NMT MONITOR

ToFscan®

NeuroMuscular Transmission monitor

User Manual
NeuroMuscular Transmission Monitor
Version 1.8 EN - ID
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idmed
an eye on your patient

CONTENTS

About this product

This operating manual provides the instructions on how to configure and use the ToFscan from IDMED. It also describes the specific procedures to clean and verify the device as part of the necessary maintenance. This manual is intended to be used only by qualified medical personnel.

Keep this operating manual with the ToFscan. A service manual is available for the technicians in charge of servicing.

Before you start, please make sure you read carefully and understand the safety information contained in this manual.

Indications for use

The ToFscan is a neuromuscular transmission monitor for monitoring the neuromuscular block of a patient in the operating theatre, recovery room or intensive care unit.
The effect of neuromuscular blocking agents (NMBAs) is monitored by measuring the acceleration of the muscle movement (acceleromyography) or by visually observing muscle contractions consequent to electrical stimulation. The ToFscan has a three-dimensional acceleration sensor (accelerometer) to detect and quantify a patient's muscle movement. For the thumb (contracting adductor pollicis), the sensor is directly integrated into the finger's splint, making it possible to obtain its optimal and reproducible positioning. For the eyebrow and big toe sensors, a correct sensor position allows for optimal and reproducible measurement.

Expected performance

The following features are essential performance of the device:
- Stimulation of an anesthetized patient with electrical pulse: repeated or single 200µs square pulse, 20mA to 60mA intensity. All values within +/- 10%
- Allow several stimulation sequences in accordance to usual practice, TOF, DBS, TETANUS, PTC, ST
- Allow comparison of muscle response placed on the thumb, toe or close to the eyebrow, during TOF (Train of Four) stimulation. It aims to detect movement and acceleration ratio between last and first movement.

Clinical benefits

The following characteristics are the clinical benefits of the ToFscan:
- Intra-operative: Enable practitioners to monitor patients' intra-operative muscle relaxation
- Post-operative: To diagnose residual blockade of the patient with the adductor pollicis

Important Information about the use of this device

The compact ToFscan is intended for use by health professionals (anaesthetists, doctors or fully qualified nurse anaesthetists) specially trained in the use of this instrument. The device and all of the settings associated with it are designed for use on adult and paediatric patients in hospital or health institutions so that the patient's neuromuscular block level can be monitored.

The ToFscan measurements of the patient's muscular response can be used to monitor the effects of neuromuscular blocking agents.

The interpretation of ToFscan results must always be subjected to clinical assessment and compared against other observed clinical signs. Sole reliance on the results or values rendered by the ToFscan for the monitoring of curare-administered patients, is strongly discouraged. The values measured in patients with neurological disorders, nervous system disorders, Bell's palsy, myasthenia or general neuromuscular disorders must be carefully interpreted.

The ToFscan is compliant with the European directive on medical devices and with the current regulatory requirements of the countries where it is distributed.

For further information, kindly contact the ToFscan manufacturer IDMED through his internet website (www.idmed.fr) or by mail at the following address:

IDMED
Hôtel Technoptic
2 rue M. DONADILLE
13013 MARSEILLE FRANCE

SAFETY MEASURES

INTRODUCTION

Read this entire manual carefully before using the ToFscan.

WARNINGS, CAUTIONS, NOTES
The terms Warning, Caution and Note have specific meanings in this manual.

• A **WARNING** cautions against certain actions or situations likely to cause bodily harm or death.
• The word **CAUTION** warns against actions or situations likely to damage the equipment, produce inaccurate data or cancel a procedure, even if bodily harm is less than likely to occur.
• A **NOTE** provides relevant information about a function or procedure.

EXPLANATION OF THE SYMBOLS
The symbols which may be displayed on the ToFscan screen are recapitulated and explained at the end of this section.

Any serious incident occurring in relation to the device must be notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Warning

Risk of explosion: do not use the ToFscan in a flammable environment or in places where flammable anaesthetic products are accumulated.

The ToFscan is not designed to operate in an environment where there are SCANNERS, M.R.I.'s or any other device creating large magnetic fields. The same applies for short-wave or medium-wave treatment devices.

The electrode cables, electrodes and connections must not come into contact with any other item, conductive or otherwise.

In order to reduce the risk of burns when using high-frequency surgical devices, do not place the ToFscan stimulation electrodes between the surgical site and the electrode leading back to the electrosurgical unit.

Simultaneously connecting a patient to a high-frequency surgical device may cause burns at the contact points of the ToFscan electrodes and cause damage to the device.

Never use the ToFscan at the same time that defibrillation devices are being used.

Like all neuromuscular transmission monitor, the ToFscan must be connected to electrical stimulation electrodes capable of supporting up to 300 volts with 60 mA current. The contact surface of the electrodes must be greater than 1.8cm².

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 ToFscan on patients wearing pacemakers without verifying and identifying the possible consequences. The user must take all the necessary precautions during the operation for this kind of patient.

Never use the ToFscan near short-wave or medium-wave treatment devices.

Prior to use, check that no other equipment, device or material is in contact with the electrodes.

Sensors and electrodes should only be in contact with clean and healthy skin

Prior to each use, check that the device, the display and the cables (electrodes and sensors) are not damaged. Do not use if a part is damaged

Handle the device with care to prevent any fall.

The ToFscan should be used during a limited time on one patient at a time and cleaned between patients.

The ToFscan can be used fully or partially during the surgery. The duration should not exceed 24H.

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

In order to prevent electromagnetic disturbance, keep minimum separation from RF communication equipment of 30cm

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

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.

Caution

Read this entire manual carefully before using the ToFscan.

Never put the ToFscan or any of its parts or accessories into an autoclave.

The device or its parts are not to be immersed in, splashed or cleaned with liquids.

