VIAMED

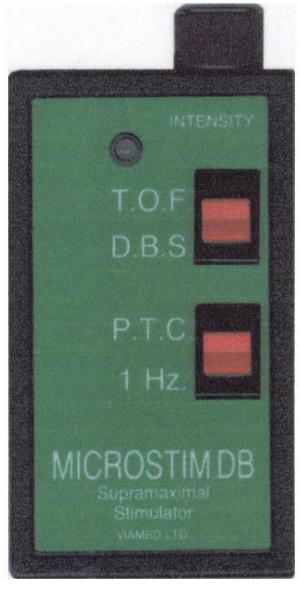
v2.4. 23/04/03.
Part No.: 0610063.

The Microstim DB,

Supramaximal Nerve Stimulator.

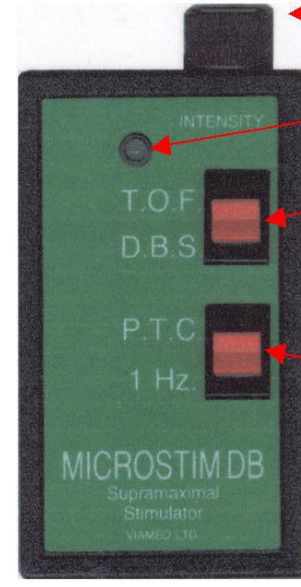
Peripheral Nerve Stimulator For Use During Anaesthesia.

User & Technical Manual.



CE 0086

Description of the Microstim DB.



Intensity control

Output / Battery Level Indicator.

Selector 1.
Up: Train of Four.
Down: Double Burst Stimulation.

Selector 2.
Up: Post Tetanic Count.
Down: 1 pulse per second (1 Hz).

Output / Battery Level Indicator.

When the Microstim DB is in use, flashes of the output / battery level indicator coincide with the pulses of stimulus being generated. When patient current flows, audio pulses are also generated. The output / battery level indicator changes from bright green and deep red with use. Replace the battery when the indicator is deep red

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 on ECG equipment during use.

How to use the Microstim DB.

- Position the stimulating electrodes.

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

1. Clean the skin with acetone or an alcohol wipe.

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

3. Connect the leads; the positive (red) electrode should usually be proximal.

4. Set the intensity control to half scale.

- Decide on the mode of stimulation.

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

- Adjust the output current.

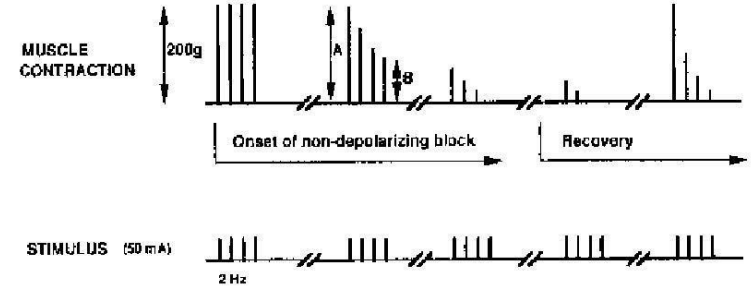
Increase the intensity until the twitch response is maximal. If the intensity is increased excessively, direct muscle stimulation will become more pronounced (see Problems and Solutions).

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

To initiate Train of Four stimulation, press and hold the T.O.F switch. The Microstim DB 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 11 block has intervened.

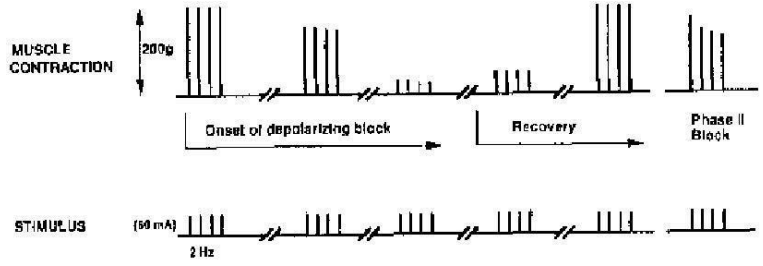


The Train Of Four ratio is the magnitude of the fourth twitch divided by the magnitude of the first twitch. In the absence of fade, the ratio would be 1.0. Even in experienced hands, it is unusual for fade to be detectable using the palpation method unless the Train Of Four ratio has fallen to below 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 11 block has intervened.

