



DEEP OSCILLATION® Personal

OPERATING INSTRUCTIONS

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DEEP OSCILLATION® Personal is a registered trademark of PHYSIOMED ELEKTROMEDIZIN AG. The therapy mode has been patented worldwide.

DEEP OSCILLATION® Personal is made in Germany in compliance with the quality requirements of EN ISO 13485:2003+AC:2007, EN ISO 9001:2008 and the applicable safety standards and regulations of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

The compliance with the regulations mentioned here is indicated by the CE label on the instrument. The declaration of conformity might be requested from the manufacturer at the address given above.

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

Last updated on July 12, 2010.

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Chapter 1 Introduction





With DEEP OSCILLATION® Personal you have acquired an extremely versatile deep oscillation system. The instrument will only show its true potential, however, if you are well informed about its functions. For this reason, carefully read these Operating Instructions and familiarise 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 *italics*.
- 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 cases of possible damage to the instrument or risks of injury

1.2 General Notes

The instrument may only be operated in dry rooms. It complies with the technical specifications of IEC 60601, VDE 0750 and is assigned to class IIa according to the Council Directive 93/42/EEC concerning Medical Devices.

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 thermal equilibrium with its environment!

The instrument is to be operated properly, i.e. in accordance with the Operating Instructions. 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, as well as simultaneous connection of the patient to high-frequency surgical instrument.

1.3 Instrument Overview

Front Panel

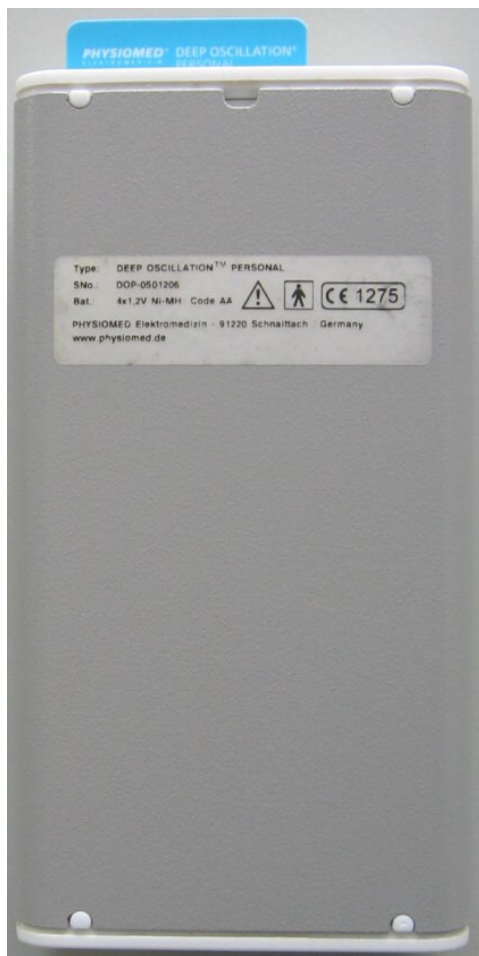


Rear Face (Back Cover removed)









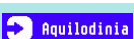


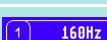

Legend

1	Display	4	Card Reader
2	Data Selector	5	Battery Compartment
3	Ports	6	Control Light
7	Charger Socket		

Rear Face (with Back Cover)**Carrying Case (Front and Rear Face)****Bottom**

1.4 Symbols in the Display

You find the following symbols in the **Display <1>**:

	Battery Indicator (refer to <i>Battery Operation</i> on page 8)
	Setup Menu (refer to <i>Basic Settings</i> on page 19)
	Confirm Settings
	Contrast of the Display <1> (refer to <i>Basic Settings</i> on page 19)
	Bar View (Contrast, Intensity), here e.g. 50%
	Button Back
	Indications Menu
	Page Selection for Information Pages
	Position Marker, here: Page 1 of 3
	Therapy Parameters (Therapy Time, Therapy Frequency, Therapy Phase)
	Timer Symbol (to Adjust the Therapy Time)

1.5 Instrument Description

DEEP OSCILLATION® Personal is a deep oscillation system which is successfully used in various areas of medicine. For the individual areas, special chipcards are available.

