



Medtronic

CATHETER PULLER

for Polygram 98



User Guide



Copyright © 2001 Medtronic Functional Diagnostics A/S. All rights reserved.

The contents of this manual are the property of Medtronic Functional Diagnostics 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 Functional Diagnostics 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 Functional Diagnostics A/S service technicians

Microsoft® is a registered trademark.

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

Contents

Contents	3
Safety Information.....	5
Product Description	5
Intended Use	5
<i>Puller Control Markers</i>	5
Operation	6
Device Description	6
<i>Parts List</i>	6
Legend.....	6
Holder and Accessories	7
Maintenance	7
Cleaning.....	7
Technical Data.....	8
<i>Model</i>	8
<i>Communication</i>	8
<i>Power Supply</i>	8
<i>Accuracy</i>	8
<i>Storage Conditions / Transportation Requirements</i>	8
<i>Operating Conditions</i>	8
Measures and Weights	8
Classification	9
Classification	9
Classification Requirements	9
<i>Service Centers</i>	10

Safety Information

Adhere to the following recommendations for safe operation of the device:

- Read this manual together with Polygram 98 User Guides, for software control of Catheter Puller.
- Never use the device near mobile telephones, CB radios or other forms of radio communication, and/or electromagnetic fields. These may affect the performance of the device.
- Do not attempt to open the case.
- Do not immerse the device or the connector in water or any other liquid (See the Maintenance/Cleaning section for specific details).
- The power connector also serves as the main power switch. Thus remove the connector to power off.
- Do not connect the Power connector or the USB connector to anything other than the appropriate input on the device.
- The use of accessory equipment not complying with the equivalent safety requirements of this equipment, may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:
 - Use of accessory in the patient vicinity.
 - Evidence that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

Product Description

The Catheter Puller is a medical assistant device used to retract a catheter at a certain speed or length to ensure repeatability for pressure studies.

Intended Use

The Catheter Puller is intended to pull a catheter at a known speed or length in conjunction with pressure studies. It is used together with Med-

tronic Functional Diagnostic's devices for assessing gastro intestinal disorders.

CAUTION Danger of electrical ignition. The device is not intended for use with anesthetic gases mixed with air, oxygen or nitrous oxide.

CAUTION In the United States, Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner.

Symbols



Attention, see accompanying documents



Applied part of type BF, i.e. the applied part is electrically isolated.



The device complies with the EC directive 93/42/EEC on medical devices.



Class II Equipment



USB Input/ Data Transfer

Puller Control Markers



1



2

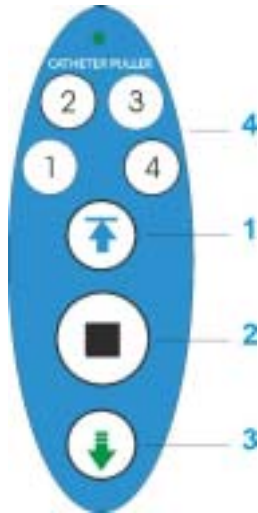


3

1. Retract to Start Position
2. Stop Pull
3. Start Pull

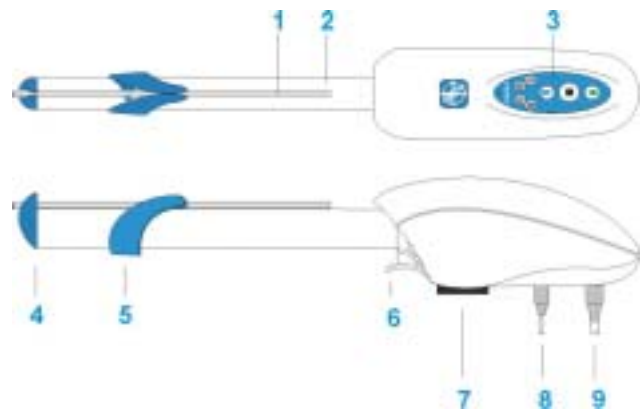
Operation

The Catheter Puller is operated from Polygram 98 allowing the operator to set the parameters such as pull length and pull speed. The Catheter Puller can be controlled either from the Polygram 98 software or manually from the Catheter Puller.



- 1 Retract to Start Position
- 2 Stop
- 3 Start Pull
- 4 Generic Markers (Software Defined)

The generic markers are software defined by Polygram 98.



Legend

- 1. Catheter
- 2. Puller Mechanism
- 3. Control Panel
- 4. Catheter Locator
- 5. Catheter Retention
- 6. Puller Mechanism Release Lever
- 7. Catheter Puller Arm Interface
- 8. USB Connector / Input
- 9. Power Connector / Input

