



Neural microTargeting™ Worldwide

Integrated Motor & Controller

Directions For Use - Supplementary Information

L011-85-03 (Rev B0, 2018-11-13)

Contains directions for the following products:
MT-LPP, C0235, C0223, C0222, 66-DA-SD



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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.		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 serial number so that a specific medical device can be identified.		Indicates the temperature limits to which the device can be exposed.
	Indicates the model number so that the model of the medical device can be identified.		Range of humidity to which medical device can be exposed.
	Date when the medical device was manufactured.		Range of atmospheric pressure to which medical device can be exposed.
	Instructions for end of life disposal.		
Unit Symbol Key			
	Set Origin		Remote Control Connection
	Auto-Retract to Origin		Increase Stimulation Amplitude
	Type BF Applied Part		Decrease Stimulation Amplitude
	Apply Simulation		Advance Drive Motor
	Drive Speed Selector		Retract Drive Motor

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

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 Guideline 5 system may be configured to include an integrated power assist system. In this case, the microTargeting motor connects directly to the Guideline 5 MPU (C0215). The Guideline 5's remote control (C0222) provides dual functionality, allowing precise control of drive depth throughout the procedure. As an alternative, when the integrated power assist system is not present, the Guideline 5 can integrate with one or more stand-alone power assist systems or allow manual entry of depth.

With any of the above methods, the Guideline application will associate the appropriate depth with all events recorded and provide a high-visibility digital representation of the current electrode depth relative to target throughout the procedure.

When a power assist system is used, a high-precision stepper motor is attached to the microTargeting or STar Drive micropositioner, advancing or retracting the drive based on user input from the remote control, and providing the operator the ability to fully control the microelectrode position from outside the sterile field. As the microTargeting motor cannot be sterilized, it is covered in a sterile drape sleeve prior to mounting on the drive.

The microTargeting motor incorporates an optical encoder to ensure rotational accuracy of the motor. To provide accurate electrode depth information, the controller must be initialized. This consists of placing the micropositioning drive at a known distance from target and pressing the Origin button on the remote control. Once initialized in this way, the microTargeting Controller will provide the current electrode depth throughout the entire procedure.

Both the microTargeting motor and the controller have been designed to provide convenient, reliable, precise control and monitoring of microelectrode depth throughout the entire neurosurgical procedure. The integrated power assist system has been optimized to minimize motion artifact during drive advancement.

Guideline 5 System Components and Connections

Installation and Initial Configuration

Integrated Power Assist System: The Integrated microTargeting Controller Card (C0223) must be installed and configured by an FHC-authorized technician only.

External Power Assist System(s): External microTargeting Controllers will connect directly to the Guideline Notebook PC via USB. Older microTargeting Controllers will require a serial to USB converter to facilitate this connection (MT-LPP-CONV). Contact FHC technical support for assistance in configuring the Guideline Application to recognize the external controller's COM Port.

For dual controller configurations supporting simultaneous bilateral procedures, the Guideline Application can work with both the internal Power Assist Controller and an external Power Assist Controller, or two external Power Assist Controllers. The C0235 microTargeting Motor is identical to the 66-DA-ME motor provided with the External Power Assist System and may be used interchangeably with it.

Specifications

C0223 – Integrated microTargeting Controller Card & C0235 – microTargeting Motor

Linear Resolution: 1 μm

Long Term, Full Scale Linear Accuracy: $\pm 25\mu\text{m}$

Minimum Speed: 10 $\mu\text{m/s}$

Maximum Speed: 500 $\mu\text{m/s}$

Acceleration/Deceleration: 1.5mm/s² (quickly reaches target speed, avoiding resonance)

Travel Rates: 0 $\mu\text{m/sec}$ (safety setting), 10 $\mu\text{m/sec}$, 50 $\mu\text{m/sec}$, 225 $\mu\text{m/sec}$ & 500 $\mu\text{m/sec}$

Safety Features:

