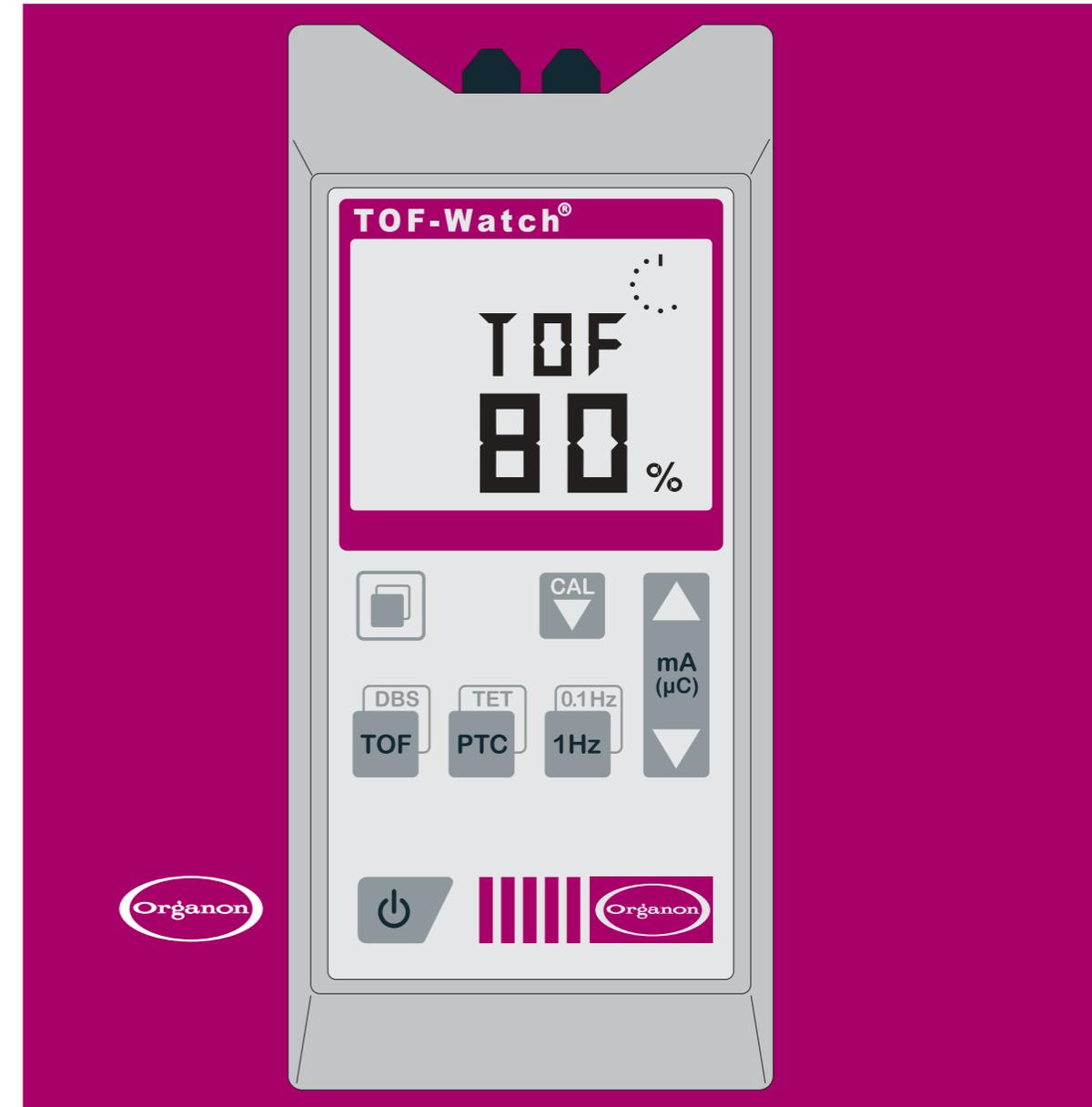


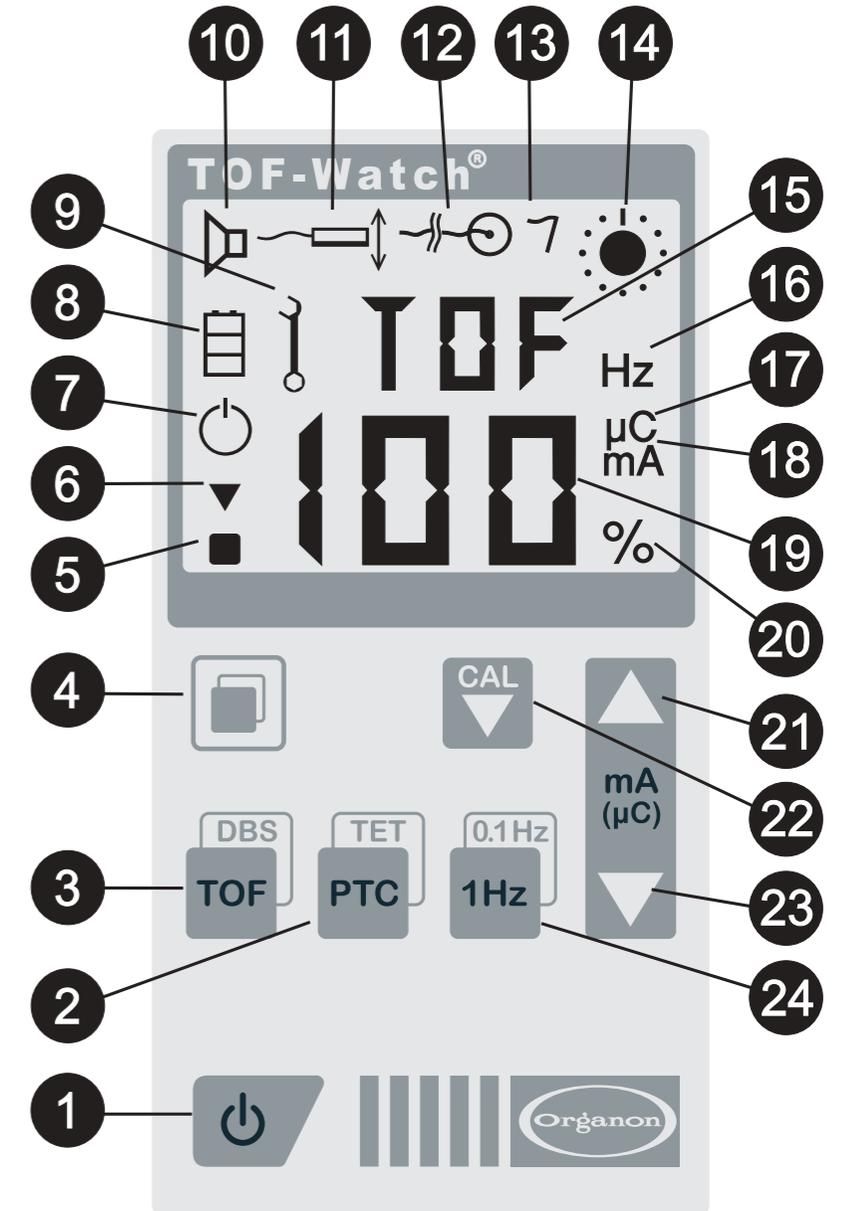
TOF-Watch®



Operator manual

TOF-Watch®

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Scheme of buttons and display symbols
Schéma des touches et symboles d'affichage
Tastaturübersicht und Displaysymbole
Esquema de los pulsadores y símbolos

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TOF-Watch®

Scheme of buttons and display symbols

- ❶ Stop / on-off button.
- ❷ Post Tetanic Count / Tetanic stimulation button.
- ❸ Train Of Four / Double Burst Stimulation button.
- ❹ Secondary function button.
- ❺ Secondary function symbol.
- ❻ Calibration symbol.
- ❼ Device on / stopped symbol.
- ❽ Battery status symbol.
- ❾ Internal error symbol.
- ❿ Stimulation beep symbol.
- ⓫ Acceleration transducer symbol.
- ⓬ Resistance too high symbol.
- ⓭ Needle electrode symbol.
- ⓮ Timer / stimulation symbol.
- ⓯ Stimulation mode indication.
- ⓰ Frequency symbol.
- ⓱ Micro-coulomb symbol.
- ⓲ Milli-ampères symbol.
- ⓳ Value for TOF ratio, Twitch height, PTC or stimulation current.
- ⓴ Percent symbol: used for TOF ratio or Twitch height.
- ⓵ mA(μ C) up button.
- ⓶ Calibration button.
- ⓷ mA(μ C) down button.
- ⓸ 1 Hz / 0.1 Hz stimulation button.

1 Introduction

1.1 General

Monitoring the effect of neuromuscular blocking agents (NMBAs) can be accomplished in several ways.

