.

- Eight independent channels
  - Inputs: differential 24-bit; 500 Hz, 1000 Hz, 2 kHz, 4 kHz, 8 kHz or 16 kHz
  - Outputs: Constant current (±10 mA) and constant voltage (±10V)
  - Independent stimulation circuit for each channel supports complex multi-source stimulation protocols such as current steering
- Pole mounting option suitable for any OR setup
- Physical (without cable): 25cm x 15cm x 10cm, 1kg
- Connections:
  - Eight 1.5mm touch-proof electrode connectors
  - One 1.5mm touch-proof reference connection
  - One 1.5mm touch-proof ground connection
  - microHDMI connector for up to 8-conductor DBS leads
  - Connector for 2m cable to Core Module

Dual Function Remote Control

The dual function remote is used to remotely set stimulation amplitude and control output during stimulation. When the optional integrated microTargeting™ Drive Controller is installed and the power assist motor is attached the remote will control motor speed and direction.

- Physical: 6cm x 5cm x 20cm, 0.5kg
- Connections: integrated 3m cable for connection to core module

Guideline 5 Cart

The Guideline 5 cart simplifies setup and storage by providing an easily positioned cart to hold all Guideline 5 components.

Cart Features:

- Lockable storage cabinet
- Larger, attached and movable speakers
- Single power connection
- Cable management features

The Guideline 5 cart allows you to quickly go from storage to operation with minimal effort.

Guideline 5 Transport Case

The Guideline 5 Transport Case[1] provides a convenient way for IONM providers to hand-carry a complete Guideline 5 system.

- Holds Core Module, laptop & power supply, two interfaces, Synchronization Unit, clip-on speaker and all cords & cables
- Smooth-rolling wheels and telescoping handle
- Dimensions: 18 x 17 x 7.25 in[2]
- Weight: 29 lbs, 13.1 kg (case with full system)

1. *The transport case is not suitable for checked baggage or shipment without a surrounding box or case.*

2. *Case should fit in overhead bin of most mid-size or larger aircraft. When in doubt, confirm dimensions with airline for your specific flight.*

Procedural Overview

The following steps provide a general overview of how the Guideline 5 system is used in a common functional neurosurgical procedure.

Setup & Configuration

1. Connect remote, interface(s), optional sync unit and laptop to Guideline 5
2. Start the Guideline 5 application and confirm a successful self-test, load user profile
3. Enter the required patient and procedure information
4. Place optional power assist motor into sterile drape sleeve than attach to microdrive and Guideline 5

Procedure

5. Prepare patient, insert microelectrodes then connect microelectrodes to UE Interface using patient leads
6. Advance electrodes and interpret MER to identify nuclei encountered
7. Perform motor neuron testing (if desired)
8. Perform micro and macro stimulation (if desired)
9. Enter testing results for each tested electrode and depth
10. Review collected track data to select potential DBS electrode location
11. Place DBS lead
12. Perform recording/stimulation tests of the DBS lead utilizing the LF Interface DBS lead connection (if desired)
13. Save/print testing results and recorded data

Post-op

14. Exit the Guideline application and log-off/shut-down the PC
15. Disconnect and store interfaces, remote and power assist motor

Ordering Information

Individual Guideline 5 components can be combined to create systems specifically tailored to your needs. Components of three common systems along with possible upgrades, optional components and consumables are shown below. Component catalog numbers are shown in parenthesis.

Common System Configurations

8-Channel UE System			
Core Module (C0215)	UE Interface (C0219)	Guideline 5 App (C0217)	Onsite train/install (C0229)
Notebook PC (C0216)	Interface Pole Mount (C0233)	Remote Control (C0222)	1 Year Guideline 5 Service Agreement (C0238)
Ethernet Cable (C0234)	Interface Cable (C0221)	High Performance Speaker (C0237)	Line Cord (66-EL-XXX)
16-Channel UE System			
Core Module (C0215)	2nd Interface Card (C0218)	2x Interface Cable (C0221)	Onsite train/install (C0229)
Notebook PC (C0216)	2x UE Interface (C0219)	Guideline 5 App (C0217)	High Performance Speaker (C0237)
Ethernet Cable (C0234)	2x Interface Pole Mount (C0233)	Remote Control (C0222)	1 Year Guideline 5 Service Agreement (C0238)
			Line Cord (66-EL-XXX)
16 Channel UE & LF System			
Core Module (C0215)	UE Interface (C0219)	Guideline 5 App (C0217)	1 Year Guideline 5 Service Agreement (C0238)
Notebook PC (C0216)	LF Interface (C0220)	Remote Control (C0222)	Line Cord (66-EL-XXX)
Ethernet Cable (C0234)	2x Interface Pole Mount (C0233)	High Performance Speaker (C0237)	
2nd Interface Card (C0218)	2x Interface Cable (C0221)	Onsite train/install (C0229)	

8-Channel System Upgrades

Upgrade to 16-Channel UE System[1]		
2nd Interface Card (C0218)	Interface Cable (C0221)	UE Interface (C0219)
Upgrade to 16-Channel UE & LF System[1]		
2nd Interface Card (C0218)	Interface Cable (C0221)	LF Interface (C0220)

Optional Components

Integrated microTargeting™ Controller & Power Assist Motor[1,2]		
mT Controller Power Assist Card (C0223)	Power Assist Motor/Encoder (C0235)	
Synchronization Unit & Cable		
Synchronization Unit (C0224)	Synchronization Cable 1m (C0225)	
Spare UE Interface and Cable[3,4]		
UE Interface (C0219)	Interface Cable 2.0m (C0221)	Interface Pole Mount (C0233)
Spare LF Interface and Cable[3,4]		
LF Interface (C0220)	Interface Cable (C0221)	Interface Pole Mount (C0233)
2nd Interface Card[1,5] (C0218)		
1 Year Guideline 5 Service Agreement (C0238)		
Guideline 5 Cart (MT-LPP-CART)		
Guideline 5 Transport Case (C0226)		

Consumables

UE Patient Lead, 1.5m - 1x, Sterile, Single-use (C0231)
UE Patient Lead, 3.0m - 1x, Sterile, Single-use (C0230)
Power Assist Motor Drape Sleeves - 20x, Sterile, Single-use (66-DA-SD)

Notes

[1] Includes field installation by FHC personnel. Price includes travel to covered areas. Contact FHC for list of covered areas or quote for other locations.
[2] Discount if option purchased with system.
[3] Spare interface does not include 2nd interface card required for simultaneous use of two interfaces.
[4] The system automatically determines which type of interface is connected during power-on self-test.
[5] Required to allow simultaneous use of two interfaces

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