# OPERATING INSTRUCTIONS

# Bodyflow™

## ONE CHANNEL VERSION

Revision: 1.0
Valid from Software Version 1.0

CE 1275

01560 AU

bodyflow™

## Legal Notice



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DISCLAIMER

The Bodyflow™ portable stimulation unit ("the product") is manufactured in Germany by PHYSIOMED ELEKTROMEDIZIN AG and is distributed in Australia by its distributor, Bodyflow™ International PTY LTD.

Bodyflow™ International PTY LTD has endeavoured to ensure that the data analysis and assessment of such data and other information as provided by the manufacturer is accurate.

Any projected information contained in the operating instructions is based on Bodyflow's or PHYSIOMED ELEKTROMEDIZIN AG's analysis and subjective estimates and assumptions and may be about circumstances, scenarios and events which may take place. As such, no representations are made by Bodyflow™ International PTY LTD or PHYSIOMED ELEKTROMEDIZIN AG as to the accuracy of such information.

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Bodyflow™ is made in Germany in compliance with the quality requirements of ISO 9001 and the applicable safety standards and regulations of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

A conformity check acc. to Annex II, approved by the notified body 1275, was carried out.

# Table of Contents

# Chapter 1 Introduction

With your Bodyflow™ you have acquired a high-quality and extremely versatile unit for stimulation current therapy. The instrument will only show its true potential, however, if you are well informed about its functions. For this reason, carefully read the Operating Instructions and familiarize yourself with the use of the instrument.

## 1.1 Conventions Used

Please note the following typographical conventions in these Operating Instructions:

- Cross references and important terms used for the first time in this document are written in *italic*.
- Names of menus and symbols on the display are written in **bold typeface**.

Paragraphs that deserve special attention are highlighted in the following way:

| Symbol | Type | Meaning |
|---|---|---|
| | Tip | Intended to give you some extra hints for more convenient operation |
| | Note | Provides background information for better understanding |
| | Important | Prevents misunderstandings that might lead to limited operation of the instrument or insufficient therapeutical results |
| | Caution | Alerts you in case of possible damage to the instrument or risks of injury |

## 1.2 General Notes

The instrument complies with the technical specifications of IEC 601, VDE 0750 and is assigned to class IIa according to the Council Directive concerning Medical Devices.

The instrument may only be operated by qualified personnel who have undergone special training. You must operate the instrument properly, i.e. in accordance with the Operating Instructions.

It is not intended for operation in explosion hazard zones or hydrotherapy rooms. Drastic temperature changes should be avoided, since condensation could be caused within the instrument. Do not start up the instrument until it is in temperature equilibrium with its environment!

Operating the instrument in the proximity (e.g. 1 m) of a short-wave or micro-wave therapy unit may cause output irregularities and should be avoided for this reason. Simultaneous connection of the patient to high-frequency surgical instrument should also be avoided.

Using the electrodes near the chest can increase the risk of heart beat irregularities.

## 1.3 Instrument Description

Bodyflow™ is a portable stimulation current therapy unit. The device is equipped with a rechargeable battery and is intended to be used as a mobile unit, e.g. in situations where no connection to the mains is available. This unit can only be used on battery power and not whilst plugged into mains power.

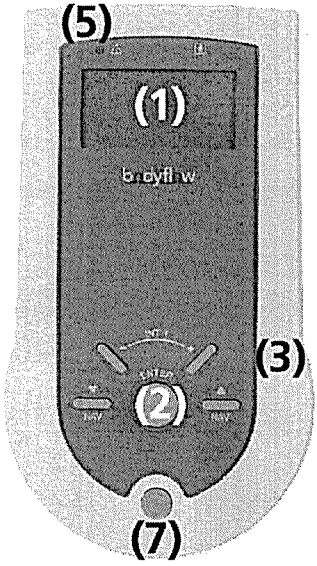
The function of Bodyflow™ is controlled by a microprocessor. Essential components are permanently controlled by the processor and thus malfunctions are prevented. After switching on, all instrument functions are checked during an automatic self-test routine.

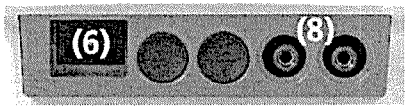
The instrument complies with all current safety standards. It meets the requirements of the EC directive concerning medical devices (93/42/EEC) and is therefore CE-labelled.