DEEP OSCILLATION® Personal has two modes of operation:

- **Treatment:** In this mode, the instrument is separated from the mains. When the battery charger is plugged in, the instrument cannot be switched on and treatment can not be continued. Connecting the battery charger with the mains will reduce the intensity automatically to zero, treatment will be interrupted, and the instrument will be switched off.
- **Charging:** While charging, treatment is not possible.



Caution

During the charging procedure, the patient must neither be connected with the titanium neutral element, nor with the hand applicator!

1.6 Application

The function of DEEP OSCILLATION® Personal is based on a pulsed electrostatic field which is built up in the patient's body region to be treated. Its frequency changes between 5 - 250 Hz, according to the selected indication. Due to the movement of the hand applicator, a vibrating or pumping effect with deep impact is induced in the patient's tissue.

Treatment with DEEP OSCILLATION® Personal has the following positive effects on the treated tissue:

- trophic enhancement

- muscle relaxation
- pain reduction
- edema reduction
- inhibition of inflammations
- enhancement of wound healing

1.7 Contraindications

Therapy with DEEP OSCILLATION® Personal is not indicated in the following cases:

- acute infections
- acute inflammations with participation of pathogenic agents
- active tuberculosis
- acute venous diseases (untreated thromboses)
- untreated malignant processes
- erysipelas
- patients and therapists with cardiac pacemakers and other electronic implants
- heart disorders and diseases, especially cardiac insufficiency, decompensated cardiac edema, and cardiac arrhythmia
- pregnancy
- hypersensitivity to electrostatic fields
- infectious skin diseases

Chapter 2 Controls and Indicators

The design of DEEP OSCILLATION® Personal allows for easy operation, in combination with a variety of functions. Because of its small size, the instrument is very easy to transport. It has been designed for operation also outside of therapy rooms, and is fed by rechargeable batteries for that reason.

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 erroneous operation and checks the instrument after switching it on.

2.1 Function of Controls and Indicators

The following section introduces the individual indicators and controls of DEEP OSCILLATION® Personal. The numbers in angle brackets refer to the *Instrument Overview* on page 3.

2.1.1 Display <1>



Display <1>

In the **Display <1>** the available options or therapy parameters are shown, depending on the context.

The battery symbol on the bottom left shows you the current state of charge of the batteries (also refer to *Battery Operation* on page 8).

You can select a parameter using the **Data Selector <2>**.

2.1.2 Data Selector <2>



Data Selector <2>

The **Data Selector <2>** serves to select the therapy parameters shown in the **Display <1>** as well as to adjust the intensity.

You can switch between the individual options by rotating the selector and call the respective function by pressing it.

2.1.3 Ports <3>



Ports <3>

The **Ports <3>** serve to connect the supplied cables for the hand applicator and the adhesive or neutral electrode with the instrument.

You can find instructions on how to connect the cables in section [How to Prepare Treatment](#) on page 15.

2.1.4 Card Reader <4>



Card Reader <4>

The **Card Reader <4>** serves to insert the therapy card which enables access to the user menus, and on which the therapy parameters are stored. The therapy card has to be inserted with *with the chip side facing down*.

2.1.5 Battery Compartment <5>



Battery Compartment <5>

The **Battery Compartment <5>** receives the rechargeable batteries and connects them with the instrument. It is protected by a rear cover made of metal, which is attached to the instruments housing by three magnets.

2.1.6 Control Light <6>

The **Control Light <6>** under the **Data Selector <2>** is on as soon as the intensity is being increased. In case of low therapy frequency, the light is flashing in sync with the pulses. When the electrostatic field is cut short, the light goes out even with non-zero intensity. The **Control Light <6>** can also be used to check the cables (refer to [Cable Check](#) on page 12).

2.1.7 Charger Socket <7>



The **Charger Socket <7>** can be found on the bottom of the instrument. The supplied battery charger (Ref.-No. 00277) to charge the batteries is plugged in here.