The ToFscan and its parts are not suitable for the processes of gas, radiation (gamma or other), water bath, steam or heat sterilisation.

Follow the instructions given in the Cleaning section for cleaning and disinfecting the ToFscan.

The ToFscan carries an internal lithium-ion battery. The ToFscan battery should under no circumstances be dissembled, modified or replaced. Any tampering with the battery poses the risk

of combustion or explosion. Only an authorised technician or IDMED employee is qualified to perform such operations.

After an extended period of disuse (storage), recharge the ToFscan battery for at least 2 hours before use. If the ToFscan does not switch on when the wheel selector is pressed, the battery needs to be replaced.

Only qualified technicians are authorised to carry out repairs or maintenance procedures with the consent of IDMED.

The ToFscan user must take care not to come into contact with other electrical devices when using the ToFscan.

Before performing electrical stimulation with the ToFscan, the practitioner must assess the appropriateness and strength of the stimulation that can be applied to the patient.

Never touch the electrodes during the stimulation phases. The electrodes are only surface electrodes and are suited for the application of electrical stimulation (CE labelling adapted).

Do not use cables or accessories other than those supplied with the ToFscan.

The using of electrosurgery device in the same time as ToFscan can interfere the measurement and the results of it.

In order to prevent electrostatic shock, the device must be used in an electrostatic limited environment. (see **Environment** section)

ToFscan has been designed to stimulate patients via electric impulsions. As a matter of fact, data recorder (EEG, ECG) can detect these electrophysiological signal impulses. These perturbations are transitional and depend how these devices are configured.

Notice on Electromagnetic Compatibility (EMC) : This device generates, uses, and can radiate radio frequency energy. If not set up and used in accordance with the instructions in this manual, electromagnetic interference may result. The equipment has been tested and found to comply with the norm IEC60601-1-2 for medical electrical equipment. These limits provide reasonable protection against electro-magnetic interference when operated in the intended use environments (e.g. hospitals)

Known contraindications to use the ToFscan : None known

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 directive on medical devices
	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 (5V, 1A)		Date of manufacture
	Temperature limit	LOT	Lot code
	Humidity limitation	REF	Catalogue reference
	Atmospheric pressure limitation		Curtis-Straus Mark (USA and Canada)
	Prescription use device in USA	MD	Medical device
	Single-use		Use-by date

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

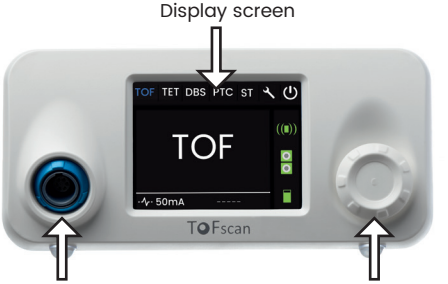
Symbols displayed on the ToFscan screen

	Battery level (green, yellow, red)		Symbol for the intensity of the stimulation current
	Symbols for accessing the configuration menu		Return to previous menu
	Symbol for battery charge in progress / or operation on mains adaptor		Switch off

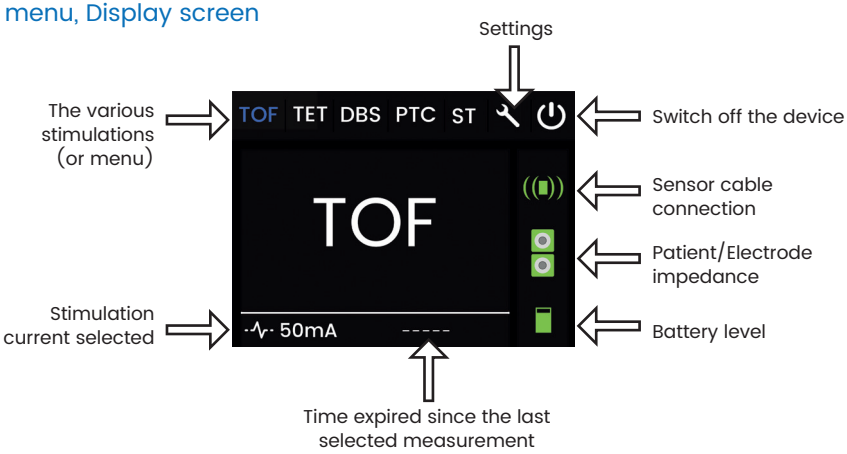
	Impedance Level Symbol (green, yellow, red)		Short circuit condition of electrode cable or electrodes (grey)
	Symbol for movement connector not connected (grey)		Symbol for movement connector connected (green)
	ECO mode on/off		Sound on/off
	Check the sensor position		Mandatory waiting time before the next stimulation
	Delete the reference value		Hold down the button
	Stop / Stop stimulation		Check the electrode patient connection
TOF	Accessing Auto-TOF mode		Auto-TOF mode On
	A reference value is available		No reference value is registered
	Possibility of unreliable measurement		

I General information

Overview of the ToFscan and its accessories

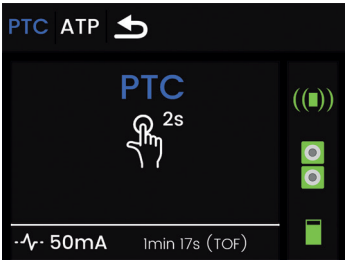


Main menu, Display screen



Menu selection

The menus, options and various tests are accessed using the selection wheel on the front of the ToFscan. The user navigates through the various menus by turning the wheel (clockwise or anti-clockwise).
To select a menu or function, press the wheel an release the wheel button(holding it down for less than 1 second).
To start a test or an electrical stimulation, to access the settings or switch off the device, press and hold the wheel button for 2 seconds. The following icon  is displayed on the screen together with the required time to hold down the button in order to start the stimulation.
Example of the selection screen for starting the PTC mode:



Battery / AC power supply operation

The ToFscan carries a battery enabling it to function independently on battery power for close to 1 month (for more information refer to the battery section). This battery is recharged by the power supply provided with ToFscan.

