

Operating Manual: Bio-logic System Corp --Telescoping Camera Pole Assembly (part number 585-CYBPSM and 580-VIDPOL) and

Device Information

Model Number:	MDL-4161
Manufacturer:	Bio-Logic Systems Corp
FDA Status:	FDA Recall Class II
Classification:	Class II Medical Device
Manual Version:	v4.7

Operating Instructions

Current Operating Protocol: Device approved for clinical use

Safety Information

WARNING: This device should only be operated by trained medical personnel. Failure to follow proper procedures may result in patient harm or device malfunction. **Indications for Use:** Bio-logic System Corp --Telescoping Camera Pole Assembly (part number 585-CYBPSM and 580-VIDPOL) and assemblies (580IPCART and 580 PNCART; Bio-Logic Systems Corporation, Mundelein, IL 60060; The Model 580-VIDPOL is used with the 580-PNCART that is wired for use with a Panasonic Camera. The pole is also a subassembly of the 585-CYBPSM with wires used in the 580-IPCART wired for the use with an Ipela Camera. Both carts are a component of the Ceegraph/Sleepscan Netlink with Video.

Contraindications: Device use suspended per recall

IMPORTANT SAFETY NOTICE

RECALL NOTICE: This device has been subject to a recall. **Reason:** Bio-logic System Corp Camera Pole may weaken and detach at the base of the telescoping camera pole during transport causing pole to break at the welded base and fall. **Risk Level:** High Please discontinue use immediately and contact the manufacturer.

Maintenance and Calibration

Regular maintenance is essential for proper device function. Follow manufacturer guidelines for calibration and preventive maintenance. Inspect device daily for signs of wear or damage. **Calibration Schedule:** Weekly **Preventive Maintenance:** Quarterly