Bodyflow™ has two modes of operation:

- *Treatment*: In this mode, the instrument is disconnected from the mains. When the battery charger is plugged in, the instrument cannot be switched on and treatment is not possible. Plugging in the battery charger into the instrument during treatment has the consequence that treatment is being interrupted and the intensity will be automatically turned down to zero and the instrument switches off.
- *Charging*: Charging is only possible when the device is switched off (refer to *Mains and Battery Operation* on page 8).

## 1.4 Instrument Overview




**Legend**

| | | | |
|---|---|---|---|
| 1 | Display | 2 | Function Keys |
| 3 | Intensity Control | | |
| 5 | Output Indicator | 6 | Power Connector |
| 7 | Power Switch | 8 | Patient Lead Connector |

**Symbols**

| | |
|---|---|
|  | Type BF component, not connected to protective ground wire! |

CAUTION! Please refer to the operating instructions and consider the physiological effects!

## 1.5 Application

Bodyflow™ was designed for the following applications:

*Stimulation current therapy*

- Pain relief therapy (analgesia)
- Circulatory stimulation
- Mobilization
- Oedema resorption

**Important**

The instrument may only be operated by qualified personnel who have undergone special training!

You must read all instructions prior to using this device!

## 1.6 Contraindications (When not to Use this Device)

Contraindications to stimulation current therapy:

- Highly inflammatory, fever-prone disorders
- Pregnancy
- Patients with cardiac pacemakers or other implanted stimulators
- Malignant tumours
- Skin lesions
- Implants containing metal parts within the area of treatment

# Chapter 2 Controls and Indicators

The design of Bodyflow™ allows for easy operation. Because of its small size, the instrument is very easy to transport. It has been designed for operation both inside and outside of therapy rooms, and is fed by rechargeable batteries for that reason (refer to *Mains and Battery Operation* on page 8).

All controls and indicators are integrated into the housing, thus allowing for easy cleaning of the instrument's surface and protecting it from dust.

The instrument's microprocessor monitors the safety-related components, prevents from malfunctions and checks the instrument after switching it on.

## 2.1 Display <1>

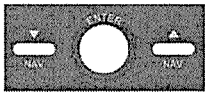

The **Display <1>** shows all menu items including the therapy parameters of the instrument. You can select the parameters using the **Function Keys <2>**.

### 2.1.1 Symbols in the Upper Status Bar

The upper status bar shows the following symbols:

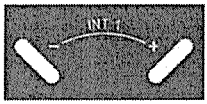
| | |
|---|---|
| | Button to open the popup menu |
| Standard | Currently selected menu |
| | State of charge of the battery (refer to *Mains and Battery Operation* on page 8) |

## 2.2 Function Keys <2>




The **function keys <2>** are used to select the therapy parameters and to operate the instrument. After switching on the instrument, the **Display <1>** shows the start screen. You can now access the desired therapy program by pressing the right or left key. To select an item, simply press the **ENTER** button in the middle.

## 2.3 Intensity Control <3>




The **Intensity Control <3>** serves to set the intensity in steps of 0.5 mA. When turning up the intensity, the therapy timer in the **Display <1>** will be started as well.

**Convenient Reduction of Intensity**

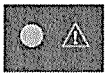
The intensity can be turned down to 0.0 mA automatically: To do so, press the **Intensity Control <3>** until you hear a short signal. Afterwards, the instrument will reduce the intensity to zero automatically.

### 2.3.1 Automatic Output Current Switch-off

Bodyflow™ features an automatic output current switch-off, activated in case the current flow of the electrodes is interrupted (electrode falls off or is disconnected from the instrument). The symbol ⟨⟩⟨⟩ will appear in alternation with the intensity on the **Display <1>** and the current will be automatically turned down to a minimum basic current in the respective circuit. The timer stops the therapy time.

To eliminate the error, you have to press **Intensity Control <3>** one time to reduce the intensity to zero. The message will disappear and you can increase the intensity again.

## 2.4 Output Indicator <5>



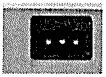
The **Output Indicator <5>** tells you to be cautious when handling the electrodes.

**Caution**

When the **Output Indicator <5>** flashes, the **Patient Lead Connector <8>** is under voltage!