The most frequently used method is clinical evaluation using a peripheral nerve stimulator. Although the technique is simple, it lacks accuracy because of its subjective interpretation of the responses.

Accurate and objective information on the degree of neuromuscular paralysis can be obtained by measuring the force of contraction of a certain muscle (mechanomyography).

However, the equipment needed is rather bulky and difficult to use during routine surgery because of the elaborate set-up procedure and its sensitivity to movement.

A good alternative for force measurement is the measurement of **acceleration** (acceleromyography). According to the second law of Newton: Force equals Mass times Acceleration ($F = M \times a$), the acceleration of a muscle has a linear correlation with the contraction force of that muscle. It has been shown that there is a good correlation between the results of acceleromyography and mechanomyography.

1.2 Intended use

The TOF-Watch is an instrument for monitoring the neuromuscular transmission during surgery or in the intensive care unit by means of acceleromyography. The TOF-Watch can also be used as a peripheral nerve stimulator. Moreover, it can be used to localize nerves for loco-regional anesthesia.

Consequently, the TOF-Watch is only to be operated by trained medical personnel.

Before operation, please refer to the *Warnings!* in chapter 11.

1.3 Actions upon delivery

Upon delivery of the TOF-Watch, please check the contents of the package for completeness and damage during transport.

The TOF-Watch should be stored at room temperature at ambient moisture conditions.

2 Short set-up

2.1 Checking patients for muscle relaxation

In the set-up menu of the TOF-Watch, display of the stimulation strength can be switched from mA (default setting) to μC , according to local preferences. As a default setting, the stimulation current is set at 50 mA.

- 1 Place electrodes in position, attach the acceleration transducer to the thumb with adhesive tape.
- 2 Turn TOF-Watch on by pressing the  button (1) and holding it down for 1 second.
- 3 Administer the induction agent.
- 4 When the patient is sedated adequately, press  (22) for automatic calibration (optional).
- 5 Hold down the  button (3) for repetitive TOF stimulation.

The TOF-Watch is now ready for further monitoring the neuromuscular transmission.

During surgery muscle relaxation can be monitored continuously to assess the need for either repeated administration of a muscle relaxant or for the use of a reversal agent during recovery.

2.2 Checking patients for residual curarization

The use of automatic set-up of the TOF-Watch on patients already relaxed will result in incorrect selection of internal gain due to fading. The following procedure should be used:

- 1 Place electrodes in position, attach the acceleration transducer to the thumb with adhesive tape.
- 2 Turn TOF-Watch on by pressing the  button (1) and holding it down for 1 second.
- 3 The strength of the stimulation (mA or μC) can be adjusted manually by pressing the mA(μC) up (21) or down button (23).
- 4 Press  (3).

Since no control twitch height has been established, only the TOF ratio yields information about the recovery of a patient and not a single twitch measurement.

2.3 Nerve location for loco-regional anesthesia

The TOF-Watch can be used for nerve location for loco-regional anesthesia using a special stimulation cable. This cable contains one lead with a connector fitting to a surface electrode and one lead with a 2 mm plug to be connected to a needle electrode.

Once this cable is inserted in the TOF-Watch, the instrument automatically reverts to the loco-regional anesthesia mode. Since only a visual assessment of the response is needed, no responses are shown.

- 1 Connect special stimulation cable to the TOF-Watch
- 2 Place the surface electrode in position
- 3 Turn TOF-Watch on by pressing the  button (1) and holding it down for 1 second.
- 4 Start the repetitive 1 Hz stimulation by pressing the  (24) button.
- 5 The strength of the stimulation (mA or μC , shown on the display) can be adjusted manually by pressing the mA(μC) up button (21) or down button (23).

The TOF-Watch is now ready for locating the nerve with the needle electrode.

3 Pre-Operative set-up

3.1 Cable connections (objective monitoring)

The TOF-Watch can be used for objective monitoring by using two cables:

A) acceleration transducer cable and B) stimulation cable.

When surface electrodes are used, the instrument automatically uses stimulation pulses of 200 μs at 0 - 60 mA (0 - 12 μC).

The pre-installed default current is set at 50 mA.

Attach the stimulation cable to the surface electrodes placed on the ulnar nerve.

Attach the acceleration transducer with its' largest flat side to the thumb by means of adhesive tape. Connect both cables to designated color-coded outlets on the TOF-Watch (reversal of the cables is not possible because of a mechanical barrier).

