

MyoFlex

MOVEMENT SENSOR

MyoFlex Movement Sensor

**Dymedix Diagnostics Inc.**

5985 Rice Creek Parkway
Shoreview, MN 55126
USA

www.dymedix.com

Phone : 888-212-1100
763-789-8280

email: info@dymedix.com

Authorized European Representative:

MedEnvoy Global B.V.
Prinses Margrietplantsoen 33
Suite 123
2595AM The Hague
The Netherlands



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

CAUTION STATEMENTS

This product is for diagnostic purposes only and is not to be used in life supporting or life sustaining situations. Any serious incident that has occurred in relation to this device should be reported to Dymedix Diagnostics and the competent authority of the Member State in which the user and/or patient is established.

FEATURES AND INTENDED USE:

The Dymedix MyoFlex Movement Sensor has been designed to detect physiological movement during neurological testing procedures. These sensors produce electrical signals when affected by movement. The signal size can be adjusted by changing the settings on the recording equipment. The use of a reusable Movement Sensor Interface Cable is required with this sensor. Features and specifications of this device are subject to change without notice.

INSTRUMENT CONNECTIONS & SETTINGS

Refer to the recording device operator's manual for direction in determining proper connection and settings. Response may be affected by variables such as sensor placement and sleep position.

SUGGESTED AMPLIFIER SETTINGS:

High frequency filter: 100 Hz
Low frequency filter: 10 Hz
60 Hz filter: On

Symbol	Definition of Symbol
	Latex Free
	Do not re-use
	Federal Law (USA) restricts this device to sale by or on the order of a physician.
	Medical Device
	Consult instructions for use
	Date of Manufacture Expressed as: YYYYMMDD
	Manufactured by

**PRECAUTIONS**

1. Store sensor at room temperature.
2. Do not sterilize sensor.
3. Connect the sensor to electrically isolated equipment.

PATIENT APPLICATION

1. Remove the release liner from the back of the MyoFlex Movement Sensor to expose the adhesive surface.
2. Apply the sensor to clean and unbroken skin on the area of the patient you would like to record movement.
3. Plug sensors into the interface cables and then plug the interface cables into the recording device inputs.

SENSOR REMOVAL INSTRUCTIONS

1. Remove the MyoFlex Movement Sensor from patient
2. Disconnect the Interface Cables from the sensors.
3. Remove the Interface Cables from the recording device
4. The adhesive sensors should be discarded.

Caution: Firmly hold connectors to remove. Pulling wires will cause damage that is not covered by warranty.

WARRANTY

Dymedix warrants its sensors to be free from defects in materials and workmanship and to perform satisfactorily for one (1) year from the date of purchase. Should the sensor fail, the sole liability of Dymedix is limited to replacement of the product with no charge for parts or labor. Under no circumstances shall Dymedix be liable for any consequential damage arising from the use of, or the inability to use this product. This warranty is rendered void for conditions resulting from: damage, marginal performance or malfunctions caused by reuse, misuse, abuse, neglect, improper amplification settings, improper line voltage, power fluctuations, or any adverse environmental conditions, tampering, unauthorized modifications, adjustments or repairs to the product or its accessories. This warranty is in lieu of all other warranties, expressed or implied and is extended only to the original purchaser.