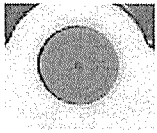
Make sure you do not touch the electrodes when the current is turned up! Touching the electrodes with your fingers may startle as the electrodes need to disperse the current evenly!

## 2.5 Power Connector <6>



The **Power Connector <6>** is located at the front side of the instrument. Here, you plug in the supplied battery charger if you want to charge the batteries.

## 2.6 Power Switch <7>



The **Power Switch <7>** is on the bottom of the instrument's upper side. By means of this switch, you can switch the instrument on and off. After switching on, a selftest is automatically carried out by the instrument (refer to *Function Check* on page 10).

## 2.7 Patient Lead Connector <9>

The **Patient Lead Connector <8>** on the front side of the instrument serves to plug in the electrodes.

The polarity is of no importance, since the instrument operates in biphase mode.

# Chapter 3 Operation of the Device

The operating steps not directly relating to the therapy are described in the following paragraphs.

## 3.1 Mains and Battery Operation

At battery operation, the battery has to be fully charged before operating it for the first time. The typical life expectancy of this battery and it's recharge life is 500 cycles or recharges.

The charging status of the batteries is displayed on the **Display <1>**:

| Battery Charge | Symbol |
|---|---|
| 0% |  |
| 25% |  |
| 50% |  |
| 75% |  |
| 100% |  |

**How to Charge the Battery**
If you want to charge the battery, proceed as follows:

(1) Plug the supplied battery charger into the **Power Connector <6>** on the front side of the device.
(2) The batteries are being charged. When the batteries are completely discharged, the charging procedure will take approx. 3 hours.

> **Important**
>
> In order to ensure a long battery life, the batteries must be charged completely when first charged. The first charging procedure should not be interrupted!

### 3.1.1 Notes on Handling the Batteries

If the battery capacity is very low during operation, the 3-step warning system is activated:

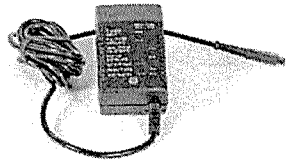
(a) The charging status symbol flashes.
(b) An acoustic signal sounds every second and the charging status symbol flashes. The intensity is reduced prematurely.
(c) The device shuts down to avoid complete discharging of the batteries.

In this case, recharge the battery, as described in section *How to Charge the Battery* on page 8.

> **Important**
>
> If the unit is not used for a longer period of time, please fully charge the battery once a month. This will help to avoid exhaustive discharge.

### 3.1.2 Battery Charger

The supplied battery charger (Ref. No 00584) has an LED to indicate the current state of the batteries.



*Battery Charger*

Depending on the current state of the batteries, the LED is illuminated or flashing in green or yellow. This has the following significance:

| State of Battery Charger | LED Light Code |
|---|---|
| Standby | LED is permanently yellow |
| Precharge | LED flashes slowly in yellow |
| Rapid Charge | LED flashes quickly in green |
| Maintain | LED flashes slowly in green |
| Error | LED flashes quickly in yellow |
| Ready | LED is permanently green |
| Wait | LED flashes slowly in green and yellow (alternating) |

**Note**

The battery charger can be equipped with different primary adaptors to match the line voltage of the destination country. One primary adaptor for the respective country is in the scope of delivery. Refer to *Available Accessories* on page 18 for available primary adaptors.

### 3.1.3 Economy Mode

The unit automatically switches over to the economy mode to save power. This will occur after approx. 20 seconds. The **Display <1>** is no longer illuminated. Pressing any key will re-activate the illumination.

## 3.2 Start-up of the Device

Before you can perform the first treatment with the Bodyflow™, you have to start the device up accordingly.

**Important**

When you want to perform a treatment, please ensure that the battery charger is unplugged! Due to safety reasons, performing a treatment and charging the battery cannot take place at the same time! This device will not work when plugged into mains power. It is intended for battery operation only!

**How to Start up the Device**
If you want to start up the device, proceed as follows:

(1) Ensure that the battery is charged (refer to *How to Charge the Battery* on page 8).
(2) Plug the electrodes into the **Patient Lead Connector <8>**.
(3) Switch the device on with the **Power Switch <7>**.
The device will conduct an automatic function check which tests all functions and start values. An acoustic signal sounds.
The device is now ready. The start screen is displayed.

**Caution**

Make sure you do not touch the electrodes when the current is turned up! Touching the electrodes with your fingers may startle as the electrodes need to disperse the current evenly!