3.2 Cable connections (subjective monitoring)

When the acceleration transducer is not connected to the TOF-Watch, the instrument can be used as a peripheral nerve stimulator.

When surface electrodes are used, the instrument automatically uses stimulation pulses of 200 μ s at 0 - 60 mA (0 - 12 μ C).

Instead of the patient response, the TOF-Watch automatically shows only the stimulation strength in mA (μ C) and stimulation mode.

The pre-installed default stimulation strength is set at 50 mA. Attach the stimulation cable to the surface electrodes placed on the ulnar nerve (see above), and connect to the designated color-coded outlet on the TOF-Watch (insertion of the cable in the wrong outlet is not possible because of a mechanical barrier).

3.3 Cable connections (loco-regional anesthesia)

When the special cable for a needle electrode is used, the TOF-Watch can be used for nerve location in loco-regional anesthesia.

The TOF-Watch will automatically revert to the loco-regional anesthesia mode, enabling stimulation with a pulse width of 40 μ s and a current ranging between 0 and 6.0 mA.

The total charge delivered varies between 0 and 0.24 μ C. In the set-up menu, display of the strength of the stimulation can be switched from μ C (pre-installed) to mA.

The pre-installed default setting is 0 μ C. No patient responses are shown on the display. Attach the special cable to a needle electrode and a surface electrode, and connect to the designated color-coded outlet on the TOF-Watch (insertion of the cable in the wrong outlet is not possible because of a mechanical barrier).

3.4 Electrodes

When monitoring neuromuscular transmission, the TOF-Watch should always be used with round surface electrodes with snap connection. Small (pediatric) electrodes are advisable to obtain a sufficient current density. In order to ensure a steady quality of the test, be sure only to use CE marked electrodes.

3.5 Electrode placement

Acceleromyography can take place by stimulating the facial nerve and monitoring the response of the orbicularis oculi muscle or by stimulating the posterior tibial nerve and monitoring the response of the flexor hallucis brevis muscle. Usually, however, for routine monitoring purposes stimulation of the ulnar nerve and acceleration measurements at the adductor pollicis is preferred.

The electrodes are placed over the ulnar nerve on the volar side of the wrist. The distal electrode is positioned where the proximal bending line crosses the radial side of the flexor carpi ulnaris muscle. The proximal electrode can be placed either 2-3 cm proximal of the distal electrode or over the ulnar nerve at the elbow.

- Correct positioning of the electrodes is important. Small displacements may result in considerable changes in stimulation current requirements. Furthermore, the electrodes must be positioned in such a way to avoid direct stimulation of the muscle.
- Place the electrodes on each side of the expected position of the ulnar nerve. In this way, the effect of any minor misjudgment of the actual nerve position is minimized.
- It has been found that slight pressure on the electrodes may improve the stimulation considerably. Therefore, taping the electrodes to the skin may be advisable.

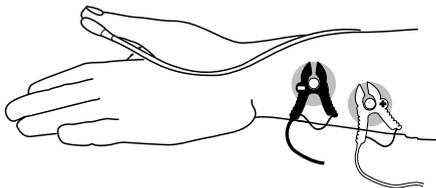


Figure 2. Electrode and transducer placement

3.6 Position of the transducer

The transducer should be placed with its largest flat side against the thumb.

The transducer cable must be fixed in such a way that no traction is applied to the transducer and that movement of the thumb is not obstructed in any way.

- Small sideways movements of the thumb may be noticed during stimulation. If this is the case, reposition the transducer in such a way that the movement is perpendicular.
- The more distal the transducer is placed on the thumb, the stronger the acceleration signal. This effect can be used to adjust the signal strength.

3.7 Arm position

The arm, used for the acceleration measurement, should be kept immobile during the whole procedure. Movement of the arm to another position may change the twitch height considerably. Although the twitch height may still differ from the original value, the train-of-four ratio remains correct. At later stages of recovery the patient may perform voluntary movements of the hand, which in turn may disturb the measurements and recordings.

3.8 Connection to stimulator

Always make sure that the TOF-Watch is switched off or that the display shows the stop symbol \odot (7) before touching the electrodes.

The proximal electrode is usually connected to the white (Positive) clip on the stimulator cable. The distal electrode should be connected to the black (Negative) clip.

If both electrodes are near the wrist, the polarity is less critical. The stimulation pulses are monophasic. Switching the electrode connection (exchanging \oplus with \ominus) may sometimes increase the stimulation considerably.

