

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

## Device Information

Model Number:	MDL-2961
Manufacturer:	Bio-Logic Systems Corp
FDA Status:	FDA Recall Class II
Classification:	Class II Medical Device
Manual Version:	v4.9

## 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:** Quarterly **Preventive Maintenance:** Annually