



# microTargeting™ Controller Power Assist System

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## Directions For Use

L011-80 (Rev B1, 2016-09-30)

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Contains directions for the following products:

66-DS-PA, 66-EL-MS, 66-EL-RM, 66-DA-ME, 66-DA-SD

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## Indications for use:

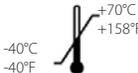
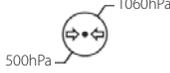
The microTargeting™ Drive System is intended to be used with commercially available stereotactic systems for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, DBS electrodes, or other instruments in the brain or nervous system.

Contraindications: Follow the general guidelines concerning the suitability of neurosurgery involving the insertion of electrodes, instruments or devices.

## Intended use:

The microTargeting™ Controller Power Assist System is intended to be used by a neurosurgeon, neurologist or clinical neurophysiologist to manipulate the position of depth electrodes, such that they may identify functional targets in the brain. The device is expected to be used on patients undergoing stereotactic and functional neurosurgical procedures.

## Symbol Key

	WARNING / Caution, consult documents		Authorized Representative in the European Community		USB interface
	Read usage instructions		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.		Zero or origin
	In reference to "Rx only" symbol; this applies to USA audiences only		<b>Caution-</b> Federal law (USA) restricts this device to sale by or on the order of a physician.		Type BF applied part
	Catalog number		Temperature limitation: Storage conditions are between -40°C and 70°C (-40°F and 158°F)		Auto retract
	Serial number		Humidity limitation: Not to exceed 100%		Retract drive
	Manufacturer		Atmospheric pressure limitation: between 500hPa and 1060hPa		Advance drive
	Telephone number		Instructions for end of life disposal		Remote control
	Non Sterile		Motor unit		
	Sterile				

## Classifications:

The controller is an IEC 60601 Class 2 medical device with two applied parts:

- The drive motor, shrouded in a sterile drape sleeve is applied to the micropositioner which is itself attached to a stereotactic frame which is attached to the patient. The drive motor is a type BF applied part.
- The hand-held remote control is intended to be held by the operator of the controller who may come into contact with the patient. The remote control is a type BF applied part.

Note: The system does not directly interface with tissue or other parts of the body. It interfaces with the micropositioner responsible for positioning a microelectrode in the brain.

## Operating Environment:

The controller and accessories are designed to be used in the normal operating room environment and require no special handling or care exceptional to other electronic devices used in that environment. The controller and hand held remote control should be positioned within 3 meters of but outside the sterile field, the motor unit is sleeved inside a sterile drape sleeve and mounted on the drive within the sterile field.

Temperature Range: +5°C to +40°C

Relative Humidity Range: 10% to 95% (non-condensing)

Atmospheric Pressure Range: 500 hPa to 1060 hPa

Altitude: ≤ 2000 m above sea level

## Storage and Transport Conditions

The microTargeting™ Controller Power Assist System should be stored and transported within the carrying case provided when not in use.

## Warnings and Cautions:

 **WARNING:** To avoid risk of electric shock, this equipment must only be connected to a supply mains power outlet with Protective Earth (3 pronged socket), never use a damaged power cord or power strip.

**CAUTION:** High voltage - there are no user serviceable parts internal to the controller housing, do not attempt to disassemble the controller or any of its accessories.

 **WARNING:** No unauthorized modification of this equipment is allowed.

 **WARNING:** Do not block the vents on the bottom or back of the controller as this could cause it to overheat. Do not remove the 4 rubber feet as this will cause the vents on the bottom of the controller to become blocked.

 **WARNING:** Carefully route all system cabling away from high traffic areas.

 **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.

 **WARNING:** Do not use the controller in the presence of flammable gas mixtures.

 **WARNING:** Do not attempt to sterilize the motor unit or the hand held remote control.

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

 **WARNING:** Always zero the controller prior to inserting electrodes.

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

 **WARNING:** If power to the controller is temporarily interrupted, it will need to be re-zeroed prior to resuming its use.

**CAUTION:** Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the Declaration of Electromagnetic Emissions section of this document.

**CAUTION:** Portable and mobile RF communications equipment can affect medical electrical equipment.

 **WARNING:** The controller should not be used adjacent to or stacked with other equipment. Where such an arrangement is necessary, the controller should be observed to verify normal operation prior to use.