3.9 Skin resistance

The skin resistance is part of the total resistance in the stimulating circuit, which also includes electrode resistance. The stimulator in the TOF-Watch is of the constant current type.

This means that the stimulation voltage automatically increases with the resistance.

As long as the voltage remains below the maximum value (= 300 V) the stimulator can deliver the selected pulse. For a maximal current of 60 mA, the maximal resistance will be 5 kOhm.

If the resistance is above this value, the "skin resistance too high" symbol \ominus (12) will be displayed, and the stimulation stops. If the current is reduced, the corresponding voltage drops and stimulation can be resumed.

- Insufficient cleaning of the skin may be the cause of too high skin resistance. Note that there is not necessarily any relation between high skin resistance and problems of reaching supramaximal stimulation.

3.10 Control twitch height

The patient should be anesthetized before operating the stimulator because nerve stimulation can be painful for a conscious patient.

Control twitch height is the twitch height when the patient is not relaxed. Control twitch height is set to 100% at calibration.

3.11 Calibration

The size of the transducer signal varies from patient to patient. In order to establish a control twitch height value of 100% for the 1 Hz or 0.1 Hz modes, the transducer gain is set by pressing the  button (22) for more than 1 sec.

- If the responses of a non-relaxed patient are too small for an accurate measurement, as can be seen in children or when using the orbicularis oculi muscle, then a gain calibration will optimize the sensitivity.

3.12 Sensitivity

It may be noticed that the thumb makes very small movements although no response is shown on the display. This is not an error: the movement is below the threshold of 3% control twitch height at which the TOF-Watch starts to display the responses.

3.13 Stimulation units

The TOF-Watch can show the strength of the electrical stimulation in both milli-ampères [mA] and micro-coulomb [μ C]. For routine monitoring the default setting is in mA, for use in loco-regional anesthesia the default setting is in μ C. It is possible to change between the two modes in the *Set-up menu* - see page 15.

4 Survey of functions

Some of the buttons have a double function: one function when activated alone, and another if the secondary function button (4) is pressed prior to the function button.

Activation of the secondary function is indicated by the  symbol on the display.

Furthermore, the period of time a button is activated determines how the function of the button is performed. A short activation (< 1 s) elicits a single stimulation, a long activation (> 1 s) of a function button enables continuous stimulation.

Abbreviations:

Short activation (**short**): < 1 s

Long activation (**long**): > 1 s (acknowledged by a short beep)

4.1 General functions

4.1.1 Stop / on-off button (1)



short:

long:

Stops stimulation/clears display

Turns TOF-Watch on/off

(if activated more than 1 second).

4.1.2 Secondary function button (4)



short: **Activation of secondary function mode.**

If this button is pressed prior to a button with a secondary function (description above the button), the secondary function is carried out instead of the primary function. This is indicated by the ■ symbol on the display. If no buttons are activated, a built-in 5 sec. time-out reverts to primary mode.

long: **Activation / deactivation of stimulation beep.**

By pressing this button for more than 1 sec. the stimulation beep is toggled on and off and the  (10) symbol is showed for 1 sec (see also *Set-up menu* on page 15).

Note: If the stimulation beep is switched on, a short beep can be heard each time the TOF-Watch performs a stimulation. When not desired, be sure to switch off the stimulation beep in cases where beeps from other operating equipment are more important (e.g. heart monitoring systems).

4.1.3 Calibration button (22)



long: **Starts calibration (adjust gain to 100% control twitch height) or returns to standard gain.**

Notes: Calibration is only possible when the  symbol is shown in the display. If  flashes after completion of calibration the acceleration transducer signal is either too low or too unstable.

4.1.4 mA(μC) up (21) and down buttons (23)



short: **Stimulation strength is shown in display, or if already shown stepped up or down.**

long: **Stimulation strength is continuously stepped up or down.**

If both up and down are activated simultaneously, the set-up mode is entered. See page 15 for more information.



4.1.5 Timer function

The display is used to show various time-related symbols.



Stop watch showing time to next stimulation.



The center dot of the stop watch indicates that the TOF-Watch is currently performing a stimulation.

The display normally holds a result for about 15 sec. after a stimulation has been performed.

After this time period, the measurement is considered to be too old for proper clinical evaluation and the result is cleared.

4.2 Primary functions

In general, when a function is activated which is not allowed, an attention beep will sound. Moreover, during a time-out period (PTC and TET), this function will also be flashing if the TOF-Watch is in stop mode \odot .

