Dornier *MedTech*

Operating Manual

System	**Dornier *Aries***
Revision	*
Date	11/2010
Software	1.1X
Language	English

Table of Contents

Trademarks

Registered trademarks, trade names and tabed names are used in this Operating Manual. Even when these are not specifically identified as such, the appropriate protective clauses apply.

Manufacturer

Dornier MedTech Systems GmbH
Postfach 12 51
D-82231 Wessling

Telephone: +49-8153-888-0
Fax: +49-8153-888-665

List of Revisions

Date	Revision	Software	Modification
11/2010	*	1.1X	First edition

Signs and Symbols

Safety and Warning Instructions

All safety and warning instructions are to be observed in order to protect the patient and the operator.

Warning Levels / Signal Word Panels

indicates a possible hazard with a medium risk that can result in death or severe bodily injury if not avoided

indicates a hazard with a slight risk that could result in slight or medium bodily injury if not avoided

indicates that there is a danger of property material if not avoided

Warning Signs

Observe all measures, which are marked by warning signs, in order to avoid injuries.

warns you of risks of injury

Further Signs

points to detailed information for the same subjects

[3]

points to positions in figures

1 Perform visual check.

2 Activate unit.

Operations that must be performed step by step in a logical order are preceded by a number in color bold print.

A single step is also numbered.

Blank page

Basic Safety Instructions

Responsibilities of Dornier MedTech Systems GmbH

Regardless of the specific requirements set by relevant liability standards, Dornier MedTech Systems GmbH assumes responsibility under the following conditions only:

- The maintenance, and modifications are performed only by Dornier MedTech Systems GmbH personnel or persons authorized by Dornier MedTech Systems GmbH.
- The electrical installation in the relevant room complies with applicable national standards.
- The Dornier *Aries* has been operated according to the applicable Operating Manual.

Dornier MedTech Systems GmbH shall not be liable for any inappropriate application or tampering with the product by unauthorized persons.

Operating Manuals

The Operating Manual is compliant with the product specification and fulfils all relevant safety standards valid of the date of publication. The Operating Manual is an essential part of the product, should be within reach at all time and is to be given with passing on of the product.

The hardware illustrated in this Operating Manual corresponds to the state of the delivery at this time.
We reserve the right to make modifications based on technical progress.

Changes of design (e.g. covers) have no influence, neither on function nor on the handling of the system.

Responsibilities of the User

Before activating the Dornier *Aries*, each user must read and understand the Operating Manual. Before each treatment, the user must ensure the Dornier *Aries* is in proper working order (see "Description / Operation" section), in order to avoid putting the patient or a third party at risk.

The corresponding tests, checks and introductory instruction shall be conducted in compliance with § 5 and § 6 of the German Medical Devices Operator Directive (MPBetreibV) or the corresponding locally applicable regulations.

Furthermore the "Safety Plan for Medical Devices – MPSV" must be observed.

The user must also follow the rules for preparation of the coupling area every time a patient is treated.

Safety Checks

Safety checks guarantee the safe and reliable operation of the Dornier *Aries*.

The operator of the Dornier *Aries* shall arrange for safety checks in compliance with § 6 of the German Medical Devices Operator Directive (MPBetreibV) or corresponding locally applicable regulations.

A safety check must be conducted at least once a year.

Only authorized persons may conduct safety checks on the Dornier *Aries*.
Authorized persons are exclusively persons who have been trained by Dornier MedTech Systems GmbH or by a company authorized by Dornier MedTech Systems GmbH. Safety checks conducted by unauthorized persons can lead to life threatening injuries of persons and/ or cause serious damage to the Dornier *Aries*.

Medical Information

Physicians conducting shock wave treatments must be familiar with the relevant medical issues, including currently applicable indications, contra-indications, and attendant side effects. Side effects and risks with an ESWT are known to be generally minor, and complications are rare. Nevertheless, the following should be observed:

The shock waves may elevate the risk of hemorrhage in the area exposed to the shock wave. This could lead to petechial bleeding or hematomas. Patients with clotting disorders or those taking anticoagulative medication such as Marcumar should not be treated, except in cases where the coagulopathy is treated or the medication is interrupted until the coagulation factors are within normal limits.

The application of shock waves in pneumatized organs, especially the lung, could lead to severe tissue damage.

With pathologic vessels, there is a risk of rupturing. Vascular anomalies should thus be examined carefully during diagnosis. In general, angiosclerosis is not a contraindication.

Special care is advisable for patients with cardiac pacemakers or those with arrhythmias who regularly take antiarrythmic drugs. The cardiac condition of the patient must be clarified. Shock wave release outside the refractive phase can affect cardiac activity. Such patients must be monitored with an ECG during ESWT. For pacemaker patients, a programming device and a pacemaker magnet must be kept at hand. It is recommended that dual-chamber pacemakers be reprogrammed to single-chamber mode. If necessary, the pacemaker should be switched over to a fixed frequency for the duration of the procedure. The pacemaker and the electrode should be kept at least 5 cm away from the shock wave focus. A cardiologist should always help in monitoring the ESWT, in order to take appropriate measures if the shock wave exposure causes the pacemaker to affect or interfere with the circulatory system or, in case of emergency, to be ready with a defibrillator and external pacemaker probe. Because of differing cardiologic requirements on the types of pacemakers, it is crucial to refer to experiences publicized in the literature for further information. ESWT should be immediately terminated when a significant arrhythmia developes.

Shock wave exposure can result in hyperventilation and, in extreme cases, in hyperventilation tetany. For this reason, it is recommended that the CO_2 and O_2 partial pressures be monitored during the treatment of patients who are at risk.

Immediately after shock wave exposure, patients, particularly hypertension patients, may experience a temporarily elevated blood pressure and vertigo. Pain during and after ESWT must be examined carefully to determine its cause.

Interaction between the shock wave and nerves cannot be ruled out. The central nervous system and plexuses should not be exposed to shock waves. Depending on the location of the nerves, an effort should be made to select a position of the patient that averts exposing nerves directly to the shock waves.

There is a correlation between the shock wave dose (shock wave intensity x number of shock waves) and the emergence of side effects. As the shock wave dose increases, so does the risk of complications. Even though it has not been scientifically proven, the risk of side effects from shock wave exposure could rise due to factors such as medication, age, blood pressure, cardiac rhythm dysfunction, vascular debility, or diabetes.

Different aspects for the therapeutic effect of the shock wave must be considered with ESWT. Their relative significance varies with the energy flux density, which is selected with the shock wave's energy levels.

The energy flux densities for the separate intensity levels can be found in the table in the "Specifications" section. Side-effects and risks are generally low for ESWT, and complications are rare. The risk increases, however, as the energy flux density rises.

In the case of applications involving shock wave coupling near the heart, e.g., in the shoulder area, it is recommended that the patient be monitored by ECG.

It must be ensured that the patient's body and the applicator are in proper contact in the shock wave entry zone, prior to release of the shock waves. The applicator must be coupled to the patient's body by using suitable coupling media such as ultrasound gel. Air bubbles between the patient's body and the applicator reduce the effectiveness of the shock waves and could lead to an unsatisfactory therapy outcome.

For applications in the shoulder area, the patient must wear ear protection, since a shock wave source located close to the ear may cause tinnitus, especially if the patient is in a prone position. It is recommended that the physician and operators also wear ear protection.

For information on the current state-of-the-art of shock wave treatments, kindly contact the nearest office of Dornier MedTech GmbH.

Safety for the Patient

Operating the Dornier *Aries*

The Dornier *Aries* may not be operated in an explosive and/or combustible atmosphere. An explosive or combustible atmosphere arises, for example, from vapors generated by anesthetics, cleaning agents, or disinfectants.

Informing Patients

The patient must be informed about the treatment process.

In particular, the patient must be informed about the noise caused by the release of shock waves. This prevents the patient from being startled and making involuntary movements during treatment.

Caution During Shock Wave Release

An acoustic shock is heard during shock wave release. It is recommended that the patient wear ear protection during shock wave treatment. The patient must wear ear protection for applications in the shoulder area.

Preparing for the Next Patient (Cleaning/Disinfection)

You must follow the rules for preparing the coupling area every time a patient is treated, in order to avoid cross-contamination between patients (see page 51).

Conduct During an Emergency

In case of emergency, pull the Dornier *Aries* plug out of the power socket.

Power Supply

Failure of the installation-end power supply (main voltage) does not create a hazardous situation.

Replacement of Parts

In order to ensure the reliable function of the Dornier *Aries* and thus the patient's safety, use only original spare parts from Dornier MedTech Systems GmbH. Spare parts are manufactured by Dornier MedTech Systems GmbH following high quality requirements regarding materials and production, and are checked for proper functionality.

Do not use parts that have not been approved.

Parts that have not been approved can cause injury to the patient or operating staff and/or material damage. Dornier MedTech Systems GmbH is not liable for parts that have not been approved or for injuries and/or material damages caused by the use of such parts.

Safety for the Operating Staff

Duty of the Operating Staff

Operating and cleaning personnel are advised to exercise extreme care when handling the system.

Each operator must read and understand the Operating Manual completely before using the system the first time.

Caution During Shock Wave Release

An acoustic shock is heard during shock wave release. It is recommended that the operating staff wear ear protection during shock wave treatment.

Cleaning and Disinfecting

Disconnect power supply before cleaning and disinfecting the system.

Safety for the Dornier *Aries* and Accessories

Electromagnetic Compatibility

The Dornier *Aries* complies with the EMC requirements according to IEC 60601-1-2. Shock wave release may cause interference with other units.

Electrical Installation

Operate the system only in an appropriate area where the electrical installation complies with
DIN VDE 0100-710 or applicable national installation standards.

To prevent the risk of electric shock, this device must be connected only to a power supply with protective conductors. Take care not to connect all accessory units to the same portable multiple outlet. Observe the requirements regarding ground leakage current.

Blank page

Preface

Application Areas of the Dornier *Aries*

The Dornier *Aries* is a shock wave therapy unit designed for extrakorporeal shock wave therapy (ESWT), suitable for the following medical applications*:

- Pain therapy in the framework of extracorporeal shock wave therapy (ESWT)
- Trigger point treatment with shock waves

As in the case of applications involving other medical units, the physician responsible is also accountable for selecting and monitoring the patient during application of this unit.

Dornier *Aries*

Indications*

In surface-adjacent soft parts of the postural and musculoskeletal system, the Dornier *Aries* can be used for the following indications:

- Epicondylopathy of the elbow
- Heel spur and plantar fasciitis
- Achillodynia
- Pain conditions in the shoulder (supraspinatus tendon, calcific shoulder tendinitis)
- Patella tendonitis
- Proximal iliotibial band friction syndrome
- Tibial edge syndrome
- Trochanter irritation
- Morton's neuroma
- Dupuytren's contracture
- Low back pain

Further indications in the muscular area are:

- Fibromyalgia
- Treatment of myofascial trigger points

The Dornier *Aries* is also suitable for the treatment of pain caused by superficial plaques:

- Induratio penis plastica (IPP)

As in the case of applications involving other medical units, the physician responsible is also accountable for selecting and monitoring the patient and for administering the shock wave therapy.

The physician conducting the treatment is obligated to make herself/himself familiar with the medical state-of-the-art for ESWT, and is to accordingly adapt the relevant application and treatment procedure.

* The relevant national approval must be observed outside the EU.

Contraindications for Shock Wave Applications

Before applying a shock wave treatment, the attending physician must examine the relevant contraindications and make an appropriate treatment decision relative to the risks presented by alternative treatment methods.

Contraindications are, among others, as follows:

- Untreated coagulation abnormalities
- Pneumatized organs in the shock wave area
- Tumor in the shock wave area
- Aneurysms in the shock wave path
- (Unclear) pathological changes in the shock wave path

Relative Contraindications are:

- Shock wave exposure in the case of infections in the treatment area
- Epiphyseal cartilage in the focal area during growth
- Spinal column in the focal area
- Polyneuropathies
- Polyarthritis

The physician conducting the treatment is obligated to make herself/himself familiar with the contra-indications in the latest medical publications. For pregnant patients or those with a cardiac pacemaker, it must be carefully verified if an ESWT can be conducted without any danger, based on criteria in the literature.

Technical Information

The Dornier *Aries* generates shock waves by means of a disk coil and a membrane. The disk coil with a membrane and the technology for generating the shock waves are called EMSE.

