USER MANUAL

WiTOF®

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WiTOF TOF station
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TABLE OF CONTENTS

About the manual

This user manual contains all the information needed to use and configure IDMED WiTOF. It also describes the particular cleaning and inspection procedures that may be needed. This manual is intended exclusively for qualified medical staff.

Make sure this user manual is kept with the WiTOF at all times. A service manual is available for maintenance.

Before using the WiTOF, read the safety measures contained in this manual.

Intended use / Indication for use

The WiTOF is a neuromuscular transmission station (nerve stimulator) that helps to pilot the neuromuscular blockade of a patient in the operating room, recovery room or intensive care unit. The effect of NMBAs (Neuromuscular Blocking Agents) is monitored by measuring the acceleration (acceleromyography) of the muscular movements or by visually observing muscular contractions following electrical stimulation. The WiTOF has a 3-D acceleration sensor (accelerometer) which detects and quantifies the patient's muscular movements (contraction of the adductor muscle of the thumb or the big toe). Its sensor is directly integrated into the patient's sensor, which allows the sensor to assume a repeatable and optimal position.

The WiTOF has a part that is applied to or may come into contact with the patient: the splint.

Expected technical performance

The WiTOF operates as follows:
- Electrical stimulation of a patient under anesthesia based on single or repeated impulses lasting 200 microseconds squared and adjustable in intensity from 20 to 60 mA. (Value precision +/- 10%)
- Users have access to electrical stimulation modes used in everyday practical clinical situations: TOF, PTC, ATP, DBS, TET, ST.
- The muscular response of the thumb or big toe is measured following an electrical stimulation (TOF). The result of this measurement is to detect a movement generated by the muscle concerned and the ratio of the amplitude of the first and last movement during the same stimulation.

Clinical performance

The WiTOF provides the following clinical benefits:
- Intra-operative: Enable practitioners to view and control intraoperative blockade of patients.
- Post-operative: The patients' residual neuromuscular block is able to be diagnosed.

Clinical benefits

NMT monitoring allows to :
- avoid complications during intubation or extubation related to the use of neuromuscular blocking agents.
- adjust the dose of neuromuscular blocking agents required for each patient.

Important information

The WiTOF station is designed for use by health professionals (intensive care anesthetist, practitioner or state-recognized anesthetists nurse) who have been trained specifically in the use of this device. The system, and all related settings, are designed for use on adult patients in a professional health environment (hospital or healthcare centre) with a view to monitoring the patient's neuromuscular transmission blockade.

The measurements taken by the WiTOF on the patient's muscular response can be used to monitor the effects of NMBAs (Neuromuscular Blocking Agents).

The results provided by the WiTOF must be interpreted according to clinical judgment and compared to any other clinical observations. It is strongly advised not to rely solely on the results or values provided by the WiTOF for the purpose of NMT monitoring in patients. The values taken from

patients affected by neurological disorders, nervous function disorders, Bell's palsy, myasthenia and any neuromuscular activity disorders, should be treated with caution.

The WiTOF complies with the requirements of the European medical device directive and the regulatory requirements applicable in the country of sale.

For further information, please contact the manufacturer, IDMED, via its website (www.idmed.fr) or by writing to the following address:

IDMED
Hôtel Technoptic
2 rue Marc Donadille
13013 MARSEILLE - FRANCE

Safety measures

INTRODUCTION

Carefully read this manual before using the WiTOF.

WARNING, CAUTION, NOTE
The terms "Warning", "Caution" and "Note" have specific meanings in this manual.

• A **WARNING** warns against certain actions or situations which may result in personal injury or death.
• A **CAUTION** warns against actions or situations which may result in damage to the equipment, produce inaccurate data or cancel a procedure, even if bodily injuries are unlikely.
• A **NOTE** provides useful information about a function or a procedure.

MEANING OF ICONS
Any icons that may appear on the WiTOF screen are summarized and explained at the end of this chapter.

Any serious incident involving the device should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is based.

Warnings

Risk of explosion: Do not use the WiTOF in a flammable atmosphere or in places where flammable anesthetics may concentrate.

The WiTOF is not designed to operate in close proximity to a scanner, MRI scanner or any other device which generates strong magnetic fields. Nor should it be operated near to any short-wave or micro-wave therapy equipment.

To reduce the risk of burns when using high-frequency surgical devices, do not place the WiTOF stimulation electrodes between the surgical site and the return electrode on the electrosurgical unit.

A patient's simultaneous connection to a high-frequency surgical device (e.g., electrosurgery) may result in burns at the contact points of the WiTOF electrodes and cause damage to the device.

Never use the WiTOF at the same time as defibrillators.

Like any other NMT monitor, the WiTOF must be connected to electrical stimulation electrodes

which withstand voltages of up to 300 Volts with a current of 60 mA. The contact surface of electrodes must be greater than 1.8 cm².

The output from electrical stimulation causes nociceptive stimulations and the intensity of these stimulations must be adapted to the patient's analgesic level.

Do not use the WiTOF on patients that have a pacemaker, unless you have previously checked and identified the possible consequences. The user must take all the normal precautions during any intervention involving this kind of patient.

Before use, check that no other equipment, device or apparatus is in contact with the electrodes.

The sensors and electrodes should only come into contact with healthy and non-damaged skin.

Before use, check that the device, screen and the sensor are not damaged. Never use the device if you detect any fault or damage.

Handle the device with care to prevent any fall.

The WiTOF must be used on a single patient for a limited time. It must be cleaned between patients.

The WiTOF will be used partially or continuously during the operation. It should never be used on a single patient for more than 24 hours.

After positioning one of the sensors in contact with the patient, check regularly at least every 2 to 3 hours to ensure that the sensor is not causing excessive pressure or stress on the patient's skin. If the skin appearance changes in any way, change the stimulation site.

Portable RF communication equipment (including peripheral devices such as antenna cables and external antennas) should not be used within 30 cm (1 foot) of any part of the WiTOF, including any accessories specified by the manufacturer.

