Medtronic

microTargeting®

Drive Accessories

User Guide

Language CD-ROM Enclosed

CE

The contents of this manual are the property of Medtronic A/S. Any reproduction in whole or in part are strictly prohibited.

At the time of printing/transfer to the CD-ROM, this manual correctly described the device and its functions. However, as modifications may have been carried out since the production of this manual, the system package may contain one or more addenda to the manual. This manual including any such addenda must be thoroughly read, before using the device.

The following situations void any guarantee(s) and obligations for Medtronic A/S:
- The device is not used according to the enclosed manuals and other accompanying documentation
- The device is installed or modified by persons other than Medtronic A/S service technicians

This system is CE marked in conformity with the requirements in the Medical Device Directive 93/42/EEC.

Contents

Safety Information

Intended Use

When used in conjunction with the microTargeting® Drive System, the Drive Accessories, in either an Encoder Option or a Motor Option, add additional positive functionality to allow a neurosurgeon to position intracranial microelectrodes, stimulating electrodes or DBS™ electrodes more precisely and safely during functional neurosurgical procedures

Indications For Use

The addition of Drive Accessories does not change the Indications For Use of the microTargeting® Drive System:

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

Warnings

Compatibility

The microTargeting® Drive Accessories are specifically designed to be use with the microTargeting® drive. Use with such other components or systems, is not authorized and may result in mechanical failure or injury.

Alternative Power Supplies and sources are not authorized for use with this equipment and may cause malfunction or injury

Disassembly

Field disassembly of components beyond the major assemblies may affect calibration and function. Units requiring repair should be returned to the manufacturer for overhaul.

Precautions

Storage

Temperature: -40°C to 70°C (-40°F to 158°F)
Relative Humidity: 10% to 100%
Atmospheric Pressure: 500hPa to 1060hPa

Component Failures

While a high degree of reliability is designed into the system, unexpected failure of components is always possible if improper storage or handling occurs. The Drive Accessories are not designed to be sterilized. Using a sterile draping system combined with sterilization may cause a malfunction. Should mechanical failure or incorrect operation of the Drive Accessories occur, remove the accessory and retract the drive by turning the knob manually, allowing the procedure to continue.

Handling and Use

Handle the Drive Accessories with extreme care. These components may be damaged if excessive force or incorrect handling occurs.

Do not force engagement when positioning the Encoder or Motor on the drive. Follow the assembly and user instructions carefully.

Place connecting cables and leads where they will not be inadvertently pulled or tangled

WARNING The device is not compatible for use in an MRI magnetic field.

CAUTION Federal law (USA) restricts this device to sale, distribution, and use by, or on the order of, a physician.

Symbols

Controls


Retract


Advance


Retract to Zero


Zero


Off / On

Connections or Devices


Encoder or Motor


Remote Control


Serial Communications Port

Information, Caution or Warning


Type BF equipment (Body Floating) electrically isolated from patient


Attention See User Guide

Operation

Features

Accessory components add increased functionality to microTargeting® Drive:

- Manual control and display of electrode position, or
- Motorized control (including hand held remote) and display of electrode position
- The Encoder or Motor Option components are coupled to autoclavable microTargeting® Drive using a sterile draping system
  - reduces turnaround time
  - decreases wear/tear on electronic components
- A bright, 1cm high display shows electrode tip position in µms
- All components are compact sized and can be mounted, sterilized (where applicable), and stored conveniently
- Computer monitoring/control available via serial port on the Encoder and Motor display Units.

Description

The microTargeting® Drive Accessories add motorized or manual positioning with display capabilities to the basic Drive System. These add-on units use a simple, field installed adapter kit and require minimal changes to the basic microTargeting® Drive System.

The basic Drive System is steam sterilizable for rapid turn around and ease of use in all environments. The Encoder and Motor Option do not require sterilization; they are designed for sterile draping sleeves. The sterile sleeve is easily applied and does not interfere with function. The Encoder or Motor is inserted inside the sterile drape which has pre-punched holes at the stretch material tip for a tight seal. The draped unit is then attached to the Drive. The cable inside the drape extends outside the sterile field for connection to the Encoder or Motor display unit.

The microTargeting® Drive can be set-up in two configurations:

- A manual Encoder Option consisting of a Display Unit and an Encoder.
- A motorized Motor Option consisting of a Controller Unit with Display, a Motor and a hand held Remote Control.

The position of the tip of the microrecording or stimulating electrode relative to the zero position is shown on a 1 cm high LED display to 1µm precision. An indicator arrow points down when the drive is being advanced, up when it is retracted, and to the display when the drive is at rest.

The Encoder Option retains the manual control of the drive advance.

The Motor Option adds a stepper motor drive controlled from a hand held Remote Control with a single function control knob. Rotating the control knob from its center position causes the drive to retract or advance - the distance from center determines the rate. The control knob is spring loaded to return to zero when the knob is released. The Motor Option includes the Encoder functions.

Pressing the Retract to Zero push button on the remote control causes the drive to return to zero at maximum rate.

In both the Encoder and Motor Option, the Zero push button can only be activated once after Power ON. Be sure to have the drive physically positioned at zero, before activating the Zero push button.