The power supply unit can be used as a permanent mains power supply unit. This means that the ToFscan will operate via its mains power supply unit without necessarily running down the battery. In this operating mode, the ToFscan displays the results and all information continuously. It will go into energy-saving mode 2 hours after it is last used or the last measurement is taken.
When ToFscan operates on battery "ECO" mode  can be activated by the user (for more information on "ECO" mode refer to the section "Parameters Menu" "ECO").

Note:

Position the ToFscan and the power supply in order to disconnect easily.

Fully charge the battery before the first use.

If the power supply unit should malfunction, never use power supply units other than those supplied by IDMED.

II ToFscan setup

Cable / Cable connection

The user connects the sensor+ electrode cable to the ToFscan prior to use. The user will make sure sensor symbol is displayed in green ((▮)) on the right side of the screen after this cable is connected to the ToFscan. If the operator is using a standard cable, the grey symbol ((▮)) should be displayed in grey on the screen.

Electrodes

The ToFscan must be connected only to surface electrodes by "press-on" connection. The electrodes must be electrodes used for electrical stimulation of patients. They should be compatible with the stimulation values currently used by a NeuroMuscular Transmission Monitor and should therefore support voltages of up to 300V and a maximum current of 60 mA. The contact surface of the electrodes on the patient's skin must be greater than 1.8cm².

Positioning of the electrodes

NMT blockade may be monitored by stimulating various nerves and observing the response of the particular muscles.
Check the availability of the sensor in your country with the authorized distributor or manufacturer.

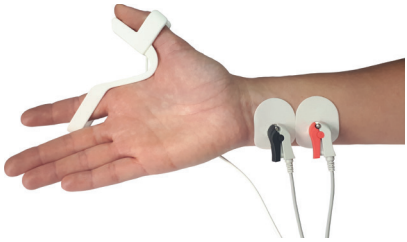
In the case of continuous monitoring, the most commonly used technique is considered to be stimulation of the ulnar nerve and measurement of acceleration in the adductor muscle of the thumb.

"Thumb" sensor:
In the case of monitoring the adductor muscle of the thumb (adult or paediatric sensor), the electrodes will be positioned along the ulnar nerve on the inner arm near the wrist. The electrodes will be spaced 2 to 5 cm apart when using single electrodes.
Note:

It is vital to position the electrodes properly in order to stimulate the nerve and not the muscle.

Position of the sensor and the electrodes:

Positioning of the electrodes (example using a double electrode)

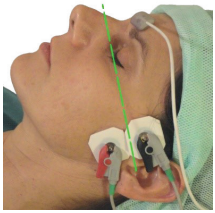


"Eyebrow" sensor

With the « eyebrow » sensor, it is possible to evaluate the level of blockade of the patient while measuring the response level of the corrugator supercilli muscle.

The stimulation electrodes are to be positioned on the root of the facial nerve next to the tragus. The positioning will be done on each side of an imaginary line going from the tragus extremity to the middle of the nose. The distance between the electrodes will range from 2 to 5 cm.
Note:
It is essential to correctly position the electrodes in order to stimulate a nerve and not a muscle.

Electrodes positioning to stimulate the facial nerve

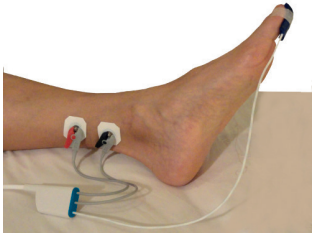


“Big Toe” sensor

The stimulation electrodes are to be positioned on the tibial nerve above the ankle. The distance between the electrodes ranges from 2 to 5 cm.

Note:

It is essential to correctly position the electrodes in order to stimulate a nerve and not a muscle.



Placing of the sensor

When positioning the sensor, the sensor cable must not apply any pressure to the sensor or the sensor clamp. It must allow the sensor to move freely according to muscle contractions. Positioning the sensor in contact with the patient must not cause excessive pressure or stress that could injure the patient.

“Thumb” sensor

The splint must follow the shape of the hand as closely as possible and be positioned so that it makes contact with the last phalanx of the thumb.

Positioning of the sensor splint on the patient’s hand.

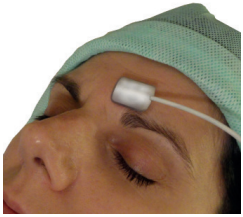
Positioning by adhesive

«Thumb» sensor for paediatric patient

«Thumb» sensor for small paediatric patient

‘Eyebrow’ sensor

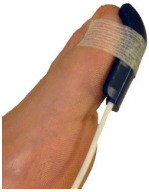
The positioning must allow the free movement of the sensor. The sensor is positioned on the corrugator supercillii muscle. The sensor cable exert no tension on the sensor. The sensor is fixed with a double sided tape on the patient’s skin. This tape must be adapted to a medical usage and allow a reliable fixing during the whole duration of the monitoring.



Positioning of the ‘eyebrow sensor’ on the patient’s eyebrow

'Big Toe' sensor

The positioning must allow the free movement of the sensor. The sensor cable exert no tension on the sensor. The sensor is fixed with one side tape to the patient's big toe. This tape must be adapted to a medical usage in contact with patient's skin. It is essential to note that the toe and ankle of the patient must be free to move.



Position of the 'big toe' sensor on the patient's toe

Single-use hand sensor

The user will position the disposable sensor on the patient's hand according to the instructions on the packaging. Ensure that the sensor does not exert excessive pressure on the patient's skin or impede the blood circulation of the fingers (avoid excessive tightening of the fingers, hand or any other patient limbs by the adhesives of the sensor). The integrated electrodes will be positioned on the path of the ulnar nerve at the wrist area inside the arm.