**Rx only CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician.

## Inventory:



Storage case: 66-DA-SC



(Left to right) Motor unit: 66-DA-ME  
Display module: 66-EL-MS, Remote control: 66-EL-RM



USB cord: N5-55-02,  
Power cord: (country specific)



**Accessory** - Sterile Drape Sleeve: 66-DA-SD

## Cleaning:

In the event that any components of the microTargeting™ Controller Power Assist System become contaminated or soiled they should be disconnected from power sources and wiped clean with an isopropyl alcohol dampened cloth, then wiped dry before they are returned to the carrying case. Do not immerse any components of the system in fluids or allow excessive moisture to remain.

## Replacing the Fuses:

Should the fuses require replacement:

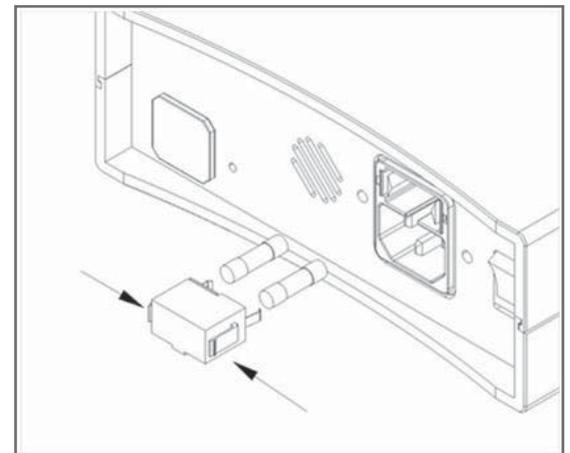
1. Unplug power cable before attempting fuse replacement.
2. Pinch together spring tabs to release fuse drawer from power entry (see arrows).
3. Remove spent fuses from fuse drawer.
4. Insert two replacement fuses into fuse drawer.
5. Slide fuse drawer with fuses into power entry. Spring tabs will snap into place once drawer is fully seated.

## Installation and Functional Checkout:

Prior to its initial use, set up the microTargeting™ Controller Power Assist System for an initial installation checkout. Practicing the mounting and engagement procedure and the assembly draping procedure several times before the first surgical use will familiarize personnel with the required steps.

The proper functioning of the remote control and the measuring function of the display can be verified by advancing the drive several times in 10mm increments, then returning to 0.00, comparing the physical scale at each step to the displayed position. There should be no discrepancy in the readings, no movement of the drive in the remote control's rocker switch center position and no movement of the drive as long as the speed selection slider is set to "zero", regardless of the state of the rocker switch.

Any error may indicate that the controller or the drive is not functioning correctly.



**FHC Part Number: E1-06-09**

**Fuse Type: 5 x 20mm 250VAC 1Amp Slow Blow**

## Sterile Draping Procedure:

1. Draping the motor can be accomplished by one person, but is facilitated if an assistant is present. The one-person method will require a sterile gloved hand ( [STERILE] ) for the drape. The other hand will be a non-sterile hand ( [NON-STERILE] ) 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 ( [STERILE] ) to handle the drape and an assistant that will have non-sterile gloves ( [NON-STERILE] ) after handling the motor. Normal draping precautions will suffice. A practice draping should be done before first surgical use.

2. [NON-STERILE] (or prior to putting on sterile gown and gloves) - Remove the protective storage cap from the motor. Coil the cable and place it on a flat surface so that the motor can be picked up with its cable in one hand.



3. [STERILE] - 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 one person, remove the included elastic bands from their tape holder and place on a sterile surface.)



4. [NON-STERILE] - Holding the non-sterile motor with the 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.

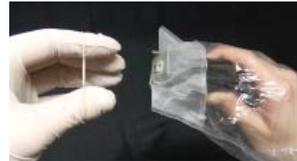


5. [STERILE] - Push the drape over [NON-STERILE] hand so the motor and cable are all the way at the end of the sleeve.
6. [STERILE] and [NON-STERILE] - Maneuver the drape and motor so that the two alignment pins and the center drive plate are entering the cutouts in the end of the drape.