Double Burst Stimulation (D.B.S).

To initiate Double Burst Stimulation, press and hold the D.B.S switch once. The Microstim DB 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, D.B.S 3,3 can be supplied on request).

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

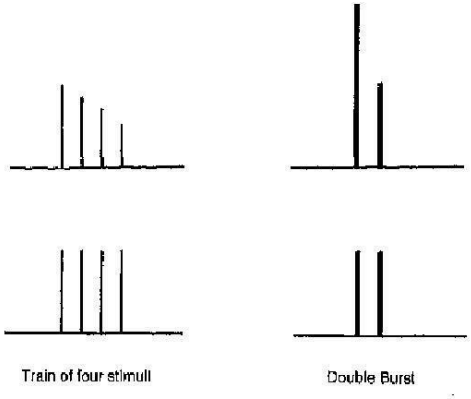
Although the Train Of Four ratio provides a method of monitoring light to moderate neuromuscular blockade, its accuracy is much reduced unless a force transducer is used to measure the response of the muscle. This is because the ability of the anaesthetist to reliably estimate the Train Of Four ratio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

Double Burst Stimulation (D.B.S) was 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 anaesthetist who is monitoring the twitch response of the thumb by the palpation method.

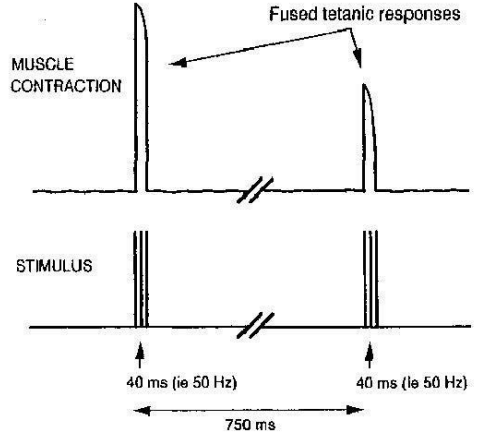
Two short tetanic bursts of stimuli are delivered and the response of the muscle is felt by the anaesthetist as two discrete twitches. It is relatively easy to quantify the extent, to which the second twitch is less powerful than the first twitch as,

(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.



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 anaesthetist who does not have access to a force transducer.



Post Tetanic Count (P.T.C).

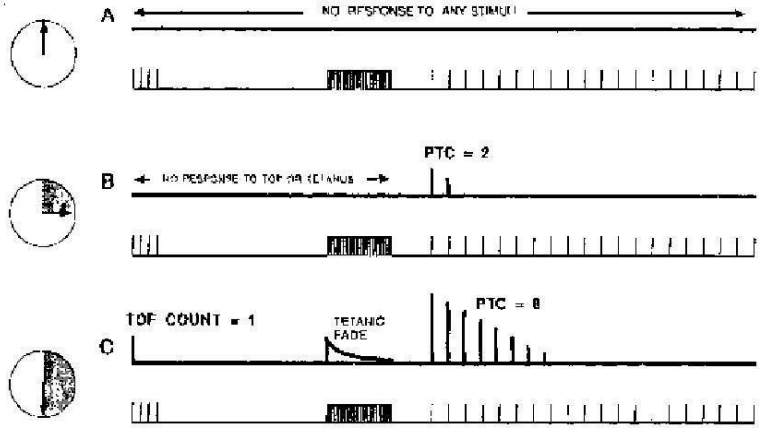
To initiate P.T.C stimulation, press and hold the P.T.C switch. The microstim will deliver the correct sequence of stimuli; 50 Hz for 5 seconds, a 3 second pause, followed by 1 Hz stimuli.

