OPERATING INSTRUCTIONS

MAGCELL® ARTHRO

01510 GB

PHYSIOMED®

TECHNOLOGY FOR THERAPY

Legal Notice

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MAGCELL® ARTHRO is made in Germany in compliance with the quality requirements of DIN ISO 13485:2003, DIN ISO 9001 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.

MAGCELL® ARTHRO is a patent applied for therapeutical system.

MAGCELL® is a registered trademark of PHYSIOMED ELEKTROMEDIZIN AG.

Last updated June 24, 2009.

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Chapter 1 Introduction

With the MAGCELL® ARTHRO you have acquired a high quality and extremely versatile mobile instrument for electrode-free electrotherapy. However, it will be appropriately useful only once you are informed about the functions of all control elements. Please read these instructions carefully and become thoroughly familiar with the instrument prior to its use.

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

Never let magnetic storage media (e.g. disks, PC hard disks and especially bank and credit cards) come into contact with the instrument, as the magnetic field of the instrument can lead to data loss!

Make sure that an appropriate distance between two therapeutic instruments or other ferrous metals is kept. Otherwise, very strong attractive forces could cause injuries or damage the instrument!

Remove all metal objects (jewellery, watches, etc.) before the treatment and be careful that clothes near the treatment area do not have any metal buttons or similar adornments.

The instrument is to be operated and stored in a dry environment only. It is to be kept away from water and other fluids. Furthermore, the instrument must not be treated with chemical fluids. For cleaning, do not use any petroleum, thinner, alcohol, substances for wax removal or other solvents!

The instrument must not be stored or operated at increased temperatures. Avoid direct solar irradiation. The maximum operating temperature is 40°C. At temperatures below 10°C, the instrument has to adjust to ambient temperature. Three minutes of acclimatization time per differing degree can be used as a guide value.

To avoid damage on the instrument itself as well as unwanted magnetic effects, the instrument should always be kept in the supplied metal case. The instrument has to be protected against falling down or being accessed by children.

Damaged instruments must not be operated. If you have any doubts, please ask the manufacturer. Only the specialised service staff is allowed to repair the instruments. Improper repairs or interventions can cause serious hazards to the user.

In general, you must not put any objects on MAGCELL® ARTHRO.

1.3 Effectiveness

Time-variable magnetic fields can be the transmission medium for electric fields. Given a sufficiently strong field, active electromagnetic fields can be induced in the tissue and be transported with relatively low loss into the deeper layers ("electrodeless electrotherapy").

Thanks to an innovative patent applied for therapeutical approach, MAGCELL® ARTHRO, despite its small size, is able to generate unusually strong magnetic fields of up to 100 mT (1000 Gauss). This generates sufficiently high and therapeutically effective flow densities in the tissue that ex-

tend into the joint structures. Threshold values for important cellular regeneration and differentiation processes are exceeded even at a tissue depth of 3 to 5 cm.

The unit therefore not only generates the systemic effects known from magnetic field therapy and electrotherapy but for the first time it also has a direct effect on defective cell functions in terms of their normalisation and regeneration. Strictly speaking, the electromagnetic field provides the cells with specific information about its frequency or amplitude pattern which the cell in turn uses to normalize (regenerate) its function.

MAGCELL® ARTHRO works with treatment parameters that were determined in empirical and clinical research in the field of bio-electromagnetism.

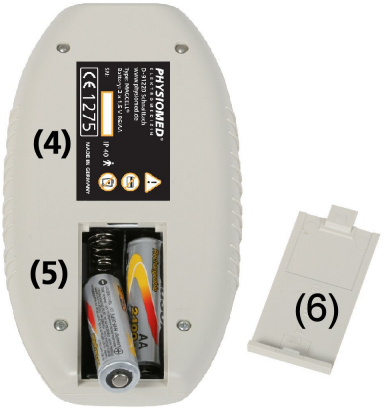
They immediately alleviate acute arthritic pain and promote long-term mobility.

1.4 Description

The MAGCELL® ARTHRO is an instrument for performing electrodeless electrical therapy for use in both clinical and private environments. The instrument is powered by standard 1.5 V AA batteries (included in the supply package) so can also be used in any location. Replacement batteries and a corresponding charger are available as accessories (see *Available Accessories* on page 14).

1.5 Instrument Overview

Front panel



Rear face

Legend

1	Effective area
2	Start button
3	Status LED
4	Type label
5	Battery case
6	Cover

1.6 Application

Basically the MAGCELL® ARTHRO is used to stimulate self-healing processes by transforming information in physical cell structures using pulsating magnetic fields of a defined frequency and strength.

