

BioTrend® Oxygen Saturation and Hematocrit System



The BioTrend®System

provides you with the technology

you need to make critical

decisions at a glance.

The product has been designed to be compatible with extracorporeal circuits of 1/4", 3/8", 1/2" inner diameter and offers you the following advantages:

- Provides real-time, in-line SO₂
 and Hematocrit values
- Uses fiber optic technology
- Tri-optic measurement cell available single sterile or pre-connected to your extracorporeal circuit
- Does not require lab values for calibration
- Offers manual offset feature to recalibrate device during operation
- Features tactile control buttons and bright LED display

BioTrend is Easily Added to Your Extracorporeal Circuit.



Setup

Setup is simple. A single fiber optic cable connects each Tri-optic Measurement Cell within the circuit to the BioTrend.

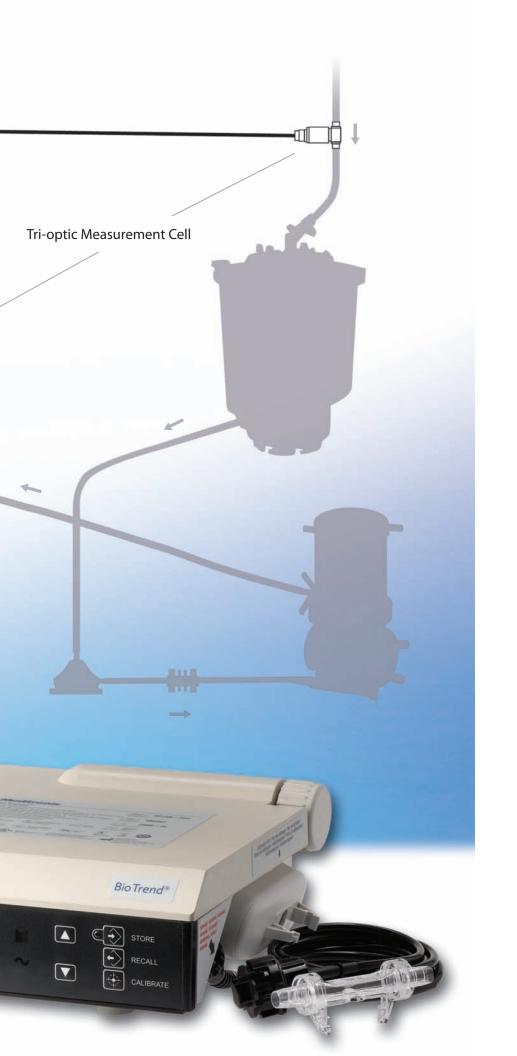
Due to this system's automated design you will not need to draw patient blood and wait for lab results in order to calibrate the BioTrend.

You may also use the optional offset adjustment feature to manually calibrate the instrument during normal operation.

The BioTrend System includes power cable, 2 fiber optic cables, battery pack and manual.

Tri-optic Measurement Cells may be ordered separately in varied sizes, coated and uncoated.





BioTrend®

Oxygen Saturation and Hematocrit System

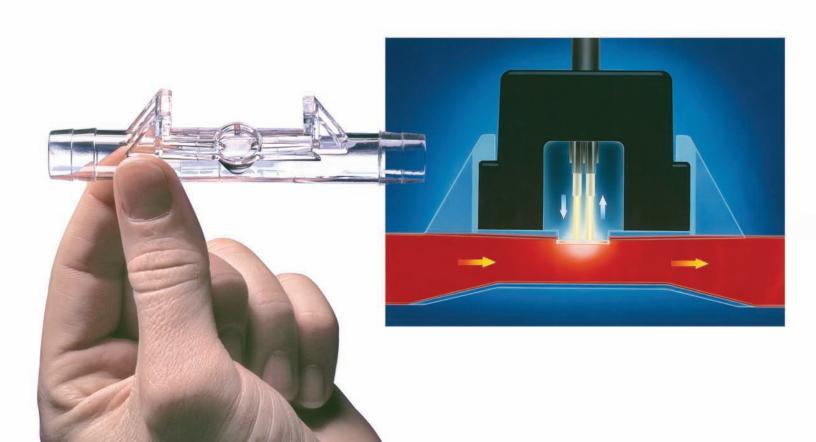
The BioTrend® Oxygen Saturation and Hematocrit System conveniently places critical data in view, at a glance. This system is designed to display hematocrit and oxygen blood saturation in real time for your convenience.

Device Technology

The BioTrend System uses fiber optic technology to transmit light to and reflected light from the clear Tri-optic Measurement Cells affixed within the extracorporeal circuit.

The system continuously monitors the light reflected by the blood as it passes through the circuit and displays the calculated venous SO_2 , arterial SO_2 and hematocrit values on the LED display.

These results are updated every 12 seconds.