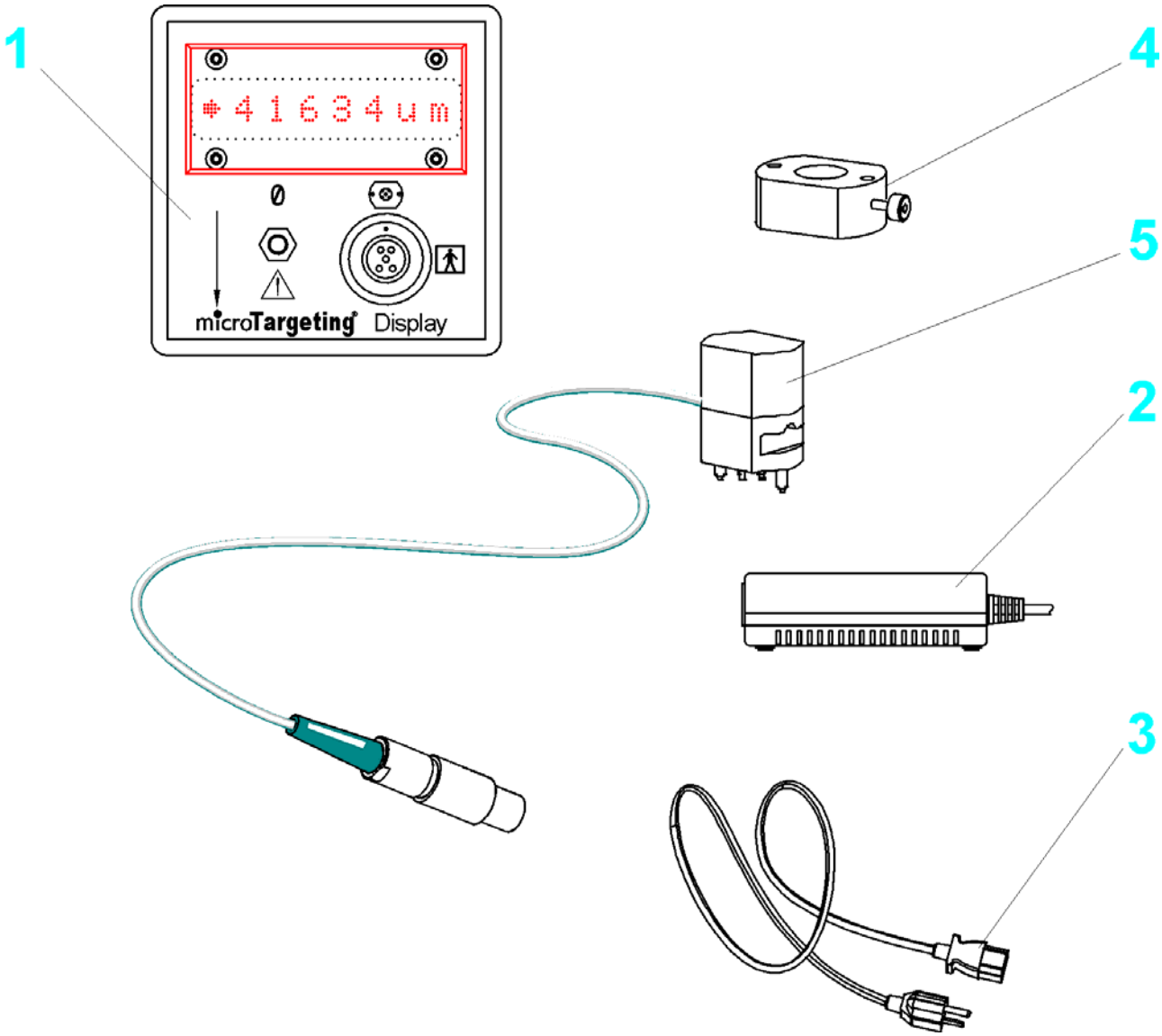
Operating Environment

The Drive 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 section Operation, gives specific instructions on the use, care and maintenance of the Drive Accessories.

Encoder Option

1. Display Unit
2. Medical Power Supply
3. Power Cord
4. Protective Storage Cap
5. Encoder with Cable

The Encoder Option also includes Tool Kit for Driver Options, Storage Case, Serial Cable and Sterile Drape Sleeves.



Motor Option

1 Controller Unit with Display

2 Medical Power Supply

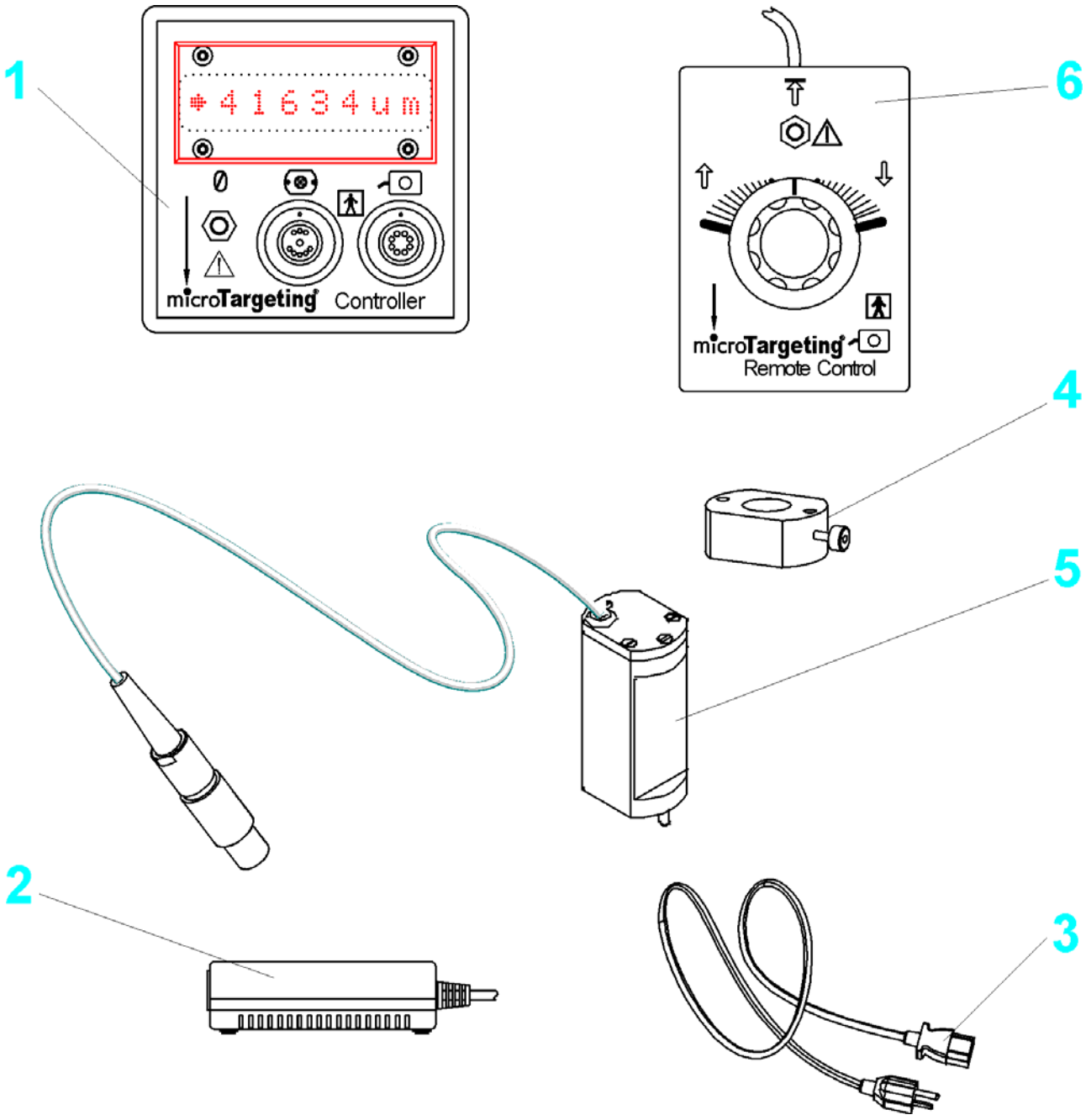
3 Power Cord

4 Protective Storage Cap

5 Motor with cable

6 Remote Control

The Motor Option also includes Tool Kit for Driver Options, Storage Case, Serial Cable and Sterile Drape Sleeves.



