

BATTERY-DRIVEN DRILL SYSTEM



GB Operating instruction in English

BATTERY-DRIVEN SYSTEM

Simple handling
Ergonomically compatible design
Simple compact and handy rechargeable battery packs offering high power

Small yet sturdy tool with extensive accessories
Steam sterilisation possible



TREU - INSTRUMENTE

Rev: 27042004

Intended purpose:

The 14-807 drill is used for drilling and thread-cutting, removing and inserting screws as well as attaching Kirschner wires in the field of bone surgery. The drill features a hollow drive axle so that drill wires can be quickly inserted and passed through the drill in the hollow drive shaft (hollow drive shaft, \varnothing 3.0 mm), thus ensuring reliable work. The tool holding fixtures (accessories) provide for fast and simple clamping (fixture) of each tool required. Compatibility with various tool ranges is ensured by selecting the necessary clamping and fixture units (accessories).

Warning!

Only accessories supplied by Treu-Instrumente GmbH are approved for usage of accessories. If accessories of other manufacturers are used, we no longer offer any warranty.

No combination with third-party components is permitted.

Method of functioning:

The electric motor in the 14-807 battery-driven drill is powered by a rechargeable battery, resulting in a speed output of 400 rpm without electronic control.

The direction of rotation can be changed especially when cutting threads and removing bone screws. To do so the upper pressure piece marked with **R** for clockwise rotation is operated for insertion and the lower pressure piece marked with **L** for anti-clockwise rotation for removal.

Note:

Please also treat the 14-810 battery, which does not have to be sterilized, with the care normally used for a surgical device although this item is not categorised as a medical product.

Start-up:

To start up the 14-807 battery-driven drill for the first time you require the following components:

charger / bench (for fast charging of 14-814 battery)

rechargeable 14-810 battery

14-807 battery-driven drill

appropriate accessories for work operation required

Before the initial start-up check that the accessory required is available. To ensure operation you require the 14-814 charger and at least one rechargeable 18-810 battery.

Note

When starting up the charger you should follow the specific operating instructions for 14-814 issued by Treu – Instrumente GmbH.

Functional check:

Before using the drill with the appropriate accessory attached you should always carry out a test run.

Briefly try out the battery-driven drill in clockwise and anti-clockwise rotation. While testing check that the coupled chuck (accessory) and the required tool are properly adapted to the battery-driven drill and also check for the correct direction of rotation and rotary action (impact if not properly adapted). When carrying out this functional check a charged 14-810 battery should be inserted in the battery-driven drill.

Cleaning, disinfection, sterilization:

Cleaning and disinfection

Immediately after use surfaces should be wiped with a lint-free cloth impregnated with cleaning agent and disinfectant or cleaned with a spray disinfectant to prevent exudates drying on and causing residual soiling. This manual cleaning process should be carried out using cleaning agents and disinfectants which are nationally approved for surface disinfection (DGHM).

Please comply with the specific data provided by the manufacturer regarding dilution ratios, action times and similar information.

In the case of heavy soiling the 14-806 battery-driven drill can also be cleaned with running water (mechanical cleaning is not permitted).

Note:

Excessive exposure to saline solutions or solutions containing iodine or chloride may cause a reaction. Equally harmful are strong acids or alkaline solutions as well as disinfectants when used incorrectly. The water quality for cleaning and rinsing can also be another factor resulting in corrosion or surface damage to this tool and accessories.

Under no circumstances should the 14-807 battery-driven drill be immersed or boiled in water or cleaning solutions.

The 14-807 battery-driven drill should always be cleaned with the cover closed.

ATTENTION

Mechanical treatment or cleaning in thermal disinfection systems is not permitted.

This disinfection process is necessary to destroy microorganisms after every surgical procedure. As the risk to persons employed in the health sector and patients is constantly increasing, appropriate cleaning and disinfection of such equipment and accessories is of great importance.

If in any doubt you should contact Treu-Instrumente GmbH and the producer of the respective disinfectant and cleaning agent.

Note:

For the accessories the operating instruction for accessories (except for rechargeable 14-810 battery and 14-814 charger / bench) shall apply.

See "Cleaning, Disinfection and Sterilization for Accessories!"

