Microstim Case II Comments.

- There are only two fixing screws (below the battery compartment). Should there be two at the top to stop the case springing open?
- Will the case plastic age well or will the moulding deform over time due to fixings stresses? Will the case joins start to come apart if only two fixing screws are used?
- The pot is stood well off the PCB. If it is not glued in place, it will be able to move. This will cause the three wire spills to snap off. How is the pot going to be secured so that this will not happen?
- Are the stand-offs for mounting the PCB a bit thin? Will their screw threads strip if the screws are repeatedly inserted/removed? Will the pillars break off from the rest of the case if stressed?
- How is the PCB assembled into/removed from the unit? Will the pot and LLD be attached to the PCB when it is inserted and the switches soldered afterwards? Can it be assembled? The PCB needs to be single sided a THP board will be difficult to desolder for board removal.
- The battery compartment floor needs to be solid so that a label can be stuck on serial number and battery type.
- How will the knob be attached to the pot? Will it be screwed as at the moment? Will the screw show?
- The LED should not be capable of being pushed backwards with a pen.
- 9 Do the two battery contacts attach to the PCB with wires?
- The two battery contacts will have to project a long way forward to ensure contact is made with the battery if the battery is hard up against the other end of the compartment.
- The moulding that stops the battery from being inserted the wrong way round needs to be made more substantial so that it cannot be broken off.
- Will it be possible for the battery contacts to touch the two case contacts from the top if someone attempts to put the battery in the wrong way round?
- 13 If there is a reliable mechanical way of preventing the battery from being inserted the wrong way round, do we need diode D1 on the PCB? Removing this would improve battery life and save cost.
- 14 How do you remove the switches for replacement?
- Will the output lead connector be mechanically secured to the case independent of the PCB so that it cannot move relative to the PCB if it has solder spill connections

to the PCB, not wire tail PCB connections? Movement could cause solder spill connections to fracture.

- Will the unit stand a 1-metre drop test onto a concrete floor?
- 17 Is the camera mount moulding substantial enough? Will it shear from the rest of the case if the case is bent away from a fixed camera mount?

P. Anderson 2nd March 2005

Subject: FW: Microstim Case II Comments - reply

te : Tue, 8 Mar 2005 10:19:00 +0000

Linked to: Samuel Sham

From : SamuelSham@automatic.com.hk (By way of helen.lamb@viamed.co.uk)

To : PETER (Peter Anderson) < GoldMine User>

Cc : SNIXON (Steve Nixon) < GoldMine User>; JSLAMB (John Lamb) < GoldMine User>

Dear Peter.

Please find below our reply.

Also we will submit a functional sample with the pervious housing to Viamed for evaluation.

The functional sample would include new jack and it will be available around 3~4 weeks later.

If any question, please let us know.

nks & Best Regards, Samuel Sham

HTI REPLY:

- 1. It can be have 2 options: (1) add 1 screw in the label recess area (3 screws.jpg), and (2) add 2 screws at asymmetrical position (4 screws.jpg). Please check per the attached and confirm.
- 2. There are several latches at the front end to locate Top and Bottom plastic housings together firmly. So no come apart should be occurred.
- / 3. We expect "pot" means "potentiometer" which will be secured by tight fit into the small housing. The housing manufactured in large size only for rapid prototyping, not the final one. Then it will be soldering onto a small board which then secured onto 2 screw bosses by screws. Please check per the attached. knob.jpg, small pcb.jpg) WITE TAIL
- 4. There are 4 stand-offs for mounting the PCB, not just 2 or 3, and with ribs for reinforcement by the way. Usually screws assembly do not expect to insert/ extract many times in manufacturing field, ust about one to two times should be accepted. Transit and drop test will be implemented to check reliability characteristic.
- 5. Please note below procedure:

to place the pot, the buzzer, and the 2 switches onto the top case.

- because the connector onto the top case by screws.
- c. to solder wires of buzzer, connector wires of pot PCB, lead of switches, and LED to the boald.
- d. secure main PCB onto the top housing by 4 screws.
- √ 6. OK to re-design has a battery compartment floor for your purpose.