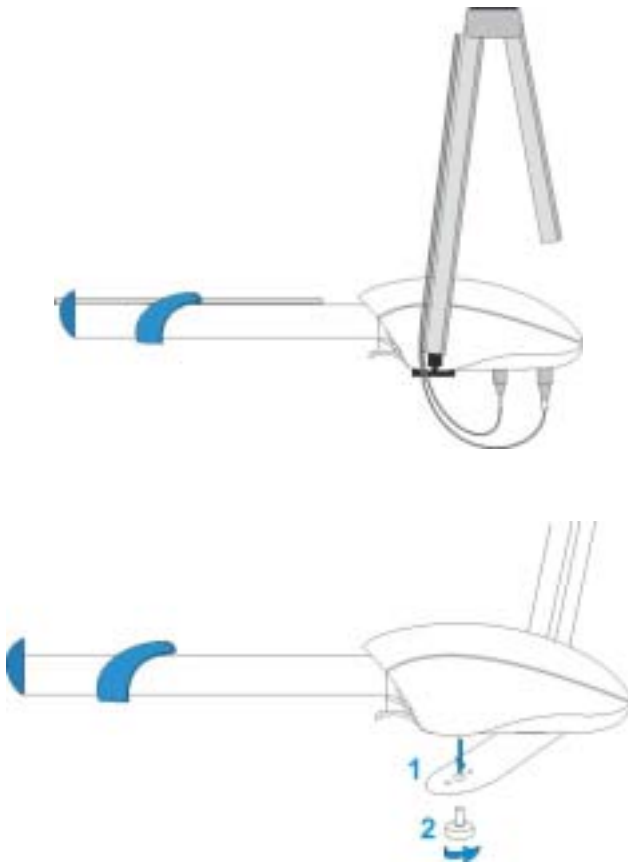
Device Description

Parts List

- 1 Catheter Puller
- 1 User Guide
- 1 Catheter Puller Mechanism
- 1 USB cable
- 1 Power cable
- 1 Registration Card

Holder and Accessories

Catheter Puller Arm Ref: 9034B010x
Power Extension Cable Ref: Country Specific



Connect the Catheter Puller to the Arm

Maintenance

On a weekly basis, test the device for proper functioning, and inspect cables for cuts and other damage. If in doubt, replace the relevant parts. The device should be cleaned daily. No additional maintenance is required.

Cleaning

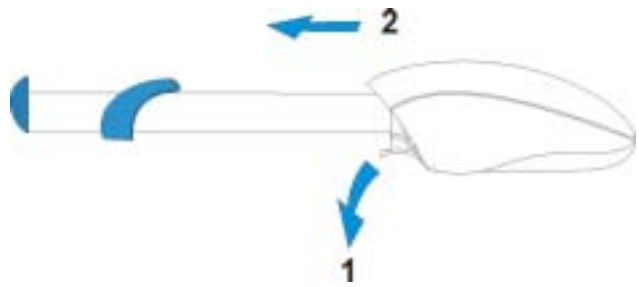
The Catheter Puller should be cleaned daily, to avoid deposits and odor. Clean the device as follows:

Quick Cleaning—with the device assembled—

- Wipe the puller mechanism with clean water and soap.
- Never immerse the connectors or Main devices into any liquid –keep it dry at all times.
- Wipe the device dry.

Thorough Cleaning—with the device disassembled—

- Disconnect the USB cable and power from the device.
- Disconnect the Puller mechanism from the main unit; Press the release lever down (1) and pull the mechanism out (2)(see picture below).



NOTE To avoid damage to the device, do not exceed the recommended cleaning temperatures for the following device component:
Puller mechanism Max 100° C/212°F

NOTE Use cleaning detergents appropriate for disinfection or autoclave.

Technical Data

Model

Catheter Puller REF 9034H0011

Communication

USB

Power Supply

Power consumption: max 1.0A
Input: 110-240V ~/50-60 Hz
Current consumption: 53 VA
Type of Protection: Safety class II

Accuracy

Speed: 0-10mm/s +/- 0.5 mm/s
Pull length: 0-300 mm +/- 1.0 mm

Storage / Transportation

Temperature -40°C to +70°C
(-40°F to 158°F)
Humidity 10% - 100%rh
-including condensation-
Atmospheric Pressure
700hPa - 1060hPa

Operating Conditions

Temperature +10°C to +40°C
(50°F to 104°F)
Humidity 30% - 75%
Atmospheric Pressure
700hPa - 1060hPa

Measures and Weights

	Width	Depth	Height	Weight
Metric	74mm	630mm	88 mm	Less than 1.4kg
US	2.91"	24.8"	3.5"	Less than 3.1 lbs.

(Values do not include the Arm).

Classification

Classification Requirements

Type of protection against electric shock:

- *Class II*: Equipment in which protection against electric does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

Method(s) of sterilization or disinfecting recommended by the manufacturer:

- Please, see section on “Maintenance”.

Degree of protection against electric shock:

- Type BF: Applied part providing a particular degree of protection against electric shock, particularly regarding:
 - Allowable leakage current
 - The applied part is electrically isolated (floating).
 - Not intended for direct cardiac application.

Degree of protection against harmful ingress of water:

- IP20: Ordinary equipment (enclosed equipment without protection against ingress of water).

Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide:

- Equipment not suitable for use in the presence of such a mixture.

Mode of operation:

- Continuous operation.

Service Centers

• **Asia** +65 776 62 55 • **Belgium** +32 2 376 95 61 • **Canada** +1 905 826 6020 • **China** +86 10 6494 8617 • **France** +33 1 5538 1700
• **Germany** +49 345 580810 • **Italy** +39 0266 1641 • **Sweden** +46 8 462 6170 • **USA** +1 763 514 9700, +1 800 227 3191

Manufactured by:



Medtronic

Medtronic Functional Diagnostics A/S

Tonsbakken 16-18

DK-2740 Skovlunde

Denmark

Tel. +45 44 57 90 00

Fax +45 44 57 90 10

E-mail: gastro.mfd@medtronic.com

<http://www.mfd.medtronic.com>

Printed in Denmark, September 2001 Reg. No 9034M2201

When Life Depends on Medical Technology