Chapter 3 Instrument Operation

3.1 Battery Operation

DEEP OSCILLATION® Personal uses rechargeable 1.2 V AA NiMH batteries for power supply, which allow for operation independently from the mains.

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

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



Battery completely charged

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 instrument shuts down to avoid complete discharging of the batteries.

In this case, recharge the batteries.

How to Recharge the Batteries



Caution

During the charging procedure, the patient must neither be connected with the titanium neutral element, nor with the hand applicator!



Note

As an alternative to the charging procedure directly on the instrument described here, you can also remove the batteries from the instrument (as described in [How to Replace the Batteries](#) on page 9) and charge them with the supplied battery charger.

- (1) Plug the supplied battery charger into the **Charger Socket <7>** on the bottom of the instrument. The batteries will be charged.
- (2) Unplug the battery charger from the instrument when the charging procedure is finished.

3.1.1 Important Notes on Handling the Batteries

Rechargeable batteries discharge over an extended period, even if the instrument is switched off. To prevent from this self-discharge process, the batteries should be removed from the instrument.

If the instrument is not in use for a longer period of time, the batteries have to be entirely charged before storage. Remove the batteries from the instrument then.

If the unit is not used for a longer period of time, please fully charge the battery at least once every two months. This will help to avoid exhaustive discharge, which may permanently affect the battery life, not enabling it to be recharged; hence, replacement will be necessary.

How to Replace the Batteries

Batteries that can no longer be recharged can be replaced by fresh ones:

- (1) Ensure that the instrument is switched off.
- (2) Hold the instrument with the rear face up and remove the back cover. The back cover is held by three magnets.
- (3) Remove the four rechargeable batteries from the instrument.
- (4) Insert the fresh batteries into the **Battery Compartment <5>** of your DEEP OSCILLATION® Personal. Ensure that the polarity is correct and the removal strip is placed below the batteries!



Important

Dispose rechargeable batteries with care and respect the legislation with respect to environment protection.

3.1.2 Battery Charger

The supplied battery charger (Ref. No. 00277) has an LED to indicate the current state of the batteries.



Battery Charger

Charging Cycle and LED Readings

LED	Mode
Yellow	Battery not connected
Yellow	Battery initialization and analysis
Orange	Quick charge mode
Green with yellow flashing light	Intermediary mode with low charging voltage

LED	Mode
Green	Maintenance charge mode
Flickering orange - green alternately	Error



The Instrument Should not Be Stored with the Charger Plugged in

If the instrument is stored with a plugged in charger, the battery discharges faster, since a discharge current also flows through the charger. This reduces the above mentioned timespan up to the excessive discharge of the battery.



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 22 for available primary adaptors.

Please find more information on the operation of the battery charger in the supplied operating instructions.

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 Preparations and Start-Up

How to Start up the Instrument

- (1) Press the **Data Selector <2>** for one second. You will hear an acoustic signal and the **Display <1>** is illuminated. The message **No CARD available in the unit! Please insert CARD.** is displayed.
- (2) Insert your card with the chip side facing down into the **Card Reader <4>**. The welcome screen is displayed.



Note

If the card is defective or incompatible, a respective error message will be displayed.

- (3) Click the **OK** symbol. The indications menu is displayed.



Indications Menu

You can now select an indication and begin treatment (refer to [How to Perform a Treatment](#) on page 15).

How to Switch off the Instrument

- (1) Press the **Data Selector <2>** for five seconds. The **Display <1>** goes out.
- (2) Remove the therapy card and unplug the cables from the **Ports <3>**.

3.3 Function Check

A function check is always necessary when you are unsure about whether the instrument is working properly.

How to Check the Function of the Instrument

- (1) Press the **Data Selector <2>** for several seconds until the instrument switches off.
- (2) Press the **Data Selector <2>** again until the instrument switches on:
 - If the instrument is properly working, the available options are displayed on the **Display <1>**. You can operate the instrument without any further precaution.
 - If an error code is displayed, there is an instrument error. Proceed as described under [Instrument Errors](#) on page 14 .