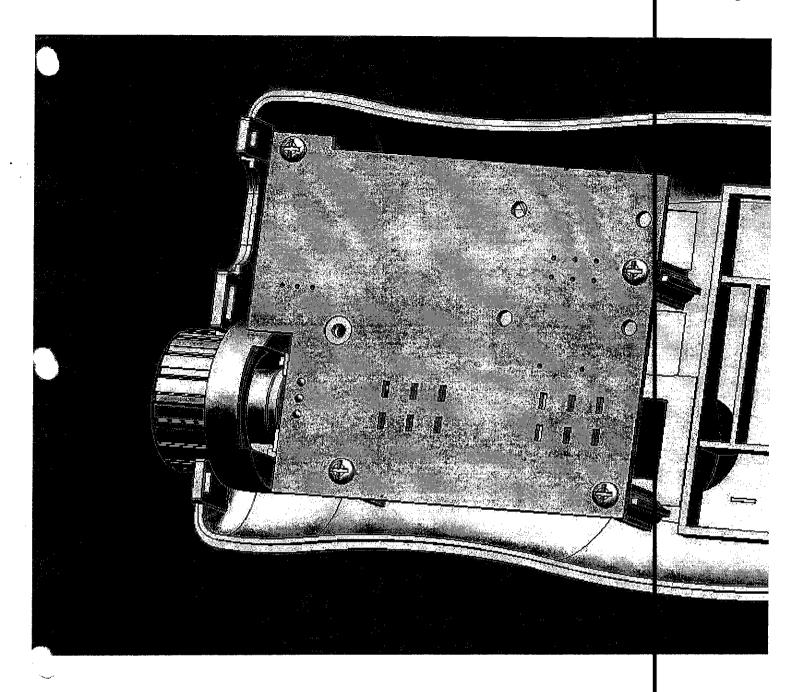
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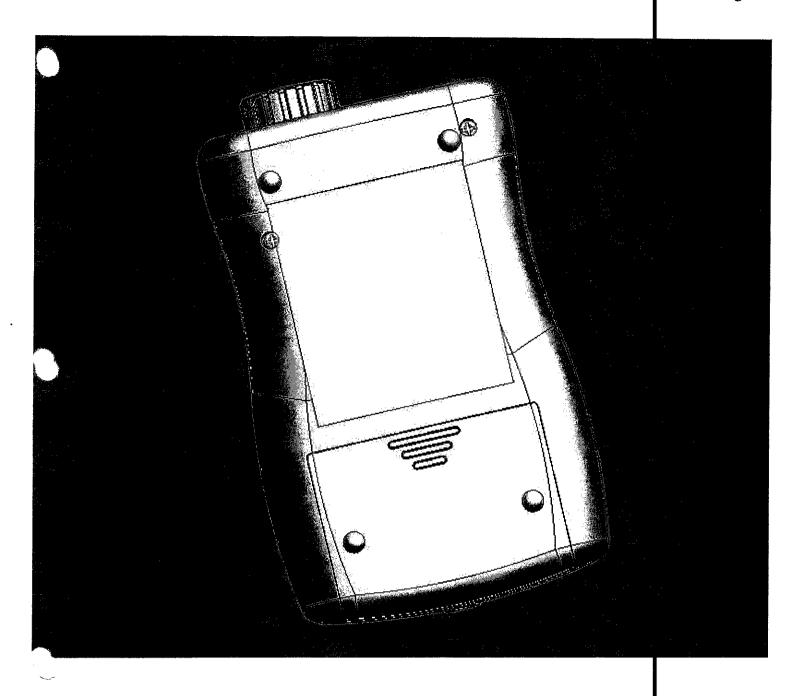
 Øcc.
- √ 7. A plastic Knob Base was welded with Knob together and sits on the shaft of pot. Two round ribs from Top and. Bottom case will locate the pot thread neck area firmly. (knob.jpg) Can knob 0 Pot be remark
- \checkmark 8. It should be the same as your previous version. However, the tip of LED should be lower than the lunar ring surface to avoid damage.
- √9. Yes
- √ 10. Not sure the question. But several spring latches around the compartment could reduce moving displacement and deterioration. But But 17 Needs to be impossible to consul butty revened
- 12. How to put the battery in wrong way round?
- 13. You may check once molding out the plastic parts in engineering sample stage.
- \checkmark 15. The output lead connector is to be secured into the case by 2 screws, and to be connected f t the board with 2 wires black and red. Yes, it should be.
- \surd 1 $_{ iny c}$ We expect the Camera Mount means the Insert molding metal thread, so it should be secure