The instrument is used to treat various forms of arthrosis and painful conditions arising from:

- Hip and knee joint arthrosis

- Hallux rigidus and valgus
- Arthrosis of the mandibular (jaw) joint
- Other arthrotic conditions

1.7 Contraindications

Magnetic field therapy should not be used in the following situations:

- Suspected or confirmed pregnancy
- Infection in the treatment area
- If there is any inflammation in the area to be treated.
- Treatment close to the heart may only be performed with the explicit permission of a medical practitioner. Treatment close to the heart should never be performed on patients with metallic or metallic-ceramic inplants (endoprosthesis, heart pacemaker, implanted defibrillators or similar implants).
- Patients who tend to develop thromboses or spasms/cramps and diabetics who are to receive treatment near the pancreas (risk of hypoglycaemia).
- In the event of chronic diseases, initial worsening of symptoms may occur, analogous to treatment with other physical therapeutic procedures or homeopathic medications. Do not discontinue the treatment in this situation, but if in doubt, contact your doctor. Isolated cases of initial worsening of symptoms can be an indication of onset reactions and blocking solutions in the body.
- Arthrosis of the mandibular (jaw) joint must only be treated if there is no acute inflammation around the gums and teeth.
- Metallic implants (also fillings)

Chapter 2 Controls and Indicators

The MAGCELL® ARTHRO is designed to allow for easy operation. Due to its small size it can be transported very easily.

2.1 Effective Field <1>

The therapeutic **effective field <1>** is marked on the upper side of the instrument and should be directly applied to the region to be treated.

2.2 Start Button <2>

Using the **start button <2>**, the instrument is switched on. The magnetic field is built up immediately and the treatment time begins to elapse. Pressing the button again will interrupt therapy at any time. After the treatment time has elapsed, the instrument is switched off automatically.

2.3 Status LED <3>

The **status LED <3>** lights up during therapy. A flashing LED indicates the pulsation of the magnetic field.

Chapter 3 Operation of the Instrument

The following sections will show you the operating steps not directly connected with therapy.

3.1 Starting up the Instrument

Prior to performing your first treatment with MAGCELL® ARTHRO, you have to start up the instrument properly.

Important

Please read the information in the user manual before starting up the instrument for the first time. The user manual should be kept in a safe place for temporarily passing on or selling the instrument.

Please check MAGCELL® ARTHRO and its accessories once you have received it to ensure that all the parts are there (according to delivery specifications) and that everything is intact and in good condition.

MAGCELL® ARTHRO must only be operated with 1.5 V batteries! Batteries with a voltage of only 1.2 V are not admissible!

How to start up the Instrument

(1) Remove the back cover of the MAGCELL® ARTHRO to open the battery compartment.
(2) Insert the included mignon batteries observing the correct polarity. Observe the labelling in the battery compartment!
(3) Close the battery compartment with the lock clicking into place. The instruments starts automatically and is now ready for application.

3.2 Changing Batteries

If the instrument does not start automatically once the batteries have been inserted, this means that the batteries have either been inserted wrongly or are already too weak. If this is the case, change the battery as described in *How to start up the Instrument* on page 7.

Caution

Inserting the batteries incorrectly may cause discharging!

If the instrument is not used for an extended period of time, you should remove the batteries to protect it from possible leaking of the batteries.

3.3 Instrument Errors

If your instrument does not function properly or therapy time ends with an uninterrupted 10 sec. acoustic signal, please change the batteries (see *How to start up the Instrument* on page 7). MAGCELL® ARTHRO will function properly again after that. If the therapy time still ends with an uninterrupted 10 sec. acoustic signal or the instrument does not function properly, please contact the service.

Chapter 4 Therapy with Magnetic Fields

In this section you will receive general information on the therapy with magnetic fields and the mode of action of the instrument.

How to Perform Treatment

(1) Start MAGCELL® ARTHRO by pressing the **start button <2>**. You will hear a short acoustic signal for confirmation.

(2) Place the MAGCELL® ARTHRO on the body with the **effective field <1>** positioned on the area to be treated and then leave the instrument there for a while or make circular movements.
The magnetic therapy frequencies are now generated. When this happens, MAGCELL® ARTHRO vibrates slightly and the green **status LED <3>** on the application side light up alternately. Here the flash frequency is proportionate to the current treatment frequency.

(3) After 2.5 minutes treatment time, MAGCELL® ARTHRO stops automatically which is confirmed by the instrument making a short sound. You can stop the treatment prematurely by pressing the **start button <2>** once again.