EMSE stands for **E**lectro **M**agnetic **S**hock wave **E**mitter.

The disk coil is charged with high voltage pulses, whereby the membrane lying directly on the coil is thrust outwards. The shock wave thus generated is focused by means of an acoustic lens.

The applicator must be positioned onto the patient in such a way that the application area is within the area influenced of the shock wave. The treatment will then take place there.

Blank page

Description / Operation

Dornier *Aries*

The applicator [7] is integrated in the handle [6] and connected with the Dornier *Aries* [1] via the supply hose [4] using a connector. The connector is located behind the flap [5].

The EMSE in the applicator generates the shock wave.

The shock wave is conducted into the patient's body via the coupling area (see page 20 for the area influenced).

[1] Dornier *Aries*

[2] Control unit with touch display

[3] Switch for power on and off

[4] Supply hose

[5] Flap of the plug connection

[6] Handle

[7] Applicator

The label [3] “Observe the Operating Manual” is located beside the switch for power on and off.

Connections

[1] Connection **for service purposes only**

[2] Connection for potential equalization

[3] Power plug connection

[4] Microfuse

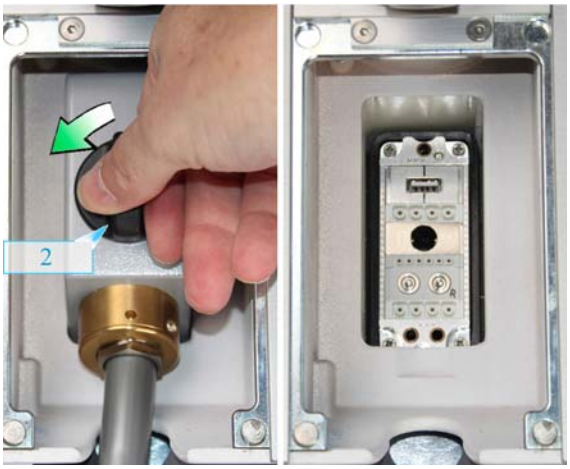
Plug Connection

Open the plug connection only for changing the applicator or for service and repair purposes.

The flap [1] covering the plug connection is fixed by magnets.

1 Switch off the Dornier *Aries*.

2 Remove the flap with light force.



3 Loosen the fixing screw [2] appr. 1½ rotations counter-clockwise.

4 Disconnect the plug.

CAUTION

Damage to electronic elements, corrosion

Penetrate from liquid into the plug or the socket

► Don't open the plug connection for and during cleaning / disinfecting the Dornier *Aries*.

Trolley*

A trolley is available to place the Dornier *Aries* optimally with respect to the patient.

The trolley is equipped with a drawer.

The front wheels of the trolley have a kick brake.

* Accessory

[1] Plus Button
[2] Minus Button
[3] Shock Wave Release Button

Applicator

Plus Button

Using the plus button [1] (convex) shock wave intensity resp. trigger frequency can be increased, depending on the preselection in the menu “Settings” (see page 32).

Minus Button

Using the minus button [2] (concave) shock wave intensity resp. trigger frequency can be decreased, depending on the preselection in the menu “Settings” (see page 32).

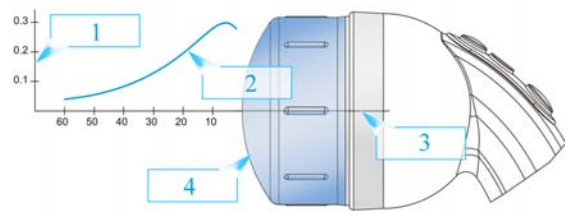
Shock Wave Release Button

The shock wave release button [3] is integrated in the handle of the applicator.

By pressing the shock wave release button single shock waves will be released.

By pressing the shock wave release button more than 2 seconds shock waves in continuous operation will be released. Pressing the shock wave release button again ends the continuous operation.
Pressing the shock wave release button more than 2 seconds proceeds with the continuous operation.

Up to 20,000 shock waves can be released in continuous operation.



The figure corresponds to energy level 20

Area Influenced

[1] Energy flux density (mJ/mm²)
[2] Energy flux density as a function of the distance to the focus
[3] Z axis (mm)
[4] Coupling area

see “Specifications, Applicator”, page 43.

Preparing the Dornier *Aries*

Pay Attention to Safety

Important safety instructions are described in the "Basic Safety Instructions" section and must be followed.

1 Observe relevant national regulations concerning the operation of shock wave units.

2 Ensure that the annual safety check has been completed.
See “Safety Checks” section, page 8.

Perform Visual Inspections

A visual inspection of the Dornier *Aries* and the treatment room must take place **daily before switching the equipment on.**

1 Check the following components for damage, deformation, wear:
- Casing
- Power cable
- Control unit
- Applicator
- Applicator supply hose

⚠ WARNING

Damaged components

Deformation, cracks, wear and tear, leaking fluid, etc.

► Do not put the Dornier *Aries* into operation; Notify Dornier Service

⚠ CAUTION

Damaged applicator coupling area

The coupling area has cracks, inclusions or holes

► You are not permitted to begin the treatment, you must notify Service.

⚠ CAUTION

Risk of stumbling

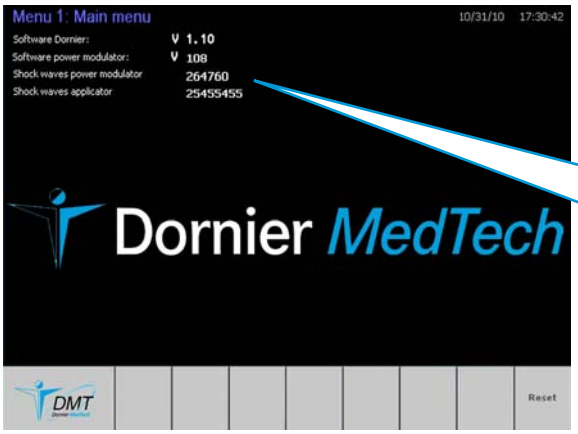
Unsecured cables and lines on the floor

► Lay the cables and lines in such a way that they do not lie in the main area where people are; if possible, secure (e.g., cable bridges).

2 Connect the power cable.

Starting the Dornier *Aries*

1 Switch on the Dornier *Aries* with the power switch.



After being switched on, the Dornier *Aries* performs the initialization.

The start display is indicated during the initialization phase. The info block shows:

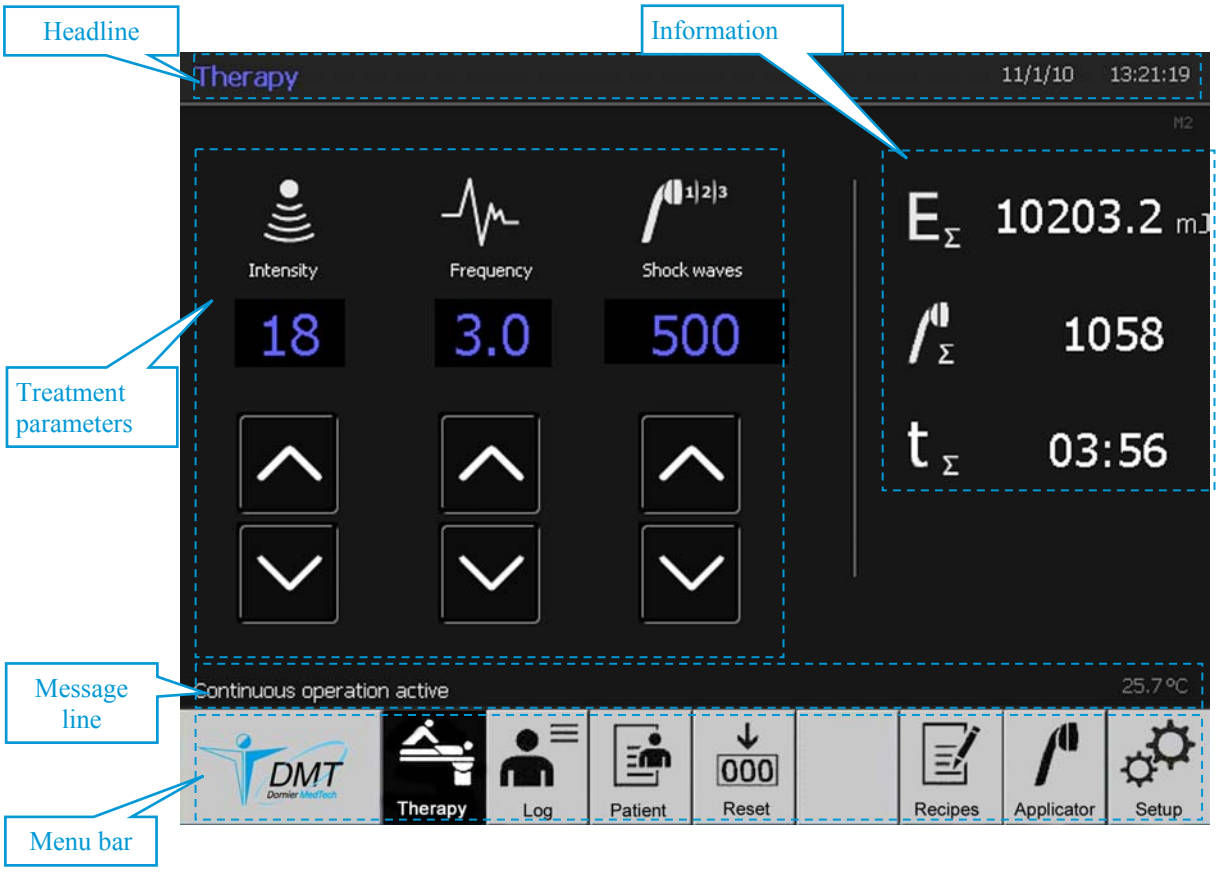
Software Dornier:	V 1.10
Software power modulator:	V 108
Shock waves power modulator	264760
Shock waves applicator	25455455

The Dornier *Aries* is ready for operation after short time. Menu “Therapy” is displayed.

Prepare Treatment

As in the case of applications involving other medical units, the physician responsible is also accountable for selecting and monitoring the patient during application of Dornier *Aries*.

Menu "Therapy"



Headline

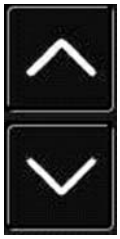
The headline shows menu name, system date, and time. Setup of date and time in menu “Setup System”, page 34.

Information

The cumulative energy, the total number of shock waves applied till now and the elapsed time of the current treatment are shown as information.

Set Treatment Parameters

The treatment parameters can be adopted from a treatment program “Recipes treatment” (see page 30), or defined in the menu ”Settings” (see page 32) or set



using the touch keys

Plus

and

Minus

as follows:

1 Set **shock wave intensity**.
The shock wave intensity can be set in energy levels from 1-20.
Level 1 corresponds to a low shock wave intensity,
level 20 to a high one.

2 Set **trigger frequency**[*].
The trigger frequency 0.5 Hz to 20 Hz
can be set in steps of 0.5 Hz.
The maximum possible frequency depends on the selected shock wave intensity.
See “Energy Levels”, page 43.

Settings for the Continuous Operation

Adopt the settings from a treatment program “Recipes treatment” (see page 30), or define in the menu “Settings” (see page 32) or set as follows

3 using the touch keys

or


or


Settings for the continuous operation are:

- number of the shock waves to be applied or
- energy in mJ to be applied or
- treatment time in minutes and seconds

[*] In the rare case that the operating temperature gets too high, the selected trigger frequency on the Dornier *Aries* is automatically reduced for safety reasons (cooling period). During this cooling period, the originally selected trigger frequency is shown on the display. After the cooling period to normal operating temperature the trigger frequency is set to the selected value.

Message Line

The message line informs about the system condition.

Menu Bar

The menu bar contains the touch keys for moving into other menus.

current menu

moves to the menu with detailed treatment data of the patient
see page 27

moves to the menu, in which the data of the last 100 treatments can be seen
see page 28

ends the current treatment
The data of treatment will be stored and subsequently the counters

- cumulative energy
- total number of shock waves and
- elapsed treatment time

are reset to “0”.

For resetting, press the touch key more than 2 seconds.

moves to the menu, in which 50 treatment programs “Recipes” can be stored.

