Instructions for Use

Microstim DB3

Supramaximal Nerve Stimulator

Peripheral nerve stimulator
for use during anaesthesia

VIAMED

CE 0086

Manufactured by:

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Quality standards accreditations:
BS EN ISO 9001:2008
ISO 13485:2003
ISO 13485:2003 CMDCAS Recognised

Distributed by:

Cautions

For use only by qualified and trained personnel.

Do not use in the presence of MRI equipment.

Do not use with needle electrodes.

Do not use as a nerve locator stimulator.

Do not use in the presence of explosive gases.

Caution in the presence of cardiac pacemakers. May cause interference with ECG equipment during use.

Index

Description of the DB3

Outputs

Black: negative

Red: positive

Intensity control

Output & battery level indicator

Switch 1
Up position:
T.O.F. (Train of Four)

Down position:
D.B.S. (Double Burst Stimulation)

Switch 2
Up position:
P.T.C. (Post Tetanic Count)

Down position:
1 Hz (Single Twitch Stimulation)

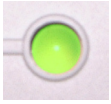
Connector for lanyard (optional)

Output & battery level indicator

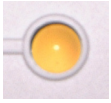
When the Microstim DB3 is in use, flashes of the output & battery level indicator coincide with stimulus pulse. When patient current flows, audio pulses are also generated.

As an indication of battery condition the indicator changes from green (good condition) to amber, then red as the battery output decreases. Replace the battery when the indicator is red.

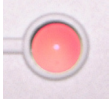
Battery installation: With the Microstim DB3 'face down' slide the rear panel battery door downwards and remove from the unit. Install the 9V Alkaline, MN1604 battery, observing correct polarity insertion. Refit the battery door.



Battery level indicator green:
Battery condition good, >8V



Battery level indicator amber:
Battery becoming depleted, >6V <8V



Battery level indicator red:
Replace battery, <6V

How to use the Microstim DB3

Position and attach the stimulating electrodes

Choose the monitoring site,
e.g. Ulnar nerve, facial nerve, tibial nerve.

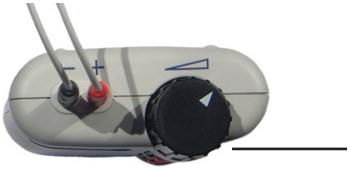
Clean the skin with an alcohol wipe.

Apply two ECG type electrodes, either along the line of the nerve or straddling the nerve.

Connect the patient lead to the electrodes; the positive (red) electrode should usually be proximal.

Connect the patient lead to the Microstim DB3.
Red cable to the +ve output socket and the black cable to the –ve output socket.

Set the intensity control to approximately half-scale.



Decide on the mode of stimulation

Surgical blockade:	Train of Four (T.O.F.) or Double Burst Stimulation (D.B.S.)
Reversal:	Double Burst Stimulation (D.B.S.)
Profound blockade:	Post-Tetanic Count (P.T.C.)

NOTE: When switching between two modes of operation, first release the switch before activating the next mode.

There are four modes of operation:

- Train of Four
- Double Burst Stimulation
- Post Tetanic Count
- 1 Hz

For details of the output of each mode, see pages 8-9.

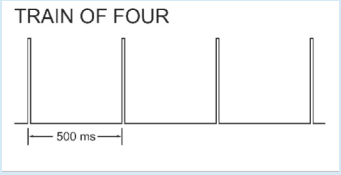
Adjust the output current

Increase the intensity until the twitch response is maximal. If the intensity is increased excessively, direct muscle stimulation will become more pronounced (see Problems and Solutions).

Train of Four

Four pulses at 2 Hz

Pulse width:	200 µs
Pulse interval:	500 ms
Number of pulses:	4

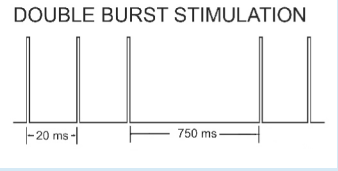


Double Burst Stimulation

Two bursts of pulses at 50 Hz, 0.75 seconds apart.

First burst, 3 pulses followed by second burst of 2 pulses i.e. ratio of 3:2.

Pulse width:	200 µs
Pulse period:	20 ms
Duration between pulses:	750 ms

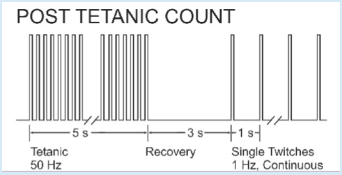


Maximum output voltage: >90V p-p with 1 KΩ load

Post Tetanic Count

5 seconds at 50 Hz (Tetanic), then a pause of 3 seconds; followed by continuous 1 Hz stimuli, duration dependent upon switch depression.