## 3.3 Function Check

If you are not sure whether your Bodyflow™ is working properly, you can perform a self-test.

**How to Perform an Automatic Self-Test**
If you want to perform an automatic self-test, proceed as follows:

(1) Use the **Power Switch <7>** to switch the device off and on again.
Please contact Bodyflow™ International PTY LTD (call +61 1300 2639 356) or the manufacturer of this device (refer to *Manufacturer* on page 17) if the monitoring note does not disappear even after several self tests! NEVER perform a treatment when the proper function of the instrument is not assured!
The device is now ready. The start screen is displayed.

## 3.4 Monitoring Notes

If a functional error is detected during the automatic function check or during operation, a corresponding note is displayed in the **Display <1>**. A numeric error code will be shown, e.g. **<Monitoring Note 205>**. These error codes simplify localizing and eliminating errors. Operation of the unit will be interrupted and the stimulation current output is switched off.

In case of a monitoring note, first perform a self-test once or several times (refer to *Function Check* on page 10), and check whether the monitoring note is still displayed afterwards.

**Important**

Please contact Bodyflow™ International PTY LTD (call +61 1300 2639 356) or the manufacturer of this device (refer to *Manufacturer* on page 17) if the monitoring note does not disappear even after several self tests! NEVER perform a treatment when the proper function of the instrument is not assured!

# Chapter 4 Therapy with Stimulation Current

In this chapter, you will find general information on the therapy with stimulation current and notes to apply electrodes.

Furthermore, the properties and operating steps of different types of treatment with Bodyflow™ are described.

**Important**

Always switch on the instrument BEFORE you attach electrodes to the patient!

Only switch off the instrument AFTER you have removed the electrodes from the patient!

**Caution**

Over use of this device should be avoided. If you are unsure of appropriate usage times please consult your medical practitioner!

## 4.1 Safety Precautions when Attaching Electrodes

Please observe the following safety precautions when attaching electrodes:

- Never apply the electrodes to skin areas which have injuries, abrasions or inflammations!
- Always use the largest electrodes possible!
- Check the electrodes regularly and have any damaged parts repaired or replaced!
- Never use electrodes that are damaged or show any signs of malfunction!

## 4.2 Safety Precautions for Stimulation Current Intensity

Please observe the following safety precautions when adjusting the intensity of the stimulation current applied to the patient:

- Always bear in mind that the patient may display an altered sensitivity, and may therefore not be properly aware of the current intensity.
- Be especially careful in measuring doses for blonde, light-skinned patients, and for thin-skinned patients.
- Explain to patients that if they experience unpleasant or even burning sensations under one of the electrodes, they must point this out. The sensation will vary from person to person.
- If you use electrodes of various different sizes during a treatment, the smaller of the two electrodes, the so-called "active electrode", is always considered when measuring the intensity.

## 4.3 Preparations and Attaching the Electrodes

To prepare the electrodes, proceed as follows:

(1) Prior to attaching the electrodes, make sure that the intensity is turned down to zero.
(2) Plug the electrodes into the **Patient Lead Connector <8>**.

> **Caution**
>
> Make sure you do not touch the electrodes when the current is turned up! Touching the electrodes with your fingers may startle as the electrodes need to disperse the current evenly!

(3) Prior to attaching the electrodes, check whether the patient's skin shows scars or lesions. Always avoid such areas!
(4) Attach the adhesive electrodes to the patient. Use only electrodes that stick well, i.e. with the whole area!

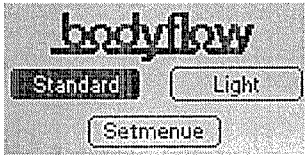
> **Caution**
>
> It is not permissible to exceed an effective current density of 2 mA/cm²! For that reason you should always use electrodes of sufficient size and attach them most carefully.
>
> If you use electrodes of various different sizes during a treatment, the smaller of the two electrodes, the so-called "active electrode", is always decisive when measuring the intensity!
>
> Only use electrodes recommended by Bodyflow™ International PTY LTD (refer to *Available Accessories* on page 18)!

## 4.4 Performing a Treatment

Bodyflow™ offers two different programs for stimulation current therapy.

