

# PRESSURE BIOFEEDBACK



**BIONEN S.A.S.**

Via P. Petrocchi, 42/1  
50127 Firenze – Italia  
[www.bionen.it](http://www.bionen.it)

**BIONEN**  
medical devices

Biofeedback is based on the principle that any normally involuntary function of the body, can be controlled at will, if it is monitored and brought to the knowledge of the individual.

The objective of BIONEN Pressure Biofeedback is to make the patient aware, by visual signals, of visceral or motor functions that normally he cannot control at will.

The application of biofeedback in fecal or urinary stress incontinence aims to teach the patient the mechanism of sphincter contraction and improve its strength and durability.

## GENERAL INFORMATION - REF.: 0032.001

**Intended use:** Rehabilitation of the pelvic floor muscles. Domestic use.

The device is used for the rehabilitation of the pelvic-perineum muscles to treat pathologies such as dyssynergia and hypotonia/hypertonia of the pelvic floor muscles, fecal or urinary stress incontinence and constipation.

### Precautions:

- the device is to be used only following doctor's advice/guidance and only after proper training.
- Use a monopatient pressure certified probe with luer-lock connection.
- Follow the instructions of the anal o vaginal probe used.
- Follow the Instruction of use of the device

**Power:** 2 batteries of 1,5 V type AA. Change the batteries if it is not possible to switch on the device.

**Cleaning instructions:** Particular attention is not required. Cleaning the device with a damp cloth after use is advised. Don't dip the device into any liquid. Follow the manufacturer's instructions for the cleaning of the probe.

**Disinfection:** Disinfect by using a cloth dampened with one of the following solutions: Amocid, Lysoformin, Alhyndex, IndicinGG

or equivalent products, at high concentration, without immersing the device into the liquids. Use the products according to the directives and regulations of the country in which the device is used

**Sterilization:** NON STERILE device. Sterilization is not necessary.

**Lifetime:** After 5 years from sale, the proper functionality of the device is not guaranteed.

**Storage:** Particular precautions for storing are not necessary but it is advisable to keep the device in its box.

Remove primary battery if equipment is not likely to be used for some time.

**Packaging:** cardboard box

**Waste disposal:** Disposal should be in accordance with the Directive 2002/96/EC - RAEE (Waste Electrical and Electronic). At the end of its useful life, the device should be disposed of at a public collection centre or returned to the distributor when buying a new device of the same type and for the same functions. This procedure of separate collection of electrical and electronic equipment is made in accordance with a European Community environmental policy with the objectives of preserving, protecting and improving the quality of the environment and to avoid potentially harmful effects on human health due to the presence of dangerous substances in such equipment or to misuse of them or parts thereof.

**Attention!** An incorrect disposal of electrical and electronic devices could result in penalties.

**Regulation:** class IIa device

Comply with the MDD 93/42/CEE (D.L. 46/97) and has been manufactured according to the procedures of BIONEN Quality System certified ISO 13485.