## Components

| Item | Description | P/N | Item | Description | P/N |
|---|---|---|---|---|---|
| 1 | Central Control Monitor | 802100 | | Occluder Module | 803480 |
| | System Configuration Card | 803739 | 17 | Occluder Head | 806455 |
| | Service Data Card | 803740 | | Temperature Module | 802114 |
| 2 | Monitor Mounting Arm | 801441 | | Temperature Sensor (YSI (Yellow Springs Instruments) Series 700 temperature probes, or equivalent) | 24710008 |
| 3 | Roller Pump, 6 in | 801041 | | Pressure Module | 802112 |
| 4 | Roller Pump, 4 in | 801040 | | Pressure Transducer Kit | 16433301 |
| 5 | Centrifugal Control Unit | 801046 | | Pressure Transducer Cable | 806747 |
| 6 | Centrifugal Drive Motor | 164267 | | Pressure Adapter Cable | 806748 |
| | Manual Drive Unit | 164268 | 18 | Pressure Monitoring Kit | 16066100 |
| | Disposable Pump (8/ctn) | 164275 | | | |
| 7 | Telescoping Pole with solution rack | 16431701 | 19 | Flowmeter Module | 802018 |
| | Mounting Pole 4 ft | 16553401 | | Flow Sensor | 6382 |
| | Short Pole | 801407 | | Flowmeter Mounting Bracket | 801550 |
| | | | | Ultrasonic Sensor Gel | 164278 |
| 8 | Crossbar | 16426 | 20 | Electronic Gas System | 801188 |
| 9 | Pole Collar | 801403 | | Oxygen Sensor | 801074 |
| 10 | Crossbar Fitting | 145980 | | Gas Supply Hose Kit (US)<br>Oxygen Hose-green; Air Hose-yellow | 814475 |
| 11 | Bracket, Hanging Bags | 146819 | | Gas Supply Hose Adapter Sets (US) | |
| 12 | Lamp, Long | 801238 | | NCG Hose Adapter Set | 144207 |
| | Lamp, Short | 801558 | | DISS Hand Tight Hose Adapter Set | 144215 |
| | | | | Ohio Diamond Hose Adapter Set | 144223 |
| 13 | Hand Crank Bracket | 802089 | | | |
| | (includes two hand cranks) | 801016 | | | |
| 14 | Roller Pump Pole Mount | 801093 | | | |
| 15 | Centrifugal Unit Pole Mount | 804372 | | Gas Supply Hose Kit (Outside the US) | 814474 |
| | Roller Pump Mntg. Ext. Large | 802523 | | Oxygen Hose-white; Air Hose-white/black | |
| | Roller Pump Mntg. Ext. Small | 802524 | | Hoses do not include adapters for hospital gas outlets. | |
| 16 | Modules in Retaining Rack | | | 95-5 Supply Hose (%O2/%CO2) | 164595 |
| | Air Bubble Detect Module | 802110 | | Interface Module for CDI™ 101/CDI™ 100 | 802558 |
| | Air Sensor 3/8 x 3/32 | 5773 | | Serial Cable | 804981 |
| | Air Sensor 1/4 x 1/16 | 5785 | | Interface Module for CDI™ 500 | 803479 |
| | Air Sensor 1/4 x 3/32 | 5791 | | Serial Cable | 804981 |
| | Cable Assembly | 149892 | | Interface Module RS-232 | 802113 |
| | Sensor Holder | 149876 | | Serial Cable | 804982 |
| | | | | Interface Module RS-485 | 803518 |
| | | | | Serial Cable | 810166 |
| | Level Sensor II Module | 802111 | | Module Cover | |
| | Level Sensor II Alarm Transducer, Red | 195274 | | Right Side | 804405 |
| | Level Sensor II Alert Transducer, Yellow | 195215 | | Left Side | 804404 |
| | Level Sensor II Mounting Pads (60 pack) | 195240 | | | |
| | Level Sensor II Gel Pad | 217390 | | | |

# Level Detection System

# Level Detect Overview

## Purpose of Device

The Level Detect Module serves as the interface between alert and alarm level sensors and the rest of the system. This module is responsible for determining if the blood level has fallen below a specified point in the venous reservoir and for communicating that status to the system.

The level sensor attaches to a rigid reservoir with a disposable adhesive pad. Ultrasonic signals are used to detect the presence or absence of fluid at the sensor position for a range of venous reservoir thicknesses.

## Affected Product

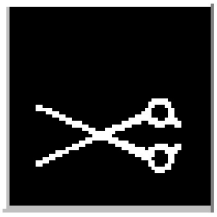
This document is applicable to the following products:

- 802111 Level Detect Module
- 195215 Ultrasonic Level II Sensor Yellow
- 195274 Ultrasonic Level II Sensor Red
- 195240 Level Sensor II Pads 60 PK

# Occluder System

P/N 803480 Occluder Module

P/N 806455 Occluder Head



## Overview

Purpose of the Device

The Occluder System provides a precision, computer-controlled, tube clamping mechanism used to regulate venous return flow in the perfusion circuit. The occluder system consists of an occluder module and occluder head.