Sterile Drape Sleeves

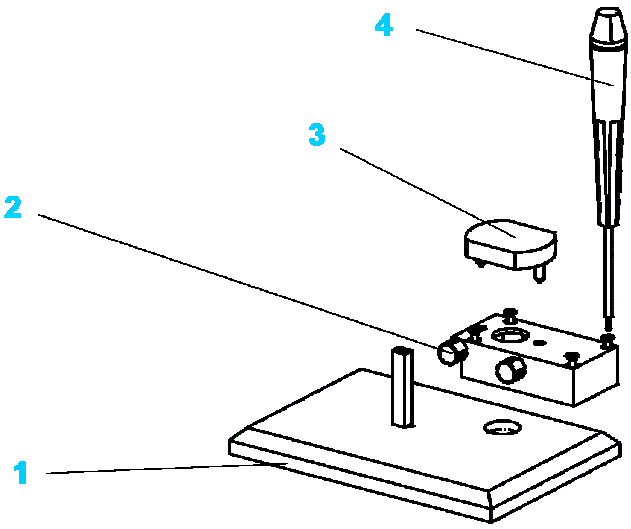
Allows safe use of the non-sterile Drive Accessories with the sterilized Drive system

Storage Case

For protection of non-sterilized Drive Accessory components of either Configuration between uses if they are not mounted on a user supplied rack. This sealed and foam padded case has storage compartments for either Drive Accessory configuration including Units, Power Supply and cables.

Tool Kit for Driver Options

1. Mounting Stand with pylon to hold the microTargeting® Drive while mounting the Encoder or Motor. This stand fits into the Sterilization Case provided with the Drive System.
2. Accessory Top Cover which acts as the interface between the microTargeting® Drive and the Encoder or Motor allowing for easy attachment.
3. Sterilization Cover plate to cover opening during sterilization and when no Drive Accessories are being used.
4. Screwdriver and 4 screws, used only for the initial Adapter Cover conversion



Serial Cable

3m special noise filtered IBM-PC 9-pin serial cable (straight through, female-female). Please follow the User Guide of the relevant data capture device.

Replacement Items

9033G070x	Encoder Option
9033G071x	Motor Option
9013S430x	Sterile Drape Sleeves (20 pcs.)
9033G472x	Motor
9033G473x	Display Unit with Power Supply and Remote Control for Motor
9033G474x	Tool kit for Drive Options
9033G475x	Encoder
9033G476x	Display Unit with Power Supply for Encoder
9033M471x	User Guide
9033G479x	Serial Cable
9033G477x	Storage Case
9033G060x	microTargeting® Drive System
	microTargeting® Electrodes
9013S0801	210
9013S0811	256
9013S0821	277
9013S0831	291
9013S0841	291A

System Configurations

Encoder Option 9033G070x

1. Display Unit
2. Medical Power Supply
3. Power Cord
4. Protective Storage Cap
5. Encoder with connector Cable
6. Tool Kit for Driver Options
7. Sterile Drape Sleeves
8. Storage Case
9. User Guide
10. Serial Cable

Motor Option 9033G071x

1. Controller Unit with Display Unit
2. Medical Power Supply
3. Power Cord
4. Protective Storage Cap
5. Motor with connector Cable
6. Tool Kit for Driver Options
7. Sterile Drape Sleeves
8. Storage Case
9. User Guide
10. Remote Control
11. Serial Cable

Technical Specification

Sterile Drape Sleeves

Material: Kraton

Dimensions: 17.8cm(d) x2.4m (7” (d) X 8'), open, 20x30x.3cm (8"x12"x1/8"), packaged

Sterilization: EtO Sterilized

Package quantity: 20 sleeves in individual sterile packages

Tool Kit for Driver Options

Material: Aluminum 6061/ Pins and Pylon 304 Stainless Steel

Finish: Black, Hard Coat Anodize with PTFE

Stand, Dimensions: Height: 4 cm (1.57”), Width: 7.8 cm (3”), Length: 11.5 cm (4.5”) Ø, Weight: 230g, (8 oz.)

Protective Storage Cap, Dimensions: Height: 1.42 cm (.56”), Width: 2.71 cm (1.06”), Length: 5.32 cm (2.09”) Ø, Weight: 28.5 grams, (1 oz.)

Sterilization Cover, Dimensions: Height: 0.64 cm (.25"), Width: 2.39 cm (0.94"), Length: 3.18 cm (1.25") Ø, Weight: 12.8 grams, (.5 oz.)

Encoder

Material: Radel R 5000 series (Black)

Dimensions: Height: 3.81cm (1.50”)

Width: 2.39cm (0.94”)

Length: 3.18cm (1.25”) Ø

Weight: 49 grams (2 oz.) not including connector/cable

Interface: Mates with Tool Kit for Driver Options, electrically isolated from drive system

Cable Length/Diameter: 3m (9.8’), 3.0mm (0.12”) Ø, shielded

Connector: 5 pin indexed, Color coded blue with strain relief (mates with Encoder Display Unit)

Linear Resolution: 1.0 µm (calculated)

Sterilization: Do not sterilize, use sterile draping system

Mode of Operation: Continuous.

Encoder Display Unit

Case Material: HIPS Plastic (Black / Granite) UL 94 HB rated

Display Module, Dimensions: Width: 8.89 cm (3.5”), Height: 8.89 cm (3.5”), Length: 11.63 cm (4.6”), Weight: 480 g (1.1 lbs.)

Medical Power Supply, Dimensions: Width: 7.4 cm (2.9”), Height: 4.4 cm (1.8”), Length: 14.9 cm (5.87”), Weight: 0.74 kg (1.6 lbs)

Power Required (Medical Power Supply): 85-264 VAC 47–63 Hz, NEMA 5-15 pattern Line Cord

Display: 8 characters, 1 cm height, red, 1 µm resolution

Mounting Options: Tabletop, 4 rubber feet prevent sliding

Mounting studs on Module side panel provide adaptability with Medtronic mounting options including External Stand and Bed Clamp

Mode of Operation: Continuous.