The use of the WiTOF in close proximity to, or on top of, other devices should be avoided to prevent disturbance and malfunctions. If it is necessary to use the device in this way, ensure that the various items are operational before use.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Use cables other than the one recommended by the manufacturer of this equipment could result in increased cyber security risks.

When the power supply is in operation, the contact time should not exceed 1 minute to avoid the risk of burns.

Caution

Carefully read this manual before using the WiTOF.

Do not place the WiTOF or any of its components or accessories into an autoclave.

The WiTOF sensor must not be in direct contact, immersed, sprayed or filled with any liquid and shall be cleaned in the same way as the WiTOF.

The WiTOF and its components are not compatible with gas, radiation (gamma or any other form), bath, steam or heat sterilization processes.

Follow the WiTOF cleaning and disinfection instructions of the "Cleaning and Disinfection" chapter.

The WiTOF carries an internal lithium-ion battery. The WiTOF battery should under no circumstances be dissembled, modified or replaced. Any tampering with the battery poses the risk of combustion or explosion. Only an authorized technician or IDMED employee is qualified to perform such operations.

If the device has been in storage for an extended period, recharge the WiTOF sensor battery for at least 2 hours before use. Hold the sensor, and if it does not respond, the battery must be replaced.

Only qualified technicians with the explicit approval of IDMED are authorized to service and repair the device.

The WiTOF user must take care not to make contact with any other electrical devices when using the WiTOF.

Before the WiTOF is used to generate an electrical stimulation, the practitioner must check the suitability and intensity of the stimulation to which to the patient may be exposed.

Never touch the electrodes during stimulation phases. The electrodes are surface electrodes and are compatible with the use of electrical stimulations.

Do not use any cables or accessories except for those supplied with the WiTOF.

The simultaneous use of a monopolar or any other kind of electrosurgery device may cause interference, distort the results of measurements or even prevent the WiTOF from taking a measurement.

To avoid electrostatic discharge, the WiTOF must be used in an environment where electrostatic discharge is controlled. (See the "Environment" chapter).

The WiTOF is designed to transmit electrical impulses to the patient. As a result, an electrophysiological signal detection device (EEG, ECG) is able to detect these impulses. This disturbance is temporary and depends on the settings of the various devices.

Comment on electromagnetic compatibility (EMC): This device generates, uses and may emit radio-frequency energy. Failure to set up and use the device in accordance with the instructions of this manual may cause electromagnetic interference.
The equipment has been tested and operates in compliance with the limits specified in IEC 60601-1-2 for medical electrical equipment. These limits provide reasonable protection against electromagnetic disturbance whenever it is used in the specified environments (e.g., hospitals)

Contraindications

None

Side effects

None

The pictures in this manual are for illustration purposes.

Explanation of the symbols

General symbols

Caution

Serial number

	Indicates a requirement for separate treatment of end-of-life general waste.		Labelling in compliance with the European regulation on medical devices Date of first CE marking: 2020
	Manufacturer	IP 30	Protection class against solid foreign bodies and liquids. Not protected against liquids.
	Refer to the operating manual		Type BF applied part
	Direct current DC		Manufacturing Date
	Temperature limit	LOT	Lot code
	Humidity limitation	REF	Catalogue reference
	Atmospheric pressure limitation		Curtis-Straus Mark (USA and Canada)
R_X Only	Prescription use device in USA	MD	Medical device
	Manufacturing Date, manufacturer		

<u>Caution:</u> USA federal law restricts this device to sale by or on the order of an anesthesiologist or other qualified practitioner.

Symbols displayed on the WiTOF screen

	Sleep mode		Symbols indicating the wireless connection status
	Access the main menu		Sensor battery charge level
	Access to the settings menu		Patient's electrode impedance level (green, yellow, red, grey)
	Sensor connection		Access to the current patient's history
	Add a new patient and delete history		Sound activated/deactivated

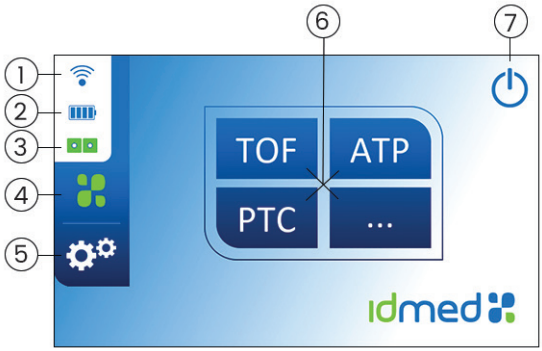
Alert settings

Unreliable measuring conditions

I General features

WiTOF and its main accessories

Main menu screen display



1. Wireless connection status
2. Battery charge level
3. Patient impedance /Electrodes
4. Access to main menu
5. Access to settings menu
6. Access to tests
7. Stand-by

Menu selection

The menus, options and various tests are accessible via the WiTOF touch screen. The user navigates through the different menus by simply pressing (for less than 1 second) on the desired function.

The touch screen makes it easy to navigate the menus even with the use of a latex glove. The various tests are accessible via the main menu.

Battery/mains operation

The WiTOF consists of a station connected to the mains and a battery-operated sensor (for further information, see the "Battery" chapter). The battery of the wireless sensor is charged by placing the sensor on the WiTOF station in the designated area.

Note:

Position the WiTOF and its power supply so that they can be easily disconnected.
Before use, make sure that the sensor battery is fully charged.

If the power supply does not work, replace it with one exclusively supplied by IDMED.

II Setting up the WiTOF

Turning the WiTOF on and off

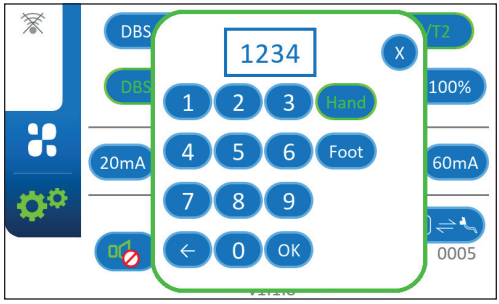
The WiTOF is switched on/off via the ON/OFF button located on the back of the device.
When the WiTOF is ON, the main screen lights up.