- System watchdog automatically resumes safe operation in case of malfunction
- Redundant position tracking systems
- Stall detection and un-driven motion monitoring
- Software limit, user configurable maximum depth allowed



C0235 microTargeting Motor

Sterilization: Do not sterilize

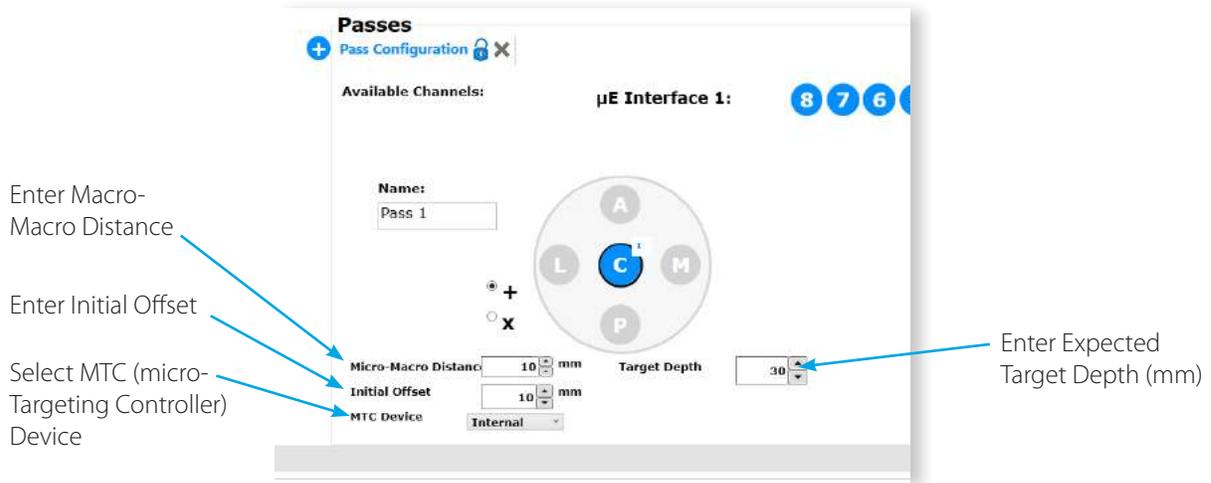
Isolation: Type BF Medical Isolation

Compatibility: FHC's microTargeting Drive & STar Drive Stereotactic Micropositioning Drives

Illustrative Procedure

Preoperative Setup

Set-up the Guideline 4000 5.0



MTC Device: Select the appropriate depth controller from the drop-down list of those available.

- **Manual:** (Manual1 or Manual2) Select Manual option when you will not be using a Power Assist System to advance the electrodes.
- **Internal:** This option will be present if the Guideline 5 is equipped with an integrated microTargeting Controller.
- **External:** (or Serial, name is configurable) If detected at start-up, all external controllers present will be listed.

Micro-Macro Distance: Enter the distance (in mm) between the microelectrode tip and the bottom of the macro-contact. This is typically 10mm but may be adjusted when using custom electrodes.

Initial Offset: Enter the desired Initial Offset. This is the depth, in mm, from 0 (as read from the scale of the micropositioning drive) that the recording pass will be started at.

Target Depth: Enter the expected depth of the target. This will typically be 30mm.

WARNING: Incorrect specification of the initial target value can cause serious injury.

WARNING: Expected target depth can change based on the stereotaxy and electrodes used. Ensure the target depth is set correctly when running the depth control in distance to target mode.

All the above information is not expected to change from one case to the next under normal circumstances. As such, these settings will be included in any User Profiles created and need not be reentered for every pass or procedure.

Mount the Motor

1. Visually inspect the motor, its cable, and connector for signs of damage prior to the procedure.
2. The motor unit must be draped to maintain sterility of the drive, it should never be sterilized.