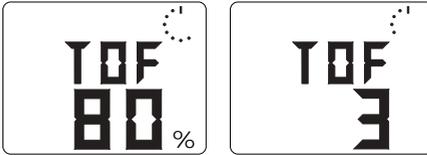
In case a function is allowed but only after some residual time (13.5 s for TOF, 20 s for DBS), a count down procedure will be initiated and indicated on the display.

4.2.1 Train Of Four stimulation press $\boxed{\text{TOF}}$ (3)

TOF

short: Starts one TOF stimulation (on demand).
long: Starts repetitive TOF stimulation.

TOF stimulation occurs in 15 second cycles. The numeric display shows the train-of-four ratio in %, if all 4 responses were detected. When less than four responses are detected or if the first twitch is less than 20%, only the number of responses is displayed (without the % symbol). The TOF-Watch automatically excludes the use of DBS and TOF for 12 sec. after the last TOF.



4.2.2 1 Hz stimulation press $\boxed{1\text{Hz}}$ (24)

1Hz

short: Starts one stimulation (on demand).
long: Starts repetitive 1 Hz stimulation.

The display shows the twitch height of the last response. However, this is only valid when the twitch has been calibrated. When not calibrated after switching on, the \blacktriangledown is flashing together with the % and an internal reference control twitch value is used for the calculation.



4.2.3 Post Tetanic Count stimulation (PTC)

press  (2)

PTC

Starts Post Tetanic Count (if allowed).

PTC starts with stimulations at a frequency of 1 Hz for 15 seconds. The display shows PTC. When no responses are detected (i.e. when the neuromuscular block is deep), this is followed by a 5 sec. 50Hz stimulation. After a 3 sec. pause, stimulations are performed at a frequency of 1 Hz for 15 seconds, while the number of detected responses (Post Tetanic Count, updated after each stimulation) is shown in the display. A short information beep indicates that the PTC is finished and the number of detected responses is shown on the display for 12 seconds after which the TOF-Watch automatically enters the continuous TOF stimulation mode.



- Post Tetanic Count can only be used when the responses to 1 Hz, 0.1 Hz or TOF have disappeared (when the patient is deeply relaxed).
- The final Post Tetanic Count remains in the display for 12 sec, after which the TOF-Watch automatically enters continuous TOF stimulation mode. If the patient responds (more than five consecutive responses) during the first 15 stimulations, the TOF-Watch automatically switches to TOF-mode after 5 seconds.
- The TOF-Watch automatically excludes the use of the PTC button for 2 minutes after successful operation of PTC or TET. If activated before the time-out period has expired an information beep will sound, PTC will, if no other test is running, be shown flashing for 5 seconds, and the TOF-Watch automatically reverts to its original mode.

4.3 Secondary functions

Secondary functions can be activated by pressing the secondary function button (4) prior to a stimulation button. If no stimulation buttons are activated within 5 seconds after pressing the secondary function button, the TOF-Watch automatically reverts to primary mode. When the secondary function button (4) is activated, the  symbol will be shown on the display.

4.3.1 Double Burst Stimulation (DBS)

first press  (4),
then  (3)

DBS
TOF

Starts one Double Burst Stimulation (3.2 or 3.3).

The TOF-Watch also includes Double Burst Stimulation as a secondary function. The set-up menu can be used to select either DBS3.2 or DBS3.3. With DBS, only tactile evaluation can be used to evaluate the patients' relaxation as no registration is performed. The display shows the stimulation strength in mA or μC , but no response. The TOF-Watch automatically excludes the use of DBS and TOF for 20 sec. after the last DBS.



4.3.2

Tetanic stimulation

first press  (4),
then  (2)



Starts tetanic stimulation (if allowed).

As another secondary function the TOF-Watch includes 5 sec. of tetanic stimulation (50 or 100 Hz in display). The TOF-Watch automatically excludes the use of this button for 2 min. after the last TET or the last PTC. The set-up menu can be used to select between 50Hz or 100Hz tetanic stimulation. The display shows the stimulation strength in mA or μC , but no response.



4.3.3

0.1 Hz stimulation button

first press  (4),
then  (24)



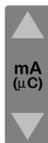
Starts repetitive 0.1 Hz stimulation.

The third secondary function is the 0.1 Hz stimulation. The display shows the twitch height of the last response. However, this is only valid when the TOF-Watch has been calibrated. If not, the ▼ flashes together with % and an internal reference control twitch value is used for the calculation.