Notes:
The station indicator light flashes when the sensor is on charge.
If a sensor is not connected, the WiTOF station will automatically enter sleep mode after 10 minutes. If a sensor is connected, the WiTOF station will enter sleep mode if left idle for 2 hours. To exit stand-by mode, touch the screen or remove the sensor from its charging base.

Connecting the sensor to the WiTOF station

The user must check the "wireless signal" icon to see whether the sensor is correctly connected to the station before use.
The number of lines indicates the strength of the signal.
(One line means the signal is weak; three lines mean the signal is strong).

If the sensor is not connected (represented by the icon), the user must go to "settings", touch the "sensor connection" icon , select either hand or foot sensor and then enter the final four digits of the serial number (SN) appearing on the sensor label to establish the connection.



Using the example of the following label, the user would enter "1-2-3-4".

Note:
In order for the connection to the sensor to be successful, it is important to ensure that the sensor is active (sensor light is red, yellow or green with rapid flashing).
If the sensor light is blue with slow flashing, reposition the sensor on the station and remove it.

Electrodes

The WiTOF sensor must only be connected to surface electrodes with a stud like connection. The electrodes must be fixed to the sensor case before the sensor is positioned on the patient.

The electrodes must allow electrical impulses to be transmitted to the patient. They must be compatible with the stimulation values routinely used by NMT monitors.

Position of electrodes

Monitoring the neuromuscular blockade can be done by stimulating different nerves and measuring the response of the muscles involved. It is essential that the electrodes are positioned correctly to stimulate the nerve and not the muscle directly.

Stimulating the ulnar nerve with the thumb adductor muscle acceleration measurement is generally considered to be the most common technique. In this case, the electrodes are placed on the ulnar nerve pathway on the surface of the wrist on the inner forearm.

If the big toe is used, the electrodes are placed on the posterior tibial nerve pathway, above the malleolus.

Note:

In order to facilitate the placement of the electrodes, it is strongly recommended that the electrodes are fixed onto the case before positioning the sensor on the patient. The sensor's light indicates the impedance level to the user.

The proximal electrode (closest to the heart) will be connected to the red side of the sensor. The distal electrode (farthest from the heart) will be connected to the black side of the sensor.

Setting up the sensor

The sensor splint must be able to move freely in response to muscle contractions. Any part of the sensor in contact with the patient must not positioned so tightly that the patient is at risk of injury. The sensor must be kept within 5 meters of its station.

Depending on the electrodes used (quality of adhesive, size of studs), the sensor case may have to be attached to the patient's arm or leg.

Position of the electrodes and the sensor on the patient's hand and foot:

Hand sensor

The splint must generally fit the shape of the patient's hand and come into contact with the distal phalange of the thumb. If the splint is not suitable for the patient's hand, medical adhesive tape can be used to keep it in the correct position. The user may also use medical adhesive tape to immobilize the patient's other three fingers with a view to increasing the thumb range of movement and obtaining a more accurate measurement during monitoring.

The user should always check that the sensor splint and index finger ring are not causing undue pressure or strain.

Foot sensor

Medical adhesive tape is used to attach the splint to the patient's big toe. Make sure that the patient's toe and ankle are unrestrained.

Notes:

While using the WiTOF, the user should check that the sensor remains in the same position as when it was installed.

After using the sensor for a while, a slight mark or redness of the skin in the contact area with the sensor may appear. This mark or redness is due to the presence of the sensor in contact with the skin. This must remain limited, harmless and not look like an injury.

Skin impedance

The green, yellow and red indicator of the WiTOF helps to maintain a patient's skin impedance at an optimum level. The indicator is represented by an indicator light on the sensor and by an icon on the station.

The WiTOF sensor includes a constant-current stimulator which means that, regardless of skin impedance, an identical current is transmitted to the patient. It can be operated as long as the voltage is below 300 V. Because of this limit, it is recommended to have a good skin impedance.
Only the green indicator allows the WiTOF to be used in good conditions. With the yellow indicator, the intensity of the electrical stimulation may be lower than expected. When this indicator is red, the WiTOF will not generate any electrical stimulation. In this case the WiTOF displays an error message (see chapter "indication messages"). It is then necessary to check and improve the contact quality of the electrodes to the patient.

Note:

Cleaning the patient's skin before positioned the electrodes may significantly reduce the skin resistance. That is why the user should clean the patient's skin before positioned the electrodes.

The quality and condition of the electrodes have a significant impact on the measured impedance value.

III Using the WiTOF

General principle

The WiTOF has 6 electrical stimulation modes: 3 primary modes (TOF, PTC, ATP) and 3 secondary modes (DBS, TET, ST). Some modes may be configured or programmed by the user.

The user selects the corresponding mode from the available options in the menu.
Do not perform successive electrical stimulations without respecting a time interval between each one, otherwise the measured values may be distorted. The WiTOF memorises and displays the time elapsed since the last stimulation on the screens of every mode. In the case where this time exceeds 10 minutes (when no Auto Mode is activated), it flashes orange to indicate that this data is obsolete and that the measurement must be performed again.
If the time elapsed since the last stimulation is shorter than the required interval, the WiTOF will block any attempt to start a new test. The selected mode screen will be greyed out and display a timer indicating how long the user must wait before proceeding ("Period X seconds").
For instance, the WiTOF requires a 12-second interval between TOF stimulations.

The icon ? before a result indicates that measuring conditions are unreliable. In this case, the user may repeat the measurement (after observing the necessary interval) or wait for the next measurement in "AUTO_TOF" mode.

Notes:

The recommended intervals between each stimulation are specified at the end of the descriptions of the various stimulation modes.

When the WiTOF is disconnected from a patient at the end of the operating time, the measurements history must be deleted before the device can be connected to another patient. To that end, the user simply adds a new patient.

New patient

To monitor a new patient, the user selects "add a new patient"  in the top left of the screen of the selected mode.

Note:

Whenever a new patient is added, the history of the current patient is deleted (for further information, see the "history screen" chapter).