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. Suppose that blockade is very profound and there is no response whatever 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.

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 and D.B.S takes over.



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.

Problems and Solutions.

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

This is due to direct stimulation of the flexors of the forearm. Try reducing the intensity of stimulation and/or repositioning the electrodes; 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 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. Try changing to D.B.S which often reveals covert fade. If there is any fade whatever, neostigmine should be given (in a reduced dose if this is appropriate),

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.

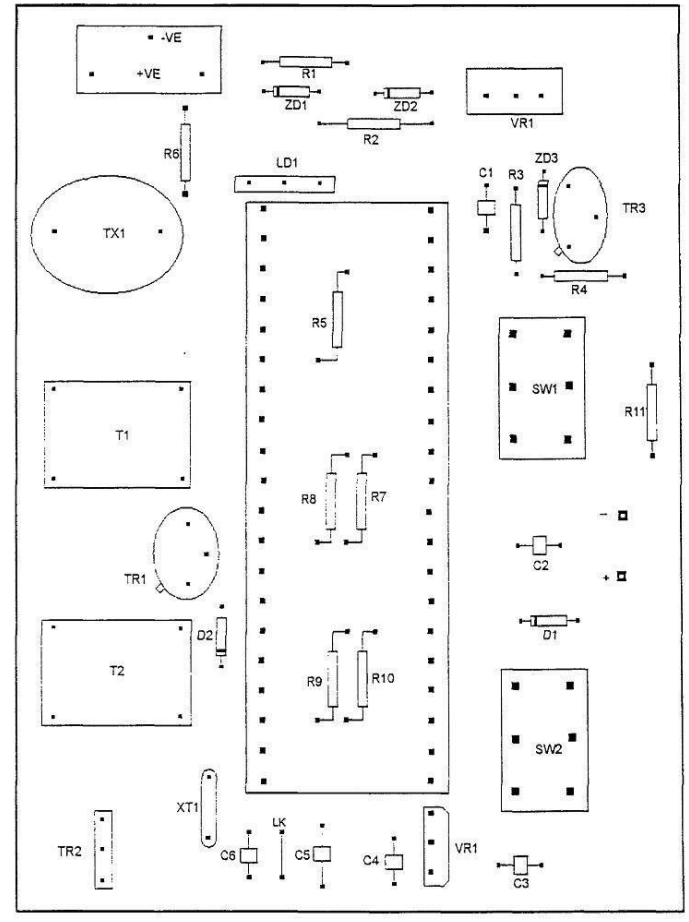
The facial muscles are relatively resistant to muscle relaxants compared with the muscles of the hand. This must be borne in mind if this monitoring site is used, otherwise it is easy to over-paralyse the patient.