3.4 Cable Check

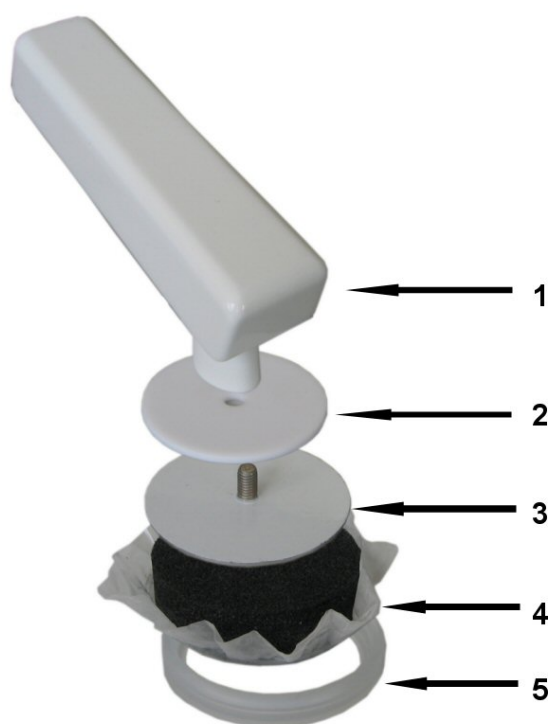
If you should have the impression that a cable is defective during treatment, you can check it using the instrument.

How to Check a Cable

- (1) Select a therapy and set the intensity to 100% using the **Data Selector <2>**.
- (2) Plug the ends of the cable to be tested into the **Ports <3>**.
- (3) Move the cable and pay attention to the **Control Light <6>** under the **Data Selector <2>**:
 - The **Control Light <6>** is permanently on: *The cable is defective.*
 - The **Control Light <6>** is off: *The cable is OK.*
 - The **Control Light <6>** flashes when moving the cable: *The cable is defective.*
- (4) Replace the defective cable immediately.

3.5 Hand Applicator

The hand applicator consists of the following parts:



(1) Handle (Ref.-No. 00379)

(2) Cover

(3) Oscillator Plate

(4) Membrane

(5) Clamp Ring

Note
 (2) - (5) make up the oscillator head in the respective size.

Hand Applicator (Exploded View)

The oscillator head is screwed into the handle. To remove the head from the handle, you have to rotate it to the left.



Important

Any damage to the oscillator membrane might lead to harmless (but unpleasant) sensations on the skin.

Replace the membrane immediately if damaged!

How to Replace the Membrane

- (1) Take off the clamping ring and remove the membrane.
- (2) Insert the new membrane with the foil facing down loosely into the clamping ring, so that the membrane foil protrudes laterally.



Changing the Membrane - Inserting

- (3) Press the oscillator plate firmly onto the foam rubber area of the membrane until the clamping ring engages with the oscillator plate. Make sure that the foil is tightly fixed with the clamping ring on the outside, and that the clamping ring is engaged!



Changing the Membrane - Engaging the Oscillator Plate

3.6 Therapy Card

All indications available for DEEP OSCILLATION® Personal are stored on the therapy card. The therapy card must be inserted to perform a treatment or to access the basic settings.



Caution

The treatment card must not be copied, and any attempt to reproduce it or read out the data will invalidate it! PHYSIOMED ELEKTROMEDIZIN AG accepts no responsibility for damage incurred in this way!

3.7 Instrument Errors

If a functional error is detected during the automatic selftest routine or operation, one of the following error codes is shown on the **Display <1>**:

- **ERROR_01 ... ERROR_05**

In this case, treatment is automatically interrupted. Switch off the instrument by pressing the **Data Selector <2>** and switch it on again. If the error code persists even after several selftests, you have to consult the technical service.

Chapter 4 Treatment

With DEEP OSCILLATION® Personal you can perform treatments according to preset indications which are stored together with the corresponding therapy parameters on the therapy card. For each displayed indication you can refer to the recommended therapy instructions. Each indication features an image of a body region to be treated, which shows the preferable direction of treatment.