Adjusting Intensity

The user may adjust the intensity of stimulations by directly selecting the value at the top of the screen. In a new window, the intensity can be adjusted between 20 mA and 60 mA.

It is generally accepted that the ulnar nerve or tibial nerve of adults must be stimulated at a current of 50 mA to obtain supra-maximal stimulus.

In particular cases, the user may adjust the value of this stimulation. The user should consider the potential risks of inappropriate stimulation for the patient.

Determining the supra-maximal stimulus:

Touching and holding down the "Supramax" icon launches a sequence of stimulations to determine the suitable supra-maximal intensity for the patient. As soon as the supra-maximal intensity is detected, it is displayed and replaces the previously displayed "mA" value.

Notes:

If the sensor movement amplitudes are too small, the supra-maximal current determination sequence stops and the message "Supramax not valid" is displayed.

Alert settings and operation

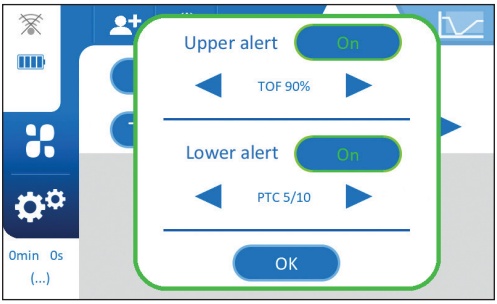
The settings can be used to adjust the upper and/or lower limits of alerts for stimulation results. The user is notified by an alert when a result obtained is above a high alert limit or below a low alert limit.

To access alert options, the user must select the alert settings icon: 

A settings window is displayed. The user can then choose to activate or deactivate the alerts. If an alert is activated, the user can select the upper and/or lower alert limit. The selection is validated by selecting OK.

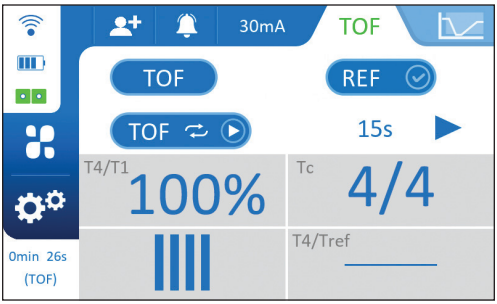
During a stimulation, if an alert threshold is crossed, a window opens to warn the user and a double beep sounds. The user clicks on Ok to make the window disappear. To stop the window from reappearing, the user must deactivate alerts in settings.

If the user no longer wishes to hear the beep, the user should turn off the sound and/or deactivate the alerts.



"TOF" mode

"TOF" mode includes several options or sub-menus. An individual description of each one is provided below. In this mode, the user has the option of directly performing the "TOF" stimulation manually, or setting a frequency for the TOF to be automatically executed.



«TOF» 

After selecting the "TOF" mode, the user can start a "TOF" stimulation (or test) by pressing the "TOF" touch button. Before that, the user must check that the selected intensity of the stimulation (current in mA) is suitable in view of the level of anaesthesia, the blockade level and the patient's profile. For further information about the stimulation intensity, see the "Adjusting Intensity" chapter.

The TOF stimulation is among the most commonly used stimulations; it involves 4 stimuli (of 200 µs) at intervals of 0.5 seconds.

The WiTOF will display after the electrical stimulation the calculation of the percentage of the amplitude of the fourth response over the first (ratio T4/T1, TOF in %) on the lower part of the screen. The WiTOF also displays a bar graph allowing the visualisation of the amplitudes of the different responses.

If the user takes a reference measurement, it will be represented on the bar chart by a yellow horizontal line, and the T4/TRef ratio will also be displayed. For further information about the reference measurement, see the "Reference test selection" section.

The number of responses considered is displayed in the form of a ratio X/4 (with X being the number of muscular responses detected).

When the WiTOF detects irregular movements or electrical disturbance during the measurement, the icon  is displayed before the results to inform the practitioner that the measurement conditions are unreliable.

The user is required to observe a 12-second interval between two "TOF" stimulations.

«AUTO TOF» 

The "AUTO TOF" mode allows TOF stimulations to be programmed according to a specific frequency. To select a frequency, the user must scroll across the available frequencies using the directional arrows and select a measurement every 15 seconds, 30 seconds, 1 minute, 2 minutes, 5 minutes and 15 minutes.

After selecting the stimulation frequency by touching the desired value to validate it, the user presses and holds the "TOF AUTO" button to start the stimulation cycle. The first stimulation is effective one second after pressing.

A programming process is ended by pressing the "AUTO_TOF" icon again; the WiTOF then displays the results at the bottom of the screen.

The displayed results are the same as those of the "TOF".

Selecting a "REFERENCE" or "REF" test

The reference test enables the user to record the patient's motor response to an electrical TOF stimulus while the patient is under anaesthesia and awaiting the administration of NMBAs.

This measurement displays the calculated ratio of the patient's muscular response range with and without NMBAs during future TOF stimulations.

This reference value can be used to improve the assessment of the reversal agents on the patient and to determine the effects of polarising NMBAs. This reference value will be recorded as "Tref".

When the box is grey, it means that no reference has been recorded.
By pressing this icon, the WiTOF performs a "TOF" stimulation to calculate the average range of the four muscular responses. This range will be used to calculate T4/Tref and displayed as part of future "TOF" stimulations.

When the box is green, it means that a reference has been recorded.
The user can press this icon to delete it.

Notes:

The interval between two "REFERENCE" stimulations is 12 seconds.

The reference value is only used to calculate the T4/Tref during electrical TOF stimulations.

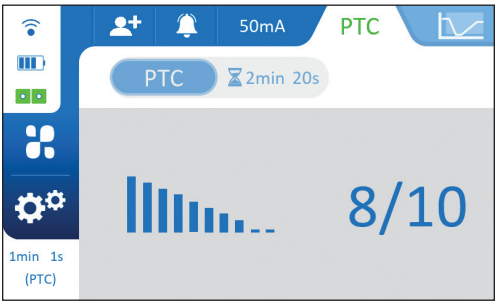
The stimulation used for the reference, as in the case of all electrical stimulations, must only be performed on anaesthetised patients. Stimulations may be very painful if the patient has not been anaesthetised.