Serial Interface: Baud Rate 19200, 1 Stop Bit, No Parity, No Handshake

Communications Protocol: ASCII

Commands Supported:
V: Version Report
C: Configuration Report
R: Position Report
L: Set Language
E: Echo to display

PIN	SIGNAL	FUNCTION	DIRECTION
1#	DTR	Data terminal ready	From mT Controller (mTC)
2	TXD	Transmit data	From mTC
3	RXD	Receive data	To mTC
4*	DCD	Data carrier detect	To mTC
5	GND	Signal ground	
6*	DSR	Data set ready	To mTC
7*	CTS	Clear to send	To mTC
8#	RTS	Request to send	From mTC
9*	RI	Ring indicator	To mTC

*Pin ignored by microTargeting® Controller

#State of output not guaranteed, client computer should ignore these signals

Motor Controller Unit with Display

Case Material: HIPS Plastic (Black / Granite) UL 94 HB rated

Motor Controller Module, Dimensions: Width: 8.9 cm (3.5”), Height: 8.9 cm (3.5”), Length: 11.6 cm (4.6”), Weight: 520 g (1.2 lbs)

Remote Control, Dimensions: Width: 6.7 cm (2.6”), Height: 4.3 cm (1.7”), Length: 9.5 cm (3.7”)

Weight: 199g (0.44lbs) (inc cable and plug)

Medical Power Adaptor, Dimensions: Width: 7.4 cm (2.9”), Height: 4.4 cm (1.8”), Length: 14.9 cm (5.87”), Weight: 0.74 kg (1.6 lbs)

Power: Display Module: 12VDC @ 2.5A Max, 30Watts

Medical Power Adaptor: 85-264 VAC 47–63 Hz

Display: 8 characters, 1cm height, red, 1 µm resolution

Mounting Options:
Tabletop, 4 rubber feet prevent sliding

Serial Interface:
Baud Rate 19200, 1Stop Bit, No Parity, No Handshake

Mode of Operation: Continuous.

Communications Protocol: ASCII

Commands Supported:
V: Version Report
C: Configuration Report

R: Position Report
+: Advance one step
- : Retract one step
L: Set Language
E: Echo to display

Motor

Material: Radel R 5000 series (Black)

Dimensions: Height: 6.13cm (2.41”)

Width: 2.39cm (0.94”)

Length: 3.18cm (1.25”) Ø

Weight: 72 grams (3 oz.), not including connector/cable

Cable Length/Diameter: 3.0m (9.8’), 3.5mm (0.14”) Ø, shielded

Connector: 9 pin indexed, Color coded blue with strain relief (mates with Motor Controller Unit with Display)

Interface: with Tool Kit for Driver Options, electrically isolated from drive system

Linear Resolution: 1.0 µm (calculated)

Maximum Speed: 1200 steps / second (0.66 mm/sec)

Sterilization: Do not sterilize use sterile draping system

Mode of Operation: Continuous.

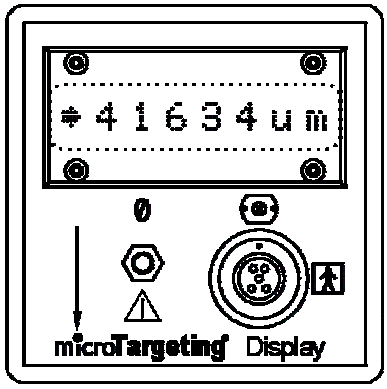
Storage Case

Material: Unbreakable black structural resin plastic shell with foam interior cut in 1.26 cm moveable segments to fit the components.

Dimensions: 41(l)x34(w)x18(h) cm, (16-1/8” (l)x 13-1/4”(w)x 7”(d)), Weight: 3.2 kg (7 lbs.)

Units and Remote Control

Encoder Display Unit



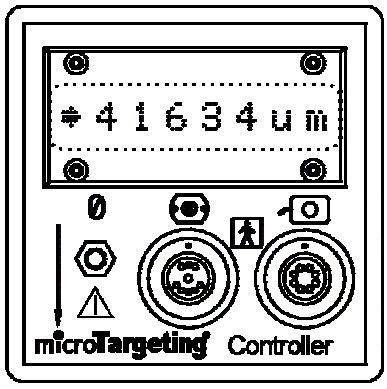
0 ***Zero:*** Push the button to zero the display after the Encoder has been mounted on the Drive and the Drive has been set to 0.00 on the scale. This also sets the display limits, and the display will flash to indicate positions above zero or below 50mm.

NOTE As a safety feature, the display Unit cannot be re-zeroed without powering off the Module.

Position Display: 8 characters, including directional arrow, Resolution: 1 µm.

Encoder Connection: 5 pin receptacle: color coded blue.

Motor Controller Unit with Display



0 ***Zero:*** Push the button to zero the display after the Motor has been mounted on the Drive and the Drive has been set to 0.00 on the scale. This also sets the drive limits, and

the drive will not move to positions above zero or below 50mm.

NOTE As a safety feature, the display cannot be re-zeroed without powering off the Module.

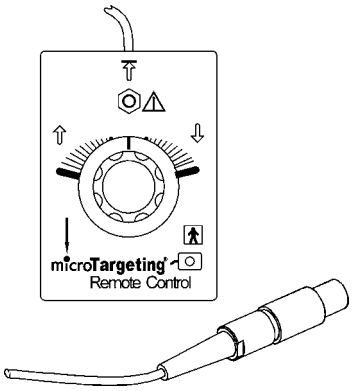
Position Display: 8 characters, Resolution: 1 µm

Motor Option Connection: 9-pin receptacle for the motor, color coded blue

Remote Control Connection: 8-pin receptacle: color coded white

The Display and Drive are initially set to 0.00 manually using the zero button on the Unit. The total travel is limited to the 50mm physical limits of the drive.

Handheld Remote Control

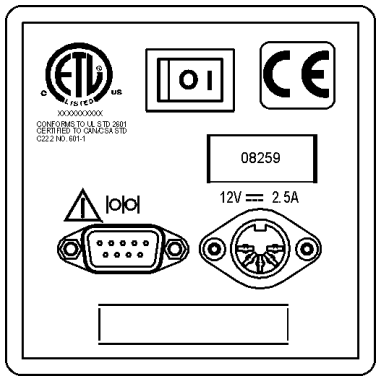


Retract To Zero: momentary push button retracts the motor back to zero, press again to cancel auto-retract.

NOTE If this push button is depressed for at least 5 seconds before the Drive is zeroed, the unit will go into the "Remote Control Calibrate" mode. (See section Installation and Functional Checkout, Remote Calibration)

Retract/Advance: Knob controlling direction and speed of the drive. Spring return to center (speed = 0) when released.

Encoder/Motor Back Panel



Power: Rocker switch for main power I = ON, 0 = OFF.

Power Entry: 5-pin circular DIN receptacle, (12VDC, Common, Earth).

COM: 9-pin male D-Sub receptacle, RS232 (serial port) uses special noise filtered IBM-PC 9-pin serial cable (straight through, female-female).

Compatibilities

The microTargeting® Drive Accessories are specifically designed to be used with the microTargeting® Drive System. Use with other components, or systems is not authorized and may result in mechanical failure or injury.

Abbreviated Procedure

Installing the Drive Accessories

1. Replace the microTargeting® Drive cover with the Accessory Top Cover by removing the four screws with the enclosed screwdriver holding the cover to the Drive.
2. Position the Sterilization Cover and secure.
3. Store the Drive and Mounting Stand (provided with the adapter kit) in the sterilization case pro-vided with the Drive.