5 Set-up menu

The set-up menu can be activated and manipulated using the buttons described below:



mA(μC) up (21) and down buttons (23)

Press both mA(μC) up (21) and down (23) simultaneously to enter the set-up menu or to store the setting.

Notes: The set-up mode can only be accessed when the TOF-Watch is stopped i.e. the  symbol is shown in the display. The setting is permanently stored in the TOF-Watch, even when the battery is removed.

Press mA(μC) up (21) or down (23) one at a time to modify the setting of the parameter.

Calibration button (22)



Press the CAL button  (22) to go to next parameter to be modified.

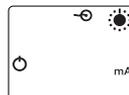
The following parameters can be changed in the set-up menu: Default settings are shown **bold**.

Set-up parameter:

Set-up Display

Surface electrode flashing (stimulation units)

mA: Surface electrode stimulation strength in milli-ampères.
μC: Surface electrode stimulation strength in micro-coulomb.



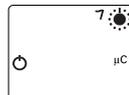
Surface electrode flashing (stimulation size)

50 mA: Default surface electrode stimulation strength can be adjusted between 0 and 60 mA/12 μC.



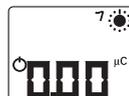
Needle electrode flashing (stimulation units)

μC: Needle stimulation strength shown in micro-coulomb.
mA: Needle stimulation strength shown in milli-ampères.



Needle electrode flashing (stimulation size)

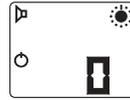
0.0 μC: Default needle electrode stimulation strength can be adjusted between 0.0 and 6.0 mA/0.24 μC.



Loudspeaker flashing

0: Stimulation beep off.

1: Stimulation beep on.



DBS flashing

3.2: DBS3.2 is used

3.3: DBS3.3 is used



100 Hz (or 50 Hz) flashing

100 Hz: 100 Hz tetanic stimulation.

50 Hz: 50 Hz tetanic stimulation.



6 Survey of display



Loudspeaker (10): used to indicate sound set-up.

Flashing "1" or "0" is used to indicate if beep is on or off.



Acceleration transducer (11; flashing). Absence of acceleration transducer or unsteady/too low signal during calibration.



Bad surface electrode connection (12; flashing).



Surface electrode (12; flashing): Skin resistance too high.

Set-up: Indicates set-up of stimulation strength for surface electrodes.



Needle electrode (13; flashing): Skin resistance too high.

Set-up: Indicates set-up of stimulation strength for needle electrodes.



Stimulation in progress (14).



Time to next stimulation (14).

Hz

Frequency of stimulation pattern (16).

μ C

μ C (used when: changing the stimulation strength, DBS, TET, LA and if no acceleration transducer is detected) (17).

mA

mA (used when: changing the stimulation current, DBS, TET, LA and if no acceleration transducer is detected) (18).

%	Percent (used for TOF, 1 Hz and 0.1 Hz) (20). TOF: Ratio between first and fourth response. 1 Hz, 0.1 Hz: Twitch height compared with reference value, flashing symbol means that the instrument has not been calibrated after switching on.
■	Second / shift mode (same symbol as on the button) (5).
▼	Device calibrated (same symbol as on the button) (6). Flashing symbol means that the instrument has not been calibrated after switching on.
⏻	Device on / stopped (same symbol as on the button) (7).
🔧	Internal Error (9).
🔋	Battery empty (8).
🔋	Battery low (8).

7 Further information

7.1 Cleaning

The TOF-Watch case may be cleaned with a damp cloth. Thorough cleaning of the device can be achieved by using a cloth moistured with either 70% ethanol, methanol, a chlorohexidine solution or 0.5% hypochlorite. Other chemical cleaners may damage the case finish and are not recommended. Do not use abrasive cleaners as these will damage the surface. Do not allow liquid to enter the case.

7.2 Unusual patterns

“Persisting responses” - Direct stimulation:

If the thumb is influenced by direct stimulation of the muscles under the stimulation electrodes this can result in an apparent response which does not disappear.

To eliminate this phenomenon the hand must be fixed in such a way that the muscle stimulation does not result in a movement of the thumb. Alternatively try changing polarity or position of the electrodes or try to lower the stimulation current.

Note: The TOF-Watch can show twitches higher than 100%.

Large twitches will be seen especially when no calibration has been performed or for a brief period of time after administration of a depolarizing relaxant.

8 Error signals

Whenever the TOF-Watch detects an error the stimulation is suspended and the user is alerted by two short attention beeps followed by one of the following error symbols (Internal error and Battery empty one long beep however):



Flashing acceleration transducer symbol (11)

Normal mode: Acceleration transducer has been removed.
Calibration mode: Unstable or too low acceleration transducer signal.