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

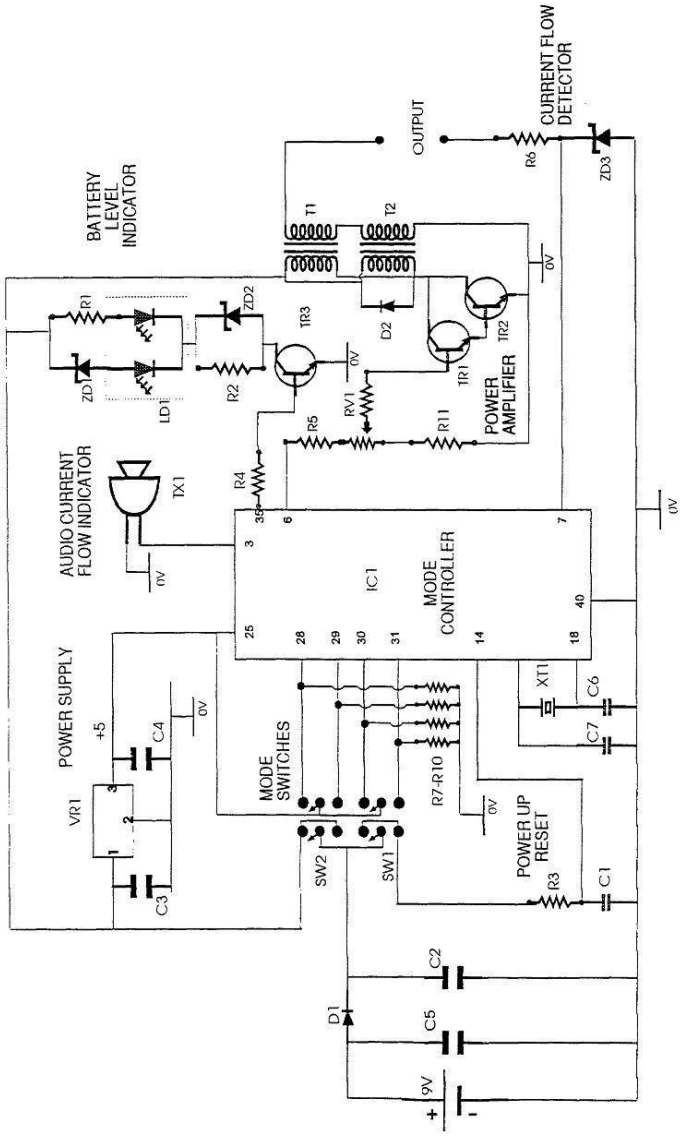
This is commonly due to dry ECG electrodes. It is preferable to use ordinary EGG electrodes rather than to keep a supply of special electrodes for neuromuscular monitoring which might become dry if they are left in a drawer for a period of time.

It would be desirable to measure neuromuscular transmission in the awake patient in the recovery room but supramaximal is too painful.

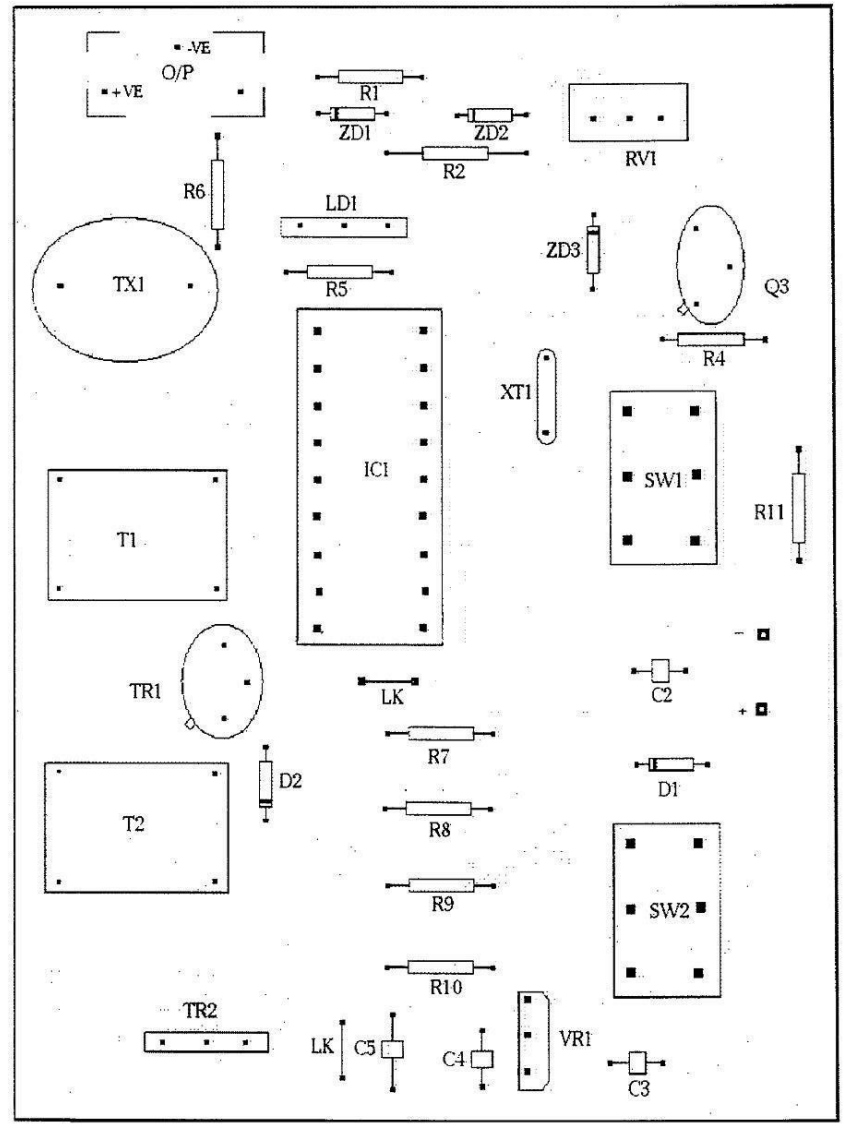
The stimulus current may be reduced to approximately 1/3 maximum (3O mA). At this level the T.O.F ratio (but not the single twitch) is not reduced compared with supramaximal stimulation and the stimuli are much less unpleasant for the patient.