Daily Use

Preoperatively

1. Sterilize the case containing the microTargeting® Drive System and Mounting Stand with steam or EtO.
2. Position the Drive on the Mounting Stand. Remove the Sterilization Cover.
3. Insert the Encoder or Motor into a sterile Draped Sleeve and extend the Sleeve over the cable. Position the draped assembly on the microTargeting® Drive and rotate the Drive advance knob until the assembly slides down onto the Drive Cover. Tighten the two knobs to secure. See Section Units and Remote Control for details.
4. Connect the assembly cable to the Encoder or Motor Unit. Zero the display after setting the Drive to zero using the visual scale on the Drive.

During the procedure

1. Mount the assembled microTargeting® Drive on the stereotactic system.
2. Load the insertion tube and electrode.
3. Advance the microelectrode either manually (Encoder Option) or using the Remote Control (Motor Option). The tip position of the electrode used in the microTargeting drive is shown on the Display as the drive is advanced.
4. The Drive Assembly can be removed during the procedure and the operation can proceed using manual control and visual scale on the Drive.
5. After the procedure is complete, remove the Motor or Encoder, discard the sterile drape, and return the sterilization cover to its position on top of the Drive.

Reference Manual

Reference Information

Shipping/Storage Containers

The corrugated and plastic unit packages used for shipping and storage of these Devices are not intended to be used during sterilization, but only as a protective case during shipping and receiving. We recommend saving the containers for future use.

Inspection

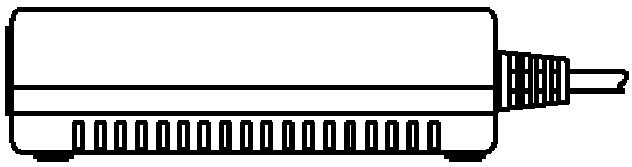
The products are factory checked and calibrated but should be carefully inspected before use.

In case of any signs of exterior damage to the shipping carton, the instrument should be inspected for obvious physical damage. The contents of each package should be physically checked against the inventory list in "Items described in this manual" to determine shortages or errors in inventory.

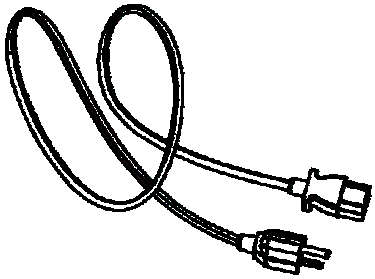
Power Connections

A 12V Medical Power Adaptor is used to power the Encoder Display Unit and the Motor Controller Unit with Display. Input power requirements are 85-264 VAC 47–63Hz. The Medical Power Supply is shipped with a line cord approved for your local voltage and connections. Alternative suitable International pattern Line Cords may be required.

CAUTION Alternative Power Supplies and sources are not authorized for use with this equipment and may cause malfunction or injury



Medical Power Adapter



Line Cord

Warranty

All 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.

Policy

It is our policy to provide our customers with the most comprehensive technical support in the industry. If any questions arise or problems occur, we encourage you to call or write and we promise to promptly and comprehensively respond to your requirements.

Service/Repairs

Should service be required, please contact our Service Department for Return Authorization Number. Carefully pack the instrument before returning. All returns must be clean and free of biological contamination. Use the original packing material or its equivalent to prevent shipping damage.

Please include a MFD Return Repair Form indicating:

1. The model number, serial number, and purchase date of the instrument.
2. The name of the Purchaser
3. The name and contact information of a person to contact if questions arise.
4. The "symptoms" indicating that repair is necessary.
5. A statement that the instrument is being shipped free of any biological contamination

If the instrument is not covered by the warranty, a quotation will be forwarded to the sender detailing the repairs necessary and charges, before repair is begun.

Motor Display Messages

Text	Explanation
ENGLISH	Language name
REMOTE CALIBRATION	String that tells the user that the remote calibration sequence has started (see Units and Remote Control, Zero)
↓ ADVANCE	String displayed during calibration that asks the user to set the most advanced position on the remote
↑ RETRACT	String displayed during calibration that asks the user to set the most retracted position on the remote
PLEASE ZERO THE DRIVE	String requesting the user to zero the drive (see Installation and Functional Checkout, Remote Calibration)
MEMORY ERROR: RETURN FOR REPAIR	String alerting the user that a (non-volatile) memory error occurred and to return the unit for repair
STALL	String indicating that the drive has stalled

Stall

If a stall is detected during a drive motion, the drive will stop moving for about 5 seconds.

- The position number reappears in the display and the drive starts moving again according to the remote control settings.
- Immediately check the position number on the display against the physical scale of the drive.
- A discrepancy of less than 25µm should not be a cause for concern. Discrepancies above 25µm or frequent stalls may, however, require that the motor option should be removed. In that case, use the physical scale of the drive and the manual advancement knob to complete the procedure.

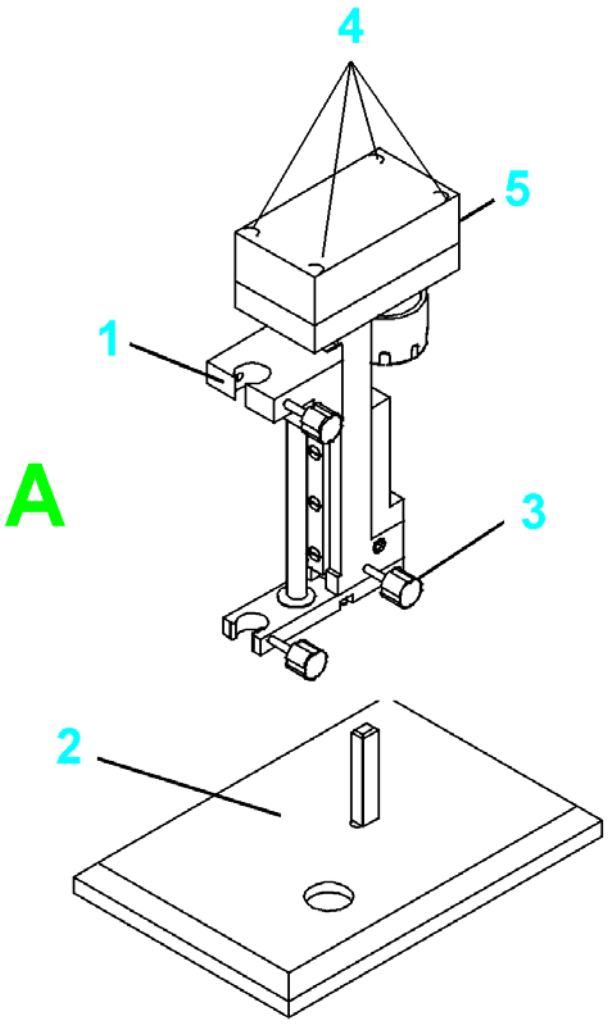
NOTE Frequent stalls indicate a possible physical damage to the drive, including residue build-up. There could also be problems with the motor option or the controller unit. Contact the manufacturer for service or repair, see section Service/Repairs.