After positioning the disposable sensor on the patient's hand, the sensor will be connected to the ToFscan cable (TOF-CS1) itself connected to the ToFscan.

Positioning of the disposable hand sensor and its electrodes

Notes:

While the device is being operated, the user should check that the sensor must keep the same position as the one from the initial set-up. The same applies for the patient's arm, leg or head which should not change position for the duration of the monitoring process.
If the 'Thumb' sensor does not fit nicely the hand, it can be fixed with medical adhesive tape to be maintained in an ideal position. The user can immobilize the last three fingers with an adhesive strap to improve the thumb range of motion and obtain more precise measure during the monitoring of the thumb.

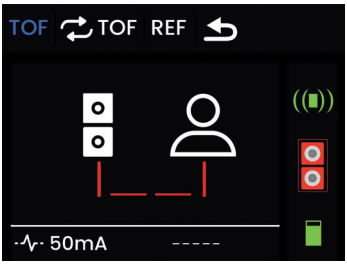
In the case of the thumb sensor, check that the splint part of the sensor or the ring around the index finger does not cause pressure or excessive stress, an adhesive positioning (see image «Positioning by adhesive») can then be put in place.

After a certain period of use of the sensor, 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 ToFscan is an electrical stimulator with a constant current. Therefore, irrespective of skin impedance it will stimulate the patient with an identical current. It will function in this way so long as the needed voltage is below 300 V. Because of this limit you need to have a good skin impedance. For example, to get a 60 mA current through a resistive charge the maximum impedance should be equal to 5 Kohms. The skin impedance is more complex than a simple resistive charge and the ToFscan will help you getting a good impedance with a colored electrodes symbol.
Only the green symbol allows to use in good condition the ToFscan. With yellow symbol the intensity of electric stimulation may be lower than expected.
If the symbol is red the ToFscan doesn't provide electric stimulations.

If you get the screen below it is necessary to check or modify the patient's connection to the electrodes.



Note:

Cleaning the patient's skin prior to positioning the electrodes significantly lowers skin resistance. The user should therefore ensure that the patient's skin has been cleaned before attaching the electrodes. The electrodes quality and condition are essential in the measured impedance value.

Connecting the cable to the ToFscan

After putting the electrodes on the patient, the user must connect them to the ToFscan with the electrodes cable. Before connecting the cable, he/she should check that the ToFscan displays the main menu and is not in stimulation phase or programmed in automatic stimulation mode.

The proximal electrode (nearest to the heart) will be connected to the red-coloured positive electrode clamp. The distal electrode (further away from the heart) will be connected to the black-coloured negative electrode clamp.

Once the cable has been connected to the electrodes, the ToFscan displays the electrodes and the sensor's connection symbol (icon in green if present and functional).

Reference or "REF"

The "REFERENCE" mode enables the user to measure the patient's motor response to TOF electrical stimulation when the patient is anaesthetised but not under the effect of a neuromuscular blocking agent. This measurement is used to display the calculation comparisons between the range of the patient's muscle response under curare and without curare during TOF stimulations.

For further information about this test, refer to the "TOF mode" section, under the "REFERENCE" menu.

III Using the ToFscan

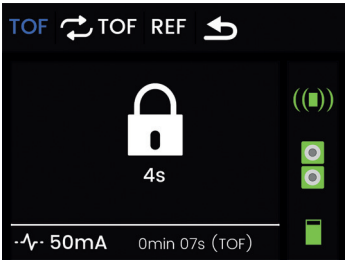
General principle

The ToFscan is used to perform 5 distinct modes of stimulation (or 5 distinct electrical stimulations). Some of these modes can be configured or programmed by the user.

All modes are selected by a brief push on the wheel button. Once in the submenu, press and hold the wheel button to start the electrical stimulation. The ToFscan will give a "beep" simultaneously to the start of the electrical stimulation.

It is important to observe a time interval between each stimulation to avoid distorting the results. The ToFscan memorises the elapsed time since the previous stimulation and displays it at the bottom of the screen. If this time period is shorter than the interval to be observed between each stimulation, the time to wait before the next stimulation is displayed in the centre of the screen together with the following symbol  .

For example, the ToFscan requires a time interval of 12-second after each TOF stimulation.



The  symbol in front of a result indicates a possible presence of a impaired measurement. The user can do the test again (while respecting the interval) or wait for the next test scheduled in the case of "AUTO TOF" mode.

Note:

The recommended intervals between each stimulation are shown at the end of each description of the various stimulations (or tests).
Only 'TOF' tests are commonly used for the NMT monitoring for the eyebrow muscle (stimulation of the facial nerve).

When disconnecting the ToFscan from a patient at the end of the operation and before connecting a new patient for new operation, the display of the ToFscan must be reset. For this, press the wheel an release the wheel button.

TOF mode

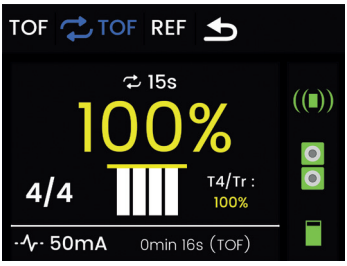
The "TOF" menu includes 3 options or sub-menus. Each of these options is detailed below. With this mode, the TOF stimulation can be done two ways, either directly by the operator, or automatically at a repeated interval selected by the user.

"TOF" sub-menu

After selecting the "TOF" menu and then the "TOF" sub-menu, the user can start a "TOF" stimulation (or test) by pressing and holding the selection wheel. Prior to this, he must verify that the output (current in mA) of the selected stimulation is appropriate for the level of anaesthesia, the level of neuromuscular blockade and the patient's profile. For further information on stimulation output, refer to the "Parameters" section.