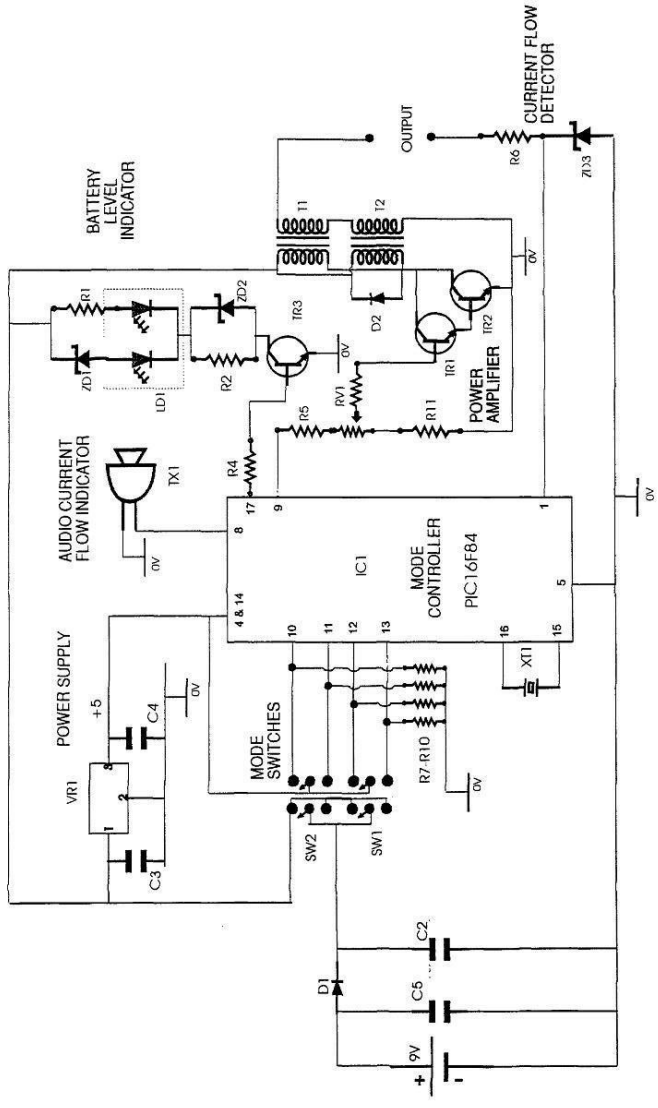
Microstim DB component layout v1 (40 pin processor).