Memory Error

The user cannot correct a memory error. The unit must be returned to the manufacturer for service or repair, see section Service/Repairs.

Installation and Functional Checkout

Modification of Drive



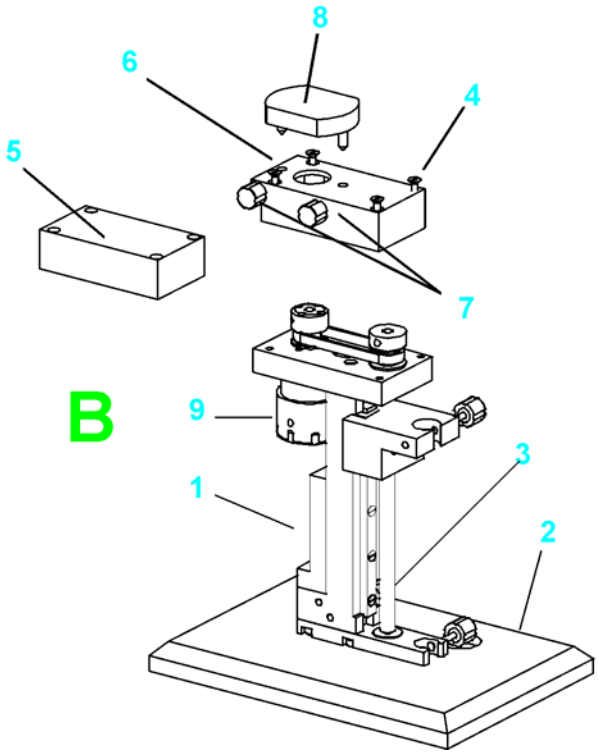
1 Install the microTargeting® drive (A1) on the pylon located on the Assembly Stand (A2)

2 Tighten the pylon locking screw to secure the drive to the stand (A3). Turn the Drive Advancement Knob (B9) in the advance direction a few turns to become familiar with the “feel" of the mechanism during normal operation.

3 Loosen the 4 screws (A4) holding the Drive Top Cover (A5) of the microTargeting® drive (A1) and replace it with the Accessory Top Cover (B6). Make sure the Accessory Top Cover (B6) is fully inserted onto the drive.

4 Secure the Accessory Top Cover by tightening the 4 screws (B4) from the Drive Top Cover.

5 Back out the Top Cover knobs (B7) at the side of the cover slightly. Install the Sterilization Cover (B8) in place, on the top of the Accessory Top Cover (B6) and secure it by tightening the Top Cover knobs (B7).



6 Turn the Drive advancement knob (B9) to check for free movement. There should be no change in the “feel” of the mechanism. Tightness or binding indicates incorrect installation of the adapter kit. Check the installation procedure to ensure all steps have been followed correctly.

1 microTargeting® drive
2 Mounting Stand
3 Pylon Locking Screw
4 Top Cover holding screws
5 microTargeting® Drive Top Cover (remove)
6 Accessory Top Cover
7 Top Cover Knobs
8 Sterilization Cover
9 Drive Advancement Knob

Language Settings

The following languages are at the moment supported by the display software:

English, Spanish, German, French, Italian, Danish and Swedish.

To choose a language (prior to zeroing the drive):

1. Press and hold the Zero button for 5 seconds. The LED display flashes to count the seconds while you press the Zero button.
2. Release the Zero button. The current language choice is displayed. Press the Zero button shortly to scroll through the available languages.
3. Press and hold the Zero button for 5 seconds to select the language shown on the display.

Encoder Option

See section Encoder Option to set up the Encoder Option for an initial installation checkout. 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. Any significant errors should be reported to Medtronic as described in Section Service/Repairs.

Motor Option

See section Motor Option to set up the Motor Option for an initial installation checkout. The proper functioning of the Remote Control and the measuring function of the Display can be verified by advancing the drive several times in 10 mm 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, and no movement of the drive in the Remote control Knob's center position. Any error may indicate that the Remote Control has lost its calibration. This is an unlikely occurrence during normal use, but a calibration procedure has been provided:

NOTE Practicing the mounting and engagement procedure and the Assembly draping procedure several times before the first surgical use will familiarize the personnel with the required steps.

Remote Calibration

Plug the Motor cable into the Motor Controller Unit with Display. Turn on the power switch on the back panel of the Motor Option Controller Unit with Display. Press on the ***Retract to Zero*** button on the Remote Control for at least 5 seconds to enter the calibration menu. On the display you will see "Remote calibration...Advance". Turn the knob in the fully clockwise position (advance) then while holding the knob in full clockwise position, press the ***Retract to Zero*** button. The display reads "Retract" Turn the knob all the way counterclockwise and hold it while pressing the ***Retract to Zero*** button. Check again for correct function, and if any errors are noted the units should be returned to the manufacturer as described in Section Service/Repairs.

Storage Case

The optional Storage Case is designed to hold non-sterilizable components of Drive Accessory Configurations between uses and is not intended for use as a sterilization case. It is lined with a foam interior which has been customized to hold the Drive Accessory components. There is available space to add additional components or alternative configurations that may be added later. The foam is pre-cut and additional compartments may be made by removing appropriate foam sections.

Do not replace the components into the case if they are soiled or contaminated. They should be cleaned as described in section Sterilization, Cleaning, and Routine Maintenance.

Operational Information

Sterilization, Cleaning, and Routine Maintenance

Sterilization

Motor or Encoder Option: Do not sterilize these Drive Accessories. They are designed to be used only with a sterile draping system, (See section Sterile Draping), and attempting to sterilize the devices may cause damage to their components. Draping is done pre-operatively, but can be redone during the procedure if inadvertent contamination occurs.

Tool Kit for Driver Options: The components of this kit are designed to replace similar components of the microTargeting® Drive System, or to be used with the Drive in a sterile condition. After the Protective Storage Cap is installed on the Drive it need not be removed again, and will be handled, cleaned, and sterilized in the same manner as described for the Drive System in the microTargeting® Drive System User Guide. The Sterilization Cover should be attached to the Protective Storage of the drive prior to sterilization and during storage to protect the interior of the Drive. It is removed just prior to attaching the Encoder/Motor. The Mounting Stand should be stored and sterilized in the Sterilization Case provided with the Drive System, and must be sterile when it is to be used to assist the draping and Assembly installation process. It is helpful but not absolutely necessary for this process.