7. [STERILE] and [NON-STERILE] - Push the pins and center drive plate through the cutouts and smooth the stretchable end of the drape over the assembly.



8. [STERILE] - Take the elastic bands and stretch them over the assembly, using at least two wraps. Be careful to smooth any wrinkles from the mating flat surface of the assembly as this is done but do not touch the pins or drive plate. Ensure the wraps are above the flanges on the assembly to prevent slipping.



9. [STERILE] - Hold the drape with the assembly inside while [NON-STERILE] pulls the cable from the drape. Be careful not to touch the pins protruding from the end of the drape.



10. [NON-STERILE] - Unfold the drape carefully as the cable is withdrawn. When the cable is out of sterile envelope distance, [NON-STERILE] can hold both cable and drape.



11. [STERILE] - Using the tape that the elastic bands came in pull in the folds of the drape tightly above the assembly and tape neatly. If no assistant is helping, this can be done after changing the non-sterile glove.



12. [NON-STERILE] - The assembly cable can be plugged into its receptacle, or [STERILE] - the whole draped apparatus set aside on a sterile surface awaiting the surgery. In this case it is best to leave the cable inside the drape and to not unfold the drape more than necessary until it is needed.

## Illustrative Procedure:

### Basic pre-use checkout

1. Visually inspect the components that are going to be used prior to the procedure. Ensure that:
  - No major physical damage (beyond what can be expected under normal use conditions, such as minor scratches of the surface) can be seen on the enclosures of the controller or the remote control
  - None of the cables that are to be used are frayed, kinked or otherwise damaged
  - The connectors are not damaged and are securely attached to the cables they terminate
  - Position the controller module such that the mains power switch on the back panel is easily accessible

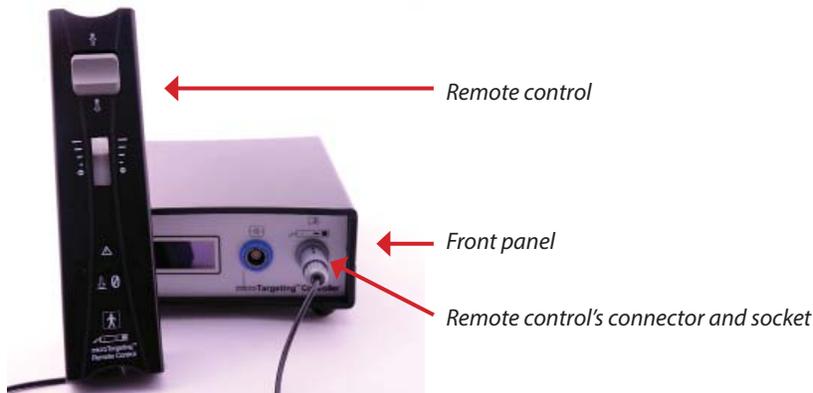


### Prepare the controller for use with the drive

2. Connect the controller module to mains, using the provided power cable.



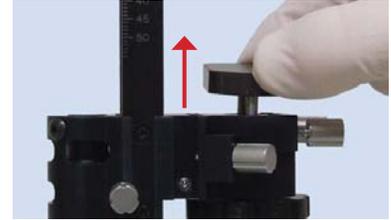
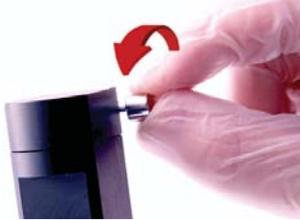
3. Connect the remote control to the controller module by plugging the remote control's connector into its socket on the front panel.



4. If you plan to interface the controller with an MER system or any other compatible device or application, remove the protective cover and connect it to the computer using the USB cable provided.

## Assemble and connect the motor unit

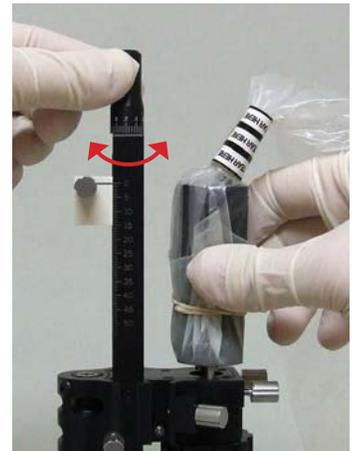
5. Remove the sterilization cover on the motor unit and the drive, if they are attached.