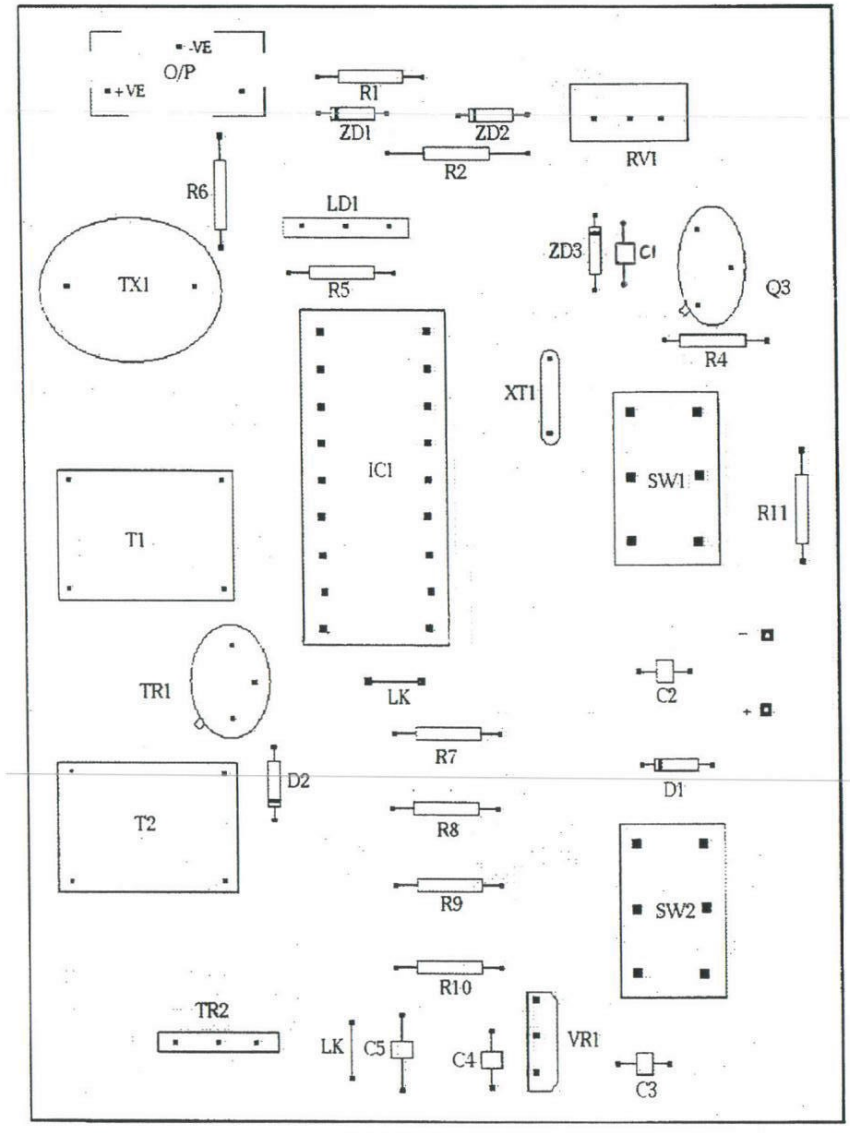
Microstim DB v1 circuit diagram.