Sterilization:

The 14-807 battery-driven drill with closure and funnel can be sterilized in a steam sterilizer up to 2 bar at max. 134° centigrade. Here it is advisable to use a piece of fabric as a base or to cover the device in a cloth to prevent any external or internal damage.

To ensure reliable sterilisation it is necessary to screw the closure onto the 14-807 battery-driven drill.

ATTENTION

The 14-810 batteries must not be sterilized under any circumstances as heating to over 65° centigrade will result in irreparable damage.

Maintenance:

The 14-807 battery-driven drill is itself maintenance-free. However, we recommend yearly servicing. Such maintenance may only be performed by the manufacturer or specialist staff authorised by the manufacturer. The frequency of maintenance depends on the number of sterilization treatments carried out on the 14-807 battery-driven drill.

Note

The closure cover seals off the battery compartment of the 14-807 battery-driven drill from water and organisms. You should therefore regularly check the sealing ring and sealing area at the handle in the closure cover.

Transport and storage conditions:

To prevent any damage

The 14-807 battery-driven drill with accessories should be transported in the aluminium case with special foam padding provided for this purpose.

This also applies to the storage of this tool. The tool should only be stored in dry closed rooms.

Safety warning: remove battery from tool.

1. before sterilization
2. with malfunctions or defects
3. during transport and storage when not in usage
4. when sent in for service

If the tool is stored or transported in any other manner for whatever reason, this may cause damage which will not fall under the warranty of the manufacturer or distributor.

Fault detection table:

Malfunction	Cause	Fault detection	Rectification
Motor running too slowly or torque too low	Ni-MH-battery is too weak Ni-MH-battery is defective or exhausted Ni-MH = nickel metal hydride		Charge 14-810 battery Check 14-814 charger, poss. replace battery
Motor not running	Motor defective Control defective Switch of trigger defective Gearing or slide bearing defective	No sound can be heard when trigger is pressed (trigger R or L pressed)	Repair by manufacturer
No switchover from anti-clockwise to clockwise rotation	Electromagnetic switch (trigger) defective control defective	Anti-clockwise / clockwise rotation does not respond Continuous operation or wrong direction of rotation	Repair by manufacturer

Repair:

The company Treu – Instrumente GmbH shall only be responsible for the safety, reliability and performance of the 14-807 battery-driven drill where:

- the 14-807 battery-driven drill is used in accordance with the operating instructions
- assembly, extensions, new settings, modifications or repairs are performed by specialist staff employed by Treu – Instrumente GmbH or explicitly authorised by Treu – Instrumente GmbH.

Only original spare parts manufactured by Treu – Instrumente GmbH may be used for repair.

The operator must ask the repairer for a description of the type and scope of the work performed including company stamp / date and signature.

WARNING

Please only send in cleaned and sterilized equipment and accessories for service.

Technical data:

Equipment type: type BF	Battery-driven drill 14-807
Voltage:	9,6 V
Rated capacity of 14-810 battery:	1,2 Ah
Speed:	630 rev / min
Max. torque:	6,5 Nm
Weight incl. Battery:	1250 grams
Motor output:	70 W
Type as per guideline of: EN 60601-1-2:1993 EN 60601-1:1990 + A1:1993 + A2:1995 MED.UMW Schutzart nach DIN EN 529	IP66

Electromagnetic compatibility - EMC:

Manufacturer's certificate of Treu – Instrumente GmbH:

It is hereby certified that the 14-807 battery-driven drill has been tested in accordance with the provisions applicable to **EMC as per EN60601-1-2:1993** and is equipped with radioshielding.

This 14-807 battery-driven drill has been tested by the specified agency for a class II.a product with an internal or external source of energy as per 93/42 EEC, Appendix II.3

Tested according to:

EN 60601 – 1 :1990 + A1:1993 + A2:1995 (EMC for electromagnetic compatibility)

EN 60601 – 1 :1990 + A1:1993 + A2:1995 (Functional safety)

EN 60601 – 1 :1990 + A1:1993 + A2:1995 (Performance requirements / product specifications (performance specifications))

EN 60601 – 1 :1990 + A1:1993 + A2:1995 (Mechanical safety)

EN 540 (Clinical data: evaluation of proofs on the basis of literature and clinical trial)

EN14971:2000 (Risk analysis: evaluation of risk analysis)