Sterile Draping Procedure

1. Draping the motor can be accomplished by one person, but is better facilitated if an assistant is present. The one-person method will require a sterile gloved hand (S) for the drape. The other hand will be a non-sterile hand (NS) after handling the motor. Most will find that the motor hand should be the least favored hand. The two-person method requires a sterile gowned and gloved person (S) to handle the drape and an assistant that will have non-sterile gloves (NS) after handling the assembly. Normal draping precautions will suffice. A practice draping should be done before first surgical use.
2. NS (or prior to putting on sterile gown and gloves) - Remove the protective storage caps from the motor and micropositioner. Coil the motor's cable and place it on a flat surface so that it can be picked up with its cable in one hand.
3. S - Remove the drape from its sterile packaging and expand the opening to allow entry of a hand. Do not pull any of the folds out at this time. (If being performed by one person, remove the included elastic bands from their tape holder and place on a sterile surface.)
4. NS - Holding the non-sterile motor with the mounting pins pointing away from you and the coiled cable in the same hand, insert it into the drape, being careful not to touch the outside of the drape.
5. S - Push the drape over NS hand so that the motor and cable are all the way at the end of the sleeve.
6. S and NS - Maneuver the drape and motor so that the two alignment pins and the center drive plate are aligned with the cutouts in the end of the drape.
7. S and NS - Push the pins and center drive plate through the cutouts and smooth the stretchable end of the drape over the motor.

Step 2



Steps 3 and 4



Steps 5 through 7



8. S - Take the elastic bands and stretch them over the draped motor, using at least two wraps. Be careful to smooth out any wrinkles from the mating flat surface of the motor as this is done, but do not touch the pins or drive plate. Ensure the wraps are above the flanges on the motor to prevent slipping.
9. S - Hold the drape with the motor inside while NS pulls the cable from the drape. Be careful not to touch the pins protruding from the end of the drape.
10. NS - Unfold the drape carefully as the cable is withdrawn. When the cable is out of the sterile envelope distance, NS can hold both cable and drape.
11. S - Using the tape that the elastic bands came in, pull in the folds of the drape tightly above the motor and tape neatly. If no assistant is helping, this can be done after changing the non-sterile glove.
12. NS - The motor cable can be plugged into its receptacle on the Guideline 5 or microTargeting Controller.

Step 8



Steps 9 and 10



Step 11



Attach the Draped Motor to the Micropositioner

1. Mount the draped motor on the micropositioner by inserting the two long alignment pins into the mating holes on the drive. There is no incorrect way to align the mounting pins. The motor may not fully seat, do not force it any farther at this time.
2. Push down lightly on the motor unit while turning the drive advancement knob slowly.
3. The motor's center drive plate pins must be exactly aligned with the mating holes in the drive before they will engage. The knob should be turned slowly in small increments. Engagement should happen within 90 degrees of knob rotation.
4. When the pins are felt to engage, push the motor unit all the way down to the mating surface of the drive. Make sure no folds of the sterile drape are caught between the surfaces. This should require little effort. Any restriction will require realigning the pins or removal and inspection of the drive and motor to identify obstructions or damaged components.
5. Tighten the motor locking knobs on the drive securely and test the motor for secure attachment.



Do not attempt to manually adjust the micro-drive depth using the knobs once the motor has been mounted, as this can damage the motor.

WARNING: Do not manually rotate the drive knobs when the motor is attached, as this could potentially damage the motor unit. Note: to ensure optimal performance and minimize motor noise, the controller system should be serviced annually to tune the controller's drive circuit and speed settings to compensate for normal motor wear



Zero the Drive

1. Proceed to the IntraOp Screen when ready. The drive depth box will display the message "Please zero the MTC drive."
2. The Power Assist System will need to be "zeroed" before it will be able to provide the current depth. If power to the Guideline 5 is interrupted during the procedure, the internal Power Assist Controller will need to be re-zeroed before resuming.
3. Select a speed using the Speed Selection Slider on the remote control. Using the rocker switch, advance or retract the drive as needed until the drive is positioned at exactly 0 μm or the initial offset location, if specified. Use the scale on the drive to position the drive at the exact starting depth specified.

Left

Please zero the MTC drive.