The parameters of stored recipes can be activated and adopted for the current treatment, see page 30.

moves to the menu “Settings”
see page 32

moves to the menu “Setup System”
see page 34

Perform Treatment

⚠ WARNING

Incorrect operation of the unit

Non-observance of safety instructions and regulations

► Read and follow safety instructions and regulations in the "Basic Safety Instructions" section in this Operating Manual.

⚠ WARNING

Risks and side-effects of the treatment

Non-observance of important information

► Read and follow important information in the "Basic Safety Instructions" chapter, "Medical Information" section.

1 Apply coupling medium (e.g. coupling gel) to the skin of the patient or to the coupling area of the applicator.

Release Single Shock Waves

1 Press the shock wave release button [1] a short-time, in order to release single shock waves.

ℹ The total numbers of shock waves, the cumulative energy, and the elapsed treatment time are displayed as information.

Release Shock Waves in Continuous Operation

1 Press the shock wave release button more than 2 seconds, in order to release shock waves in continuous operation.

ℹ The continuous operation will be interrupted by pressing the shock wave release button a short-time.

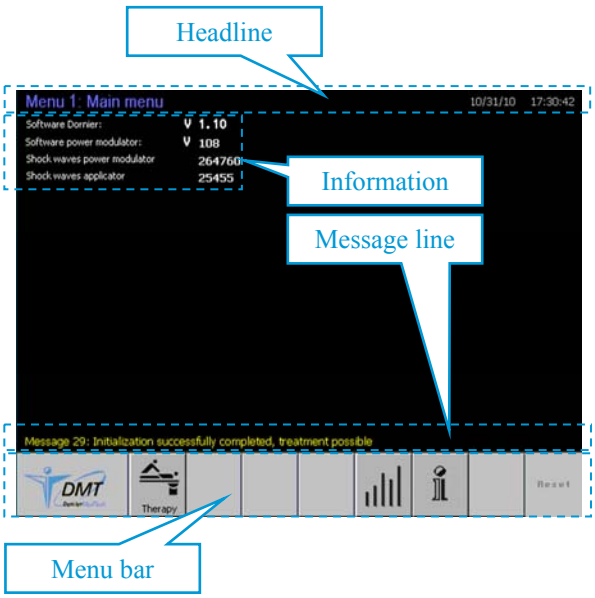
2 If requested, press the shock wave release button [1] a short-time, in order to release single shock waves during the interruption.

3 Press the shock wave release button more than 2 seconds, in order to proceed with the continuous operation.

ℹ Shock waves, which were not released in continuous operation (single shock waves) during the treatment, will be added to the preselected number.

ℹ **The reset of the counters** (shock waves, cumulative energy, and elapsed treatment time) can be activated at any time and **ends the current treatment**, see page 29.
To reset press the touch key more than 2 seconds.

Main Menu



Press the button, in order to move to the main menu.

Headline

The headline shows menu name, system date, and time. Setup of date and time in menu "Setup System", page 34.

Information

The info block shows:

- the software version of the system
- the software version of the power modulator
- the total number of shock waves of the power modulator
- the total number of shock waves of the applicator

Message Line

The message line informs about the current system condition.

Menu Bar

The menu bar shows the touch keys.

Active touch keys have symbols and are described as follows.

Pressing the button more than one second moves to the password menu.
The password levels are reserved for the Dornier Service.

moves to menu 2 "Therapy"
(page 22)

moves to menu 23: "Histogram"
(page 36)

shows the menu 52: "Fault log" in the main menu
(page 38)

Reboot of the system

Auxiliary Menus

Auxiliary menus offers the operator

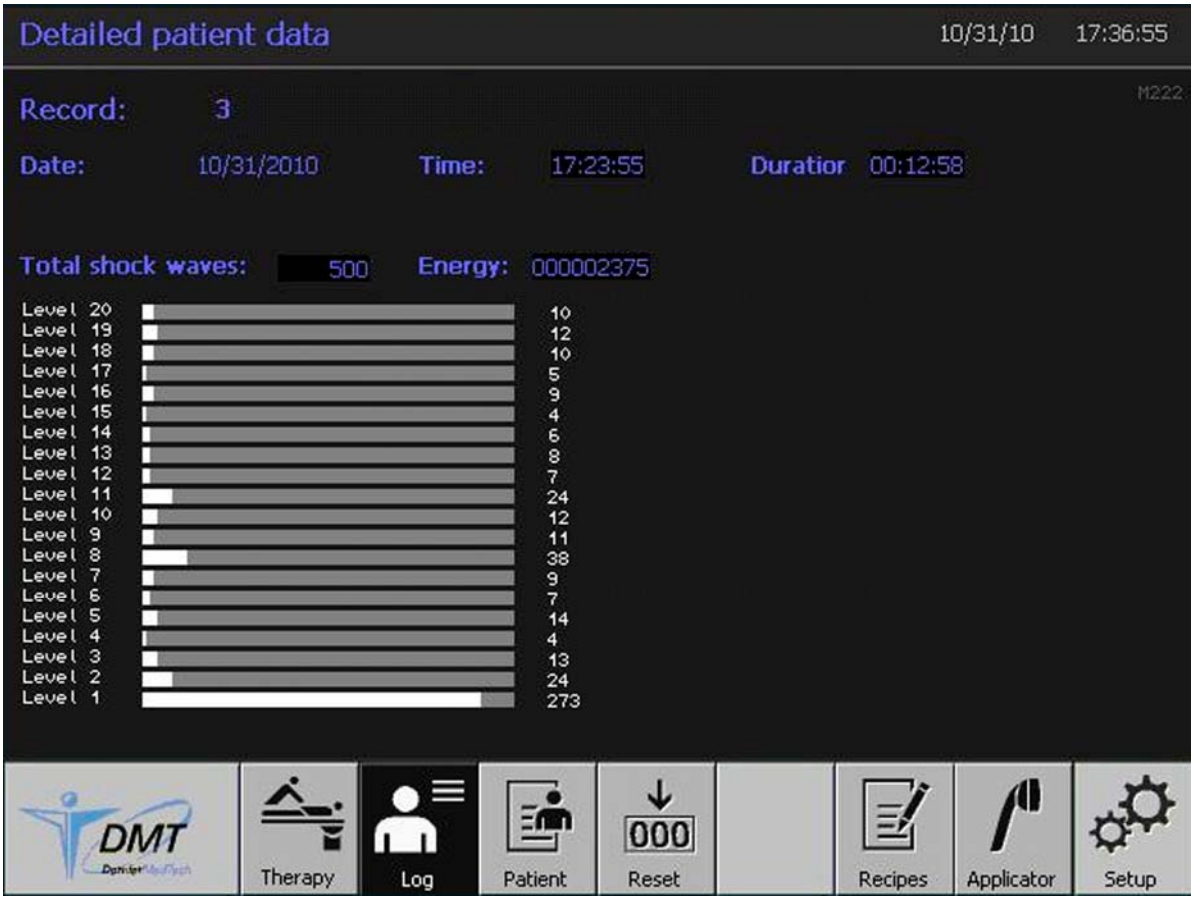
- the possibility
  – to select presettings
  – to carry out settings
  – to define treatment programs
- information about treatment data

Menu “Detailed patient data”

1 Press touch key, in order to activate the menu “Detailed patient data”.

The following example shows the details of the set of data 3, the treatment dated 31st of Oct. 2010, time 17:36:55.

The details of the set of data 0 are active after the Dornier *Aries* has been switched on (see page 28).



Press the touch key, in order to select another set of data to be displayed.

Menu „Patient data tables“

1 Press touch key, in order to activate the menu “Patient data table”
The set of data 0 (active) and the first 5 stored sets of data are displayed.

The sets of data of the last 100 treatments are stored in the menu “Patient data tables”.

Record / Change the Patient Name

The name of the patient can be recorded resp. changed before or after the treatment.

1 Press the touch field “Name, first name” resp. the touch field with the requested patient name, in order to enter resp. to change the name.
An alphanumeric keyboard will be faded in.

i Corrections can be made using the touch key „←“.

2 Enter the name and confirm with „↵“, in order to adopt the new name
or
interrupt with „**Esc**“, without adopting the new name.
The alphanumeric keyboard will be faded out.

Store Treatment Data

The treatment data of the current set of data (0) is stored on position 1 of the patient data table by pressing the touch key “Reset” (see menu “Therapy”, page 22).

All previous sets of data will be shifted about one position.
The last set of data (No: 100) will be deleted.

View the Patient Data

1 Press the touch key, in order to display the previous 5 sets of data (96 to 100).

or

Press the touch key, in order to display the next 5 sets of data (6 to 10).

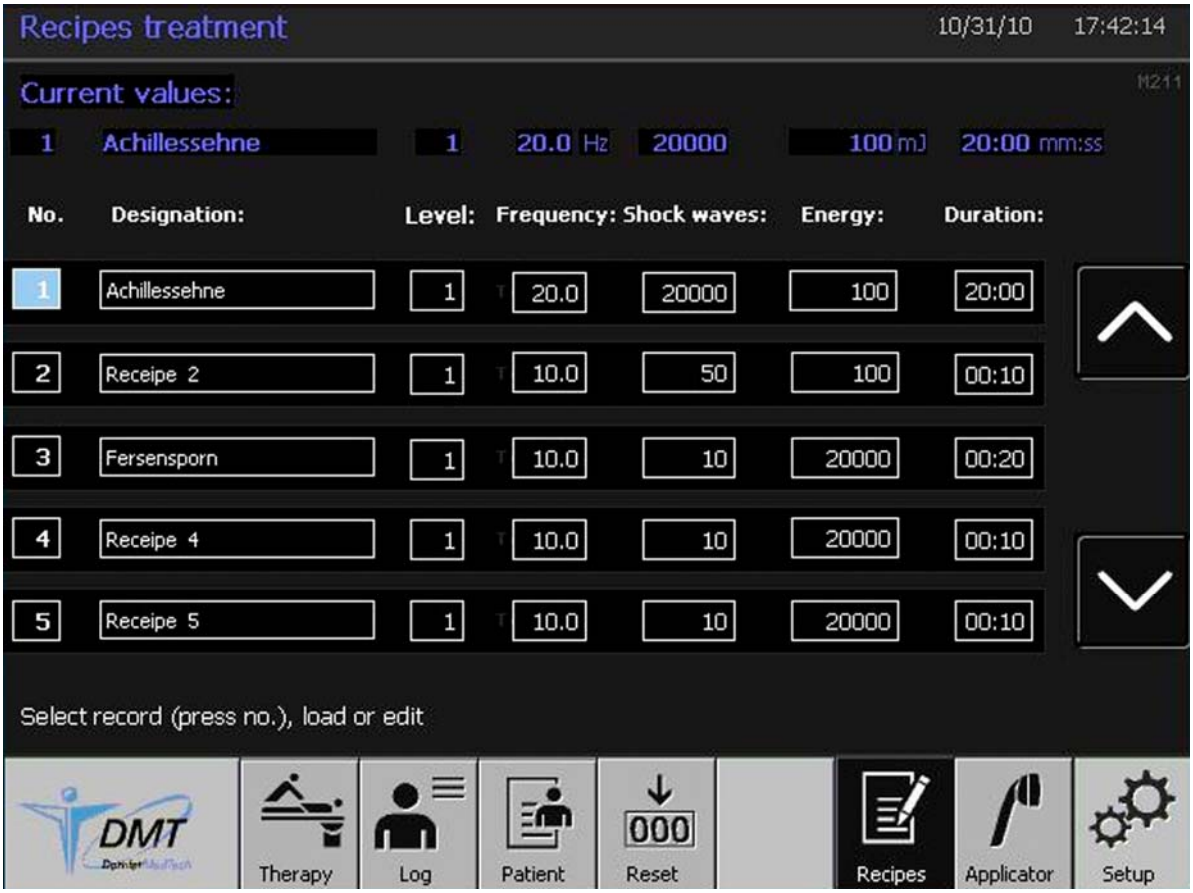
2 Press the touch field with the number of the requested set of data (e.g. 3), in order to activate this set of data.

3 Press the touch key, in order to display the detailed treatment data of the activated set of data (see page 27).

Menu “Recipes treatment”

1 Press the touch key, in order to activate the menu „Recipes treatment“.
The current values of the active set of data and the first 5 stored sets of data (recipes) are displayed.

The treatment parameters for 50 recipes (sets of data) can be defined, stored, and modified in the menu “Recipes treatment”.