Cleaning

Assemblies and Units: In the event the Assemblies or Units become contaminated or soiled they should be disconnected from power sources and wiped clean with an isopropyl alcohol dampened cloth, then dried before they are returned to their storage case. Do not Immerse them in fluids or allow excessive moisture to remain on the devices.

Routine Maintenance

The Drive Accessories are designed to match the microTargeting® Drive maintenance schedule. They should be returned to the manufacturer for inspection and calibration after 100 uses. They should be inspected visually prior to each use for physical damage, frayed or kinked cables or damaged connectors. None of the components require lubrication of any kind.

Sterile Draping

Encoder/Motor, Drive and Sterile Drape

Draping the Encoder/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 for the drape. The other hand will be a non-sterile hand after handling the Encoder/Motor. Most will find that the Encoder/Motor hand should be the least favored hand. The two-person method requires a sterile gowned and gloved person to handle the drape and an assistant that will have non-sterile gloves after handling the Encoder/Motor. Normal draping precautions will suffice. A practice draping should be done before first surgical use.

Encoder/Motor and Coiled Cable

Non-sterile hand: (or prior to putting on sterile gown and gloves) Remove the Protective Storage Cap from the Coupling Unit. Coil the Encoder/Motor cable and place it on a flat surface so that it can be picked up with the cable in one hand

Expanded Drape

Sterile gloved hand: Remove the drape from its sterile packaging expanding the opening to allow for the entry of a hand. Do not pull any of the folds out at this time. Remove the included elastic bands from their tape holder and place on a sterile surface.

Insertion of the Assembly into the Drape

Non-sterile hand: Holding the non-sterile Encoder/Motor with the pins pointing away from you, and the coiled cable in the same hand, enter it into the drape, being careful not to touch the outside of the drape

Push the drape over the non-sterile hand so that the Encoder/Motor and cable are all the way at the end of the sleeve.

Sterile gloved hand (and Non-sterile hand) Maneuver the drape and assembly so that the two alignment pins and the center drive plate are entering the cutouts in the end of the drape

Alignment of Pins and Center Drive Plate with Cutouts

Sterile gloved hand/Non-sterile hand: Push the pins and center drive plate through the cutouts and smooth the stretchable end of the drape over the assembly.

Wrapping of the Drape around the Encoder/Motor

Sterile gloved hand: Stretch the elastic bands 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.

Pull out the Cable of the Sterile Drape

Sterile gloved hand: Hold the drape with the assembly inside while the non-sterile hand pulls the cable from the drape. Be careful not to touch the pins protruding from the end of the drape.

Unfolding the drape over the cable

Non-sterile hand: Unfold the drape carefully as the cable is withdrawn. When the cable is out of sterile envelope distance, the non-sterile hand can hold both cable and drape.

Taping of the drape around the assembly

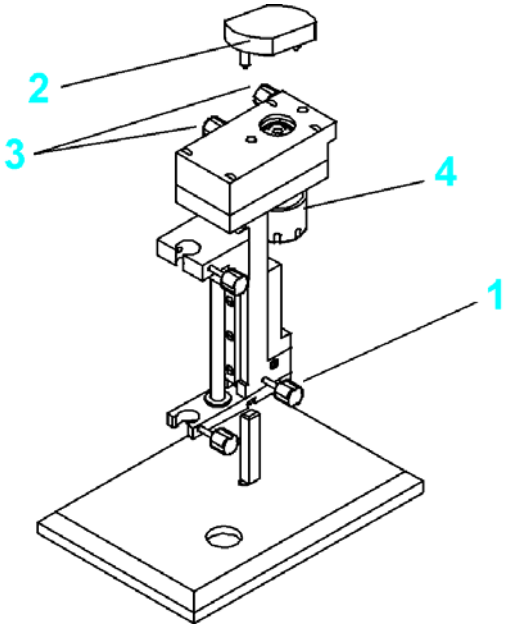
Sterile gloved hand: Use the tape that the elastic bands came in to pull in the folds of the drape tightly above the assembly and tape neatly. If no assistant is helping, this can be done after changing the non-sterile glove.

Non-sterile hand: The Encoder/Motor cable can be plugged into its receptacle (See Section Encoder Option/Motor Option) or (Sterilized gloved hand) 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, not unfolding the drape more than necessary until it is needed.

Encoder Option

Mount the Encoder

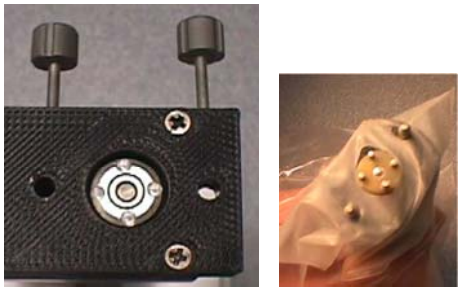
This is done prior to mounting the microTargeting Drive on the stereotactic system. The Encoder will be in its sterile drape (see Sterile Draping for sterile draping procedure) and the Drive will have been sterilized.



Drive mounting on the Stand

1 Drive locking knob
2 Sterilization Cover
3 Assembly locking screws
4 Drive advancement knob

1 Mount the microTargeting® drive on the pylon of the sterile Mounting Stand and tighten the drive-locking knob to secure it. Back out the locking screws on the side of the top cover slightly and remove the sterilization cover if it is attached. Zero the scales on the side of the drive and the knob by rotating the knob.



Drive Top Cover and Encoder pins

2 Pick up the Encoder and enter the two long alignment pins slightly into the holes in the top cover. There is no incorrect way to align the pins. Do not force the Encoder any farther at this time.

3 Push down lightly on the Encoder while turning the Drive advancement knob slowly.

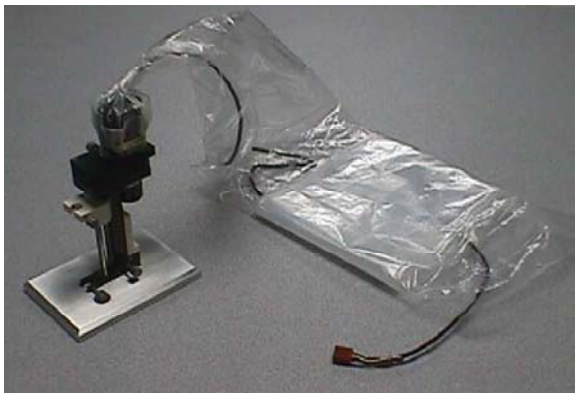
Encoder mounting onto the Drive

4 The Encoder center drive plate pins must be exactly aligned with the holes in the plate in the drive before they will engage. The advancement knob should be turned slowly in small increments. Engagement should happen within 90 degrees of knob rotation.

Since the center drive plate of the Encoder turns so easily it may be necessary to pull it away from the turning plate in the Drive slightly and push down lightly several times before alignment occurs.