The user may adjust the value recorded as a reference measurement as many times as necessary. For further information about the applicable procedure, see the "History screen" menu.

“PTC” mode

The “PTC” or “Post Tetanic Count” stimulation mode is used for deep level of blockade and in the absence of a response to the TOF stimulation. The “PTC” stimulation involves one “TETANUS” stimulus which lasts for 5 seconds at 50 Hz followed by a 3-second pause and then by 10 “SINGLE TWITCH” stimulations.

The user presses the “PTC” icon to begin the PTC stimulation. At the end of the stimulation (duration of 18 seconds) the WiTOF displays the number of muscular responses detected. They are displayed as graph bars so the respective amplitudes can be compared.
The interval between two “PTC” stimulations is 3 minutes.



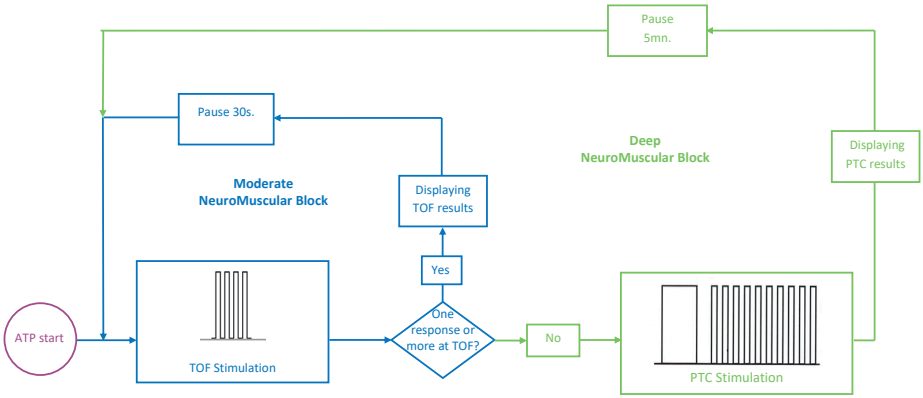
“ATP” mode

ATP is an automatic mode which measures light, moderate and deep levels of blockade. The ATP mode uses the TOF or PTC stimulations appropriately. The stimulation is repeated every 30 seconds or 5 minutes depending on the level of the patient’s responses to the TOF and PTC stimulations.

The aim of the ATP mode is to use electrical TOF and PTC stimulations according to the patient’s blockade level. It displays the results of the measurements taken according to the stimulation applied to the patient. It will therefore use a TOF stimulation followed by a PTC stimulation if no response has been measured after the TOF stimulation. The results calculated at the end of each TOF or PTC stimulation are displayed on screen.

If the patient has at least one response to the TOF stimulation, the WiTOF will display the measured results and allow a period of 30 seconds to elapse before stimulating the patient again. If the patient is unresponsive to the TOF stimulation, the WiTOF will stimulate the patient with a PTC stimulation and will display the corresponding results. The WiTOF will then allow a period of 5 minutes to elapse before stimulating the patient again.

Timing chart of the ATP mode:

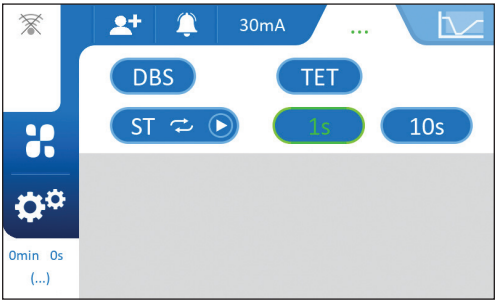


Notes:

The ATP mode must only be used with non-depolarising NMBAs. It may be ended at any time by pressing ATP .

In the absence of movements following several stimulations, the ATP mode will end.
The required interval following the use of "ATP" mode is 3 minutes. It is important to remember that "PTC" stimulations are only normally used in the absence of responses to "Single Twitch" and "TOF" stimulations.

Secondary modes



The secondary modes available on the WiTOF are Double Burst stimulation (DBS), Tetanus (TET) and Single Twitch (ST). To select the desired mode, the user must select the menu ... on the main screen and then press the corresponding icon on the touch screen.

"DBS" mode

"Double Burst Stimulations" or "DBS" can be performed on the WiTOF. The user has access to 2 "DBS" mode types via the "DBS MODE" menu. The DBS mode is able to detect any residual effects of NMBAs. "DBS" stimulations involve two series of stimuli at 50 hertz at intervals of 750 ms. According to the selected "DBS", the series consist of 2 or 3 impulses (duration of impulses: 200 µs). When the DBS stimulation has been performed, the measured response number and the relative range of each one are displayed in the form of white bars. A percentage representing the ratio of the amplitude of the second response to the amplitude of the first is displayed on the left of the screen.

The user may select various "DBS" types by pressing the desired mode on the "Settings" menu. The WiTOF authorises "DBS 3.3" and "DBS 3.2" modes. By default, the WiTOF proposes the "DBS 3.3" stimulation.

Note:

The interval following a "DBS" stimulation is 20 seconds.

"Tetanus" or "TET" mode

The tetanus or "TETANUS" stimulation stimulates a patient for 5 seconds at 50 Hz or 100 Hz (according to the chosen settings). The patient's motor response is not measured by the WiTOF sensor; it is visually assessed by the user.

Note:

The interval between two "TET" stimulations is 3 minutes.

"Single Twitch" or "ST" mode

The "Single Twitch" stimulation is an impulse stimulation lasting for 0.2 ms. It causes a single muscular contraction. The patient's motor response is not measured by the WiTOF sensor; it is visually assessed by the user.
Before starting the stimulation, the user must select the frequency of the stimulation: 1 second or 10 seconds according to the corresponding icon. After pressing ST , the stimulation will begin.

Selection of "10 s" (i.e. 0.1Hz): this option enables the WiTOF to repeat a Single Twitch stimulation every 10 seconds.