2 Press the touch key, in order to display the previous 5 sets of data (46 to 50).

or

Press the touch key, in order to display the next 5 sets of data (6 to 10).

Adopt Recipe for the Treatment

1 Press the touch key with the number of the requested set of data (e.g. 3). The set of data will be activated.

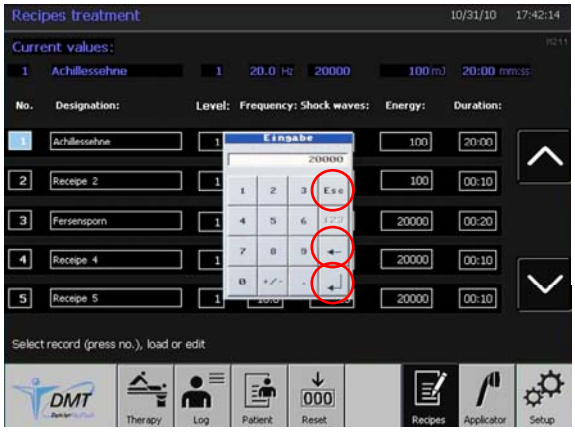
2 Press the touch key, in order to adopt the name and parameters of the recipe for the treatment. The name is displayed in the headline of the menu “Therapy” (page 22).

Create / Process Recipe

1 Press the touch field with the designation of the requested “Recipe”, in order to enter resp. to change the name.
An alphanumeric keyboard will be faded in.

ℹ Corrections can be made using the touch key „←“.

2 Enter the name and confirm with „↵“, in order to adopt the new name
or
interrupt with „**Esc**“, without adopting the new name.
The alphanumeric keyboard will be faded out.



3 Press the touch field with the corresponding parameter (e.g. level) of the requested recipe, in order to enter resp. to change the value.
A numeric keyboard will be faded in.

ℹ Corrections can be made using the touch key „←“.

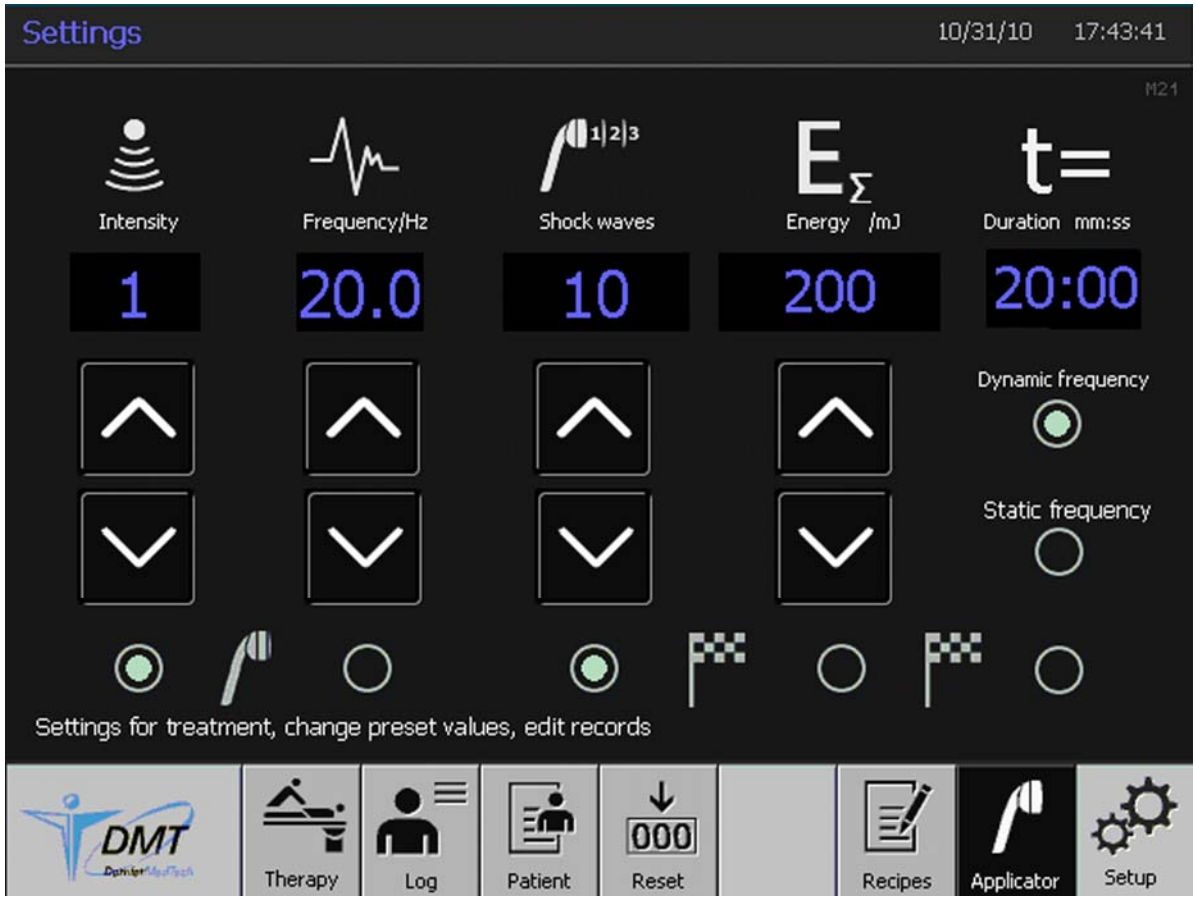
4 Enter the value and confirm with „↵“, in order to adopt the new value
or
interrupt with „**Esc**“, without adopting the new value.
The numeric keyboard will be faded out.

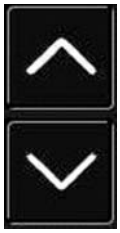
ℹ The values, which can be entered as described in step 3, must be within the defined limits. See pages 32 and 43.
Entered values, which are too high, are reduced by the software to the utmost value.

5 Press the touch key, in order to adopt name and parameters of the modified “Recipe” for the current treatment.

Menu “Settings”

1 Press the touch key, in order to come to the menu “Settings”.





Use the touch keys

Plus

and

Minus

to preselect the values for

- shock wave intensity
  possible settings: level 1 to 20

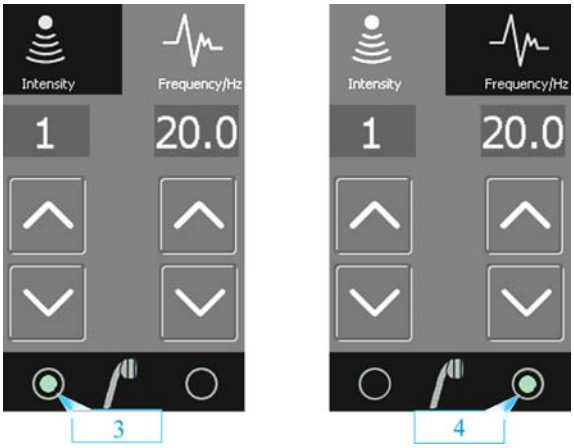
- shock wave frequency
  possible settings: trigger frequency 0.5 to 20 Hz

- shock waves to be applied in continuous operation
  possible setting: 2 to 20,000 shock waves
- energy to be applied in continuous operation
  possible setting: 100 to 200,000 mJ
- time (duration) of the continuous operation
  possible setting: 10 seconds to 59 minutes

Configure the Operation Buttons of the Applicator

The function of the applicator's plus and minus button can be preset in such a way, that either the shock wave intensity or the shock wave release frequency can be changed.

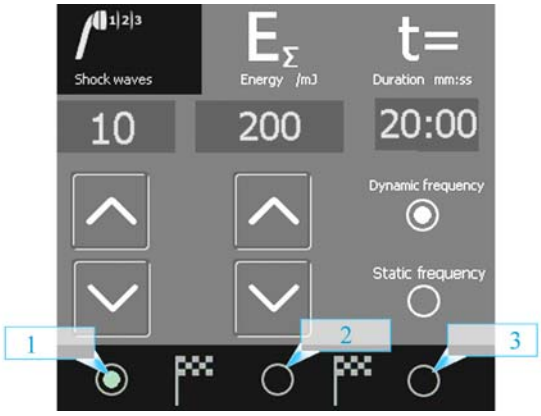
[1] Plus button
[2] Minus button



Activate circle [3] (press function key), if the shock wave intensity should be changed by using plus button [1] resp. minus button [2] of the applicator.

Activate circle [4] (press function key), if the shock wave release frequency should be changed by using plus button [1] resp. minus button [2] of the applicator.

Activate the Settings for Continuous Operation

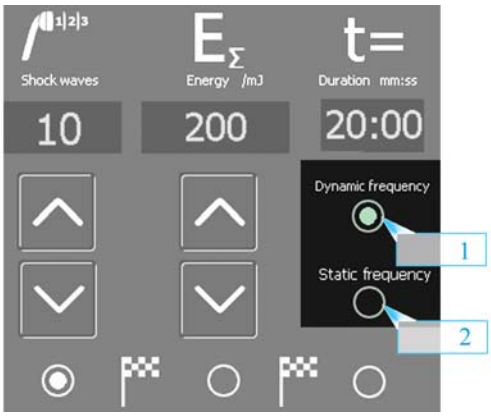


Activate circle [1] (press the function key), in order to apply the number of the set shock waves in continuous operation.

Activate circle [2] (press the function key), in order to apply the set energy in continuous operation.

Activate circle [3] (press the function key), in order to process the set treatment time in continuous operation.

Set the Characteristics of the Frequency



The setting of the characteristics of the frequency is only relevant for the continuous operation.

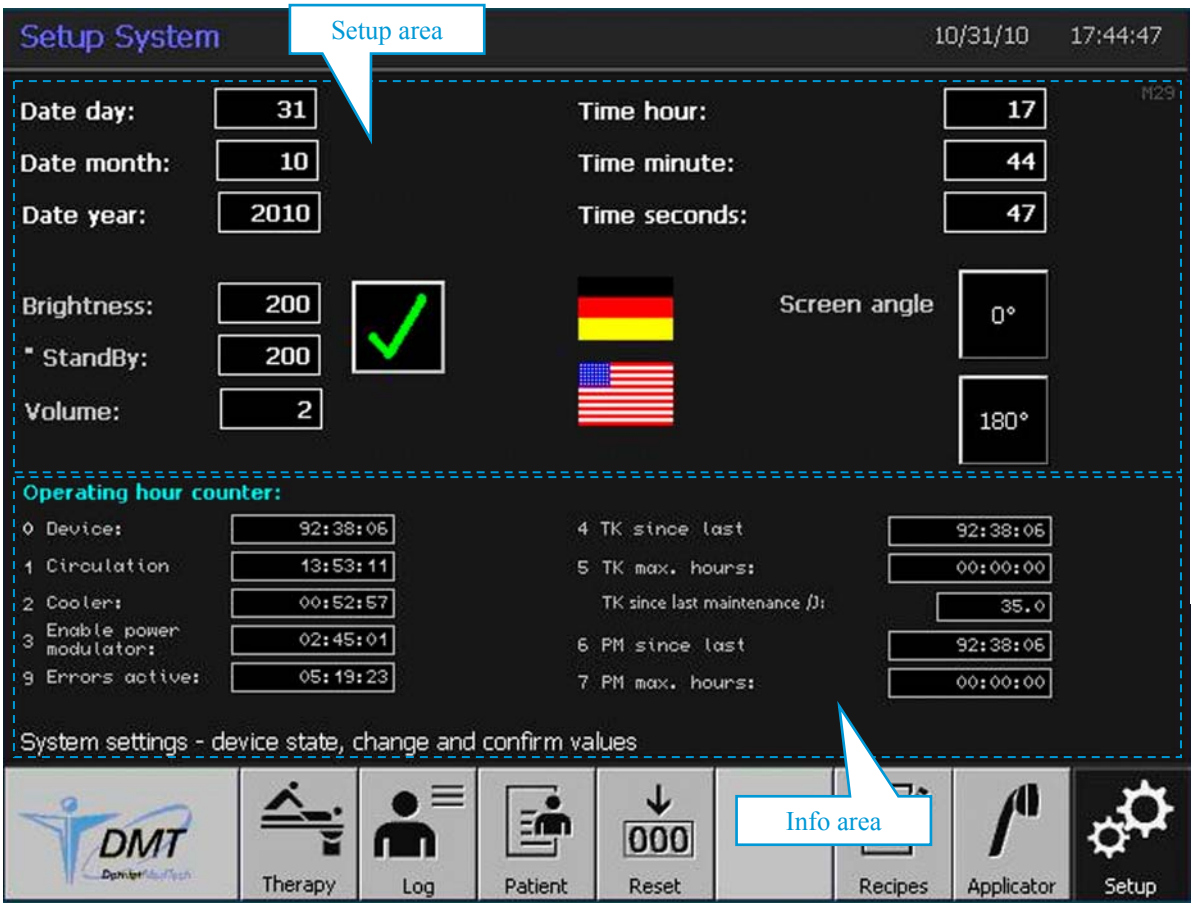
Activate circle [1] (press function key), if the maximum possible shock wave frequency should be selected automatically, while changing the shock wave intensity during the continuous operation.