**How to Perform a Treatment**
If you want to perform a treatment, proceed as follows:

(1) Press the **Power Switch <7>** to switch the device on. The start screen is displayed:




*Start Screen*

(2) Fix the electrodes at the points of treatment.
(3) On the **Display <1>**, select the desired program (**Standard** or **Light**) and press the **ENTER** key. The therapy menu is displayed with the therapy time preset.


*Standard Program*

(4) Press the **NAV** buttons to change the therapy time in steps of one minute (max. 90 min). Press **ENTER** to confirm.

(5) Slowly turn up the intensity with the **Intensity Control <3>**. The therapy time elapses.

**Caution**

Make sure you do not touch the electrodes when the current is turned up! Touching the electrodes with your fingers may startle as the electrodes need to disperse the current evenly!

(6) After treatment, an acoustic signal will be issued. The intensity is turned down to zero automatically. Remove the electrodes.

**Note**

You can open a popup menu if you want to stop a treatment and return to the start screen:

Press the **ENTER** button. A popup menu with the options Stop and Return will appear.

- Click on **Stop** to stop the current treatment.
- Click on **Return** to return to the start screen.
- Click on the symbol on the top left to close this popup and to return to the current treatment.

# Appendix A Annex

## A.1 Service, Repairs, Maintenance

The manufacturer is only obliged to guarantee the safety features of the instrument in its original state. In principle, the instrument must be operated in accordance with the Operating Instructions.

Repairs to the instrument may only be performed by parties duly authorised by the manufacturer. Any repairs performed by an authorised agent must be accompanied by written certification, describing the nature and extent of the repairs undertaken, as applicable with details regarding changes to nominal operating values or the operational range. he certification must also contain the date performed, the name of the repair company and the signature of the repairman. When defective, components affecting the safe operation of the instrument must be replaced by manufacturer's original parts. Upon request, wiring diagrams, parts lists and service instructions can be made available to qualified technical personnel employed by the customer.

We recommend having the instrument, including all accessories, serviced at regular intervals.

**Important**

Warranty repairs will be void if the device is not serviced every 24 months. Please contact Bodyflow™ International PTY LTD or the manufacturer (refer to *Manufacturer* on page 17) for having the device serviced!

## A.2 Cleaning and Disinfection

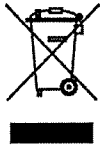
Clean accessories and instrument on a regular basis with a disinfecting agent based on aldehyde. By any means, switch off the device prior to this and pull the mains plug.

Use a soft sponge cloth for cleaning. Be careful that no liquid substances invade the instrument.

Regularly check your accessories and replace them if necessary.

## A.3 Disposal

After the service life of the instrument, dispose it in conformance with the applicable regulations for environment protection.



*Environment Protection Symbol*

## A.4 Setmenue

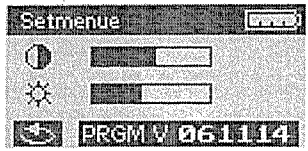
In the *Setmenue*, you can adjust the following device parameters:

| Symbol | Meaning |
|---|---|
| ◑ | Contrast of the **Display <1>** |
| ☼ | Brightness of the **Display <1>** |
| ⮌ | Back to start screen |

**How to Change the Basic Settings**

(1) Switch the device on.

(2) On the start screen, click on the **Setmenu** symbol.
You get to the *Setmenu*.




*Basic Settings*

(3) Press the **function keys <2>** to access the symbol for the parameter you want to change (e.g. for the contrast ◑ ) and press the **ENTER** key.
The selected symbol flashes.

(4) Press the **function keys <2>** until the parameter has the desired value.

(5) Press the **ENTER** key.
If you want to return to the start screen, select the ⮌ symbol. The changed settings are immediately effective.

## A.5 Technical Data

**Treatment**

| | |
|---|---|
| Protection class acc. to VDE 0750 / IEC 601 | Battery Mode Only, Type BF |

**Charging**

| | |
|---|---|
| Protection class acc. to VDE 0750 / IEC 601 | II, Type BF |
| Input voltage | 17 VDC |

| | |
|---|---|
| Input current | 0.8 ADC |

**General Technical Data**

| | |
|---|---|
| CE characterization | acc. to Council Directive concerning medical devices (93/42 EEC) |
| Class acc. to Council Directive concerning medical devices | IIa |
| Ambient temperature (operation) | + 10 °C ... + 40 °C |
| Storage temperature | + 10 °C ... + 40 °C |
| Dimensions (W x H x D) | 17.5 cm x 4.5 cm x 10 cm |
| Weight | 0.485 kg |