TOF stimulation is one of the most commonly used forms of stimulation, comprising 4 stimulations (of 200 µs) at 0.5 second intervals.

If the ToFscan is connected to a cable fitted with an accelerometer sensor, after the electrical stimulation it will display a calculation of the percentage of the range of the 4th response against the first (ratio T4/T1 TOF as a %) in yellow in the middle of the screen. The ToFscan also displays a bar graph allowing the visualization of the range of the different responses.
If a "Reference" test (or stimulation) was performed, it will be symbolized on the top of the bar graph by a horizontal yellow line. ToFscan automatically displays the T4/Tref ratio.
Example of a screen with a result of 100% following a TOF stimulation:



The number of responses detected (TOF count) is displayed as an X/4 ratio (X being the number of muscle response detected).
When ToFscan detects artefact movements or electric noises in the measurement process, a symbol  will be displayed in front of results. This symbol informs users about a possible non reliable measurements/results.

The time interval required by the ToFscan between two "TOF" stimulations is 12 seconds.

Note:

The user should validate the results readout by pressing the selection wheel in order to perform other stimulations. The percentage calculations are limited to 100% so that values which are not pertinent will not be displayed.

"AUTO TOF" sub-menu 

The "TOF AUTO" mode allows you to program TOF stimuli at regular intervals. Thus the ToFscan performs "TOF" stimulations at an interval selected by the user. The available intervals are every 15s., 30s., 1min., 2min., 5min. and 15min.

After selecting the stimulation interval, the user starts the stimulation cycle by pressing and holding the selection wheel (for at least 2 seconds). The first stimulation is delivered 4 seconds after the selection wheel has been pressed.

To stop a programme, press the selection wheel; the ToFscan then returns to the "AUTO TOF" menu.
The results displayed are the same as in the "TOF" menu.

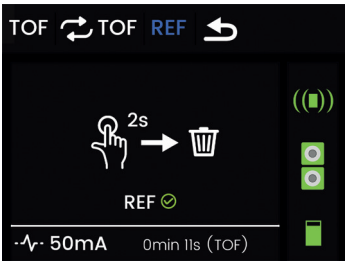
The stimulation interval can be changed after starting TOF AUTO mode.
The frequency of intervals can be changed by rotating and pressing the knob without holding it down.

"REFERENCE" or "REF" sub-menu

The reference mode enables the user to store the patient's response to a TOF electrical stimulation when the patient is anaesthetised but not under the effect of neuromuscular blocking agent. This value can help the user to evaluate the recovery of neuromuscular function and the efficiency of agent depolarizing neuromuscular blocking.

The ToFscan delivers the TOF stimulation in order to calculate the average amplitude of the four muscle responses; this value will be recorded as Tref. This average amplitude will be used to calculate T4/Tref and will be displayed for subsequent TOF stimulations.

The time interval between two "REFERENCE" stimulations is 12 seconds.
Reference value can be erased by holding down the wheel button in the sub-menu "Reference".
Example of a screen for deleting a reference:



Note:
The reference value is used only to calculate T4/Tref during a TOF electrical stimulation and only if the ToFscan is connected to a cable with an integrated sensor (accelerometer sensor).

Like all electrical stimulations, the stimulation used for the reference must only be performed on anaesthetised patients. Stimulations can be very painful for non-anaesthetised patients.

After the results are displayed, the selection wheel must be pressed to return to the selection menu.

TET mode

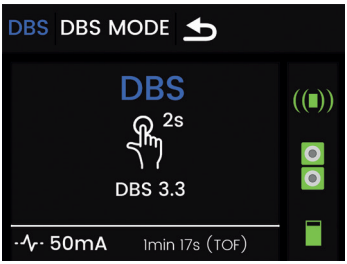
Tetanic stimulation or "TETANUS" stimulation is used to stimulate a patient for 5s at 50 Hz. As the ToFscan does not display a measurement at the end of this test, no user validation is expected at the end of the stimulation in order to reactivate the selection wheel navigation function. The patient's motor response is not measured by the ToFscan sensor, but is visually gauged by the user.

Note:

The time interval required by the ToFscan between two "TET" stimulations is 3 minutes. The "TET" stimulation is absolutely not recommended in case of the eyebrow muscle monitoring.

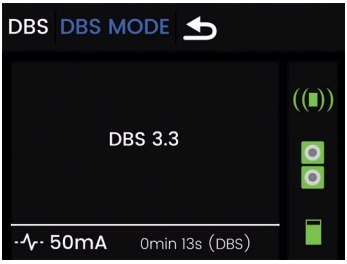
DBS mode

The ToFscan is used to perform "Double Burst Stimulations" or "DBS". It offers the user 2 types of DBS mode under the "DBS MODE" menu. The DBS mode can help to detect a possible residual blockade. DBS stimulations consist of two bursts of 50 hertz stimulations spaced 750 ms. Depending on the selected DBS mode, each burst will have 2 or 3 impulses (impulse duration: 200 µs). After DBS stimulation applied, the number of responses measured is displayed with their relative amplitudes by 2 white bars. The percentage of the ratio between the amplitude of the second response and the first is displayed at left side on the screen.



"DBS" sub-menu

The ToFscan provides "DBS 3.3" stimulation by default. The user can activate this stimulation by pressing and holding the selection wheel, or the "DBS 3.2" stimulation after having selected it under the "DBS Mode" menu.



"DBS MODE" sub-menu

This menu is used to select the various types of DBS stimulations. The ToFscan allows DBS 3.3 and DBS 3.2.

Note:

The time interval after a "DBS" stimulation is 20 seconds. The « DBS » stimulation is absolutely not recommended in case of the eyebrow muscle monitoring.