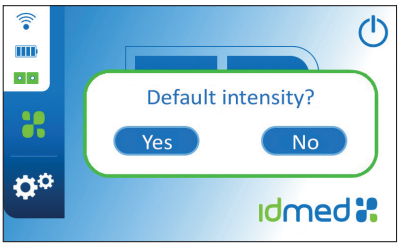
Selection of "1s" (i.e., 1Hz): this option enables the WiTOF to repeat a Single Twitch stimulation every second.

The ST stimulation can be stopped simply by pressing 

Note:

Repeated "0.1HZ" and "1 HZ" stimulations last for a period of 10 minutes; after this period, the WiTOF ends the stimulation. There is no waiting time imposed in the WiTOF following this form of stimulation. The practitioner will determine the length of the interval according to the number of stimulations carried out.

Instruction messages



Default intensity
When the WiTOF is turned on, a window will appear giving the user the option of operating under "default intensity" if, during the previous use, the user changed the stimulation current intensity.
The user will then have to choose yes to restore the default intensity or no to keep the last used intensity.

New patient
Whenever the WiTOF is turned on, if it has stored previously recorded measurements, a message will appear giving the user the option of adding a new patient. The user selects either yes or no. If the user selects yes, the current patient's history will be deleted.

Sensor not detected
If the sensor is not connected to the WiTOF when the user selects a mode, a "Sensor not detected" error message will be displayed.
The user must check the sensor connection. To this end, see the "Connecting the sensor to the station" chapter.

Damaged sensor
If the sensor is non-functional for any reason and the user presses a mode to start a stimulation, they will get an error message saying "Sensor damaged".
The user should then check the condition of the splint and the cable connecting it to the sensor and restart the sensor by placing it on its base and removing it.
If there is any abnormality on the splint or the message still appears after restarting, please contact customer service.

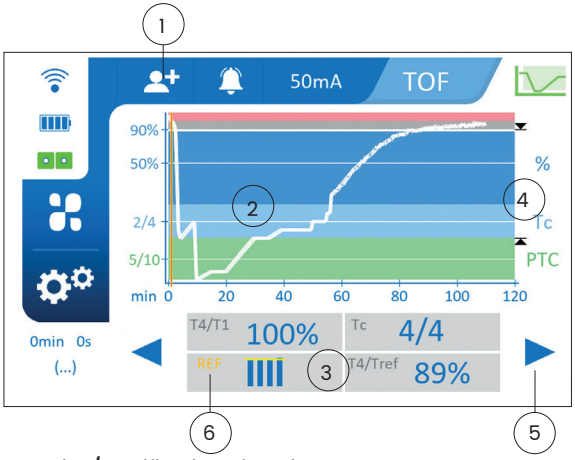
Battery low
If the sensor battery is not sufficiently charged to start a test when the user selects a mode, a "Low Battery" error message will be displayed.
The user must charge the sensor battery. To this end, see the "Battery/Battery recharge" chapter.

Poor impedance
If the impedance symbol is red, the WiTOF will not deliver an electrical stimulation and will display a "Bad impedance" error message.
The user should then check or change the patient's connection to the electrodes.

History screen

After the stimulation has ended, the user must select  in the top right of the screen to access the current patient's history screen.

Presentation of the history screen

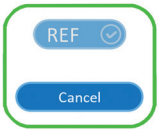


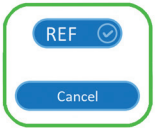
1. Adding a new patient and deleting the current patient's history
2. Test result curve
3. Stimulation result zone
4. Alert level indicators
5. Selection arrows
6. Reference indicator

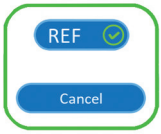
Selection/Modification of a reference value

To select a measure, the user must touch the graph and then use the selection arrows left or right to select a specific measure.

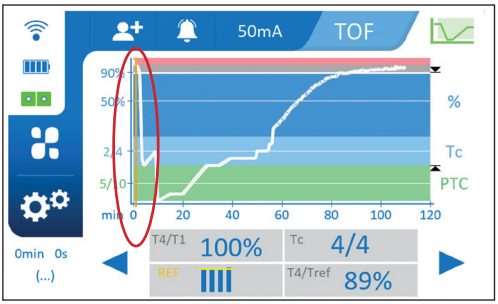
Once the measure is selected, the user must touch the stimulation result zone. A new window is displayed on the screen (3 alternatives)







Alternative 1	Alternative 2	Alternative 3
The selected measure can't be used as a reference.	The selected measure can be used as a reference by touching the REF button.	The selected measure is already a reference. When touching the REF button, a pop-up appears allowing the user to erase the reference measurement. Once the reference has been erased, the user is in the same case as alternative 2.



Once the reference is selected, a yellow bar will appear on the results curve.

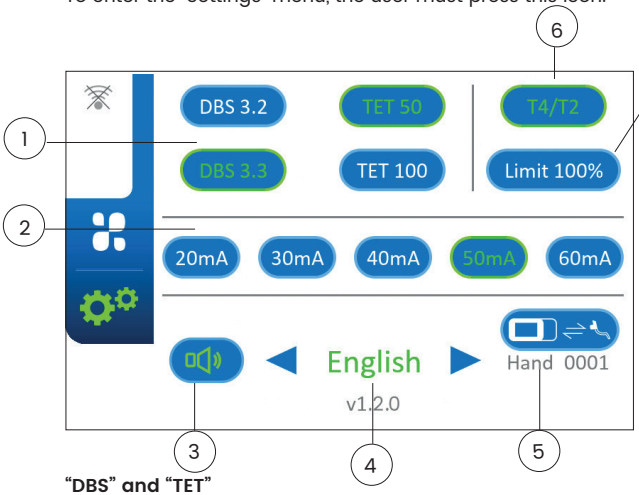
Note:

The history is only valid for the current patient. The WiTOF does not save the history of all patients.

Settings menu

The "Settings" menu allows the user to select the general settings of WiTOF. This menu is identified on screen by the following icon: 

To enter the "Settings" menu, the user must press this icon.