6. The motor unit must be draped to maintain sterility of the drive, **it should not be sterilized**. For detailed step by step instructions on the proper draping of the motor unit while maintaining sterility, please refer to the "Sterile Draping Procedure" on page 6, or see the Directions For Use which accompanied the drive system.
7. Mount the draped motor unit on the drive by inserting the two long alignment pins into the mating holes on the drive. There is no incorrect way to align the pins. Do not force the assembly any farther at this time.



8. Push down lightly on the motor unit while turning the drive advancement knob slowly.
9. The motor unit'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.
10. 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, and any restriction will require realigning the pins or removal and inspection of the drive and motor for obstructions or damaged components.
11. Tighten the motor locking knobs on the drive securely and test the assembly for secure attachment.



Motor unit attached to Star™ Drive and microTargeting™ Drive

12. Plug the motor unit into the controller by inserting its connector into the corresponding socket on the front panel.

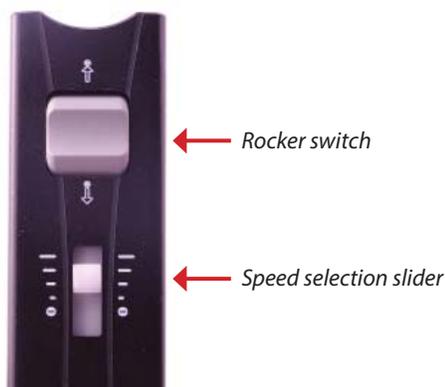


### Zero the drive

13. Activate the ON/OFF switch of the controller module. The controller should boot and display the "Set drive origin" message.



14. If an initial offset is to be used, it should be programmed into the controller now. Note that the initial offset will reset to 0mm every time the power to the controller is cycled.
15. 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  $\mu\text{m}$  or the initial offset location if specified.



16. Press the zero button on the remote control to indicate that the current position is at 0  $\mu\text{m}$ . From now on, pressing and holding down the Zero button for 3 seconds will return the drive to this position.



17. If connecting to an MER system, verify that the current depth is appropriately displayed on that system.



### Typical operative use

18. Mount the assembled drive on the stereotactic system.
19. Load the insertion tube and electrode.
20. Control the position of the electrode(s) as follows using the remote control:
- Set the desired motion speed using the speed selection slider. When set to 0, no motion will occur. Sensible defaults are provided for the other speed steps, but they can be adjusted through the USB Interface.
  - Pressing and holding the rocker switch on the remote control in its "Advance" position will cause the drive to advance towards the target at the set speed for as long as the rocker switch is held. Releasing the rocker switch will immediately stop any motion.
  - Pressing and holding the rocker switch on the remote control in its "Retract" position will cause the drive to be retracted away from the target at the set speed for as long as the rocker switch is held in the "Retract" position. Releasing the rocker switch will immediately stop any motion.



21. Navigate to the expected position of the target using the controls described above. For MER recording, motion artifact will be significantly reduced by selecting a lower rate of advance.
22. Decrease the speed for fine position adjustment and advance or retract the electrode until the target is reached and the necessary procedure performed.
23. Returning to the starting point: pressing and holding the zero button on the remote for three seconds will cause the controller module to return the drive to its starting position at the maximum possible speed. This motion can be interrupted by pressing the rocker switch in any direction or by changing the current speed selection using the speed selection slider. Returning to zero can also be performed at a controlled speed by simply retracting the drive using the rocker switch.
24. The motor unit can be removed from the drive at any point during the procedure and the operation can proceed using the manual control and visual scale on the drive.

### After completion of the procedure

25. Remove the motor unit, discard the sterile drape and return the sterilization covers to their positions on top of the drive and on the motor unit.
26. Unplug the remote control and power cord. Store the controller unit and all its accessories in the carrying case.

### Stall Detection

The torque of the stepper motor is quite high, especially when amplified by the drive screw, but the motor can be made to stall if it encounters a physical obstruction or if the operator attempts to use the manual drive advancement knob while the motor is operating. This is especially true at higher speeds. While this is a situation that should not occur during normal use, a stall detection algorithm has been provided.