PTC Mode

"PTC" or "Post Tetanic Count" stimulation is generally used for deep neuromuscular block or when there is no response to TOF stimulation. "PTC" stimulation comprises a 5-second "TETANUS" stimulation at 50 Hz followed by a 3-second pause and then 10 "SINGLE TWITCH" stimulations.

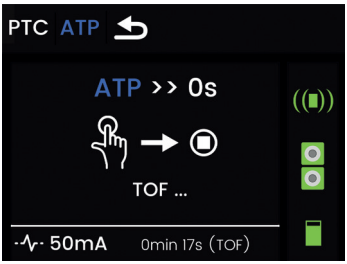
"PTC" sub-menu

When selecting this sub-menu, the user starts PTC stimulation by pressing and holding the selection wheel. Upon completion of the stimulation (18 seconds' duration) the ToFscan displays the number of muscle responses detected. It maps out each of these in the form of a bar chart to compare their respective ranges.
When measurements are disrupted (parasitised), a symbol ? will be displayed instead of the measurement (bar).

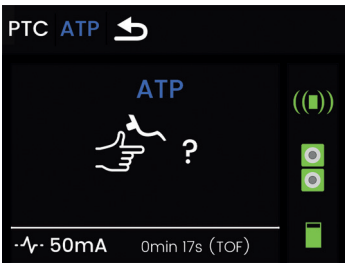
"ATP" sub-menu

ATP (Automated TOF PTC) is an automatic mode to measure deep, average and light neuromuscular blockade using the thumb sensor only. ATP mode uses TOF and PTC stimulations in appropriate ways. Stimulations are repeated every 30 seconds or every 5 minutes depending on the number of responses measured after each TOF or PTC stimulation.

Example of an ATP mode screen during a TOF stimulation:



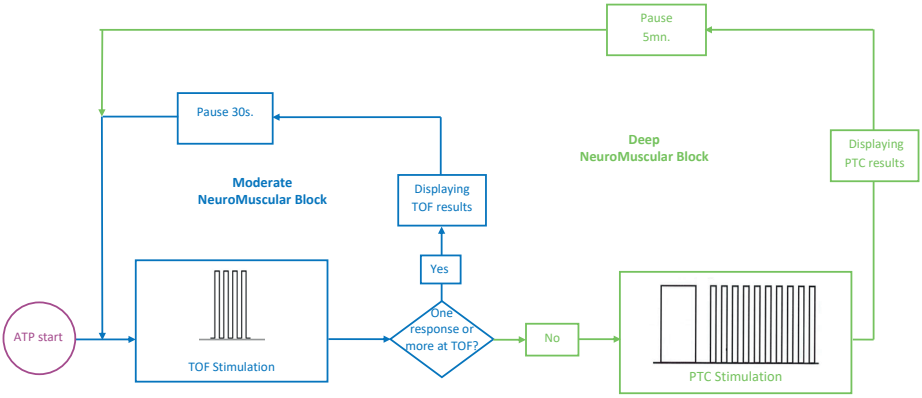
If you get the screen below, it means that the measurement conditions are disrupted. Please check the position of the sensor.



Principle

The ATP mode is an automatic mode. ATP can be stopped at any time by the user by pushing the wheel button. ATP mode uses TOF and PTC stimulations depending on the depth of blockade. Results are displayed as per the stimulation applied. ATP delivers TOF stimulation, in case of no response from the TOF stimulation, a PTC stimulation will be applied. After all stimulations (TOF or PTC) the ToFscan displays the results. If the patient has had at least one response to TOF stimulation, the ToFscan will then display the measured results and there will be a pause of 30s before the next set of TOF stimulation. If the patient doesn't have a response to TOF stimulation, the ToFscan will stimulate the patient with a PTC stimulation and display the results. After a PTC stimulation there is a pause of 5 minutes before the next set of stimulation.

ATP Process



Note:

The ATP mode must only be used with the thumb sensor and only with non-depolarizing neuromuscular blocking agents. It can be stopped at any time by pushing the wheel button. The ATP mode can automatically deactivate or stop when the acceleration is not measurable.
The interval required by the ToFscan following "PTC" stimulation or "ATP" mode is 3 minutes. It is important to remember that "PTC" stimulations is only normally used when no responses to "Single Twitch" or "TOF" stimulations are detected. **"PTC" stimulation and "ATP" mode are absolutely not recommended for eyebrow muscle monitoring.**

ST Mode

This is the simplest form of stimulation producing a single muscle contraction. The patient's motor response is not measured by the ToFscan sensor but is visually gauged by the user.

"Twitch" sub-menu

Stimulation is activated by pressing (2s) the selection wheel.

"0.1HZ" sub-menu

The ToFscan produces one twitch every 10 seconds when the selection wheel is pressed and held. The user stops the 0.1 HZ stimulation by simply pressing the selection wheel.

"1HZ" sub-menu

The ToFscan produces one twitch every second when the selection wheel is pressed and held. The user stops the 1 HZ stimulation by simply pressing the selection wheel.

Note:

The "0.1 HZ" or "1 HZ" stimulations are automatically repeated during 10 minutes, after which

the ToFscan stops the stimulation. No time interval is necessary between each “twitch” stimulation. No waiting period is required by the ToFscan after this category of stimulations. The practitioner will gauge the length of the waiting period required depending on the number of stimulations delivered.

Parameters Menu

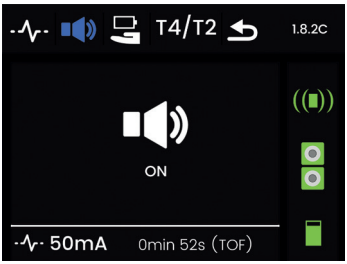
The “Parameters” menu will enable the user to modify the standard parameters of the ToFscan. This menu is represented on the screen by the following icon:

To go to the “Configuration” menu, the selection wheel must be pressed and held (2s).