The occluder head serves as the tube clamping mechanism. A section of tubing is positioned between the plunger and the occluder cap. The tubing occlusion can be adjusted by controlling the occluder head, using the central control monitor (CCM) controls to move the plunger toward or away from the occluder cap.

The occluder module serves as the interface between the occluder head and the system. The occluder head receives its power and control signals from the occluder module. The occluder head can be unplugged from the occluder module.

The user controls the occluder system from the CCM and can configure it to respond to the arterial pump, either roller or centrifugal types. The responses can be set to open, close, or go to a particular %Flow.

Operating Parameters

*Occluder Requirements*

**Tube Size**

The occluder supports tubing sizes in the range 1/4 in (6,4 mm) I.D. x 1/16 in (1,6 mm) wall thickness to 1/2 in (12,7 mm) I.D. x 3/32 in (2,4 mm) wall thickness.

**Fluid Temperatures**

20°C to 40°C

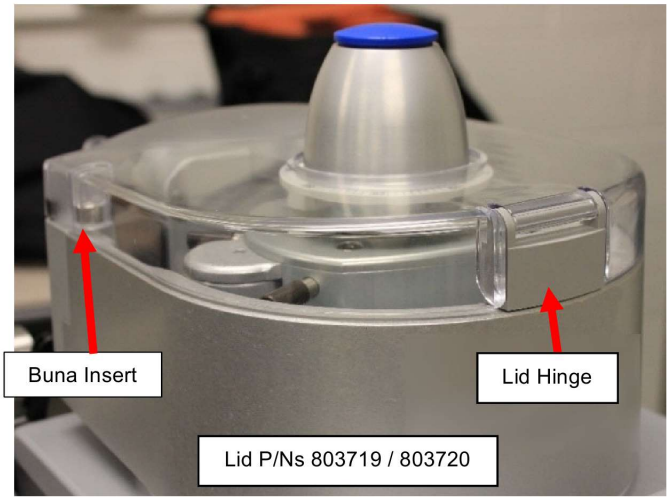
*Occluder Performance*

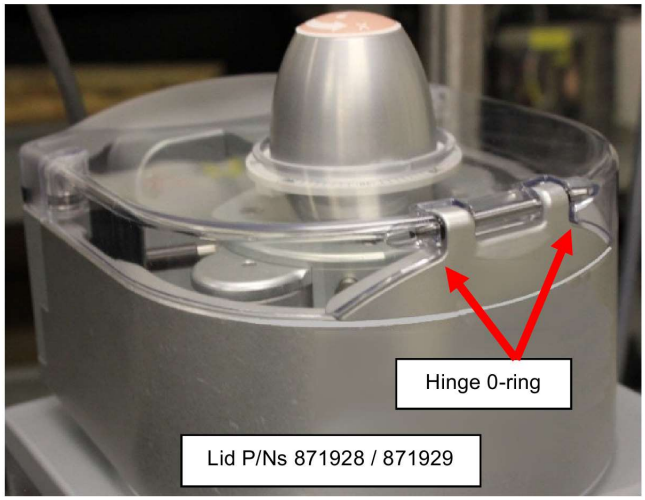
**Voltage**

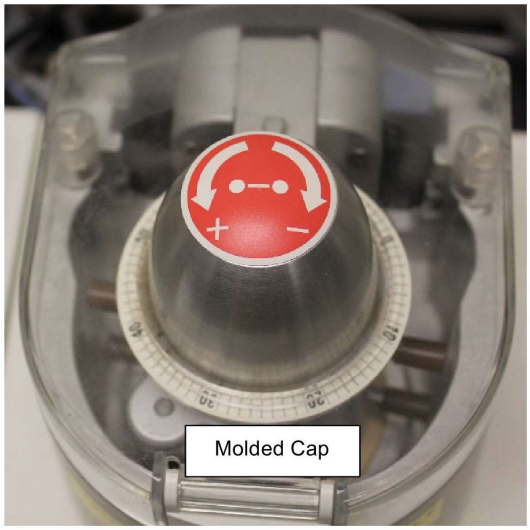
24 VDC nominal

12 VDC ± 5%

| Roller Pump: External Components | | | |
|---|---|---|---|
| | Part or Sub-Assembly | Disassembly | Reassembly |
| 1. | Lid Assembly<br><br>Molded Lid Hinge<br><br>Buna Drag Insert<br><br>Occlusion Cap | a. Remove molded cap from top of occlusion knob.<br>b. Remove lid assembly from race.<br>c. Pull molded lid hinge from assembly.<br>NOTE: Applicable for lids P/Ns 803719 and 803720 only. Hinge is not replaceable for lids P/Ns 871928 and 871929.<br>NOTE: There is no disassembly required for drag inserts. | a. Press buna inserts into lid (if new lid).<br>NOTE: Use P-80 rubber lubricant if needed.<br>b. Install molded lid hinge to lid.<br>c. Install lid assembly onto race.<br>d. For lid (P/Ns 871928 and 871929), apply linear lube to hinge o-rings if hinge squeaks.<br>e. Insert cap onto top of occlusion knob. |