1. Type of impulse for DBS and TET modes
2. Adjusting the default intensity
3. Screen beep sound level
4. Selecting the WiTOF station language
5. Sensor connection and information
6. Activating the T4/T2
7. 100% limit

"DBS" and "TET"

The user may select the type of impulse for the DBS and TET stimulation. DBS impulses may be 3.2 or 3.3.
TET pulses may be 50 or 100 Hz.
For further information about DBS and TET stimulations, see the "Secondary Modes" chapter.

Adjusting the "STIM" intensity level

The intensity level adjustment sub-menu allows the default intensity to be adjusted whenever a new patient is added. The stimulation intensity may be adjusted directly on the stimulation page.

"Sound"

The "SOUND" sub-menu allows to activate or deactivate the sound signals emitted by the WiTOF during measurements, selections, alerts and electrical stimulations performed by the user.

"Language"

The language sub-menu is used to select the language of the WiTOF display. The user must use the directional arrows to change language.

T4/T2 Activation

The "T4/T2" sub-menu is used to activate or deactivate the T4/T2 ratio display as a replacement for the T4/T1 ratio calculation when the T2 response range is greater than the T1 response range.

100% limit

The "100% limit" button allows the user to activate the limitation of the value displayed for a TOF result superior to 100%. It means that even when the result is greater than 100%, the value displayed is 100% (in that case the value is displayed in dark pink).

IV Maintenance, cleaning and disinfection

Maintenance and Preventive Maintenance

For a consistent performance level, it is advisable to check the following points once every two years:

- The integrity of the case, the screen and the labels,
- The sensor battery recharging process,
- The condition of the electrode cable, its electrode clamp ends and its sensor clamp,
- The intensity of electrical stimulations; sensor measurements.

As long as the WiTOF is operated and maintained according to the instructions of this manual, the station has a service life of 5 years (2 years for the sensor).

Caution:

Only qualified technicians with the explicit approval of IDMED are authorised to service and repair the device.

Battery/Battery recharge

Battery

The WiTOF sensor integrates a rechargeable Lithium-Ion battery. The battery has thermal protection and short-circuit protection. The sensor charges automatically when it is correctly attached to the WiTOF. The indicator light of the sensor flashes when the sensor is charging. The autonomy of fully-charged sensors is 12 hours.

The WiTOF displays a level gauge to indicate the battery charge level.

When the battery is charged, all the bars are filled. The bars gradually disappear as the battery is discharged.

The battery is covered by a 1-year warranty (its autonomy at 1 year must be more than 50% of its theoretical autonomy). The battery has a normal service life of 2 years.

Note:

Only qualified technicians are authorized to carry out repairs or maintenance operations after obtaining the consent of IDMED.

Battery Recharge

The battery charging is done when the WiTOF station is powered on and the sensor is well positioned on the station (i.e. when the station light is blinking). The battery can be fully recharged within 3 hours. The charger used to power the WiTOF is supplied by IDMED.

The station indicator light flashes when the sensor is charging.

The battery can be recharged at any time regardless of its charge level. When the WiTOF displays the low battery symbol (battery with only one visible blue bar), the battery must be recharged as soon as possible.

The charging process is automatic, so when the battery is fully charged the WiTOF stops the process.

If the sensor is incorrectly positioned on its charging stand, the WiTOF indicates that there is an error. The LED on the station lights up red and a "charging error" message appears on the screen. The user must then reposition the sensor.

Notes:

Only technicians with special WiTOF training or IDMED staff members are authorized to service or repair the battery.

Maintenance on the battery consists only of checking the charging cycle once every two years. This means checking that the charge cycle does not exceed 3 hours. The gauge goes from no visible bar when charger is fully discharged to all visible blue bars when the battery is full.

Cleaning and disinfection

Caution

Do not place the WiTOF or any of its components or accessories into an autoclave.

Under no circumstances should the WiTOF or any of its components or accessories be in direct contact, immersed, sprayed or filled, with any liquid.

The WiTOF and its components and accessories are non-sterile devices. Under no circumstances should the WiTOF or any of its accessories be sterilized.

The WiTOF must be cleaned and disinfected after every use. A low-level disinfection procedure is sufficient.

The surface of the WiTOF and its accessories must be cleaned using a lintless cloth soaked in quaternary ammonium disinfectant, with 70% isopropyl alcohol. Before using this solution, refer to the manufacturer documentation and test it out on a small area.

Example of recommended products:
- mikrozid® sensitive liquid produced by Schülke & Mayr GmbH.
- clinell® Universal Spray produced by Gama Healthcare Ltd.

Contact your approved local distributor or the manufacturer to check the availability of approved products in your country.

The WiTOF sensor must not be in direct contact, immersed, sprayed or filled with any liquid and shall be cleaned in the same way as the WiTOF.

When cleaning the WiTOF splint cables, care should be taken not to pull excessively on the splint as it could lead to premature breakage of the wires inside the sheath.

V Appendices

Diagnostics / Possible malfunctions

The table below identifies potential malfunctions and possible solutions.

Malfunction	Solutions
The sensor is unresponsive or spontaneously shuts down after a few seconds ("Low Battery" message)	Put the sensor on charge (see the "Battery/ Recharge Battery" chapter)
The device displays the grey/red impedance icon or "no patient" message, despite the sensor being attached to the patient.	Check the position of the electrodes (see the "position of electrodes" chapter) and check the connection between the electrodes and the sensor.

The sensor does not connect to the station.	Check that the sensor does not display a blue flashing light; if it does, place the sensor back on the station and remove it again. Check the sensor's serial number (see the "sensor connection sensor" chapter). Check that the sensor is located near to the station.

Note:

If a problem persists or is unable to be resolved according to the instructions above, contact the WiTOF distributor.

Recycling

To help protect the environment, you must engage the services of an agency that is approved to collect and process devices which contain electronic components and accumulators such as Lithium Ion.

When disposing of or recycling the device components, please contact a recycling company specializing in electronic devices.
Any electronic products that have not been sorted at source are potentially hazardous for the environment.
Packaging materials must be disposed of or recycled in accordance with applicable regulations.