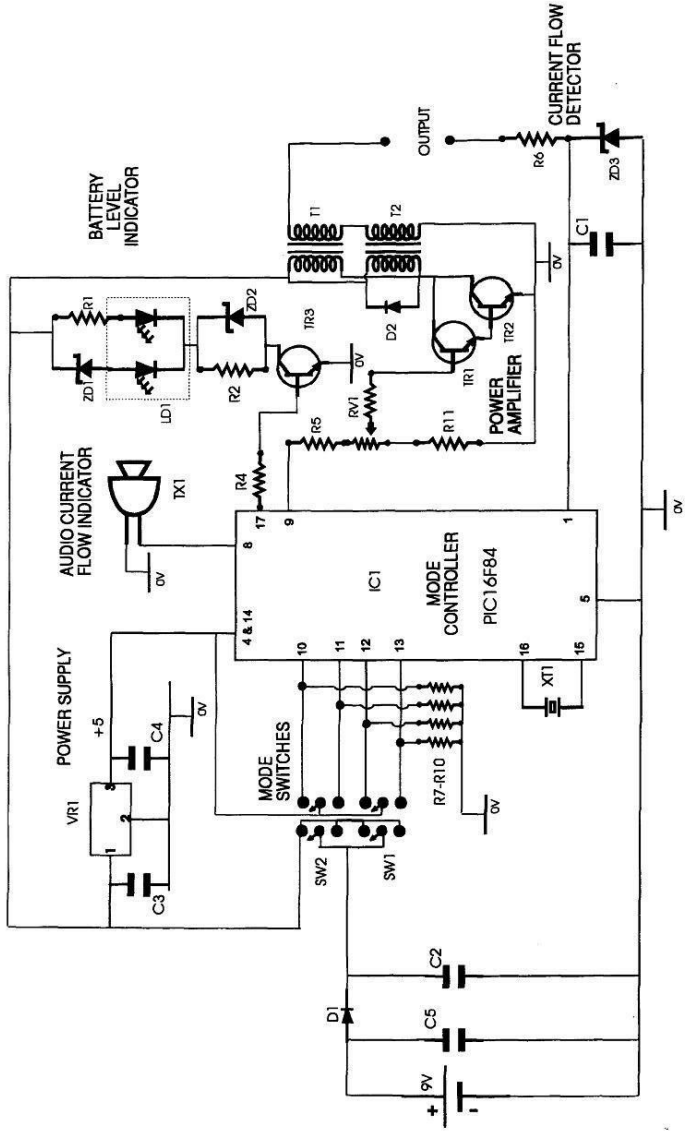
Microstim DB component layout v2.3 (18 pin processor).



Microstim DB v2.3 circuit diagram.



Microstim DB component layout v2.4 (18 pin processor).



Microstim DB v2.4 circuit diagram.

Microstim DB v1 & v2 : Parts & Components.

Part No.	Item.	Description.
DB01	R1	Res 1K0 CFR 0.33W 5%
DB02	R2	Res 1K0 CFR 0.33W 5%
DB03	R3	Res 10K0 CFR 0.33W 5% (v1)
DB04	R4	Res 10K0 CFR 0.33W 5%
DB05	R5	Res 1K0 CFR 0.33W 5%
DB06	R6	Res 470R0 CFR 0.33W 5%
DB07	R7	Res 1K0 CFR 0.33W 5%
DB08	R8	Res 1K0 CFR 0.33W 5%
DB09	R9	Res 1K0 CFR 0.33W 5%
DB10	R10	Res 1K0 CFR 0.33W 5%
DB11	R11	Res 4K7 CFR 0.33W 5%
DB12	C1	Capacitor 0.33 µF (v1)
DB13	C2	Capacitor 220 µF (10v)
DB14	C3	Capacitor 100 µF (10v)
DB15	C4	Capacitor 4.7 nF
DB16	C5	Capacitor 220 µF (10v)
DB17	C6	Capacitor 12 pF (v1)
DB18	C7	Capacitor 12 pF (v1)
DB19	T1	Transformer Eagle LT700
DB20	T2	Transformer Eagle LT700
DB21	TR1	Transistor BC107 (MG)
DB22	TR2	Transistor BC107 (MG)
DB23	TR3	Transistor BD131
DB24	TX1	Audio Transducer
DB25	D1	Diode switching IN4148
DB26	D2	Diode switching IN4148
DB27	ZD1	Zener Diode 3.9V BZX9C3V9
DB28	ZD2	Zener Diode 3.9V BZX9C3V9
DB29	ZD3	Zener Diode 3.9V BZX9C3V9
DB30	VR1	Regulator 5V, 100mA UA78LO5
DB31	IC1	IC TMS77C82 NL (v1)
DB32	SC1	Socket IC 40 pin (v1)
DB33	CS1	Case undrilled
DB34	LB1	Label Front Panel Green DBS
DB35	LB2	Label Rear Cover DB