Left

-20.00 mm

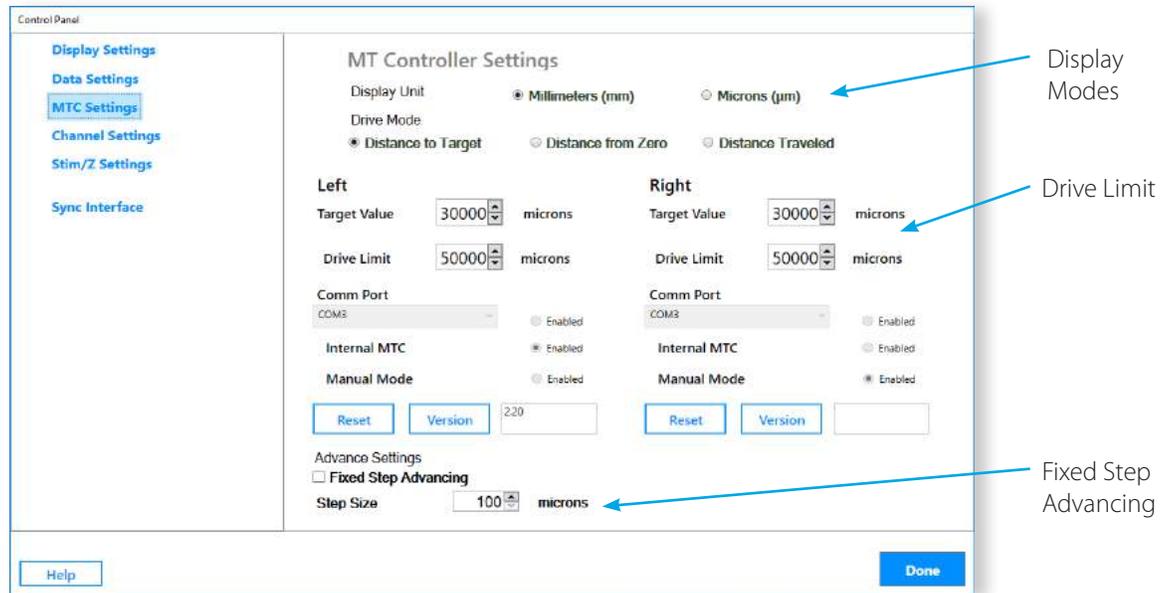
- Press the Zero button on the remote control to indicate that it is currently at the initial offset position. From now on, pressing and holding down the Zero button for 3 seconds will initiate the Auto-Retract function, automatically retracting the drive to this depth.
- Verify that the current depth is displayed in the Drive Depth box as shown in the above example on the right.

 **WARNING:** Incorrect zeroing of the microTargeting Controller can cause serious patient injury.

IntraOp Use

A Review of Configuration Options

There are a number of configuration options that can be set according to preference. The following settings are all elements of the User Profile and do not need to be set or adjusted prior to every use. The MTC page of the Control Panel is shown below:



Display Units: The Power Assist will report the current depth in millimeters or microns (1mm = 1000µm) depending on the selection here. Using microns, depth will be displayed to a resolution of 1 micron. In millimeter mode, the displayed depth will have a resolution of 0.01mm (10 microns). Regardless of the display mode selected, the power assist system will maintain an internal precision of 1 micron.

Depth Display Mode: The Guideline 5 can report the current depth in two different ways.

- Distance to Target:** The depth will be 0 at target depth, negative above target and positive below target. In Distance to Target mode, the depth displayed in the depth display box will always be preceded by a +/- sign.
- Distance from Zero:** The depth displayed will correspond to the depth as read off the scale of the micropositioning drive, with fully retracted being 0mm.

Drive Limit: The drive limit is a software-enforced depth beyond which the motor will not advance. By default, this will be set at 50000µm to correspond with the physical limit of the microTargeting and STar Drive micropositioner. This value may be adjusted as desired to prevent unintended over-travel.