If a stall is detected during drive movement, the word "STALL" will appear, replacing the position number on the display, and the drive will stop moving for approximately 5 seconds to alert the operator that a stall has occurred. Then the position will be redisplayed and the drive will continue moving at the speed controlled by the remote. The number displayed should be checked against the drive's physical scale. There may be no noticeable difference due to the sensitivity of the detection routine. A small discrepancy of less than 25 microns should not be a cause for concern.

Discrepancies of over 25 microns or frequent stall indications may require that the motor unit be removed and the manual advancement knob be used to complete the procedure. Frequent stall indications are a sign that there may be a physical problem with the drive resulting in excessive torque requirements, or a problem with the motor unit or controller. Contact FHC for additional diagnostic help and to set up a repair.

## Reference Information:

### Carrying Case

The carrying case used for shipping is intended to be used as a protective case during shipping, storage and transport of the system. It has been designed to protect the system from damage. It is lined with a foam interior which has been customized to hold the microTargeting™ Controller Power Assist System components. There is available space to add additional equipment if desired, the foam is pre-cut and additional compartments may be made by removing appropriate foam sections. The carrying case is not intended for use as a sterilization case, none of the components of the microTargeting™ Controller Power Assist System require sterilization. The foam lining of the case cannot be cleaned. If it becomes soiled or contaminated, contact FHC for a replacement lining.

### Inspection

All FHC products undergo a rigorous quality assurance inspection at the factory but should be carefully inspected before use. If any exterior damage to the shipping carton is noted, the instrument should be inspected for obvious physical damage. The contents of each package should be physically checked against the list in the inventory section to ensure all parts have been received.

### Warranty

All FHC products are unconditionally guaranteed against defects in workmanship for one year from date of shipment as long as they have been exposed to normal and proper use. Even though the one year warranty may have expired, please contact our service department before attempting any repairs or alterations. Many of these repairs will still be performed at the factory at no charge to the customer.

### Service/Repairs

Should service be required, please contact our service department for return instructions at 1(800)326-2905 or +1-207-666-8190. Carefully pack the instrument and all accessories in the provided carrying case before returning.

**All returns must be clean and free of biological contamination.**

Please include a note indicating:

1. The Returned Material Authorization (RMA) Number provided by the service department
2. The name and contact information of a person to contact if questions arise.
3. The "symptoms" indicating that repair is necessary.
4. A statement that the instrument is being shipped free of any biological contamination.

### Preventive Maintenance

The components of the drive accessories are not user repairable or serviceable. For continued optimal performance, contact FHC to arrange a periodic preventive maintenance service. In most cases, this can be done on site. FHC recommends an annual preventive maintenance contract for this purpose. Included with a preventive maintenance contract are free firmware upgrades for functional enhancements as they become available and free service and repair should any problems arise.

### End of Life Disposal



In order to be environmentally responsible, the microTargeting™ Controller Power Assist System should not be disposed of in a landfill or with municipal waste. FHC will gladly recycle the system once it has reached its end of life in an environmentally responsible manner. Please contact your local FHC representative for instructions on where to return the microTargeting™ Controller Power Assist System.

## Technical Summary:

### Physical Dimensions

	Controller Module	Hand-held Remote	Motor
Width	16 cm	5 cm	3 cm
Height	7 cm	4 cm	8 cm
Length	21 cm	19 cm	2 cm
Weight	0.8 kg	0.2 kg	0.1 kg

### Mechanical and Material Profile

Case Material:	ABS, Non-conductive, UL94 V-O
Display:	16x2 Character Display, Yellow
	Wide (120°) viewing angle

### Electrical Specifications

Power Supply:	100-240 VAC, 50/60 Hz internal power supply
Power Consumption:	10W max.