Evaluation of Checklist of Basic Requirements for this medical product

TESTING WAS PERFORMED BY: TÜV Product Service in Munich

Accessories:

Designation	Catalogue number	
Battery-driven drill with closure cover	14-807	Medical product
Battery	14-810	Not a medical product
Charger / bench	14-814	Not a medical product
Concentric chuck up to ø 7.0 mm Round and triangular shanks With chuck key	14-830	Medical product
Quick-action chuck for drill wires from ø 0.8 mm up to 3.0 mm	14-842	Medical product
Adaptor for AO and Aesculap Attachments	14-862	Medical product
Adaptor dor DIN attachments	14-864	Medical product




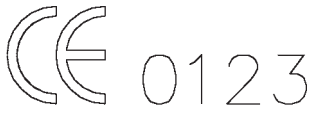
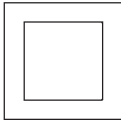
Disposal:

Disposal of the 14-807 battery-driven drill and its accessories is carried out by the manufacturer Treu-Instrumente GmbH (no contamination of the environment), according to the provisions of MED.UMW



Disposal is carried out by Treu – Instrumente GmbH

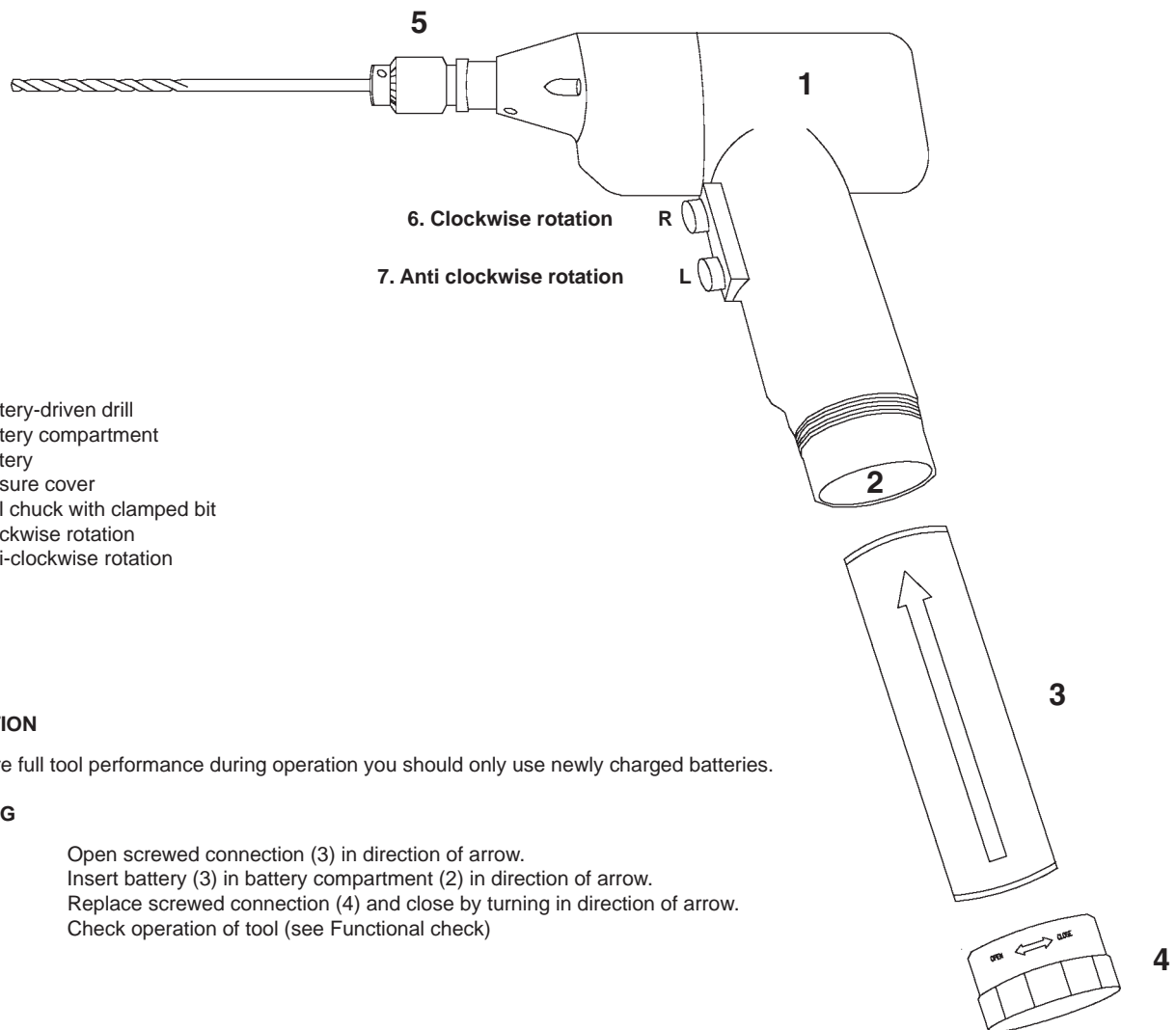
Key to symbols

Symbol No. 1		Comply with operating instructions
Symbol No. 2		Classification type BF
Symbol No. 3		Suitable for recycling
Symbol No. 4		CE-labelling as per directive 93/42 EEC
Symbol No. 5		Tool belongs to protection class II

Symbol key

- R= Clockwise rotation**
- L = Anti-clockwise rotation**

OVERVIEW:



1. Battery-driven drill
2. Battery compartment
3. Battery
4. Closure cover
5. Drill chuck with clamped bit
6. Clockwise rotation
7. Anti-clockwise rotation

ATTENTION

To ensure full tool performance during operation you should only use newly charged batteries.

LOADING

- Step 1. Open screwed connection (3) in direction of arrow.
- Step 2. Insert battery (3) in battery compartment (2) in direction of arrow.
- Step 3. Replace screwed connection (4) and close by turning in direction of arrow.
- Step 4. Check operation of tool (see Functional check)