Caution

Before each treatment, adjust the intensity to match the respective conditions and pay attention to the contraindications (refer to [Contraindications](#) on page 5)!

During the charging procedure, the patient must neither be connected with the titanium neutral element, nor with the hand applicator!

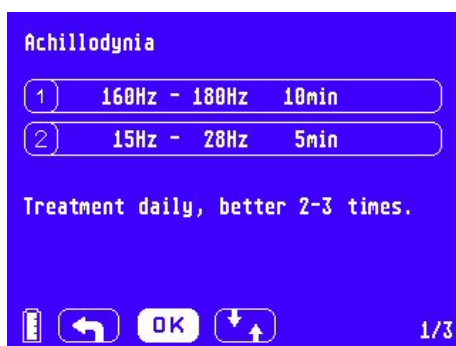
4.1 Treatment with the Hand Applicator

How to Prepare Treatment

- (1) Before treatment, prepare the patient's skin area to be treated by drying or powdering.
- (2) Plug in the cables for the hand applicator as well as for the Titanium neutral element (ref.-no. 00382) into the **Ports <3>**. The instrument operates in biphas mode; therefore, you don't have to pay attention to the polarity.
- (3) Connect the Titanium neutral element with the other end of the cable and let the patient grip it. Alternatively, you can attach it on any part of the patient's body.
- (4) Connect the applicator to the appropriate cable.

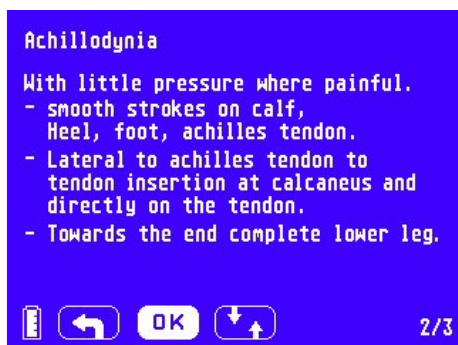
How to Perform a Treatment

- (1) Start up the instrument as described under [How to Start up the Instrument](#) on page 11.
- (2) Select an indication from the indications menu. The therapy parameters of the selected indication are displayed.




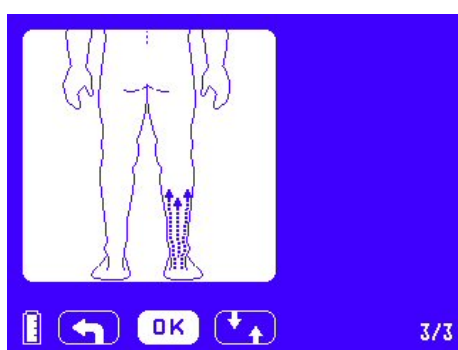
Therapy Instructions - Parameters

- (3) Click the  symbol. Instructions on how to perform the treatment are shown.



Therapy Instructions - Text

- (4) Rotate the **Data Selector <2>** until the  symbol flashes. An image showing a body area to be treated as well as the treatment direction is displayed.




Therapy Instructions - Image

- (5) Click the  symbol. The preset therapy parameters are displayed.



Treatment

- (6) Click the  symbol and set the desired intensity by rotating the **Data Selector <2>**. As soon as the intensity is set, treatment begins, the therapy time elapses, and the **Control Light <6>** under the **Data Selector <2>** is on.

In the example shown here, treatment with two different therapy phases is performed. Perform the treatment and pay attention to the therapy instructions shown before.

In the case of treatments with more than one phase, therapy parameters are automatically switched after the end of the first therapy phase. As soon as the time for the last treatment phase has elapsed, the intensity decreases to zero. You can now perform one more treatment, or switch off the instrument.

**Important**

You have to choose the intensity according to the minimum dose principle, i.e. in the lower effective range!

The hand applicator should stay in contact with the patient's skin and should be moved on the body surface without lifting or stopping. Distinguish between therapy movement and leading movement: The therapy movement (to the centre of the body) has to be performed with the appropriate pressure, the leading movement (back from the centre of the body) without pressure.