### Medical Profile

Medical Certification:	AAMI/IEC 60601 3rd Ed.
Sterilization:	Do not sterilize

### Performance Specifications

Linear Resolution:	1 $\mu\text{m}$
Long Term Linear Accuracy:	25 $\mu\text{m}$
Minimum Speed:	1 $\mu\text{m/s}$
Maximum Speed:	500 $\mu\text{m/s}$
Acceleration/Deceleration:	1800 steps/s - Quickly reaches target speed, avoiding resonance
Travel Rates:	4 User-adjustable speeds between 1 and 500 $\mu\text{m/s}$
Safety Features:	System watchdog automatically resumes safe operation in case of malfunction Redundant position tracking systems Stall detection and un-driven motion monitoring

### Noise Figures

Improvement over legacy design:	40% less mechanical noise
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### Connectivity

PC Interface:	USB 2.0 with RS-232 Emulation (19.2kBPS)
Operating Systems:	Windows XP, Vista, 7, 8, 8.1, 32/64-bit

## Concepts & Terminology:

**Auto-Retract:** Pressing and holding the zero button for approximately three seconds will initiate the auto-retract function. Once initiated, the controller will retract the motor at top speed to the origin point. If an initial offset has been specified, this is where the drive will stop. Initiating the auto-retract function while at the initial offset origin will cause the drive to retract to the zero point. Pressing any control during the auto-retract cycle will immediately cancel the auto-retract cycle.

**Display Mode:** The controller can be configured to display the current depth value in distance from zero mode where it will always match the reading obtained from the scale of the drive or in distance from target mode where the target depth will be the zero point with positive depth values below target and negative values above.

**Display Units:** The controller can be configured to display the current depth in microns (XXXXX $\mu$ m) or in millimeters (XX.XXmm) according to user preferences.

**Drive:** The micropositioner, this should be either a microTargeting™ Drive or a STar™ Drive.

**Initial Offset:** When desired, the origin point used while zeroing the drive need not be the 0 mm mark of the drive. If desired, an initial offset value can be entered through the USB interface to begin the procedure at a depth other than zero. For instance, if an initial offset of 15mm is entered, to zero the drive – one would position it at the 15mm mark and press the zero button. The initial offset value will reset to 0mm every time the controller is powered down.

**Language Support:** The controller is capable of displaying all front panel information in numerous languages. The language setting is changed through the USB interface. Supported languages include: English, French, German, Italian, Spanish, Danish, and Swedish (others may be added in later updates).

**Limit:** A depth limit value that can be entered through the USB interface. The controller will not allow the drive to be advanced beyond this point. The limit value will be retained when the controller is powered down and is set to 50mm by default. Note that both the microTargeting™ Drive and the STar™ Drive provide a physical stop at approximately 55mm.

**Querying Settings:** The current settings for initial offset, target and limit depths will be displayed by the controller when the zero button is pressed any time after zeroing the drive.

**Speeds:** There are four speed options available, they can be set from 1 micron per second up to 500 microns per second. The default drive speeds are set to: 10, 50, 225 and 500  $\mu$ m/s. These can be adjusted through the USB interface according to preferences. To select a speed, simply adjust the speed slider switch on the remote control. The first speed position of the slider switch is always STOP (or 0 microns per second) and will prevent the controller from moving.

**Stop Points:** The controller can automatically stop advancing periodically to facilitate MER, once every mm for instance. Through the USB interface, one sets a step size then presses and holds the Advance rocker switch on the hand held remote control. The controller will automatically stop advancing once the step size distance has been traveled. To advance to the next stop point, one releases the advance button and re-engages it. Alternately, one can issue a GO command through the USB interface to resume advancing.

**Target:** The depth at which the target is expected to be reached can be set to any value between the initial offset and the limit values. The target value will be retained when the controller is powered down and is set to 30mm by default.

**USB Interface:** The controller's USB interface emulates a serial (COM) port. When first plugged into a PC, the driver for the controller will be installed and a virtual COM port will appear. To establish communications with the controller, a terminal emulator application will need to be installed and run on the PC (such as Window's HyperTerminal). Baud rate should be set to 19200 bps, 8 bit words. See the reference information section for a description of commands supported.

**User Profiles:** The controller can save and store up to 5 different user profiles to allow users to easily configure the controller according to different user's speed preferences and/or optimized settings for different types of procedures. A user profile contains all available speed settings. Profiles are loaded and saved through the USB interface.

**Zeroing the Drive:** Mounting the motor unit onto the drive and using the hand held remote control to adjust the drive depth to the origin. Once the drive is positioned at the origin, press the zero button on the hand held remote control and the depth of the drive will be tracked by the controller for the remainder of the procedure.