Overview for accessories:

NOTE

All couplings and adaptors for the battery-driven drill system are fitted in the same manner.

- Step 1. Slide back coupling sleeve (1) in direction of arrow.
- Slide couplings (2) in direction of arrow on shaft (3) until they stop.
- Release coupling sleeve (1).
- Turn coupling slightly until it snaps into place in the shaft (3).
- Check the connection.
- Hold the drill chuck (4) with the left hand and pull in the opposite direction away from the tool.

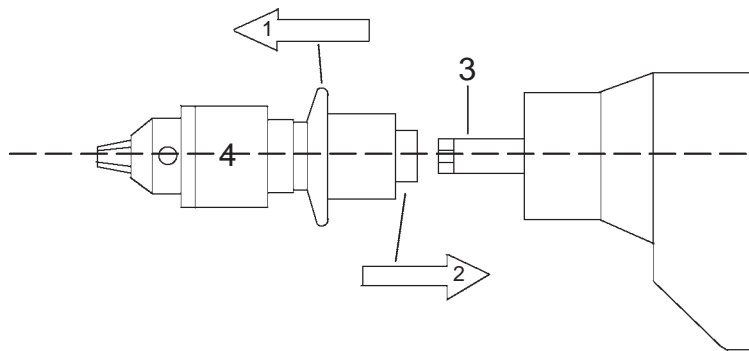
Malfunction

Coupling does not snap into shaft ↔

Rectification

If soiled clean, if damaged send in for service

Use only from manufacturer proven accessories



Cleaning, disinfection and sterilization of accessories:

(except 14-810 battery and 14-814 charger / bench as these products do not come under Medical Products)

CLEANING AND DISINFECTION:

CARE AND MAINTENANCE

Care and maintenance are absolutely essential to maintain the condition and functionality of equipment.

Causes of corrosion occurring with rust-resistant instrument steel materials?

Corrosion involves damage or wear which may be caused by a chemical reaction, including:

- 1.) damaged surfaces
- 2.) action of surgical exudates: blood, pus or bodily secretions during lengthy contact with instruments.
- 3.) excessive exposure to certain solutions: saline and iodine solutions, chloride and strong acids, alkaline solutions as well as disinfectants when used incorrectly.
- 4.) poor water quality during cleaning, steam sterilization or rinsing of instruments and accessories: e.g. ingress of rust or metal particles in steam sterilizers through rusty pipework.
- 5.) inadequate maintenance for instruments and accessories: with the formation of rust this can be transferred to other instruments and accessories (avoid contact without fail, as very risky during sterilization).