Technical Specifications and warranty

The WiTOF integrates a micro-controller and an LCD colour screen for optimum visibility and simplified use.

Safety

- Biocompatible sensor materials (component in contact with the patient). Latex-free.
- In accordance with the European regulation 2017/745 concerning medical devices Class 2A (CE 0459 LNE/G-MED)
- In accordance with IEC 60601-1 class II devices.
- In accordance with IEC 60601-2-10
- EMC: IEC 60601-1-2

EMC Emission

Emission test	Compliance	EMC Instructions/cautions
RF Emissions CISPR 11	Group 1	The WiTOF uses RF energy only for internal functions. Therefore RF emissions are very low and should not disturb other nearby devices.
RF Emissions CISPR 11		
Harmonics IEC 61000-3-2	Class B	The WiTOF must be use in professional healthcare facility environment
Voltage fluctuations	Class A	
and flicker IEC 61000-3-3	Compliant	The WiTOF can be connected to the public mains network

EMC Immunity

Phenomenon	Basic EMC standard	Professional healthcare facility environment Immunity Test Levels	Compliance levels	EMC Instructions/precautions
ELECTROSTATIC DISCHARGE (ESD)	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	In order to reduce ESD, the device must be used in a 35% humidity environment or more
Radiated RF EM Fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	Complies to table 9 of IEC 60601-1-2 (2014)	Complies to table 9 of IEC 60601-1-2 (2014)	In order to prevent electromagnetic disturbance, keep minimum separation from RF communication equipment of 30cm
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	The WiTOF may temporarily not display result during transient electromagnetic disturbances such as the use of electrosurgery device. In that case, the WiTOF will maintain the safety of the patient and the user.
Surges Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV	Mains power quality should be that of a typical residential, commercial or hospital environment.
Surges Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV	Mains power quality should be that of a typical residential, commercial or hospital environment.
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	In order to prevent electromagnetic disturbance, keep minimum separation from RF communication equipment of 30cm
RATED power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Mains power quality should be that of a typical residential, commercial or hospital environment

Voltage dips	IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains power quality should be that of a typical residential, commercial or hospital environment.
		0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0°	
Voltage interruptions	IEC 61000-4-11			Mains power quality should be that of a typical residential, commercial or hospital environment.

Stimulations
- TOF (Train Of Four), calculation of T4/T1 and of T4/Tref.
- AUTO TOF (TOF programmed from 15 seconds to 15 minutes).
- TET (Tetanus 50 Hz and 100 Hz)
- DBS (Double Burst Stimulation) mode 3.3 and 3.2.
- PTC (Post Tetanic Count)
- ATP (Automatic TOF and PTC mode)
- TWITCH (Single Twitch) 0.1 Hz and 1 Hz.

Acceleration sensor
- 3D accelerometer (+/- 8 G over 10 bits, Fq: 200 Hz, Resolution 0.016 G)

Electrical stimulation
- Constant output current from 0 to 60 mA (precision +/- 10%) (under resistive load of 4 Kohms)
- Single-phase, pulse duration 200 µs, frequency 50 Hz
- Stimulation electrodes or ECG electrodes:
  - Able to withstand up to 300 volts with a current of 60 mA.
  - The contact surface must be greater than 1.8 cm².

Recommended electrode examples:
- RED DOT electrodes from 3M - ref 2560

Contact the approved distributor or the manufacturer to check the availability of approved products in your country.

Maximum distance between sensor/station during use
- Maximum distance of 5 metres

Data transfer
- Optical output for fibre optic connection
- IDMED-approved optic connection wires must be used to connect the WiTOF to any other device.

Power pack
- Lithium-Ion battery of at least 660 mAh/ 3.7 V (integrating thermal and short-circuit protection)
- Autonomy: 15 hours
- Charger/External power supply (continuous 5 V, 1 A minimum)

Size/Weight
- 290x110x50 mm (main case).
- 500 g (approx.)

Warranty
- Warranty period: 2 years, 6 months for accessories and sensors

Energy consumption

• Maximum consumption of 4.5 W (sensor on charge) and 0.1 W in stand-by mode (sensor not on charge).

Environment

Shipment and storage conditions

The WiTOF and its accessories must be stored or transported subject to the following procedures and conditions. These conditions presume that the device is not operational during storage and transport.

Temperature	10 °C to +50 °C
Humidity	15% to 95% (without condensation)
Pressure	500 hPa to 1060 hPa

The original packaging must be used during storage and transport.

Do not expose the WiTOF to any sudden change in temperature as it may cause condensation.

Operating environment

Reminders:

Risk of explosion: Do not use the WiTOF in a flammable atmosphere or in places where flammable anesthetics may concentrate.

The WiTOF is not designed to operate in close proximity to a scanner, MRI scanner or any other device which generates strong magnetic fields. To limit electrostatic discharge, humidity must be kept above 35% and the use of an anti-static floor covering is recommended.

The WiTOF is designed to operate safely under the following conditions. Any situation other than those described may interfere with the reliability of the device.

Temperature	10 °C to +35 °C
Humidity	35% to 90% (without condensation)
Pressure	700 hPa to 1060 hPa

Accessories

The WiTOF (reference: WiTOF-MU) comes with several accessories. Here is a list of the main accessories along with a description and their own particular IDMED reference. The full list of accessories is available from WiTOF distributors.

Medical accessories of the WiTOF

Reference	Description
WiTOF-S	3D-AMG wireless adult hand sensor
WiTOF-FS	3D-AMG wireless foot sensor
TOF-CHAR_XX	Charger/Power supplies : XX type code for plug types

Other accessories:

Reference	Description
TOF-RS1	Optic-Serial (RS232) cable to connect ToFscan (length: 1 meter - 3FT)
TOF-RS2	Optic-Serial (RS232) cable to connect ToFscan (length: 2,5 meters - 8FT)
TOF-CLA3	Fixation clamp – regular size
TOF-CLA2B	Fixation clamp – large size

Contact the approved distributor or the manufacturer to check the availability of accessories in your country.

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