“STIM” sub-menu

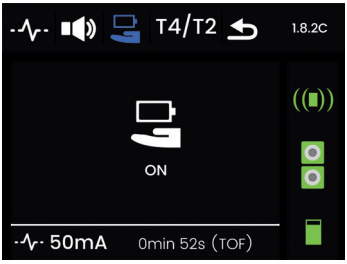
When this sub-menu is selected by pressing the selection wheel, the user can adjust the current of the stimulations. The ToFscan is configured to 50 mA by default. It is generally acknowledged that in order to obtain supra-maximal stimulation, the current required for the stimulation of the Ulnar or tibial nerve for the adult is 50mA. This value is 30mA for a paediatric usage on the same nerves. The value for the stimulation in the case of the eyebrow muscle (Corrugator Supercilli) is 30mA. In special cases where considered appropriate by the user, he/she may adjust this stimulation value. The user should consider the potential risks of an unsuitable stimulation current for a patient.

“SND” sub-menu



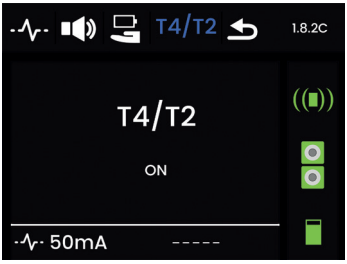
The SND sub-menu allows activating or deactivating the sound “beep” emitted by the ToFscan during measurements, selections and electrical stimulation.

“ECO” sub-menu



The ECO sub-menu allows selecting the eco mode. “ECO” mode reduces the length of display to increase the time life of battery if the ToFscan is not connected to the power supply. In this case, the display becomes inactive 40s after the last measurement or action of the user (5s in case of “TOF-AUTO” automatic mode). Otherwise, the measurements display lasts 16 minutes.

“T4/T2” sub-menu T4/T2



“T4/T2” sub-menu allows inactivating display of ratio T4/T2 instead of ratio T4/T1 when the amplitude of T2 response is higher than the amplitude of T1 response. T2 bar is yellow when ratio T4/T2 is displayed instead of ratio T4/T1.

IV Servicing, Disinfection cleaning

Preventive servicing, Maintenance

In order to maintain its performance, it is strongly recommended that the following tests be carried out on the device at least once every two years:

- Checking of the integrity of the casing, screen and labelling
- Checking of the battery charging process
- Checking of the condition of the electrode cable, its electrode clamp ends and its sensor clamp
- Checking for the value of current of electrical stimulations.
- Checking the sensor measures.

The lifetime of the ToFscan, under the required operating and maintenance conditions, is 5 years (2 years for accessories).

Caution:
Only qualified technicians are authorised to carry out some repairs with the consent of IDMED.

Battery / Battery charge

Battery

The ToFscan includes a Lithium-Ion rechargeable battery. The battery is equipped with thermal protection and short-circuits protection. At full charge, battery power lasts for approximately 1 month at a rate of 10 "TOF" stimulations per day ("Eco" mode activated).

Level and colour gauges indicates the level of charge of the battery

	Battery level (green, yellow, red)
	The battery is above 70% of its maximum capacity
	The battery is between 20% and 70% of its maximum capacity
	The battery is below 20% of its maximum capacity

The battery has a one-year warranty (its battery power at one year should be 50% more than its estimated battery power). The normal service life of the battery is 2 years.

Note :

Only qualified technicians are authorised to carry out repairs or maintenance operations with the consent of IDMED.

Battery Charge

The battery is charged with the charger supplied by IDMED. It can charge a flat battery in less than 8 hours.


Icon for battery charge in progress or icon for operation on the AC power adaptor

The battery can be charged regardless of its level. Whenever the ToFscan displays the flat battery symbol (coloured red) , the battery must be charged as soon as possible.

Charging is automatic, consequently when the charge is complete the ToFscan stops the process.

Note :

Only qualified technicians or IDMED employees are authorized to carry out repairs or maintenance operations on the battery.

Maintenance work on the battery is restricted to checking its charge cycle once every two years. By doing this, it can be verified that the charge cycle does not exceed 8 hours (a change from red to green for the battery charge gauge).

Cleaning

Caution:

Do not place the ToFscan or any of its parts or accessories inside an autoclave.

Under no circumstances must the ToFscan or any of its parts or accessories come into direct contact with, be immersed in or filled with liquid.

The ToFscan and its parts and accessories are non-sterile devices. Under no circumstances must the ToFscan or any of its accessories be sterilized.

The ToFscan must be cleaned and disinfected between each patient. Low-level disinfection is generally sufficient.

The surfaces of the ToFscan and its accessories have to be cleaned with a lint-free cloth moistened with a Quaternary Ammonium Compound (QACs), isopropyl alcohol 70%. Before using any of these solutions, refer to the manufacturer's documentation and test on a reduced surface.

Example of recommended Quaternary Ammonium product:
- mikrozid® sensitive liquid from the manufacturer Schülke & Mayr GmbH.
Please check with your local authorized distributor or with the manufacturer which products are available and approved in your country.

The ToFscan cable (electrode and/or sensor) must not come **into direct contact with, be immersed in, splashed or filled with liquid and is to be cleaned in the same manner as the ToFscan.**

When cleaning the cables of the ToFscan, be careful not to create excessive traction on the splint that could cause premature breakage of the wires inside the sheath.

Diagnostic / Malfunction

The table below summarises a list of possible malfunctions and the solutions for resolving them.

Malfunction	Solution
The device does not start or stops on its own after a few seconds (Message "Low Battery")	Set the device to charge (refer to the section "Battery and battery charge")
The sensor icon is displayed in grey  even though the sensor is connected.	Check the condition of the cable and the sensor. Disconnect the cable and reconnect to the ToFscan
The ToFscan displays the impedance value in red  (impedance too high)	Check the positioning of the electrodes and how they couple with the patient (refer to the section "Connection and positioning of stimulation electrodes").