The constant usage of instruments and accessories is a natural wear process which reduces their service life accordingly. Instruments and accessories that are used frequently should be replaced.

ACTION AND MEASURES PREVENTING CORROSION:

- 1.) Carefully assemble correctly packed and sterilized instruments and accessories prior to operation: selection according to type of procedure. Make sure you check for the intactness of the external packaging and the expiry date.
- 2.) Use sterilization indicator inside sieve to check that contents have been sterilised.
- 3.) Arrange instruments and accessories according to sequence of usage during operation: leave instruments not required in sieve and only prepare instruments and accessories just before operation.
- 4.) Remove blood and other exudates from instruments and accessories during operation: after usage return instruments and accessories to their proper place.
- 5.) Rinse through hollow instruments to prevent blood and bone meal from drying on.
- 6.) Use Ringer's lactate solution or saline solution to clean instruments and accessories, however, do not immerse in solutions.
- 7.) Start the cleaning process immediately after the operation: instruments and accessories used during the operation should be treated as being contaminated. Instruments used on patients with possible infections should be disposed of in a similar manner. Wipe off any traces of blood, bone meal or tissue.
- 8.) Clean instruments at a location provided for this purpose within the operating suite. If instruments are to go directly to the central sterilization unit, please cover beforehand due to the risk of contamination for staff or surroundings. When dealing with contaminated instruments and accessories, please wear protective clothing.

CLEANING WITH DISASSEMBLY:

Instruments and accessories with detachable parts should be taken apart, with screws, nuts, bolts and other small parts being collected and stored according to a clear system. The persons responsible for disassembly and assembly should have undergone appropriate training. Remove blood or traces of bone meal from individual parts to prevent drying on during sterilization and thus causing irreparable damage.

DISINFECTION:

When using chemical disinfectants you should strictly comply with the specifications of the respective manufacturer: solutions are always used in diluted form. With a thermal disinfection phase using hot water, the water must be free of foreign bodies.

Please note: instruments and accessories made of anodised aluminium should not come into contact with certain disinfectant solutions or cleaning agents. You should therefore check the solution used before exposing the metal to a chemical reaction.

CLEANING:

Whether using mechanical or manual cleaning, it should be carefully checked which cleaning agent is used with which method. Please make sure you observe the instructions for dilution and usage. **Recommended pH value: between 7.0 and 8.5.**

1. MECHANICAL CLEANING:

Mechanical cleaning is the preferred cleaning method. Please exactly comply with the operating instructions supplied by the manufacturer of the cleaning equipment. Prepare the instruments and accessories for mechanical cleaning; multi-part instruments and accessories that can be taken apart should be cleaned while disassembled or opened. All sharp tips and sensitive parts should be cleaned manually. Do not overload wire sieves. Place heavy parts at the bottom of the sieve. Parts showing heavy soiling (hollow instruments and accessories) should possibly be soaked and rinsed through before being put in the washer.

2. ULTRASOUND CLEANING (categorised as mechanical cleaning):

Before placing an instrument or accessory in the ultrasound cleaning bath, please remove all traces of exudate. Ultrasound baths are recommended for example for thread cutters or instruments and accessories with deep grooves. Ultrasound treatment has to be followed by normal rinsing.

3. MANUAL CLEANING:

Involves various nylon brushes, a blow tube and nozzle, a clean compressed air unit, cleaning agents and solutions as for mechanical cleaning. When using cleaning additives comply with the manufacturer's specifications. Steel wool and wire brushes should not be used. Make sure you treat anodised aluminium with extreme care. All traces of material following brush cleaning must be completely removed.

4. DRYING:

Every instrument and accessory has to be dried completely on both the inside and outside to prevent the formation of rust and subsequent malfunction. The compressed air unit can be used for hollow parts or hinges.

Please note: if the instruments and accessories are to be reused again immediately and sterilised without packaging, drying is not necessary.

5. GREASING AND OILING:

Instruments and accessories with moving parts have to be greased or oiled at the joints and all moving parts after usage and cleaning. Only biological oils and greases without acidic constituents should be used; pure bone oil is recommended. When using special instrument oil solutions, the instruments and accessories can be immersed in the solution for a fixed period of time. Certain instrument washers include lubrication. Rinsing is not necessary. Remove surplus oil before packaging.