Activate circle [2] (press function key), if the maximum possible shock wave frequency should not be selected again, while changing the shock wave intensity during the continuous operation.

See "Max. trigger frequency", page 43.

Menu „Setup System“

1 Press the touch key, in order to come to the menu “Setup System”.



Info Area

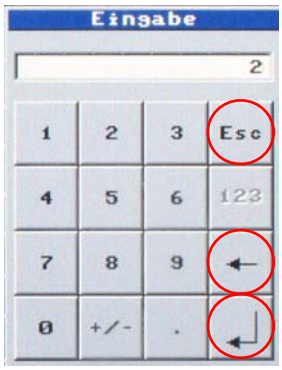
The info area shows the operating hours. The values cannot be changed.

Setup Area

Possible settings in the setup area:

- the date
  – day (numeric field)
  – month (numeric field)
  – year (numeric field)
- the time
  – hour (numeric field)
  – minute (numeric field)
  – second (numeric field)
- the brightness
  – standby
- the volume
- the language
- the screen orientation

oder



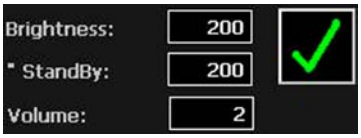
Set Date and Time

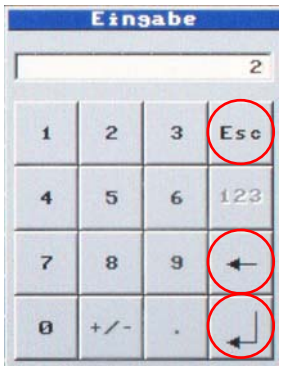
1 Press the corresponding numeric field (e.g.: „10“ for the month).
The numeric keyboard will be faded in.

ℹ Corrections can be made using the touch key „←“.

2 Enter the value and confirm with „↵“, in order to adopt the new value
or
interrupt with „**Esc**“, without adopting the new value.
The numeric keyboard will be faded out.

ℹ The input of a value by mistake, which is not feasible (for example month: “15”), will be corrected by the system to the maximum possible value (e.g. month: 12), as soon as the numeric keyboard is closed.





Set Brightness and Volume

1 Press the corresponding numeric field (e.g.: „210“ for the brightness).
The numeric keyboard will be faded in.

ℹ Corrections can be made using the touch key „←“.

2 Enter the value (between 50 and 255) and confirm with „↵“, in order to adopt the new value
or
interrupt with „**Esc**“, without adopting the new value.
The numeric keyboard will be faded out.

3 Press the button ✓, in order to store the adopted value. The symbol is displayed in yellow during the storing procedure.

Set Language

1 Press the touch key for the requested language.

Set Angle of the Screen

The display of the Dornier *Aries* can be rotated about 180°.

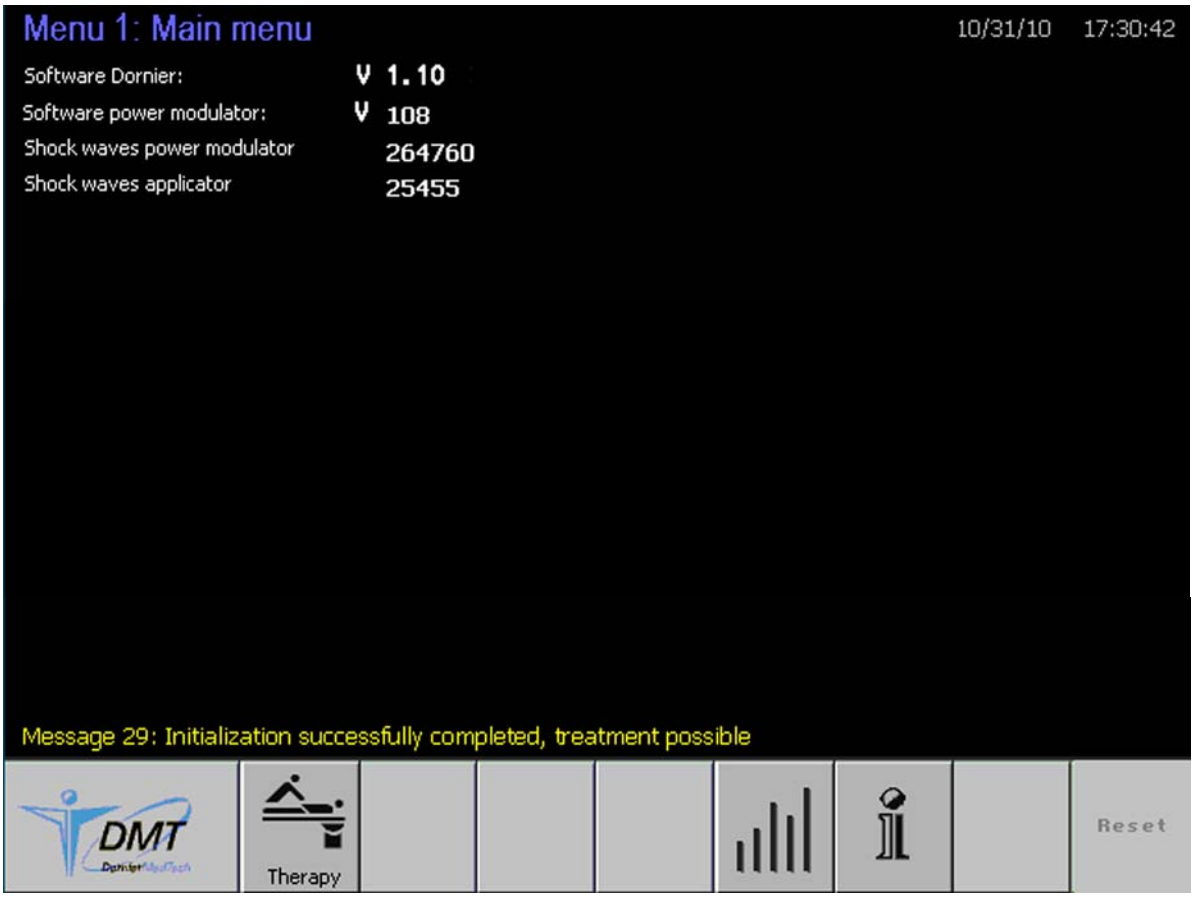
1 Press the touch key with the degree of angle (0° or 180°) of the requested screen orientation at minimum for 2 seconds.

Menu “Histogram”

The menu “Histogram” shows the following histograms in sequence:

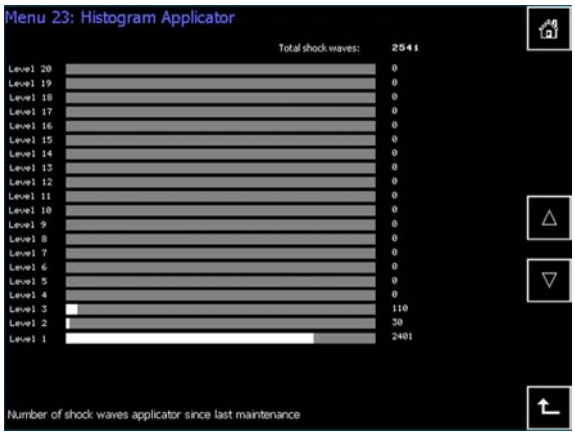
- Histogram Applicator
  Display of the shock waves, which where released since the last maintenance of the applicator
- Histogram Power Modulator
  Display of the shock waves, which where released since the last maintenance of the power modulator

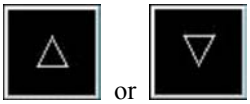
1 Press the touch key, in order to come to the main menu.



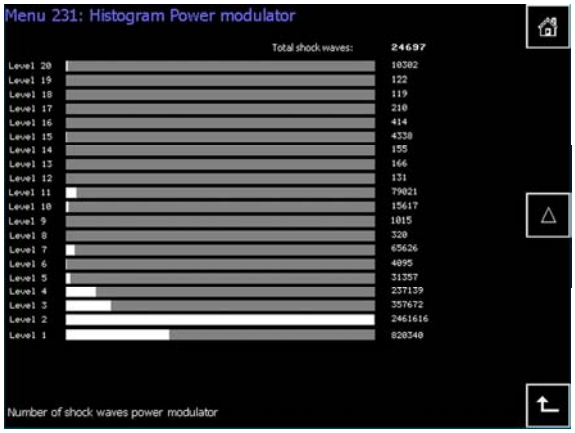
2 Press the touch key, in order to open the menu “Histogram” (see page 37).

Submenus “Histogram”





3 Press the touch key, in order to display the next histogram.



4 Press the touch key, in order to come to the menu “Therapy”.

5 Press the touch key, in order to come to the main menu.

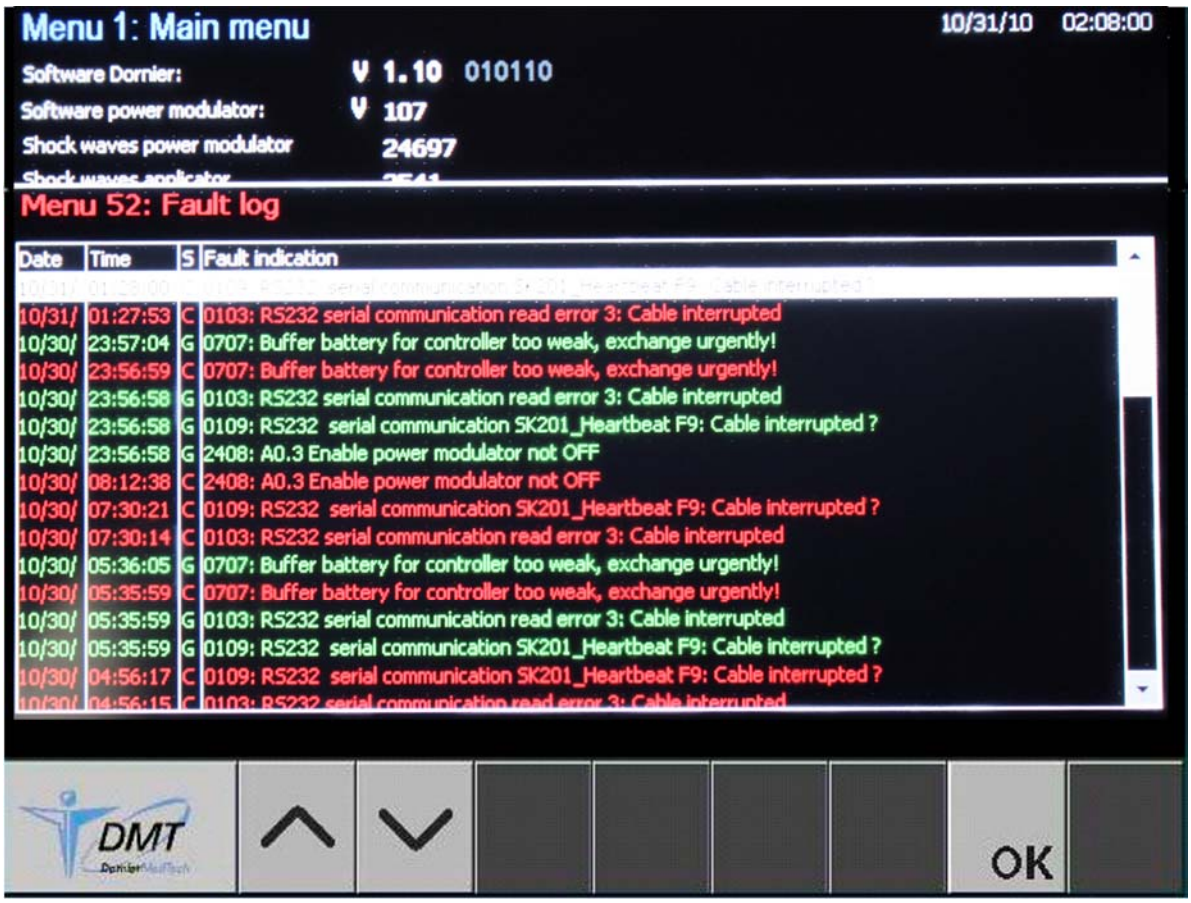
Menu “Fault log”

1 Press the touch key, in order to come to the main menu.

2 Press the touch key, in order to fade in the menu “Fault log” into the main menu and in order to get information about faults.