Fixed Step Advancing: When enabled, this feature allows the user to periodically stop advancement after the specified distance has been traveled. To resume advancing the electrodes, the user must release the advance rocker switch and then re-engage it. This makes it very convenient evaluate recordings at regularly spaced intervals along the pass.

Depth Control

The Guideline 5 remote control has dual functionality. When the stimulation dialog is open, it will control the stimulator and no movement of the electrodes will be possible; at all other times, the remote control will control the Power Assist System. The motor will only advance the electrodes when the rocker switch is held in the Advance position. Releasing the rocker switch will immediately halt all motion of the motor.



The speed selector switch is used to control the speed at which the motor advances and retracts. In its lowest setting of 0µm/sec, it will disable all motion of the drive- this is a safety position. Other available settings ,from low to high, are 10, 50, 225 and 500µm/sec. The power assist system has been optimized to minimize the amount of motion artifact introduced into the MER recordings while the motor is in motion. Specifically, advancing at 10 or 50µm/sec while searching for neural activity is easily possible.

⚠ WARNING: Do not rest objects on the remote control.

Depth Confirmation Dialogs

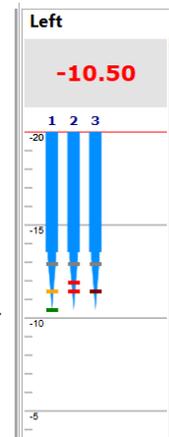
After every five millimeters of advancement, the Guideline 5 will launch the depth confirmation dialog requesting that the operator compare the current depth reading with the scale reading of the Microdrive. This is a safety precaution. If desired, the automated depth confirmation dialogs may be discontinued by checking the box at the bottom of this dialog.

⚠ WARNING: Periodically (every 5mm is recommended) verify that the depth reported by the controller matches that shown on the drive scale.

Two-Dimensional Track Viewer

The IntraOp screen contains a 2-D Track Viewer to provide an easy-to-interpret visual depiction of the current depth of the electrodes along the track. Visible within this view is the thickening of the electrodes, which represent the current location of the macro-electrode contacts. In the image to the right, a micro-macro distance of 3mm has been depicted. The microelectrode depth is 10.50mm above target and the macro-contact depth is 13.5mm above target.

Anytime an event is created or a neuron is classified, a colored marker will appear along the appropriate electrode. These are color coded based on the type of neural activity the user identifies at each location. Gray markers indicate events where there is no associated classification. Clicking on any of these markers will launch the dialog associated with the event for further review.



Drive Depth Box

The drive depth box, unless hidden, will always be visible on screen. It can be resized according to preference by dragging the corners and positioned wherever wanted by dragging it from the top. The hemisphere associated with the depth reading is shown at the top of the box. This box may be disabled by right-clicking on the depth and selecting Hide. To re-enable a hidden box, right-click on the depth display within the 2-D Track Viewer.

Auto-Retract

Pressing and holding the Auto-retract button for about 3 seconds will initiate the auto-retract function. Once initiated, the drive will be retracted back to the starting position for the pass with no further user control required. Retraction may be canceled at any time during the auto-retract sequence by pressing any button on the remote. If the auto-retract button is pressed and held when the drive is already at the starting position, the drive will further retract up to zero if an initial offset was specified.

Stall Detection

The power assist system will maintain the correct depth reading once properly zeroed. If the system detects that the motor is not turning when it is supposed to or that it is turning when it is not supposed to a STALL warning will appear in the Depth display box. If a stall warning is seen, check the micropositioner drive to ensure there is nothing preventing it from advancing or retracting normally. The power assist system will maintain the correct depth when a stall condition occurs.

If the motor stalls repeatedly, discontinue use of the power assist system and remove the motor from the micropositioner for the remainder of the procedure. Contact FHC Technical Services to resolve the issue.

PostOp procedure

Following the procedure remove the motor unit from the micropositioner, discard the sterile drape and return the sterilization covers to their positions on top of the drive and on the motor unit.

If the motor becomes contaminated, it may be cleaned per the instructions in L011-85. The motor contains no user-serviceable parts.