Part No	Item	Description
DB36	LB3	Label Top DB
DB37	RV1	Pot 10K0 Potentiometer
DB38	P1	Rib-Loc Press in Sockets 2 mm Black
DB39	P2	Rib-Loc Press in Sockets 2 mm red
DB40	KN1	Knob 22mm
DB41	XT1	Crystal 6 MHz (v1)
DB42	L1	LED Tri Colour LTL52RG
DB43	LR1	LED Clip & Ring LTL001B
DB44	SW1	Switch DPDT CO Momm 2028TJWO
DB45	SB1	Switch Bezel (AT207K)
DB46	SR1	Switch Rocker Actuator Red (A4750R)
DB47	SW2	Switch DPDT CO Momm 2028TJWO
DB48	SB2	Switch Bezel (AT207K)
DB49	SR2	Switch Rocker Actuator Red (A4750R)
DB50	SR2	PCB no components (v1)
DB51	B1	Duracell MN1604 Alkaline (PP3 size)
DB52	LB4	Label Knob
DB53	LB5	Label Front Panel Welcome
DB54	SL	Stimulator Leads twin 2 mm plug
DB55	IM1	Instruction Manual v1.1
DB56		Carrying case soft
DB57		Carrying case hard
DB59	XT1	Crystal 4MHz
DB60	SC1	Socket IC 18 pin
DB61	IC1	IC PIC 16F84
DB63	2M2	Instruction Manual (v2.2)
DB64	PCB	PCB no components DBS(v2.3)
DB65	C1	Capacitor 4.7 nF (v2.4)

IC1 (TMS77C82) was discontinued and has been replaced with IC1 (PIC16F84). This involved other component changes. DBO3, DB12, DB17 & DB18 are no longer required. DB41 (6 MHz crystal) has been replaced with DB59 (4MHz crystal). DB32 (40 pin IC socket) has been replaced with DB60 (18 pin socket). C1 (DB??) introduced in v2.4. The software has been re-written so that both v1 & v2 models have identical outputs, functions and specifications.

VIAMED

Declaration of Conformity
Class IIa Medical Devices

Manufacturer's name: Viamed Limited

Manufacturer's address: 15 Station Road, Cross Hills
Keighley, West Yorkshire BD20 7DT
United Kingdom

Device:

Microstim DB

Supramaximal Nerve Stimulator

It is hereby declared that the medical devices specified above conform with the essential requirements listed in Annex I of the EC Council Directive 93/42/EEC of 14 June 1993.

This declaration is supported by:

Technical documentation required by the MDD (Annex VII) retained by: Viamed Limited

EC Quality Assurance BS EN ISO 9001 FS28344 Certificate No. FS 28344
EN 46001 Certificate No. CE 01389

Issued by: British Standards Institute Date: 8 February 1999 Amended 18th October 1999

Notified body number CE 0086

Signed: Date: December 2, 1999 Position: Managing Director

Document number: CE-DC-100

RS 28343 RS 28344

Viamed Limited, 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT
Tel +44 (0)1535 634542/636757 Fax +44 (0)1535 635582
Email info@viamed.co.uk
Registration No 12917565 in England

Cleaning Instructions.

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

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.

Cables and transducers are not included.

Viamed Ltd.
15 Station Road,
Cross Hills,
Keighley,
West Yorkshire,
BD2O 7DT,
United Kingdom.

Tel : +44 (0) 1535 634542.
Fax : +44 (0) 1535 635582.
Email : info@viamed.co.uk.
Website : www.viamed.co.uk.