Note:

Should the problem persists or is not solved by the actions listed in the table above, you must contact the distributor. .

V End-of-life disposal / Recycling

In the interest of environmental safety, you are required to pass your used system on to a collection body with the capability to treat devices containing electronic components and Lithium-ion storage batteries.

To dispose of or recycle device components, contact a company specialising in the recycling of electronic devices.

Unsorted electronic waste products are potentially hazardous to the environment.
Packaging materials must be disposed of or recycled in accordance with the regulations in force.

VI Technical specifications and warranty

The ToFscan comes with a microcontroller and a colour LCD screen for optimal legibility and ease of use.

Safety

- Biocompatible material sensors (part in contact with the patient). Latex free
- Compliant with European directive CEE 93/42. Class 2a device (CE 0459 LNE/G-MED)
- Compliant with standards IEC 60601-1. Class II equipment.
- Compliant with standards IEC 60601-2-10.
- EMC: IEC 60601-1-2

EMC Emission

Emission test	Compliance	EMC Instructions/cautions
RF Emissions CISPR 11	Group 1	The ToFscan 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 ToFscan must be use in professional healthcare facility environment
Voltage fluctuations	Class A	
and flicker IEC 61000-3-3	Compliant	The ToFscan 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	± 8 kV contact	In order to reduce ESD, the device must be used in a 35% humidity environment or more
		± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 2 kV, ± 4 kV, ± 8 kV air	
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 ToFscan may temporarily not display result during transient electromagnetic disturbances such as the use of electrosurgery device. In that case, the ToFscan 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), T4/T1 and T4/Tref calculations.
- AUTO TOF (ToF programmed from 15s to 15min).
- TET (Tetanus 50 Hz)
- DBS (Double Burst Stimulation) modes 3.3 and 3.2
- PTC (Post Tetanic Count)
- ATP (Automatic TOF PTC)
- TWITCH (Single Twitch) 0.1 Hz and 1 Hz.

Acceleration sensor

- Three-dimensional accelerometer (+/- 8 G at 10 bits, Fq:200 Hz, Resolution 0.016G)

Electrical stimulations

- Constant output current of 0 to 60mA (accuracy +/- 10%) (on an resistive load of 4 Kohms)
- Monophasic, duration of impulse 200 µs, frequency 50 Hz

• Stimulation or ECG electrodes:
  - Capable of supporting up to 300 volts with 60 mA current.
  - Contact surface must be greater than 1.8cm².

Examples of recommended electrodes:
- RED DOT electrodes ref.2560 from the company 3M
- F9047 electrodes from the company FIAB

Please check with your authorized distributor or with the manufacturer which products are available and approved in your country.

Data transfer

• Optical output for fiber optic connection
• TOF-RS1 and TOF-RS2 are the only recommended Optic-Serial (RS232) cable to connect ToFscan to other monitors.

Power supply

• 2900 mAh (minimum)/ 3.7V Lithium-Ion battery (comes with thermal protection and protection against short-circuits)
• Battery power for about one month with normal use (10 TOF measurements a day).
• Charger / External power supply (continuous 5V, 1 A minimum).

Dimensions / Weight

• 60x150x55 mm (monitor only).
• 320 g (approximately) with battery and cable and electrode. (190g excluding cable).

Warranty

• Length of warranty: 2 years, 6 months for accessories and sensor.

Power consumption

• With power supply connected: 1 Watt while in use and 0,1 Watt while in sleep mode.

Environment

Shipping and storage conditions

The ToFscan and its accessories must be stored or transported under the following restrictions and conditions. These conditions apply to non-operational storage and transport conditions.

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

For storage and transport, the original packaging must be used.
Protect the ToFscan from pikes in temperature which can cause condensation.

Operating environment

Reminders:
Risk of explosion: do not use the ToFscan in a flammable environment or in locations where flammable anaesthetics may be accumulated.

The ToFscan is not designed to operate in an environment where there are SCANNERS, M.R.I.'s or any other devices creating large magnetic fields. In order to limit electrostatic discharge, the humidity must be maintaining above 35% and an antistatic floor is recommended.

The ToFscan is designed to operate safely under the following conditions. Situations other than those described are likely to compromise the reliability of the device.

Temperature	10°C to +40°C
Humidity	35% to 90% (without condensation)
Pressure	700 hPa to 1060 hPa

VII Accessories

The ToFscan (reference : TOF-MU) is delivered with a number of accessories. Here is a list of the main accessories with their designations and IDMED references. The complete accessories list is available from the ToFscan distributor.

Accessories of medical device ToFscan

Reference	Description
TOF-DS1	Disposable 3D-AMG hand sensor with stimulation electrodes
TOF-CS1	Cable to connect disposable hand sensor to the ToFscan (length: 3 meters)
TOF-S2_B	Hand Sensor (length: 3 meters)
TOF-ES_B	Corrugator (eyebrow) Sensor (length: 3 meters)
TOF-FS_B	Foot Sensor (length: 3 meters)
TOF-PS_B	Pediatric Hand Sensor (length: 3 meters)
TOF-PS2_B	Small Pediatric Hand Sensor (length: 3 meters)
TOF-STICKER1	Double sided tape for eyebrow sensor
TOF-CHAR_XX	Charger/Power supplies : XX type code for plug types

Other Accessories

Reference	Description
TOF-C1	Extension Cable (length 1,8 m)
TOF-RS1	Optic-Serial (RS232) cable to connect ToFscan (length: 1 meter)
TOF-RS2	Optic-Serial (RS232) cable to connect ToFscan (length: 2,5 meters)
TOF-CLA3	Fixation clamp – regular size
TOF-CLA2B	Fixation clamp – large size
TOF-HK1	Cable support

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