Technical Information:

Oxygen saturation range:	40-99%
Hematocrit range:	16-38%
Display update:	12 seconds
Power sources:	AC power (100-240 VAC, 50-60 Hz, 13.2W, 240mA), Battery back-up
Battery life:	6 hours
Battery recharge:	24 hours to charge when connected to AC power source. AC indicator flashes while charging and remains on when fully charged
Pole mount:	Vertical, 3⁄4″ to 2″ diameter (1.91 cm to 5.08 cm)
Weight:	13 lbs. (5.9 Kg)
Dimensions:	9 34" wide x 3 5/8" high x 11" deep (24.77 cm x 9.22 cm x 27.94 cm)

Ordering Information:

Product Code	Description
95198-004	BioTrend System: Includes power cable, 2 fiber optic cables, battery pack and manual
TMC 25	Tri-optic Measurement Cell 1/4"x 1/4" (.64 cm x .64 cm)
TMC 38	Tri-optic Measurement Cell 3/8" x 3/8" (.95 cm x .95 cm)
TMC 50	Tri-optic Measurement Cell 1/2" x 1/2" (1.27 cm x 1.27 cm)
TMC 25T	Tri-optic Measurement Cell, Trillium Coated 1/4" x 1/4" (.64 cm x .64 cm)
TMC 38T	Tri-optic Measurement Cell, Trillium Coated 3/8" x 3/8" (.95 cm x .95 cm)
TMC 50T	Tri-optic Measurement Cell, Trillium Coated 1/2" x 1/2" (1.27 cm x 1.27 cm)

^{*}Tri-optic Measurement Cells are available with Carmeda® coating when ordered with custom extracorporeal circuits.

Caution:

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

Contraindications:

The BioTrend system is not intended to substitute for regular patient observation and laboratory testing. Prior to any therapeutic treatment, the oxygen saturation and hematocrit should be determined by laboratory methods. The BioTrend system has not been tested for Magnetic Resonance Imaging (MRI) compatibility and should not be used in that environment.

Warnings and Precautions:

Read all Warnings, Precautions, and Instructions for Use carefully prior to use. Failure to read and follow all instructions, or failure to observe all stated warnings, could cause serious injury or death to the patient.

Warnings:

Possible explosion hazard—do not use in the presence of flammable anesthetics or other explosive gases.

Do not autoclave, sterilize, or submerge the instrument in a liquid.

Do not autoclave, sterilize, or submerge the sensor cables in a liquid.

Do not autoclave or resterilize a Tri-optic Measurement Cell (TMC).

Do not reuse a TMC.

Do not kink or coil the sensor cables.

Do not touch the optical interfaces of the instrument, sensor cables, or $\ensuremath{\mathsf{TMC}}$

Do not drop the instrument.

Do not place any object on this instrument.

Do not attempt any repair of the instrument. Class 1 LED product.

Precautions:

The BioTrend system is an on-line monitoring instrument not intended to substitute for regular patient observation and laboratory testing. Prior to any therapeutic treatment, the oxygen saturation and hematocrit should be determined by laboratory methods.

An electrical shock hazard exists when the instrument housing is open. Refer servicing to a qualified Medtronic service representative.

Oxygen saturation levels are known to be affected by fetal hemoglobin. The effect of fetal hemoglobin on the BioTrend system has not been quantified.

For more information contact your local Medtronic Sales Representative or call Customer Service toll-free at 1-800-328-1357.

www.medtronic.com

World Headquarters Medtronic, Inc.

710 Medtronic Parkway Minneapolis, MN 55432-5604 USA

Tel: (763) 514-4000 Fax: (763) 514-4879

Medtronic USA, Inc. Toll-free: 1 (800) 328-2518 (24-hour technical support for physicians and medical professionals)

Europe

Medtronic International Trading Sàrl

Route du Molliau 31 Case postale 84 CH-1131 Tolochenaz Switzerland Tel: 41.21.802.7000 Fax: 41.21.802.7900

Canada

Medtronic of Canada Ltd. 99 Hereford Street Brampton, Ontario L6Y 0R3 Canada Tel: (905) 460-3800 Fax: (905) 826-6620

Toll-free: 1 (800) 268-5346

enquiryap@medtronic.com

Medtronic USA, Inc. Doral Corporate Center II 3750 NW 87th Avenue Suite 700 Miami, FL 33178

Medtronic International, Ltd.

Suite 1602 16/F, Manulife Plaza

The Lee Gardens, 33 Hysan Avenue

USA Tel: (30

Asia

Causeway Bay Hong Kong Tel: (852) 2891 4068

Latin America

Fax: (852) 2591 0313

Tel: (305) 500-9328 Fax: (786) 709-4244

LifeLine

CardioVascular Technical Support

Tel: (877) 526-7890 Tel: (763) 526-7890 Fax: (763) 526-7888

E-mail: rs.cstechsupport@medtronic.com