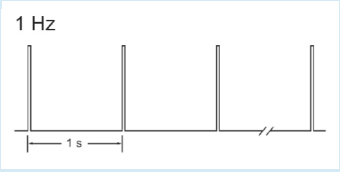
Pulse width:	200 µs
Pulse period, Tetanic:	20 ms
Pulse period, after recovery period:	1 second



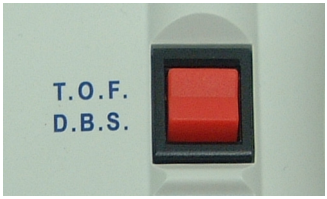
1 Hz

Continuous 1 Hz stimuli, duration dependent upon switch depression.

Pulse width:	200 µs
Pulse interval:	1 second
Number of Pulses:	Continuous



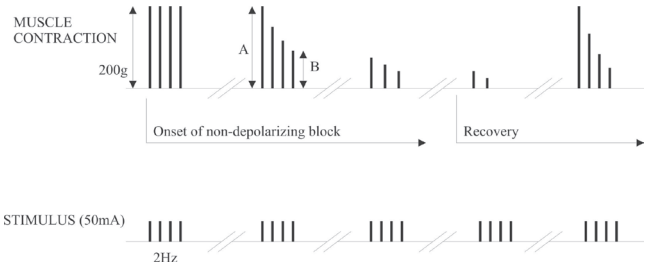
Train of Four (T.O.F.) Stimulation



To initiate Train of Four stimulation, press and hold switch one in the T.O.F. 'up' position. The Microstim DB3 delivers the correct sequence of stimuli; four stimuli at a frequency of 2 Hz.

An interval of at least 10 seconds should be allowed between successive T.O.F estimation.

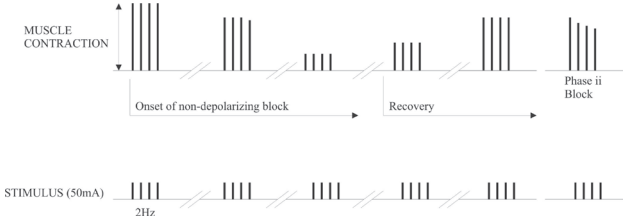
This mode of stimulation, first described in 1970, permits the user to assess the depth of neuromuscular blockade without recourse to a "control twitch" obtained before the muscle relaxant was given. Each train comprises four stimuli of equal intensity at a frequency of 2 Hz. During partial non-depolarising blockade there is a characteristic fade in the magnitude of the resulting four twitches. Depolarising blockade does not produce significant fade unless Phase II block has intervened.



The Train of Four ratio is the magnitude of the fourth twitch divided by the magnitude of the first twitch. In the absence of fade, the ratio would be 1.0. Even in experienced hands, it is unusual for fade to be detectable using the palpation method unless the Train of Four ratio has fallen to below 0.5. At this level of blockade, the patient's ability to breathe adequately may still be impaired (see Double Burst Stimulation).

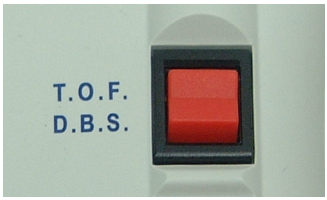
When blockade is more profound (at a level more appropriate to surgery) the twitches successively disappear, so that only one or two small responses remain. The number of twitches remaining is the Train of Four count. A count of one or two is usually compatible with adequate surgical relaxation and also indicates that reversal with neostigmine will be satisfactory.

Occasionally, four small responses persist even at profound blockade (see Problems and Solutions).



Depolarising blockade does not produce significant fade unless Phase II block has intervened.

Double Burst Stimulation (D.B.S.)



To initiate Double Burst Stimulation, press and hold selector one in the D.B.S 'down' position. The Microstim DB3 delivers the correct sequence of stimuli; two bursts of stimuli at 50 pulses per second separated by 750 ms.

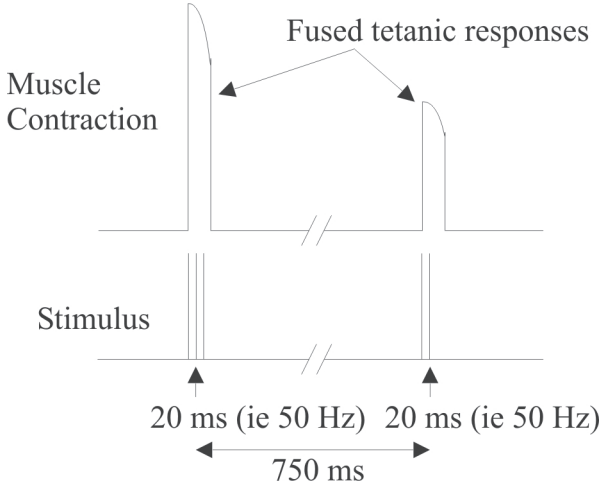
D.B.S 3.2 is standard because it is more sensitive to residual neuromuscular blockade at the end of surgery.