4.1 Treatment Recommendations

Place the switched on MAGCELL® ARTHRO with the marked active surface onto the area to be treated. It is not necessary to apply pressure. The strong magnetic fields can easily penetrate clothing, so that as a rule no direct skin contact is necessary.

The therapeutic effect is based on repeated short-time treatments.

- Frequency of treatments: Unless otherwise prescribed by the medical practicioner, up to 10 sessions daily can be performed under acute conditions of pain. The frequency of treatments should be reduced as soon as the painful conditions are ceasing.
- Duration of one treatment session: At least 2 x 2.5 minutes each per joint, for big joints also up to 4 x 2.5 minutes. The position of the instrument should be changed after each treatment cycle (2.5 minutes) to cover as many parts of the joint and its surrounding tissue; e.g. on the "top" and "bottom" of the toes, the "inside" and "outside" of the knees, or the "front" and "back" of the hips as well as "two different positions on

the outside". To remind you that you have to change the position, the instrument shuts off every 2.5 minutes and has to be switched on again.

Note

Further information relating to this can also be obtained from PHYSIOMED ELEKTROMEDIZIN AG on +49 (0)9126 2587 0.

4.1.1 Alleviation Process

Based on observations made so far regarding arthropaties, a noticeable but not enduring improvement in mobility and pain alleviation may be felt even after the first treatment.

Frequently during or following treatment a tingling sensation is experienced which is due to an increase in the capillary blood flow.

On the other hand, during the initial treatment sessions, a patient's symptoms can sometimes deteriorate and occasionally ***symmetrization*** can also occur (this is when discomfort or pain arises in a joint that is not affected). Both phenomena usually disappear quickly and are a result of the commencing healing process.

4.1.2 Duration of a Treatment Series

In principle the treatment should be continued until there is a significant reduction or elimination of pain, or until mobility has been restored. Depending on the kind of indication and the severity, this can take several weeks.

Since treatment with the MAGCELL® ARTHRO involves a therapy without any side effects, this can also be performed as a long-term treatment. Therapy can be discontinued as soon as the patient's problems have been eliminated. Should the symptoms reoccur, it is advisable to resume the therapy as quickly as possible.

The phases of temporary reduction in symptoms become longer after this and the duration of the treatment sessions shorter.

If after the first treatment sessions the symptoms significantly and enduringly worsen, consult your medical practitioner to check whether the joint has become inflamed.

In any case, the treatment should be stopped for a week.

Appendix A Attachment

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 15 for the safety regulations control.

A.2 Transport and Packaging

The MAGCELL® ARTHRO is supplied in a metal case. It should always be stored and transported in this case to protect it from damage and to prevent undesired effects.

A.3 Cleaning and disinfection

Clean the instrument on a regular basis with a disinfecting agent based on aldehyde. By any means, switch off the instrument prior to this and remove the batteries!

Use a soft sponge cloth for cleaning. Do not spray the agent directly onto the

instrument and be careful that no liquid substances invade the instrument.

A.4 Service Life and Disposal

Due to legislation, the service life of this medical product has a limit of vier 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.5 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.6 Technical Data

Type of Instrument	Magnetic field stimulator with permanent magnetic field
Rated Voltage	3,0 V
Power Consumption	ca. 0.4 W
Treatment Duration	approx. 2.5 min
Housing	ABS
Temperature (Operation)	+ 10°C ... + 40°C
Temperature (Storage)	- 10°C ... + 50°C
Air Humidity	30 % bis 75 %
Air Pressure	700 ... 1,060 hPa
Dimensions (W x H x D)	8.3 x 15.2 x 2.5 cm
Strength of Magnetic Field	max. 200 mT
Weight	210 g
Power Supply	2 x 1.5 V R6 alkaline batteries
Protection Degree	IP 40

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

MAGCELL® ARTHRO is supplied with the following accessories:

Ref.-No.	Designation	Quantity
00398	Battery 15A LR6 AA 1.5 V	2
01108	Magnetic Field Therapy Unit MAGCELL®ARTHRO	1
00350	Metal Case	1
01510	Operating Instructions (English)	1

B.2 Available Accessories

The following accessories are available for MAGCELL® ARTHRO:

Ref.-No.	Designation
00399	Bag MAGCELL® incl. elastic velcro strap
00472	Battery, AA size, 1.5 V (pack of 2)
00398	Battery 15A LR6 AA 1.5 V
00471	Battery Charger
00350	Metal Case

Appendix C Supplementary Documents

C.1 Manufacturer's Recommendations

PHYSIOMED®

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

INSTRUMENT:	**MAGCELL®**
MANUFACTURER:	PHYSIOMED ELEKTROMEDIZIN AG

We recommend to have this instrument undergone 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

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