When treating with low frequencies (10 - 40 Hz), perform the therapy movement especially slow. The leading movement may be quicker.

After switching to a new therapy phase, it might be necessary to re-adjust the intensity to reach the same strength of oscillation!

In case of adverse reactions of the patient during the treatment (e.g. in cases of inflammation) you can also cut short the therapy steps. Proceed in the following way:

- (1) Click the timer symbol with the **Data Selector <2>** to make it flash.
- (2) Rotate the **Data Selector<2>** to the left and cut short the therapy time to the desired value.
- (3) Press the **Data Selector <2>** to confirm the selected therapy time.

Appendix A Appendix

A.1 Service, Repairs, Maintenance

The manufacturer guarantees the safety of the instrument only in its original state. The instrument must be operated in accordance with the Operating Instructions.

Repairs to the instrument may only be performed by parties duly authorised by PHYSIOMED ELEKTROMEDIZIN AG. 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. The certification must also contain the date performed, the name of the repair company and the signature of the service person. 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 that also private persons operating the instrument have it serviced at regular intervals, including all accessories. Please refer to the *Manufacturer's Recommendations* on page 24 for the safety regulations control.

A.2 Cleaning and Disinfection

Clean the device and the accessories regularly with an aldehyde-based disinfectant. Switch off the instrument by any means before cleaning!

Use a soft sponge cloth for cleaning. Ensure that the back cover is secured tightly and use caution so that no liquid substances penetrate into the instrument!

For the hand applicator, use a new or disinfected oscillator head for each patient. Clean, disinfect or sterilise the hand applicator regularly. The clamping ring, oscillator plate and handle are resistant against disinfecting agents and can be sterilised up to 135°C.



Important

All parts of the oscillator head must be absolutely dry before using them next time!

A.3 Service Life and Disposal

Due to legislation, the service life of this medical product has a limit of 4 years.

The instrument has to be disposed in compliance with the legal obligations. Therefore, pay attention to the applicable regulations for environment protection.

Please contribute to environment protection by not putting used instruments into your domestic waste.

A.4 Electromagnetic Compatibility




Declaration in accordance with standard EN 60601-1-2: Electromagnetic compatibility

Medical electrical devices are subject to particular precautions regarding electromagnetic compatibility and must be used in accordance with the instructions on electromagnetic compatibility contained in the accompanying documents.

Portable and mobile HF communication devices can affect medical electrical devices (see the supplement on electromagnetic compatibility, technical description).


A.5 Basic Settings

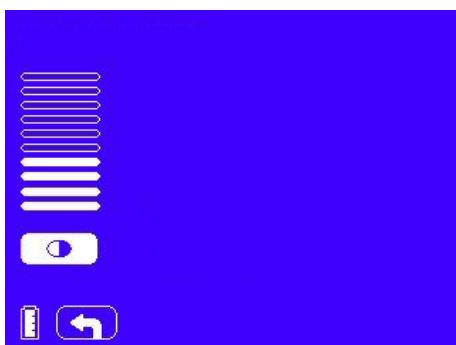
In the **Basic Settings** menu, you can configure the following instrument settings:

Symbol	Meaning
	Contrast of the Display <1>



You can access the basic settings menu from the welcome screen which is displayed as soon as you insert the therapy card.

How to Configure the Basic Settings

- (1) Ensure that the instrument is switched off or press the **Data Selector <2>** for a few seconds until the **Display <1>** goes out.
- (2) Press the **Data Selector <2>** again, until the instrument switches on.
- (3) Insert the therapy card into the **Card Reader <4>**. The welcome screen opens.
- (4) Click the  symbol. The basic settings are displayed.



Basic Settings

- (5) Click the symbol of the parameter you want to configure (e.g. for the contrast ).
- (6) Rotate the **Data Selector <2>** until the parameter has the desired value.
- (7) Click the  symbol. The indications menu opens.
The new settings are immediately active.