An interval of at least 15 seconds should be allowed between D.B.S estimations.

Although the Train of Four ratio provides a method of monitoring light to moderate neuromuscular blockade, its accuracy is much reduced unless a force transducer or other objective measurement device is used to measure the response of the muscle. This is because the ability of the clinician to estimate the Train of Four ratio reliably is limited. Fade in the four responses may exist without the clinician being aware of the risk of residual blockade.

Double Burst Stimulation (D.B.S) is designed to produce the same degree of fade as the Train of Four with the advantage that D.B.S fade is more easily detected and quantified by the clinician who is monitoring the twitch response of the thumb by the palpation method.

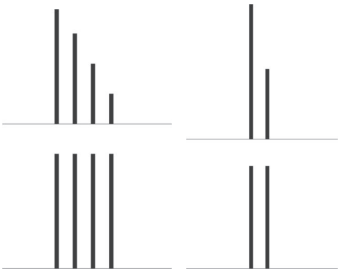
Two short tetanic bursts of stimuli are delivered and the response of the muscle is felt by the anaesthetist as two discrete twitches.



It is relatively easy to quantify the extent of D.B.S fade because:

(i) Both twitches are larger than the T.O.F twitches,

(ii) The two middle twitches of the T.O.F normally confound the comparison of the first & fourth responses.



Train of Four Stimuli *Double Burst*

During spontaneous recovery, the first D.B.S response reappears slightly earlier than the first T.O.F response and the second D.B.S response reappears slightly earlier than the fourth T.O.F response. These differences are unlikely to be of clinical significance, and D.B.S and T.O.F can be used interchangeably, with the advantage that D.B.S provides more accurate information to the clinician who does not have access to a force transducer.

Post Tetanic Count (P.T.C).

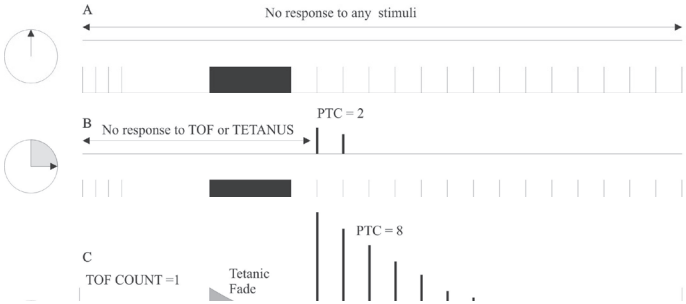
To initiate P.T.C stimulation, press and hold Selector 2 in the P.T.C. 'up' position. The Microstim DB3 will deliver the correct sequence of stimuli; 50 Hz for 5 seconds, a 3 second pause, followed by 1 Hz stimuli. An interval of at least 5-6 minutes should be permitted between successive estimations of P.T.C.

This method of measuring the depth of profound non-depolarising neuromuscular blockade was introduced in 1981. It operates as follows: suppose that blockade is very profound and there is no response whatsoever to other modes of nerve stimulation. A difficulty exists in quantifying such extreme blockade. However, for a short while following a burst of tetanic stimulation (for example, 50 Hz for 5 seconds), the process of mobilization of acetyl-choline at the motor nerve terminal persists in a state of enhanced activity.

If, at this stage, the nerve is stimulated at a much slower rate (for example at 1 Hz), the twitch response is initially boosted by the greater quantity of acetyl-choline that is released by each stimulus. This is the phenomenon of post-tetanic

facilitation. The enhancement of transmitter release soon wanes, and the twitch response also declines to the level that existed before the tetanic burst was given. The number of palpable facilitated twitches can easily be counted; this number is the Post Tetanic Count (P.T.C).

P.T.C is useful in monitoring the progress of profound blockade soon after a dose of relaxant has been given or when any sudden spontaneous diaphragmatic movement is undesirable, for example during neurosurgery.



The more profound the blockade, the lower is the Post Tetanic Count (P.T.C). As neuromuscular transmission recovers, the number of palpable post-tetanic twitches increases until, at a P.T.C of approximately 6-10 (depending on the muscle relaxant) spontaneous recovery has progressed sufficiently for the first response of the T.O.F to become just detectable. From this point onwards, P.T.C loses its usefulness and T.O.F or D.B.S takes over.

