

66-EL-MS-01

Digital Display Unit (DDU) for use with Nexdrive by Medtronic

The FHC DDU is for use as an accessory with the Nexdrive Model MI-1000 only

Directions For Use

L011-56 (Rev. B0, June 2014)



DDU shown with Nexdrive model MI-1000



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Indications for use: The Digital Display Unit is intended to be used as an optional accessory to the MI-1000 drive system for neurosurgical procedures which require the accurate positioning of microelectrodes, stimulation electrodes, or other instruments in the brain or nervous system.


Compatibilities: The microTargeting™ Digital Display Unit is specifically designed to be used with the Nexdrive Disposable Microdrive, catalog number MI-1000. Use with other components or systems is not authorized and may result in mechanical failure or injury.


Symbol Key

 **Warnings should be read carefully because if they are not heeded they could lead to situations which may result in serious injury or death.**

General Warnings

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

 **WARNING:** *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.

 **WARNING:** Do not operate the DDU unit in the presence of flammable anesthetics.

General Cautions

CAUTION: *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 Digital Display Unit is not designed to be sterilized.

CAUTION: *Handling and use* - Handle the Digital Display Unit with care. Components may be damaged if excessive force or incorrect handling occurs.

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


CAUTION: Avoid the use of liquids on or near the Digital Display Unit. If liquids come into contact with this device, damage may occur.


CAUTION: Use care when placing the sterile cable that attaches the DDU to the Nexdrive Micropositioning Drive to avoid any force pulling on the drive.

CAUTION: It is recommended that the DDU be returned to FHC for review after 100 procedures for evaluation.


CAUTION: The DDU components should be inspected visually prior to each use for physical damage, frayed or kinked cables, or damaged connectors.

Illustrated Procedure


 **WARNING:** Position connecting cables and leads where they will not be inadvertently pulled or tangled.

 **WARNING:** During the DDU startup, do not zero the device until prompted by the display. Failure to do so will result in display fluctuation.

1. Set the DDU display module on an OR stand outside of the sterile field.
2. Plug the DDU power adapter into a 100-240 VAC power outlet.
3. Hand the Nexdrive cable out of the sterile field and plug the other end of the cable into the DDU.
4. Set the Nexdrive carriage to 30.
5. Depress the Ø button.

 **WARNING:** When the carriage is set to 30 on the Nexdrive MER scale and the Ø button is depressed, the drive must be calibrated so that the electrode tip is 30.00 mm above target (-30.00 on display).

6. Continue the procedure as described in the Nexdrive System Manual.

 **WARNING:** Periodically during the procedure, compare the Nexdrive MER scale depth reading with the DDU reading to ensure proper operation during the procedure. If the DDU and the Nexdrive MER scale readings vary by more than 250 microns, revert to the Nexdrive MER scale.

Notes

- The DDU is intended to be used outside of the sterile field and is reusable.
- The sign convention for the FHC 66-EL-MS-01 DDU is negative (-) for above the target and positive (+) for below the target.

Warranty and Service

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. Although 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.

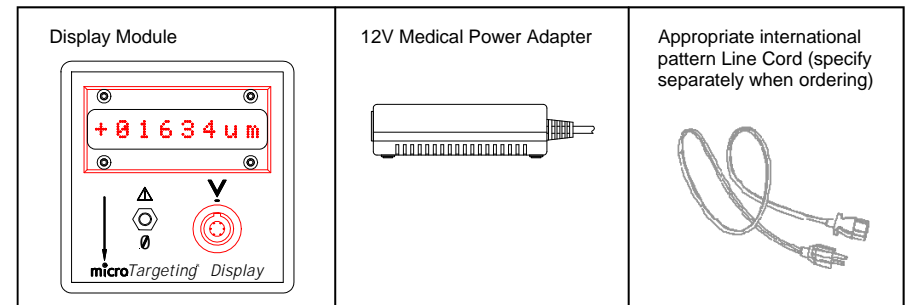
Should service be required, please contact our Service Department for a return authorization number and instructions (207-666-8190). Please have the model and serial number on hand (Both are located on the back panel). Carefully pack the instrument before returning.

Please include a note indicating:

1. The model number and purchase date of the instrument
2. The person to contact if questions arise
3. The "symptoms" indicating that repair is necessary

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.

Inventory



Functional Checkout

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. Any significant errors should be reported to the manufacturer.

Specifications

Dimensions:	Digital Display (DDU)	Power Adaptor
Width:	8.9 cm (3.5")	7.4 cm (2.9")
Height:	8.9 cm (3.5")	4.4 cm (1.8")
Length:	19.1 cm (7.5")	14.9 cm (5.87")
Weight:	0.78 kg (1.8 lbs)	0.74 kg (1.6 lbs) (inc cable and plug)
Case Material:	HIPS Plastic (Black / Granite) UL 94 HB rated	
Power:	Display Module: 12VDC @ 2.5A Max, 30Watts Power Adaptor: 85-264 VAC 47-63 Hz	
Display:	8 characters, 1cm height, red	
Mode of Operation:	Continuous	
Serial Interface:	RS-232: Baud Rate 19200, 1 Stop Bit, No Parity, No Handshake Communications Protocol: ASCII	

Commands Supported:

V: Version Report
C: Configuration Report
R: Position Report (from 0um @ a display reading of -30mm to 50000um @ +20mm)
E: Echo to display
UM: display reads in microns
MM: display reads in millimeters
AVG#: Size of rolling average filter for display update
AXON+: Enables continuous position reporting over serial port
AXON-: Disables continuous position reporting over serial port

Micropositioner Interface:	6 pin Redel panel mount (Lemo)	
	PIN	SIGNAL
	1	Digital Ground
	2	micropositioner sense
	3	Analog Ground (cable shield)
	4	+10.0V
	5	-10.0V

Controls:

Origin: Push button to zero the display after the Display Assembly has been mounted on the Drive and Drive has been set to -30.00 on the scale. This also sets the Display limits, and the Display will flash to indicate positions -30 to +20 mm. NOTE: As a safety feature, the display cannot be re-zeroed without powering off the Module.

Position Display: 8 characters, Resolution: 1 micron

Connectors:

Display Assembly: 6 pin receptacle

Controls:

POWER: Rocker switch for main power I = ON, O = OFF

Connectors:

POWER ENTRY: 5 pin circular DIN receptacle, (12VDC, Common, Earth)

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