STERILIZATION:

Used instruments should be immediately cleaned and dried; when doing so do not use cleaning agents or disinfectants containing very acidic or alkaline additives (e.g. soda, sodium hydroxide solution or acids). The most gentle cleaning method is machine (mechanical) cleaning, as already described in the operating instructions.

"INSTRUMENTS AND ACCESSORIES SHOULD ONLY BE SUBJECTED TO STEAM STERILIZATION"

TECHNICAL INFORMATION ON STERILIZATION

Before the operation check the instruments and accessories for function and intactness.

STERILIZER: Steam autoclave, temperature = 121°C to 123°C, pressure = 15 to 17 psi (1 to 1,2 bar), min. 30 minutes in packaged state. At temperature 131°C to 133°C, 15 to 17 psi (1 to 1.2 bar) pressure reduces action time to approx. 20 minutes.

STERILIZER: Autoclave with prevacuum: during the prevacuum phase the air is first extracted from the chamber before steam is introduced. Standard circulation for packaged items = 132°C to 135°C at 27 to 30 psi (2 to 3 bar) with a minimum action time of between 4 to 10 minutes.

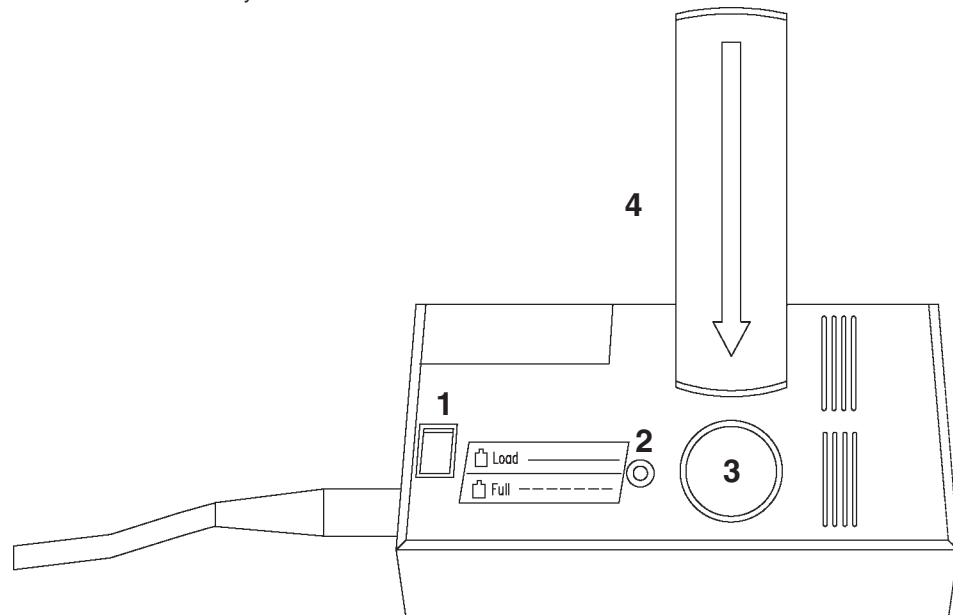
IMPORTANT NOTES: Before usage or sterilisation all instrument parts should always be checked for proper functioning.

FOLLOWING PROVEN FAILURE TO COMPLY WITH THESE OPERATING INSTRUCTIONS NO WARRANTY ENTITLEMENT SHALL EXIST

Operating instructions for accessories 14-814 charging station / bench

Revision 1.: 26.10.2000

- | | | |
|-------------------------------|---|---|
| 1. Main switch / control lamp | ↔ | Switch lights up when switched on |
| 2. Charger control lamp | ↔ | Lights up continuously during charging of discharged 14-810 battery |
| 2. Charger control lamp | ↔ | Flashes when 14-810 battery is fully charged |
| 3. Charger shaft | ↔ | For insertion of 14-810 battery in direction of arrow |
| 4. Battery | ↔ | 14-810 battery |



Start-up:

- Step 1.** Insert power plug in appropriate socket and activate main switch (1) . Control lamp (1) lights up.
- Step 2.** Insert 14-810 battery (4) in charger compartment (3) in direction of arrow .
- Step 3.** Charger control lamp (2) must light up continuously with discharged state of 14-810 battery (4) .
The charging time for a discharged 14-810 battery (4) is approx. sixty minutes.
The 14-814 charger and the 14-810 battery become warm during charging but this does not indicate any malfunction. As soon as the 14-810 battery is fully charged, the control lamp (2) starts to flash.
The 14-814 charger switches automatically to trickle charging when the 14-810 battery is fully charged, i.e. you can let the 14-810 battery rest for lengthy periods in the 14-814 charger while operational so that it always offers optimum capacity without becoming discharged or overcharged.
The 14-810 battery should be charged before every usage.