The menu “Fault log” shows status messages and error messages according:

- Date (month day)
- Time (hour minutes seconds)
- S (classification of the fault)
- Fault indication (description)



3 Use the scrollbar on the right side in menu 52 to scroll forwards and backwards.

4 Press touch key "up" resp. "down", in order to select the previous resp. the next message.

5 Press touch key, in order to close the menu “Fault log”.

Conclude Treatment

If requested, the name of the patient can be entered resp. changed in the current set of data of the “Patient data tables” (see page 28).

1 Reset the shock wave counter, the cumulative energy, and the elapsed treatment time, in order to store the data in the “Patient data tables”.

The data of the last treatment are also stored even if the Dornier *Aries* is switched off or by loss of power.

2 Switch off the Dornier *Aries*.

3 Clean the applicator (see page 50).

4 Place the applicator, as shown.

Blank page

Specifications

All the specifications are typical values unless tolerance is specified.

Classification

Protection class according to EN 60601-1	I
System classification according to 93/42/EEC	IIb
Explosion protection	Operation in potentially explosive and/or combustible environments is not permitted.

IP Protection Class According to DIN 40 050

Basic unit	IP 54, IP 43
Applicator	IP 65

Voltage / Frequency / Power

Voltage	100 - 240 V AC
Frequency	50/60 Hz
Power	max. 250 VA

Dimensions

Basic unit with applicator and holder (W x D x H)	426 x 513 x 241 mm / 16.8 x 20.2 x 9.5 inches
Applicator (diameter)	72 mm / 2.83 inches

Weight

Basic unit	195,2 N / 43.9 lbs
Applicator	14.7 N / 3.3 lbs

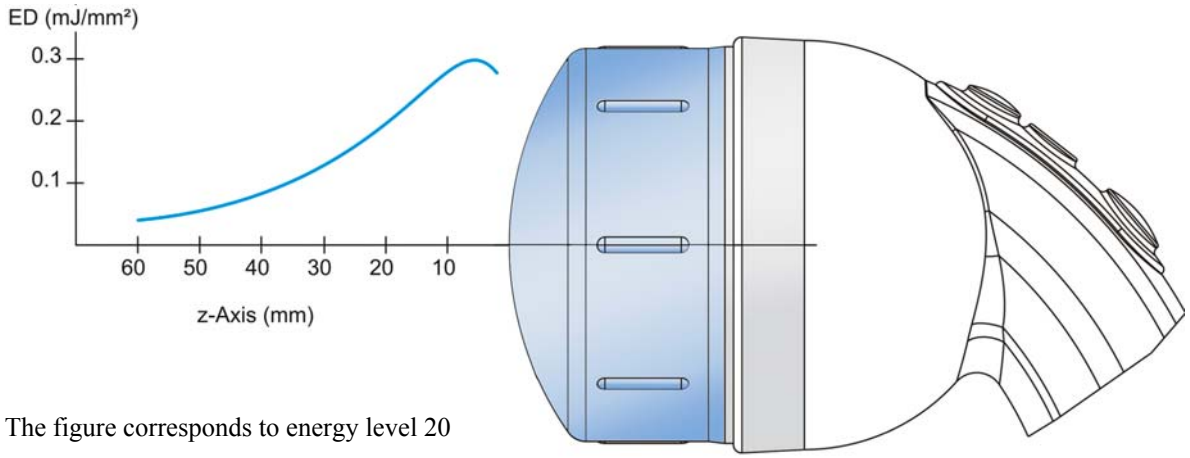
Operation

Continuous operation	100 %

Applicator

Shock wave generation principle	EMSE
Coupling unit geometry	Spherical segment
Coupling area temperature	max. 41 °C / 106 °F
Focus area	Permanently set, see diagram “Treatment Area, Area Influenced”

Treatment Area, Area Influenced



The figure corresponds to energy level 20

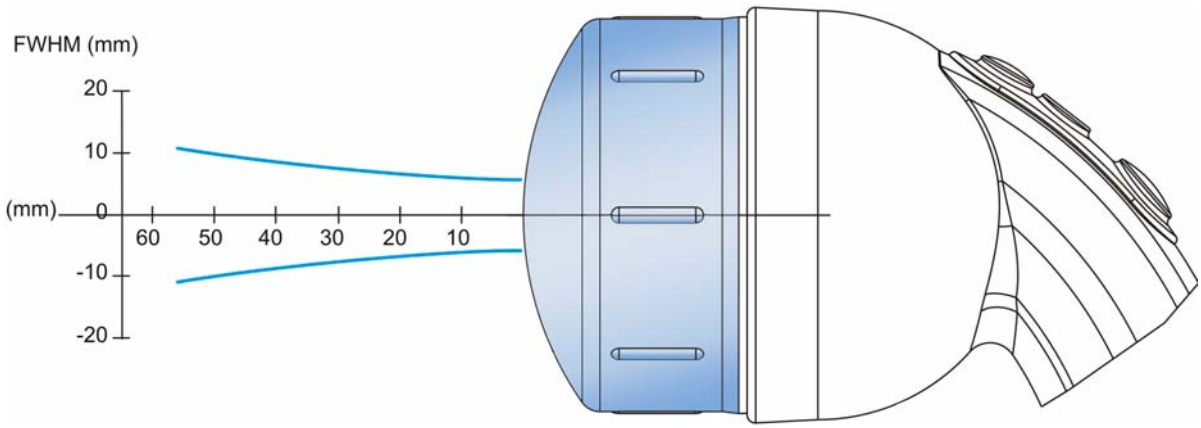
Energy Levels

Level	Max. trigger frequency (Hz)	Max. energy flux density* (mJ/mm²)	Max. energy (12mm)* (mJ)
1	20	0.010	0.28
2	16	0.013	0.85
3	10	0.028	2.00
4	8	0.051	3.40
5	6	0.062	4.67
6	5	0.084	5.77
7	5	0.096	6.64
8	4	0.117	8.12
9	4	0.130	9.24
10	4	0.150	10.5
11	4	0.169	11.8
12	3	0.179	12.5
13	3	0.200	14.1
14	3	0.212	14.9
15	3	0.224	15.7
16	3	0.249	17.5
17	3	0.262	18.5
18	3	0.280	19.0
19	2.5	0.290	20.5
20	2.5	0.306	21.6

* Measured values are valid at T = + 20 °C / + 68 °F, room temperature

Representation of the Caustic

Development of the “half-power bandwidth” (FWHM)
(half of the max. energy flux density)
across the distance to the focuss



Sound Level

	Appraisal level L (dB(A))			
Exposure Time	**1 hour**	**2 hours**	**3 hours**	**4 hours**
Level 1 / 20Hz	65.7	68.7	70.5	71.7
Level 3 / 10Hz	72.9	75.7	77.6	78.9
Level 10 / 4Hz	80.7	83.7	85.4	86.7
Level 20 / 2.5Hz	84.3	87.3	89.0	90.3

Standby sound level (fan and pump active, 1 m in front of the Dornier *Aries*) = 47.8 dB(A)

Legend: Exposure time = Time of shock wave application during an 8-hour work day
Measurement point = 50 cm / 19.7 inches behind the applicator (coupling to patient phantom)
Highlighted values require the following measures, according to the EC "Noise Directive (2003/10/EC)": 80 dB(A) < L < 85 dB(A): Provide ear protection.
L ≥ 85 dB(A): Ear protection must be worn.

Environment

Temperature

Operation	0 °C to 32 °C/32 °F to 90 °F
Transport / storage	-10 °C to 60 °C/14 °F to 140 °F

Relative Humidity

Operation	30 to 75 % (non-condensing)
Transport / storage	10 to 90 % (non-condensing)

Atmospheric pressure

Operation	700 to 1060 hPa
Transport / storage	500 to 1060 hPa

Messages,
Error Corrections

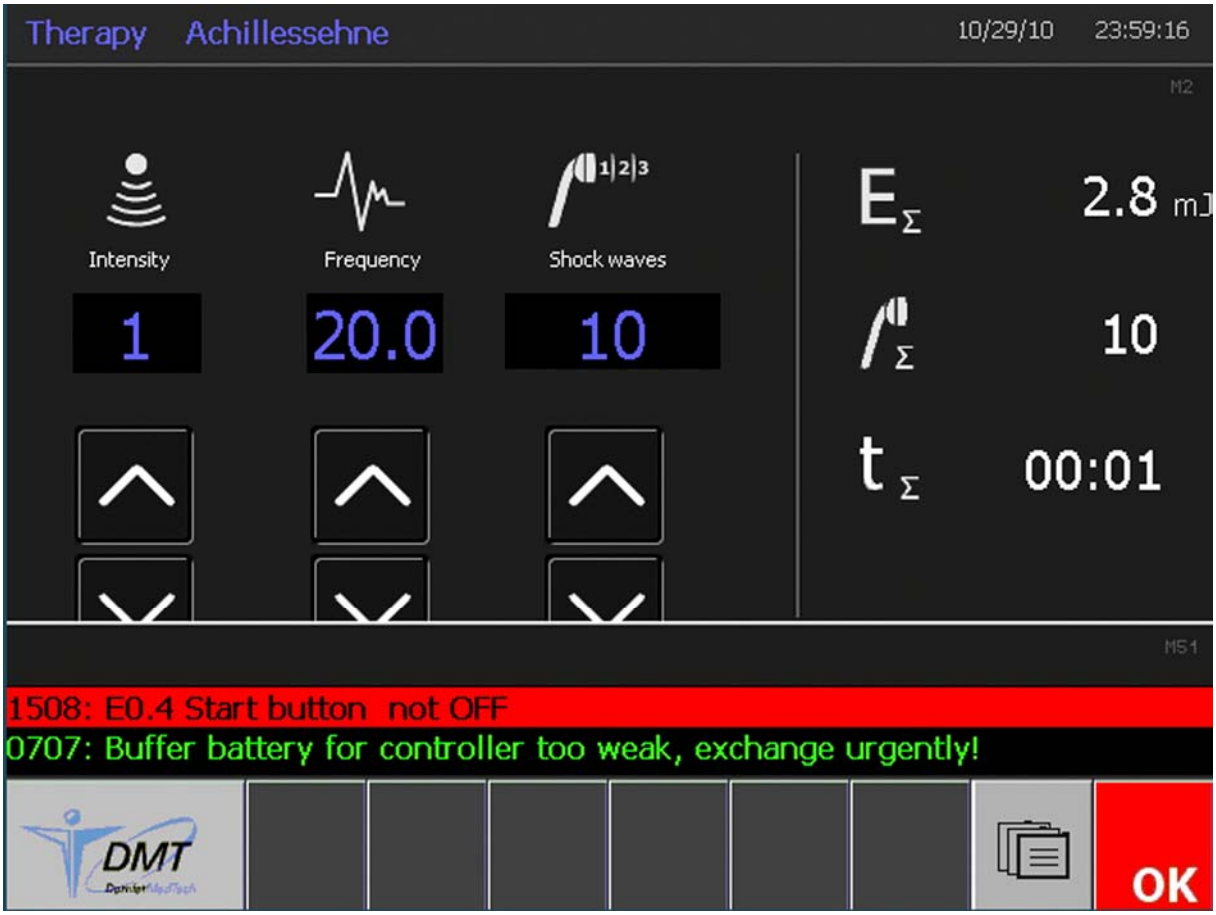
Messages

Status Messages

Status messages are displayed in the menu “Fault log” (see page 38).

Error Messages

Error messages must be acknowledged.