A.6 Technical Data

Treatment

Protection Class according to IEC 60601-1	Internal Power Supply, Type BF
---	--------------------------------

Charging

Protection Class according to IEC 60601-1	II
Input Voltage	7.2 VDC (4 cells)
Input Current	1.3 ADC

General Technical Data

CE label	acc. to Council Directive concerning medical devices (93/42 EEC)
Class according to 93/42/ECC	Ila
Output Voltage (max.)	400 Vs
Power Supply	4 x NiMH rechargeable battery, size AA, 1.2 V
Output Impedance	10 MOhm
Output Frequency	5 ... 250 Hz
Modulation	1/4, 1/3, 1/2, 2/3, 3/4
Ambient Temperature (Operation)	+ 10°C ... + 40°C
Storage Temperature	+ 10°C ... + 40°C
Dimensions (W x H x D)	10.0 x 3.1 x 19.0 cm
Weight	0.7 kg



Important

Please note that a high storage temperature leads to increased self discharge of the battery!

Battery Charger

Type (to be used exclusively)	Type 2116 (mascot NiCd/NiMH battery charger, 3-6 cells)
Mains Voltage	100 ... 240 VAC
Input Current	0.35 A
Mains Frequency	50 ... 60 Hz
Output Voltage	7.2 VDC (4 cells)
Output Current	1.3 ADC

A.7 Training

As a manufacturer we have to offer trainings on the instrument. The operating instructions are used as training material. Please submit your requests for trainings to the 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

DEEP OSCILLATION® Personal is supplied with the following accessories:

Ref.-No.	Designation	Quantity
00379	Applicator Handle	2
00384	Battery Charger	1
00277	Battery Charger with suitable Adaptor (00278, 00279, 00280, 00281)	1
00261	Connection Cable DEEP OSCILLATION®	2
00391	Membrane Set, 5.0 cm	2
00383	NiMH Rechargeable Battery, Size AA, 1.2 V	8
00381	Oscillator Head, 5.0 cm	2
00386	Oscillator Head, 9.5 cm	2
00348	Powder, Package	1
00395	Soft Carrying Case	1
00385, 00397, 00414, 00458	Therapy Card SPORTS, AESTHETICS, FITNESS or POSTPARTUM (one out of four)	1
00382	Titanium Neutral Element	1
00949	Operating Instructions (English)	1

B.2 Available Accessories

The following accessories are available for DEEP OSCILLATION® Personal:

Ref.-No.	Designation
00379	Applicator Handle
00384	Battery Charger
00277	Battery Charger with suitable Adaptor (00278, 00279, 00280, 00281)
00394	Carrying Belt
00390	Clamping Ring, 1.5 cm
00388	Clamping Ring, 5 cm
00389	Clamping Ring, 9.5 cm

Ref.-No.	Designation
00261	Connection Cable DEEP OSCILLATION®
00393	Membrane Set 1.5 cm
00391	Membrane Set 5 cm
00392	Membrane Set, 9.5 cm
00383	NiMH Rechargeable Battery, size AA, 1.2 V (Package, 4 Items)
00387	Oscillator Head 1.5 cm
00381	Oscillator Head 5 cm
00386	Oscillator Head, 9.5 cm
00396	Pin Applicator
00280	Primary Adaptor AU
00278	Primary Adaptor EU
00279	Primary Adaptor UK
00281	Primary Adaptor US/JP
00348	Powder, Package
00395	Soft Carrying Case
00397	Therapy Card AESTHETICS
00414	Therapy Card FITNESS
00458	Therapy Card POSTPARTUM
00385	Therapy Card SPORTS
00382	Titanium Neutral Element

Appendix C Supplementary Documents

C.1 Manufacturer's Recommendations

PHYSIOMED®

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

INSTRUMENT: **DEEP OSCILLATION® Personal**
MANUFACTURER: PHYSIOMED ELEKTROMEDIZIN AG

The instrument has to undergo a safety regulation control every 18 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 shapes of output parameters
- (5) Output current at the ports
- (6) Electrical safety according to EN 62353:2008, Substitute patient leakage current:
Limiting value according to EN 62353:2008: 5 mA
Value first measured (NEW INSTRUMENT): 0,05 mA

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