# EC Certificate

## Directive 93/42/EEC Annex II, excluding Section 4
## Full Quality Assurance System
## Medical Devices

**Registration No.:** HD 60121893 0001

**Report No.:** 12031336 001

**Manufacturer:**
Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

**Products:**
see attachement for products included

Replaces Approval, Registration No.: HD 60077473 0001

**Expiry Date:** 2022-08-29

**The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.**

**Effective Date:** 2017-08-30

**Date:** 2017-08-25

Notified Body

M.Sc. M. Aihara

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

**TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.**

TÜVRheinland®

Doc. 1/2, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** HD 60121893 0001
**Report No.:** 12031336 001

**Manufacturer:** Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products included:

- Blood Bags
- Blood Donor Set with/without Blood Transfusion Filter
- Blood Transfusion Filter
- Intravenous Catheter
- Intravenous Administration Set
- Hypodermic Syringe
- Winged Needle
- Dental Needle
- Other Medical Needle
- Blood Administration Set
- Lancet

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

**Notified Body**

**Date:** 2017-08-25

M.Sc. M. Aihara

TÜVRheinland®

Doc. 2/2, Rev. 0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to Certificate**
**Registration No.:** HD 60121893 0001
**Report No.:** 12031336 001

**Manufacturer:** Terumo Corporation
44-1, 2-chome, Hatagaya
Shibuya-Ku, Tokyo 151-0072
Japan

Products included:
- Extra-corporeal Membrane Oxygenator
- Cardiopulmonary Bypass Arterial Line Blood Filter
- Heart-Lung Bypass Defoamer
- Cardiotomy Reservoir
- Cardiopulmonary Bypass Blood Reservoir
- Haemoconcentration Filter
- Centrifugal Pump
- Angiographic Catheter
- Balloon Dilatation Catheter
- Catheter Guide Wire
- Guiding Catheter
- Catheter Introducer
- Stents
- Extension Tube
- Temperature Control Unit for Heart-Lung Bypass System Module
- Infusion Pump
- Syringe Infusion Pump
- Clinical Electronic Thermometer

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

**Notified Body**

**Date:** 2017-08-25

M.Aihara

**M.Sc. M. Aihara**

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

# Certificate

## No. Q5 037584 0026 Rev. 01

**Holder of Certificate:** **Terumo Medical Products (Hangzhou) Co., Ltd.**
M4-9-5 Hangzhou Economic &
Technological Development Zone
310018 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**


**Scope of Certificate:**

**Design and Development, Production and Distribution of Connector, Balloon Catheter, Silicone Balloon Catheter, Silicone Balloon Catheter with Temperature Sensor, Extension Tube, Three-Way Stopcock with Extension Tube, Suction Catheter, P-Type Catheter with Aspirator Collector, Nelaton Catheter, Stomach Tube, Feeding Tube, Connecting Tube, Oxygen Catheter, Three-way Stopcock, Surplug Needle-Free Connector, Intravenous Hyperalimentation, Solution Administration Set for Infusion Pump, Solution Administration Set for Pediatric, Solution Administration Set, Volumetric Solution Administration Set for Infusion Pump, Disposable Volumetric Solution Administration Set, Volumetric Blood Administration Set, Winged Infusion Set, Winged Blood Sampling Set, Surplug Needle-Free Connector with Extension Tube, Surplug Solution Administration Set, Surplug Three-Way Stopcock, Final Filter PS, Automated Peritoneal Dialysis, Blood Administration Set for Infusion Pump, Extra-Corporeal Membrane Oxygenator, Digital Electronic Sphygmomanometer, Electronic Thermometer, Surplug AD, Surplug AD Manifold, Surplug AD Three Way Stopcock, Surplug AD Extension Tube, Surplug AD Administration Set, Intravenous Catheter for Single Use, Nasogastric Tube for Single Use**
**Production and Distribution of Cardiotomy Reservoir**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** SH1907321

**Valid from:** 2019-12-01
**Valid until:** 2022-11-30

**Date,** 2019-11-19

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

# Certificate

## No. Q5 037584 0026 Rev. 01

**Applied Standard(s):**

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

**Facility(ies):**

Terumo Medical Products (Hangzhou) Co., Ltd.
M4-9-5 Hangzhou Economic &, Technological Development Zone,
310018 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

A4 / 07.17


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