Pressing the button confirms the acknowledgement of the message and ends the display.

In case the power modulator fails, the Dornier *Aries* must be switched off and on again after acknowledgement of the message.

Press the touch key, in order to move to the menu “Fault log”.

Error Corrections

Fault	possible reason	recommended reaction
The Dornier *Aries* cannot be switched on.	Switch for power on and power off defective	Call Dornier Service
	Microfuse defective	Inform your technical department
	Missing power supply	Inform your technical department
	unknown reason	Call Dornier Service
Fault message while switching on the Dornier *Aries* "Buffer battery for controller too weak, exchange urgently!"	Too long storage time of the Dornier *Aries* Lifetime of the battery (depending on the conditions 2 to 5 years) reached	Arrange battery exchange by Dornier Service

Blank page

Cleaning and Disinfecting

Clean and Disinfect the Dornier *Aries*

Users of this equipment have an obligation and responsibility to provide the highest degree of infection control possible to patients, co-workers and themselves.

⚠ CAUTION

Infection / cross-contamination

Non-observance of hygiene regulations

► Follow all hygiene control policies regarding personnel and equipment that apply to your work area, department or hospital.

⚠ CAUTION

Risk of infection

Non-observance of hygiene regulations

► Only personnel especially trained resp. instructed in handling hygiene are permitted to clean or disinfect medical devices. It must be ensured in each case that the particular responsible person can perform his/her job on the basis of his/her position and qualification.

⚠ CAUTION

Contamination

Working without protective gloves

► Use disposable gloves when cleaning / disinfecting.

⚠ CAUTION

Short-circuit or damage to electronic elements

Penetrate from liquid into the unit, plugs or sockets

► In principle never use disinfectants in spray form.

► Before cleaning and disinfecting switch off the Dornier *Aries* and pull the power plug out of the wall outlet.

► Keep plugs and sockets always dry.

CAUTION

Corrosion

Use of unsuitable cleaning or disinfection solutions

► Do not use any abrasive or corrosive solutions.

► Instructions given by the manufacturer of the cleaning and disinfection solutions should be closely followed.

► Never let the cleaning or disinfection solutions penetrate into the unit.

Proper cleaning is crucial for successful subsequent disinfection.

Cleaning Agent, Cleaning Process

Wear disposable gloves throughout the entire cleaning process.

Commercially available cleaning agents for medical devices can be used for cleaning.

The surfaces are resistant to many chemical substances. They can be damaged by aggressive chemicals, however.

Never clean the surfaces with abrasive agent or rough objects.

Surfaces can be cleaned with a soft, moistened cloth.

Please use only lint-free, disposable wipes that are not made of recycled materials.

Visible impurities must be removed immediately.

When cleaning, make sure that no liquids penetrate into the unit. Wet spots must be dried immediately.

Clean and Disinfect the Applicator

⚠ CAUTION

Short-circuit or corrosion on the applicator

Immersion of the applicator into fluid

► Do not immerse applicator/connector in fluid.

Cleaning agent, cleaning process, see above.
This does not apply for the coupling area, to this see “Cleaning and Disinfecting the Coupling Area of the Applicator”, page 51.

Cleaning and Disinfecting the Coupling Area of the Applicator

⚠ CAUTION

Infection

Non-observance of hygiene regulations

► Only personnel especially trained or instructed in handling hygiene are permitted to clean or disinfect medical devices. It must be ensured in each case that the particular responsible person can perform his/her job on the basis of his/her position and qualification.

CAUTION

Damage to the coupling area

Direct sunlight

► Avoid any direct sunlight on the material.

CAUTION

Damage to the coupling area resulting from detergents and disinfectants

Limited resistance to solvents and compatibility of the applicator and its coupling area

► Use only detergents and disinfectants that have been suggested and approved by Dornier MedTech GmbH.

► If other detergents and wiping disinfectants are used, observe the datasheets of the respective agents regarding the solvent resistance and compatibility:
these agents are not permitted to contain alcohols, solvents (e.g., benzene, acetone, chlorinated hydrocarbons), aldehydes and oils.

► Do not expose the coupling area to a temperature higher than 70 °C / 158 °F during the reprocessing.

► Do not sterilize.

An independent laboratory has proven that the coupling area can be effectively cleaned and disinfected using the detergent *Desmofix N* and the disinfectant *Microbac forte* from Bode Chemie, Hamburg, Germany, and by following the described procedure.

The coupling area is generally classified as a non-critical product, although there are risks, especially if patients have open wounds or skin injuries.

The coupling area is a reusable medical device. It has to be prepared before each new treatment and each new patients (cleaning/disinfection; it should not be sterilized). Cleaning and disinfection must be defined in the hospital's / medical practice's hygiene plan using a procedure validated for the particular product and method.

Use only separate detergents and disinfectants. The disinfectant has to be proven to be effective (such as DGHM listing, CE symbol or FDA approval) and must be approved for disinfecting plastic surfaces by wiping. Furthermore, the detergent and disinfectant have to be compatible with one another.

Always observe the information provided by the manufacturer of the detergent and disinfectant regarding the concentration and duration of the application, areas and type of application, etc. If the concentration is too high, it could damage the material surface. If the concentration is too low, sufficient disinfection cannot be guaranteed.

Please use only lint-free disposable wipes that are not made of recycling materials.

ℹ Always check the coupling area for cleanliness and damage before each treatment.
If the time to the next patient treatment is longer than 14 days in covered condition, you should completely clean and disinfect the coupling area again.

How to proceed

⚠ CAUTION

Contamination

Working without protective gloves

► Use disposable gloves when cleaning / disinfecting.

CAUTION

Damage to the surface

Use of sharp objects

► Be sure to avoid using sharp objects.

CAUTION

Damage to electronic elements

Use of disinfectants in spray form

► Disinfectants in spray form are never permitted to be used.

Please also observe any special national regulations in your country or special rules in your clinic / medical practice.

Pre-cleaning

Use clean disposable wipes to thoroughly remove the coupling gel from the coupling area immediately after treating each patient (no more than 10 min). The coupling area should be almost free of coupling gel after pre-cleaning.

Cleaning

Then continue to clean the coupling area with the aid of a water-soluble detergent (within 2 hours of the last treatment or pre-cleaning). You must always observe the manufacturer's specifications for the detergent regarding concentration and duration of application. Clean the coupling area 3 to 4 times.

Make sure that no moisture gets into the Dornier *Aries* and/or applicator during the cleaning. Dry any wet spots immediately. Pay special attention to the coupling area when cleaning.

Clean it until soiling or coupling gel residues can no longer be seen.

Remove the remaining cleaning solution with a clean disposable wipe after the application time given by the manufacturer.

Disinfection by Wiping

Then disinfect the coupling area with the aid of a disinfectant (within 2 hours of the last treatment or pre-cleaning). You must always observe the manufacturer's specifications for the disinfectant regarding concentration and duration of application.

Make sure that no moisture gets into the Dornier *Aries* and/or applicator during the disinfecting. Dry any wet spots immediately.

Pay special attention to the coupling area when disinfecting.

Remove the remaining disinfectant solution with a clean disposable wipe after the application time given by the manufacturer.

Check the coupling area for any damage after the cleaning and disinfection. Notify the Dornier Service Department if there are justified doubts as to whether the coupling area is undamaged.

After making a check, disinfect the coupling area again as per the procedure described.

Maintenance

Safety

⚠ WARNING

Life threatening injuries of persons and / or serious damage to the Dornier *Aries*

Unprofessional performing of service tasks

► Performing of the service tasks only by authorized service personnel.

Authorized Service Persons

Only authorized persons should service the Dornier *Aries*.
Authorized persons are exclusively persons who have been trained by Dornier MedTech Systems GmbH or by a company authorized by Dornier MedTech Systems GmbH.
Persons authorized to perform service tasks are, for example, Dornier MedTech Service personnel.

Maintenance Intervals

Variable maintenance intervals can be defined, with the exception of safety inspections, which must be conducted at least every 12 months.

Information

Declaration of Conformity*

Dornier MedTech

DMT

Konformitätserklärung / Declaration de Conformité
Dichiarazione di Conformità / Declaration of Conformity

Dornier MedTech GmbH
Argelsrieder Feld 7
D-82234 Wessling

mit der Fertigungsstätte
avec le site de production
con il stabilimento di manifatturiero
with the manufacturing site

Dornier MedTech Systems GmbH
Argelsrieder Feld 7
D-82234 Wessling

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto nostra responsabilità che / We declare under our sole responsibility that

	Typ / type / tipo / type	*Modelle / modéle / modello / variants*
das Medizinprodukt le dispositif médical il dispositivo medico the medical device	***AR2R***	***Dornier Aries***

der Serialnummern / avec des numéros de série / con I numeri di serie / with serial numbers ***0*** bis/á/a/to ***200***

der Klasse / de la classe / della classe / of class **II b**
nach Anhang II der Richtlinie 93/42/EWG / selon l'annexe II de la directive 93/42/CEE / secondo l'allegato II della direttiva 93/42/CEE / according to annex II of directive 93/42/EEC

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht, die anwendbar sind / remplit toutes les exigences de la directive sur les dispositifs medicaux 93/42/CEE qui le concernent / soddisfa tutte le disposizione della direttiva 93/42/CEE che lo riguardano / meets all provisions of the directive 93/42/EEC which apply to it.

Angewandte harmonisierte Normen, nationale Normen Normes harmonisées, normes nationales appliqués Norme armonizzate o nazionali applicate	**DIN EN 60601-1:1996**	*Electrical safety of medical products*
	DIN EN 60601-1-2:2007	*Electromagnetic compatibility*
	DIN EN 60601-1-6:2008	*Usability*
	DIN EN 60601-2-36:1997	*Extracorporeally induced lithotripsy*
	DIN EN 60601-1-4:2001	*progr. electrical medical systems*
Applied harmonized standards, national standards	**DIN EN ISO 13485:2003+AC:2007**	*Quality management system*
	und andere / et d'autres / ed altri / and others	

Konformitätsbewertungsverfahren Procédure d´évaluation de la conformité Procedimento di valutazione della conformità Conformity assessment procedure	nach Anhang II der Richtlinie 93/42/EWG / selon l'annexe II de la directive 93/42/CEE Secondo l´allegato II della direttiva 93/42/CEE / according to annex II of directive 93/42/EEC (EG – Konformitätserklärung) (Declaration de Conformité de la CE) (Dichiarazione di Conformità di CE) (Declaration of CE Conformity)
Konformitätsbewertungsstelle Organe resp. de l´évaluat. de la conformità Organo incaric. della valutaz. della conform Notified Body	CE 1275 LGA InterCert GmbH Tillystr. 2, D-90431 Nürnberg

techn. Unterlagen archiviert bei: / documentation technique archivée à: / documentazione tecnica archiviata a: / techn. documentations archived at:
Dornier MedTech Systems GmbH, Quality Management Dept., Argelsrieder Feld 7, D-82234 Wessling

Wessling, 29. Juli 2010

Leiter Qualitätsmanagement
Director Quality Management
Dornier MedTech GmbH
Dornier MedTech Systems GmbH

* The relevant national approval must be observed outside the EU

Manufacturer's Declaration Regarding Safety Inspections

Dornier MedTech

Dornier MedTech GmbH

Herstellererklärung zu Sicherheitstechnischen Kontrollen

Manufacturer's Declaration Regarding Safety Inspections

Dornier MedTech GmbH schreibt folgende sicherheitstechnische Kontrollen vor, die regelmäßig, jedoch mindestens ein Mal im Jahr, erfolgen sollten:

- Feststellung der tatsächlichen Zweckbestimmung des Gerätes.
- Sichtprüfung des allgemeinen Gerätezustandes unter Einbeziehung des Zubehörs, der Einmalartikel, der Verschleißteile und der mit diesem Punkt als Kombination gemeinsam verwendeten Produkte, soweit diese Produkte die Sicherheit des Grundproduktes beeinflussen können. Zu der Sichtprüfung gehört ferner die Bewertung, ob die Voraussetzung der CE Kennzeichnung noch erfüllt ist.
- Funktionsprüfung aller Schutzsysteme wie, soweit zutreffend, z.B. Kollisionsschutz, Übertemperaturschutz, Endschalterfunktion und weiteren automatisch abschaltende Schutzsystemen.
- Prüfung der elektrischen Sicherheit durch Beurteilung des Schutzleiterwiderstandes und des Erdableitstromes. Die Grenzwerte dazu sind der jeweils gültigen Fassung der DIN VDE 0751 Teil 1 zu entnehmen.
- Prüfung der bestimmungsgemäßen Funktion durch Inbetriebnahme des Medizinproduktes anhand der Gebrauchsanweisung und Kontrolle der Funktionsfähigkeit aller Komponenten, sowie, soweit zutreffend, z.B. der F2 - Überprüfung, der Druckprüfung der Stoßwelle, der Strahlengang und der Verfahrung.