Single Twitch Stimulation (1 Hz)

To initiate 1 Hz stimulation, press and hold Selector 2 in the 1 Hz ‘down’ position. The Microstim DB3 will deliver the correct single stimuli applied repetitively at a frequency of 1 Hz whilst the Selector 2 is maintained in the down position.

The pulses are rectangular and have duration of 200 µs milliseconds to avoid repetitive nerve firing.

Problems and Solutions

During T.O.F or D.B.S stimulation, all the twitch responses persist even at profound blockade.

This is due to direct electrical stimulation of the muscles underlying the electrodes.

Try reducing the intensity of stimulation and/or repositioning the electrodes. If monitoring the hand muscles, try moving the positive electrode to the ulnar groove at the elbow.

Avoid the temptation to assess the muscle response visually; always use tactile assessment and apply a gentle pre-load to the patient's thumb.

At the end of the surgical procedure movement of the reservoir bag appears to indicate adequate tidal breathing and there is no fade in the T.O.F responses; should neostigmine still be given?

Tactile assessment of the T.O.F ratio is inaccurate. The T.O.F ratio can be less than 0.5 with no apparent clinical fade. At the end of the surgical procedure it is preferable to use D.B.S, which often reveals covert fade. If there is any fade whatsoever, neostigmine should be given.

The response of the facial muscles to stimulation of the facial nerve indicates that the patient is fully reversed but the patient is clearly partially paralysed.

The facial muscles are relatively resistant to muscle relaxants compared with the muscles of the hand. This must be borne in mind if this monitoring site is used; otherwise it is easy to over-paralyse the patient.

There is very little response to nerve stimulation but the patient is clearly insufficiently relaxed for surgery.

This is commonly due to dry stimulating electrodes. It is preferable to use ordinary EGG electrodes rather than to keep a supply of special electrodes for neuromuscular monitoring which might become dry if they are left in storage for a period of time.

I would like to measure neuromuscular transmission in the recovery room, but supramaximal stimulation is too painful when the patient is awake.

The stimulus current may be reduced to approximately 1/3 maximum (30 mA). At this level of current the T.O.F or D.B.S. ratio is not reduced compared with supramaximal stimulation and the stimuli are much less unpleasant for the patient.

Cleaning Instructions

The instrument case and leads can be cleaned using isopropyl alcohol. The instrument and leads are not intended to be sterilized. Do not autoclave.

Servicing Information

The Microstim DB3 is designed to be robust yet compact in size. Without access to specialised equipment, troubleshooting and repair of circuit board components is not feasible.

With the exception of replacing the battery, there are no user serviceable components within the unit.

If a problem arises with the Microstim DB3, the unit must be returned to Viamed Ltd. for repair or replacement (quote ref. number 2540000).

We also offer an annual service option when local requirements necessitate an authorised documented annual service check to be carried out (quote ref. number 2580000).

Note: The serial number label is located in the battery compartment.

Warranty

Viamed warranty ensures that goods are free from defects of manufacture for a period of one year from the date of shipment from Viamed. Liability shall be limited solely to the replacement and repair of the goods and shall not include shipping costs or other incidental damages.

This warranty is null and void if any items are subjected to misuse, negligence, accident, or repairs other than those performed by Viamed or an authorised service centre.

Parts List

Description	Part Number
Microstim DB3 Nerve Stimulator	2510000
Includes:	
1 x Patient lead, 0.9m, press stud connectors	2520000
1 x Battery, 9V Alkaline, MN1604	9950055
1 x Instructions for Use	2590000
Optional accessories:	
Lanyard, with screw thread for use with Microstim DB3	9910127
Patient lead, 1.5m, press stud connectors	2520001
Patient lead, 1.5m, pinch clamp connectors	2520003
Electrodes, box of 300	2550004
Microstim DB3 Tester	2510005

Symbol Definitions

ISO 7000-0434A
Caution
Indicates the need for the user to consult the instructions for use for important cautionary information

ISO 7010-M002
Refer to instructions manual/booklet

On ME Equipment “Follow instructions for use”

Disposal

The Microstim DB3 should be disposed of as WEEE (Waste Electrical and Electronic Equipment) in accordance with local ordinances and regulations, or it can be returned to Viamed. You are responsible for the return packaging and carriage costs, but we will process the returned WEEE free of charge on your behalf.

Return address for WEEE:

Viamed Ltd.
WEEE Processing
15 Station Road
Cross Hills, Keighley
West Yorkshire, BD20 7DT
United Kingdom

Viamed Limited · 15 Station Road · Cross Hills
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Email: info@viamed.co.uk Website: www.viamed.co.uk

Instructions for Use
Microstim DB3
V1.4 June 2023

Specifications Subject to Change

Instructions for Use Part Number: 2590000
Microstim DB3 Part Number: 2510000