Do not attempt to force engagement as damage to the mechanism can occur.

5 When the pins are felt to engage, push the Encoder all the way down to the Top Cover of the Drive. Make sure no parts 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 Assembly for obstructions or damaged components.



Drive With Encoder mounted

6 Tighten the Encoder locking knobs securely and test the Encoder for secure attachment and operation.

Encoder Display Unit

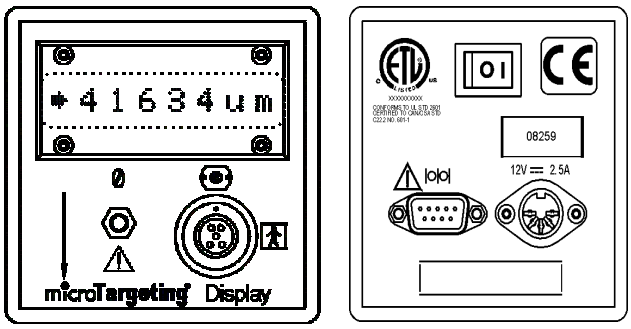
It is assumed at this point that the Encoder is draped and mounted on the Drive.

- Ensure that the Medical Power Supply's line cord is plugged into a power source.
- Connect the Encoder to the Display Unit by inserting its connector into the socket on the front panel.
- Connect the 12v Medical Power Supply to the Display Unit at the back panel.
- Activate the ON/OFF switch at the back of the Display Module.
- Re-zero the Drive by aligning the marks to zero on the vertical scale and knob using the Drive advancement knob.
- When the Drive is at zero, press the zero button. This will reset the display to 00000µm.

CAUTION The display should never be reset unless the Drive has been physically set to 0.00.

- As soon as the Drive is advanced towards the target, the position report on the display will be updated and will show the real distance traveled from the zero position. Distance is shown in micrometers. The arrow symbol in front of the position number indicates direction of travel or will point to the position readout at rest. It is advisable to occasionally compare the position readout to the Drive's physical scale. If there is any noticeable discrepancy, the Drive should be retracted to 0.00, the Module powered off and on again, and the display reset with the zero button. If the discrepancy between the Drive and Display continues, the physical scale of the Drive should be used to complete the procedure and the Display Module returned to the manufacturer for repair. (Section Service/Repairs)

CAUTION Be careful when moving the drive above the zero mark or below 50mm. It is possible to move the drive into its physical limits. If the knob becomes difficult to turn, stop immediately and verify that this has not occurred. After initial zeroing, the display will flash to indicate that the Drive is out of its limits.



1 2

Front (1) and back (2) panel of the Display Unit

Motor Option

Mount the Motor

This is done prior to mounting the microTargeting® drive on the stereotactic system. The Motor will be in its sterile drape (see Sterile Draping for sterile draping) and the Drive will have been sterilized.

1 Mount the microTargeting® drive on the pylon of the sterile stand and tighten the Drive locking knob to secure it. Back out the Motor locking screws on the side of the top cover slightly and remove the Sterilization Cover if it is attached. Zero the scales on the side of the drive and the knob by rotating the knob.

2 Pick up the Motor and enter the two long alignment pins slightly into the holes in the top cover. There is no incorrect way to align the pins. Do not force the Motor any farther at this time.

3 Push down lightly on the Motor while turning the Drive advancement knob slowly.

The Motor center drive plate pins must be exactly aligned with the holes in the plate 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 all the way down to the Top Cover of the drive. Make sure no parts 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 assembly for obstructions or damaged components.

5 Tighten the Motor locking knobs securely and test the Motor for secure attachment and for function.

Motor Controller Unit with Display

It is assumed at this point that the Motor is draped (Section Sterile Draping) and that the Motor is attached to the Drive.

- Ensure that the Medical Power Supply's line cord is plugged into a power source.
- Connect the Motor to the Controller Unit with Display.
- Connect the Remote Control to the Controller Unit with Display.
- Connect the 12v Medical Power Supply to the Controller Unit with Display back panel
- Activate the ON/OFF switch at the back panel of the Unit.

NOTE If the ***Return to Zero*** button on the Remote Control is inadvertently pressed for at least 5 seconds before the next step, the Module will go into its Remote calibration mode. The simple calibration procedure described in Section Installation and Functional Checkout, Remote Calibration must be followed before the Remote will function normally.

- Re-zero the Drive by aligning the marks to zero on the vertical scale and knob using the Remote Control unit for the Controller Unit with Display (turning the Remote Control knob clockwise advances the Drive towards the target, while turning the knob counterclockwise retracts the Drive away from the target location. Full clockwise position will advance the Drive at the highest possible speed, full counterclockwise position will retract the Drive at highest possible speed)
- When the Drive is at zero, press on the zero-button (front panel on the Module). This will reset the display to 00000µm.

CAUTION The display should never be reset unless the Drive has been physically set to 0.00.

- As soon as the Drive is advanced towards the target, the position report on the display will be updated and will show the real distance traveled from the zero position. Distance is shown in micrometers. The arrow symbol in front of the position number indicates direction of travel or will point to the position readout at rest. It is advisable to occasionally compare the position readout to the Drive's physical scale.

  If there is any noticeable discrepancy, the Drive should be retracted to 0.00, the Module powered off and on again, and the display reset with the zero button. If the discrepancy between the Drive and Display continues, the physical scale of the Drive should be used to complete the procedure and the Display Module returned to the manufacturer for repair. (Section Service/Repairs)

CAUTION Be careful when moving the drive above the zero mark or below 50mm prior to pressing the zero button. It is possible to move the drive into its physical limits. Carefully observe travel direction when using the Remote Control before the drive is zeroed. After the drive has been zeroed, the Controller will not allow movement beyond the drive limits of 0.00 and 50.0mm

Scheduled Maintenance

The components of the Drive Accessories are not user repairable or serviceable. For best operation, they should be returned to the manufacturer for inspection, calibration, and service after EVERY 100 uses.

Index

Service Centers

USA +1 763 514 9700, +1 800 227 3191 **Canada** +1 905 826 6020 **Asia** +65 776 62 55 **Italy** +39 0266 1641
Germany +49 345 580810 **France** +33 1 5538 1700 **Belgium** +32 2 456 09 10 **Sweden** +46 8 462 6170

Manufactured by/for:

Medtronic A/S
Tonsbakken 16-18
DK-2740 Skovlunde
Denmark
Telephone: +45 44 57 90 00
Fax: +45 44 57 90 10
www.medtronic.com

US Office

Medtronic, Inc.
4000 Lexington Ave. North
Shoreview, MN 55126-9866 USA
Telephone: (763) 514-9700
Fax: (763) 514-9745
Toll-free: (800) 227-3191
www.medtronic.com

Printed in Denmark, February 2004 Reg. No 9033M4715