Die durchgeführte sicherheitstechnische Kontrolle ist im Medizinproduktebuch zu dokumentieren und bei Bedarf vorzulegen.

Wessling, Dezember 2009

Dornier MedTech GmbH stipulates the following safety inspections, which should take place routinely, but at least once a year:

- Establishment of the unit's actually intended use.
- Visual inspection of the unit's general condition, including accessories, disposable articles, wearing parts and the products used together with this point in combination, if these products can influence the safety of the basic product. Furthermore, included in the visual inspection is the evaluation of whether the CE label requirement is still met.
- Function check of all protective systems, such as, where applicable, collision protection, overheating protection, limit switch function and further automatically disconnecting protective systems.
- Inspection of the electrical safety by evaluation of the ground conductor resistance and the ground leakage current. The limiting values for these can be found in the applicable DIN VDE 0751 Part 1 version in each case.
- Inspection of the prescribed function by starting up the medical device using the Operating Manual and check of the reliability of all components, as well as, where applicable, the F2 inspection, pressure check of the shock wave, the radiation passage and the traversing, for example.

The performed safety inspection must be documented in the Medical Equipment Book and presented as required.

Wessling, December 2009

Walter Aberl

Director of Quality Management
Dornier MedTech GmbH,
Dornier MedTech Systems GmbH

Warning and Safety Precautions for Electromagnetic Compatibility

⚠ CAUTION

Increased emission or reduced interference immunity

Use of unsuitable accessory or lines

► Exclusive use of the listed accessory or lines - with the exception of internal original spare part components.

Warning and Safety Precautions for Electromagnetic Compatibility in Compliance with European EMC Standard IEC 60601-1-2

Electric medical units are subject to special precautionary measures with regard to EMC and may only be installed and put into operation in compliance with the EMC information contained in the Operating Manual.

Portable and mobile radiofrequency communication devices can influence electric medical devices.

The EMC requirements according to IEC 60601-1-2 apply in connection with the power line connected to the Dornier *Aries,* type EU (length appr. 1.5 m).

Guidelines and Manufacturer's Declaration – Electromagnetic Emission		
The Dornier *Aries* unit is intended for operation in the electromagnetic environment specified below. The customer or user of the Dornier *Aries* must ensure that it is used in such an environment.		
Emission measurements	**Conformance**	**Electromagnetic environment – guidelines**
Radiofrequency emissions according to CISPR 11	Group 1	The Dornier *Aries* uses radiofrequency energy exclusively for its internal function. For this reason, its radiofrequency emission is very slight and it is unlikely that there will be interference with neighboring electronic units.
Radiofrequency emissions according to CISPR 11	Class B	The Dornier *Aries* is intended for use in all facilities, including residential areas and such as are directly connected to a public supply network that also supplies buildings that are used for residential purposes.
Harmonics according to IEC 61000-3-2	Class A	
Voltage fluctuations/flicker according to IEC 61000-3-3	applicable	

⚠ CAUTION

Improper function of the Dornier *Aries*

Influence on the Dornier *Aries* by other devices

► Check proper function in the arrangement used:
The Dornier *Aries* is not permitted to be used directly next to other devices or in an arrangement with other devices; if it is necessary to operate it close to or with other devices, the Dornier *Aries* should be observed in order to verify that it operates properly in this arrangement.

Guidelines and Manufacturer's Declaration – Electromagnetic Interference Immunity			
The Dornier *Aries* unit is intended for operation in the electromagnetic environment specified below. The customer or user of the Dornier *Aries* must ensure that it is used in such an environment.			
Interference immunity tests	**IEC 60601 test level**	**Conformance level**	**Electromagnetic environment guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or should be covered with ceramic tiles. If the floor is covered with synthetic material, the relative air humidity must be at least 30%.
Bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The line voltage quality should correspond to that for a typical business or hospital environment.
Impulse voltages (surges) according to IEC 61000-4-5	± 1 kV normal mode voltage ± 2 kV common mode voltage	± 1 kV normal mode voltage ± 2 kV common mode voltage	The line voltage quality should correspond to that for a typical business or hospital environment.
Voltage dips, short breaks and fluctuations in the line voltage according to IEC 61000-4-11	< 5 % V_T for ½ period (> 95 % dip) 40 % V_T for 5 periods (60 % dip) 70 % V_T for 25 periods (30 % dip) > 5 % V_T for 5 s (> 95 % dip)	< 5 % V_T for ½ period (> 95 % dip) 40 % V_T for 5 periods (60 % dip) 70 % V_T for 25 periods (30 % dip) > 5 % V_T for 5 s (> 95 % dip)	The line voltage quality should correspond to that for a typical business or hospital environment. If the Dornier *Aries* user requires continued function even when breaks occur in the energy supply, we recommend that the Dornier *Aries* be supplied from an uninterruptible power supply or battery.
Magnetic field at supply frequency (50/60Hz) according to IEC 61000-4-8	3A/m	3A/m	Magnetic fields at line frequency should correspond to the typical levels found in business and hospital environments.
Note: V_T is the AC supply voltage before application of the test level.			

<table>
<tr><th colspan="4">Guidelines and Manufacturer's Declaration – Electromagnetic Interference Immunity</th></tr>
<tr><td colspan="4">The Dornier Aries unit is intended for operation in the electromagnetic environment specified below. The customer or user of the Dornier Aries should ensure that it is used in such an environment.</td></tr>
<tr><th>Interference immunity tests</th><th>IEC 60601 test level</th><th>Conformance level</th><th>Electromagnetic environment guidelines</th></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile radio devices should not be used at a distance to the Dornier Aries (including the lines) that is less than the recommended working clearance that is calculated according to the equation that is appropriate for the transmit frequency.</td></tr>
<tr><td>Conducted radiofrequency disturbances according to IEC 61000-4-6</td><td>3 V_{eff}
150 kHz to 80 MHz</td><td>3 V_{eff}</td><td>Recommended working clearance:
$d = \frac{3.5}{3\ V_{eff}} \sqrt{P}$</td></tr>
<tr><td rowspan="2">Radiated radiofrequency disturbances according to IEC 61000-4-3</td><td rowspan="2">3 V/m
80 MHz to 2.5 GHz</td><td rowspan="2">3 V/m</td><td>$d = \frac{3.5}{3\text{V/m}} \sqrt{P}$
80 MHz to 800 MHz</td></tr>
<tr><td>$d = \frac{7}{3\text{V/m}} \sqrt{P}$
800 MHz to 2.5 GHz
where P is the transmitter's nominal output in watts (W) according to information provided by the transmitter manufacturer and d is the recommended working clearance in meters (m).
The field strength of stationary radio transmitters should be less than the conformance level[b] for all frequencies, according to an examination at the location[a].
Disturbances are possible in the vicinity of devices that carry the following symbol.
  </td></tr>
<tr><td colspan="4">Note 1: At 80 MHz and 800 MHz, the higher frequency applies.
Note 2: These guidelines may not hold true in all cases. The propagation of electromagnetic values is influenced by absorptions and by reflections from buildings, objects and people.</td></tr>
<tr><td colspan="4">[a] Theoretically, the field strength of stationary radio transmitters, such as base stations for radio communication telephones and mobile land radio services, amateur stations, AM and FM radio and television broadcasts, cannot be accurately determined in advance. In order to determine the electromagnetic environment with regard to stationary transmitters, a study of the electromagnetic phenomenons of the location should be conducted. If the measured field strength at the location where the Dornier Aries is used exceeds the above conformance levels, the Dornier Aries should be observed in order to verify that it functions properly. If unusual characteristics are observed, you may have to take additional measures, such as changing the alignment or placing the Dornier Aries in a different location.
[b] The field strength is less than 3 V/m above the frequency range of 150 kHz to 80 MHz.</td></tr>
</table>

Recommended Working Clearances Between Portable and Mobile Radiofrequency Communication Devices and the Dornier *Aries.*

The Dornier *Aries* unit is intended for operation in an electromagnetic environment in which the radiofrequency disturbances are controlled.

The customer or user of the Dornier *Aries* can help to avoid electromagnetic disturbances by maintaining the minimum distance between portable and mobile radiofrequency devices (transmitters) and the Dornier *Aries,* depending on the output power of the communication device, as specified below.

Transmitter's nominal output (W)	**Working clearance according to transmit frequency (m)**		
	150 kHz to 80 MHz $d = \frac{3.5}{3\ V_{eff}} \sqrt{P}$	**80 MHz to 800 MHz** $d = \frac{3.5}{3 V/m} \sqrt{P}$	**800 MHz to 2.5 GHz** $d = \frac{7}{3 V/m} \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23

For transmitters whose maximum nominal output is not specified in the above table, the recommended working clearance *d* in meter can be determined by using the equation that belongs to the particular column, where *P* is the transmitter's nominal output in watts (W) according to the transmitter manufacturer's information.

Note 1: At 80 MHz and 800 MHz, the higher frequency applies.

Note 2: These guidelines may not hold true in all cases. The propagation of electromagnetic values is influenced by absorptions and by reflections from buildings, objects and people.

The Dornier *Aries* Medical Equipment Book

The Medical Equipment Book is supplied with the Dornier *Aries*.

Storing the Dornier *Aries*

Store the Dornier *Aries* in accordance with storage conditions
(see “Specifications, Environment” section).

Lifetime

The lifetime of the Dornier *Aries* is designed for utilization within a time period of 8 years.

Environment Note

The Dornier *Aries* must be disposed of in accordance with the applicable local directives. The different materials (packaging, electronic scrap, plastics, metal, etc.) must be disposed of in accordance with the relevant applicable national regulations. If you have any questions concerning the prevention of personal injury or damage to the environment, please contact us before the Dornier *Aries* is finally decommissioned.

China-RoHS Conformity

This product complies with the Ministry of Information Industry Order # 39 of the People's Republic of China issued on February 28th, 2006, effective since March 1st, 2007 (law of "Administration on the Control of Pollution Caused by Electronic Information Products").

This product is provided with EFUP pollution control marking (Environmental Friendly Use Period) according to Electronic Industry Standard SJ/T11364–2006.

This mark indicates that the product may contain certain toxic or hazardous substances and can be used safely during its EFU period. This duration is given with the figure in the logo and is counted in years (e.g. 50 = 50 years EFUP).

References

Glossary

Caustic	As caustic is designated into this Operating Manual the representation of a geometrical model of energy flux density, which represents the quality of the focusing.
Coupling Area	Part of the applicator that lies against the patient’s body and that couples the shock wave into the body.
Coupling gel, coupling medium	Medium used to eliminate air between patient's skin and coupling area. Air impairs effect of shock waves.
Display	Screen
EMSE	Technical unit with which a shock wave can be generated using an electrical coil and a diaphragm.

List of Abbreviations

AC	Alternating current
AM	Amplitude Mode
CE	Communauté Européenne
CISPR	International Special Committee on Radio Interferences
DC	Direct current
DGHM	German Society for Hygiene and Microbiology
ECG	Electrocardiogram
ED	Energy flux density
EFUP	Environmental Friendly Use Period
EMC	Electromagnetic Compatibility
EMSE	Electromagnetic Shock Wave Emitter
EN	European Standard
ESWT	Extracorporeal Shock Wave Therapy
EEC	European Economic Community
EU	European Union
FDA	Food and Drug Administration
FM	Frequency Modulation
FWHM	Half-Power Bandwidth
HF	High Frequency
IEC	International Electro Technical Commission
IP	International Protection
IPP	Induratio Penis Plastica
LED	Light emitting Diode
MPBetreibV	German Medical Devices Operator Directive
MPSV	Safety Plan for Medical Devices
RoHS	Restriction of the use of certain hazardous substances in electrical and electronic equipment
SW	Shock Waves
VDE	Association German Electrical Engineering

Index

R

S

T

V

W

Blank page