Flashing bad surface electrode connection symbol (12)

All modes: Missing or bad electrode connection.



Flashing surface electrode symbol (12)

All modes: Skin resistance too high.



Flashing bad needle electrode connection symbol (13)

All modes: Missing or bad electrode connection.



Flashing needle electrode symbol (13)

All modes: Skin resistance too high.



Both symbols flashing simultaneously (12) + (13)

All modes: No stimulation cable connected to TOF-Watch



Battery empty symbol (8)

All modes: Battery empty.



Internal error symbol (9)

All modes: Internal error detected.

9 Accessories

Standard (Included in TOF-Watch package)

- Acceleration transducer with cable 1.5 m.
- Stimulation cable for surface electrodes 1.5 m.
- Operating manual.

Optional

- Clamp for IV-pole mount.
- Stimulation cable for a needle electrode 1.5 m (loco-regional anesthesia).
- Surface electrodes.

Spare parts

- Acceleration transducer with cable 1.5 m.
- Stimulation cable for surface electrodes 1.5 m.

10 Technical specifications

Microprocessor-controlled.

Custom design LCD with numerical presentation of twitch data.

Automatic calibration:	Automatic adjustment for optimal gain and 100% reference.
Stimulation modes:	TOF (Train Of Four) PTC (Post Tetanic Count) 1 Hz twitch 0.1 Hz twitch DBS3.3 and 3.2 (Double Burst) Tetanic stimulation (Burst), 5 sec. - 50 Hz or 100 Hz
Output (accuracy $\pm 5\%$ of full scale value):	
Surface electrodes	Constant current, 0 - 60 mA (0 - 12 μC) up to 5 kOhm. Monophasic, 200 μs pulse width.
Needle electrodes	Constant current, 0 - 6 mA or (0 - 0.24 μC) up to 5 kOhm. Monophasic, 40 μs pulse width.
Transducer:	Acceleration transducer (accuracy $\pm 5\%$ of full scale value).
Battery:	9V Alkaline or NiCd (6LR61 / 6AM6).
Supply voltage:	9V=, 140 mA max.
Type:	BF 
Weight:	Approximately 250 gram with battery.
Dimensions:	200 x 90 x 50 mm.
Safety:	Complies with IEC601-1.
EMC:	Complies with EMC directive, 89/336/EEC, § 10 part. 1 when used with <i>standard</i> or <i>optional</i> accessories.

11 Symbols



Attention, consult accompanying documents.



Type BF equipment.

IPX0

Degree of protection against ingress of water (non-protected).



Complies with Medical Device Directive, 93/42/EEC (class 2A).

12 Warnings!



- Caution** (US only): Federal law restricts this device to sale by or on the order of a physician.
- Do not apply the TOF-Watch to patients with cardiac pacemakers without checking that the stimulation does not influence the pacemaker.
- Always make sure that no other equipment can touch the stimulation electrodes.
- Cover the stimulation electrodes with insulating material so that, e.g., catheters can never be exposed to stimulation.
- Check each time before use that the material insulating the acceleration transducer and the stimulation cable is intact and does not show signs of wear and tear.
- Never touch the electrodes unless the stimulation has been stopped. When the display shows the stop symbol (7) there is no stimulation. If this is not the case, press the  button (1).
- Do not use the TOF-Watch in the presence of flammable anesthetics.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operation in close proximity (e.g. 1 m) to short-wave or micro-wave therapy equipment may produce instability in the stimulator output.
- Do not stack the TOF-Watch directly on top of other electronic equipment. If stacking is necessary, observe the TOF-Watch to verify normal operation before applying it to the patient.
- Patients with nerve damage, Bell's palsy, Myasthenia gravis or other neuromuscular problems may not respond properly to stimulation. Therefore the TOF-Watch may show unusual patterns when monitoring relaxation in these patients.
- Do not apply electrodes to patients in areas where inflammation or injury is evident.
- The TOF-Watch adds information on the patient's situation as far as relaxation is concerned. It does not replace any clinical judgment performed hitherto, or any test made when no TOF-Watch was available.
- Monitoring neuromuscular transmission or neuromuscular block can only be performed using surface electrodes.
- Be sure only to use CE marked electrodes.
- Use of accessories, transducers, and cables other than the ones supplied with TOF-Watch may result in degrade electromagnetic compatibility performance of the device.