Malfunction:

After insertion of the 14-810 battery (4) in the charger compartment (3) of the 14-814 charger , the control lamp (2) does not light up.



CORRECTION OF MALFUNCTION:

Slightly turn the 14-810 battery (4) in the charger compartment (3) of the 14-814 charger and push lightly down in the direction of the arrow.

NOTE AND WARNING

With a power failure control lamps (1) and (2) do not light up.

The 14-810 charger is not a medical product and should therefore only be used in closed rooms outside the operating theatre. Usage only in closed rooms which are free of dust and moisture (should not be used in wet rooms).

ATTENTION: SAFETY NOTE

Storage only in dry closed rooms in the original packaging.

Under no circumstances should the 14-810 battery or the 14-814 charger be sterilized.

Only compatible 14-810 batteries supplied by Treu – Instrumente GmbH should be used.

Any combination with third-party makes is prohibited.

Do not immerse 14-814 charger or 14-810 battery in liquid.

Maintenance and Care:

Remove the power plug before cleaning.

To clean the 14-814 charger and the 14-810 battery use a damp cloth without any cleaning agent; make sure that no moisture reaches the contacts of the 14-810 battery or the charger shaft (**3**) of the 14-814 charger.

Under no circumstances immerse in liquids or clean under running water.

Repair:

The company Treu - Instrumente GmbH shall only be responsible for the safety, reliability and performance of the 14-814 charger and 14-810 battery, where:

- the 14-814 charger und the 14-810 battery are used in accordance with the operating instructions
- assembly, extensions, new settings, modifications or repairs are performed by the company Treu - Instrumente GmbH or specialist staff explicitly authorised by Treu - Instrumente GmbH.

Only original spare parts manufactured by Treu - Instrumente GmbH may be used for repair.

The operator must ask the repairer for a description of the type and scope of the work performed including company stamp / date and signature.

WARNING

Please only send in cleaned and sterilized equipment and accessories for service.

Transport and storage conditions:

To prevent any damage

The 14-814 charger and the 14-810 battery should be transported in the aluminium case with special foam padding provided for this purpose. This also applies to the storage of this equipment. The equipment should only be stored in dry closed rooms.

Safety warning:

- 1. with malfunctions or defects
- 2. during transport and storage when not in usage
- 3. when sent in for service

If the equipment is stored or transported in any other manner for whatever reason, this may cause damage which will not fall under the warranty of the manufacturer or distributor.

Electromagnetic compatibility - EMC:

Manufacturer's certificate of Treu – Instrumente GmbH:

It is hereby certified that the 14-814 charger has been tested in accordance with the provisions applicable to **EMC** as per **EN60601-1-2:1993** and is equipped with radioshielding. The 14-814 charger has been tested according to **EN60335-2-29/A11:1998** and complies with the equipment safety regulations (**GSG**) for the distribution of technical work aids as per report No. 014-100611417 TÜV Product Service.

Technical data:

Equipment type	charger 14-814
Rated voltage:	230 V
Rated frequency:	50 Hz
Rated input:	14 VA
Rated output voltage:	12 V
Rated output current:	1100 mA max.
Protection class:	II
Protection type as per DIN EN 529	IPX0

Function:

The 14-807 charger is controlled and monitored by a microcontroller. Independently of the charging state of the battery the controller measures the current capacity and controls charging.

Charging takes approx. 1 hour.

After charging the device automatically switches to impulse trickle charging.

A long service life of the 14-810 battery is guaranteed due to gentle charging.

Pole reversal is unfortunately precluded by the design.

Technical data for 14-810 battery

The 14-810 battery is a Ni MH (nickel metal hydride) battery.

Type : VA AA

Under normal load levels:

1.2 V - 1250 mAh

125 mA - 16h

With high loads:

1250 mA - 1.2h

Notice:



Notice:



TREU - INSTRUMENTE



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