**Battery Charger**

| | |
|---|---|
| Type (to be used exclusively) | Switchmode Charger FW 7219 / NI 4-10 NTC |
| Mains supply | 100 ... 240 VAC |
| Input current | 0.1 ... 0.3 A |
| Mains frequency | 50 ... 60 Hz |
| Output voltage | 17 VDC |
| Output current | 0.8 ADC |

## A.5.1 Manufacturer

PHYSIOMED ELEKTROMEDIZIN AG
Hutweide 10
91220 Schnaittach/Laipersdorf
Germany

# Appendix B Scope of Delivery and Accessories

**Important**

For safety reasons, the instrument is to be used exclusively with original accessories. The use of other manufacturers' accessories is at the user's risk!

## B.1 Scope of Delivery

Bodyflow™ is supplied with the following accessories:

| Ref. No. | Designation | Quantity |
|---|---|---|
| 00584 | Battery Charger | 1 |
| 00503 | Connection Cable *Bodyflow* (pair, red) | 2 |
| 00545 | *Bodyflow* Adhesive Electrode 8 x 13 cm; set of 2 | 2 |
| | Primary Adaptor (according to destination) | 1 |
| 00579 | Transportation Bag *Bodyflow* | 1 |
| 00506 | Y Junction Cable *Bodyflow*, red | 2 |
| 01560 | Operating Instructions (English) | 1 |

## B.2 Available Accessories

For Bodyflow™, the following additional accessories are available:

| Art.-No. | Designation |
|---|---|
| 00584 | Battery Charger |
| 00547 | *Bodyflow* Adhesive Electrode 5 x 5 cm; set of 4 |
| 00548 | *Bodyflow* Adhesive Electrode 5 x 9 cm; set of 4 |
| 00545 | *Bodyflow* Adhesive Electrode 8 x 13 cm; set of 2 |
| 00546 | *Bodyflow* Adhesive Electrode Ø 3.2 cm; set of 4 |
| 00503 | Connection Cable *Bodyflow* (pair, red) |
| 00504 | Connection Cable *Bodyflow* (pair, black) |
| 00514 | Primary Adaptor AU |
| 00512 | Primary Adaptor EU |
| 00513 | Primary Adaptor UK |
| 00515 | Primary Adaptor US/JP |
| 00579 | Transportation Bag *Bodyflow* |

# Appendix C Supplementary Documents

## C.1 Manufacturer's Recommendations

PHYSIOMED®
ELEKTROMEDIZIN

MANUFACTURER'S RECOMMENDATIONS
SAFTEY REGULATIONS CONTROL
according to Medical Devices Directive

INSTRUMENT: **bodyflow™-P1CH**
MANUFACTURER: PHYSIOMED ELEKTROMEDIZIN AG

The instrument has to undergo a safety regulation control every 24 months.

EXTENT:

| | | | |
|---|---|---|---|
| (1) | Visual inspection of the instrument, accessories and accompanying papers | | |
| (2) | Function of controls and indicators | | |
| (3) | Functional testing of instrument and accessories | | |
| (4) | Curve shape of output parameters | | |
| (5) | Output current at the patient connector | | |
| (6) | Electrical safety according to VDE 0751 | | |
| | | Limiting value according to VDE 0751 | Value first measured NEW INSTRUMENT |
| (6.1) | Earth-conductor resistance (incl. power cable 3 m) | 0.3 Ohm | |
| (6.2) | Substitute device leakage current | 1.0 mA | |
| (6.3) | Substitute patient leakage current | 5.0 mA | 0.100 mA |

## C.2 Declaration of Conformity

PHYSIOMED®
ELEKTROMEDIZIN

CE DECLARATION OF CONFORMITY

| | |
|---|---|
| MANUFACTURER: | PHYSIOMED ELEKTROMEDIZIN AG<br>Hutweide 10<br>91220 Schnaittach/Laipersdorf<br>Germany |
| TYPE: | **bodyflow™-P1CH** |
| PRODUCT: | Stimulation Current Instrument Class IIa |

The above instrument complies with the Medical Devices Directive 93/42/EEC.

A conformity check acc. to Annex II, approved by the notified body 1275, was carried out.

CE Label: CE 1275

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## W