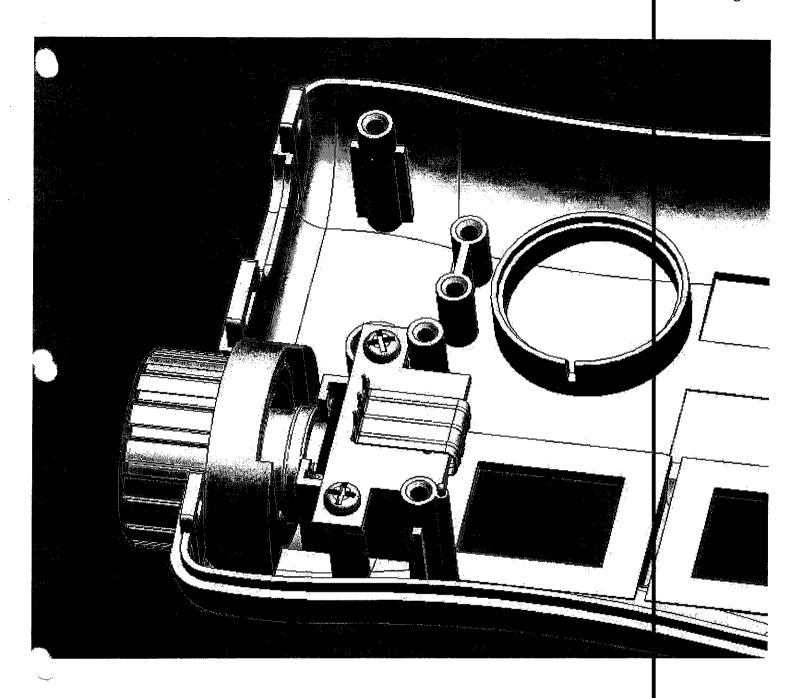
about: blank the bed 2 semetims feelt off, who the flow concrete

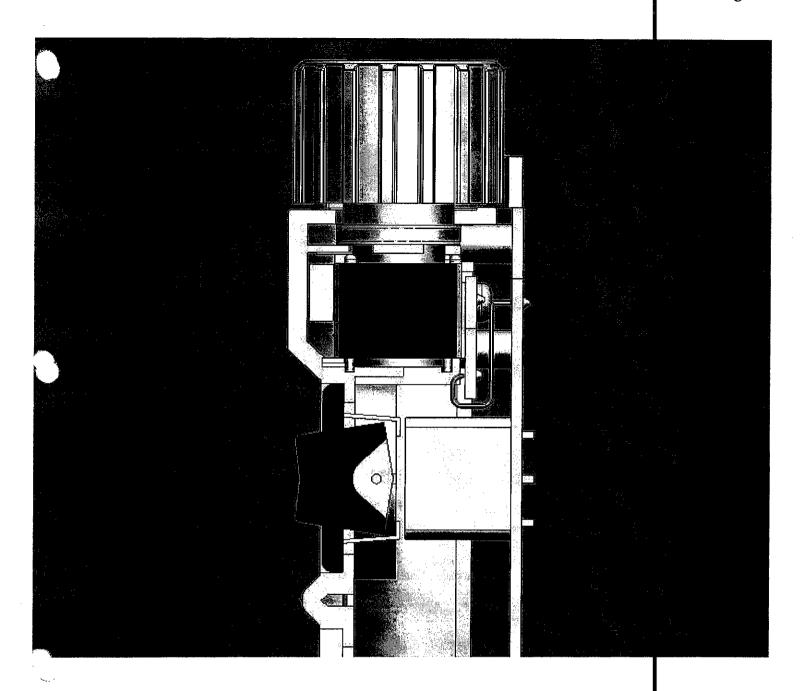
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Pate: Wed. 16 Mar 2005 15:53:08 +0000

i m: Peter Anderson <peter.anderson@viamed.co.uk> Subject: re: FW: Microstim Case II Comments - reply To: Samuel Sham <SamuelSham@automatic.com.hk>

In-Reply-To: <QjA2WFQzRSkkLVEuLjpXNDUwMzMwOA@host>

Mime-Version: 1.0 Organization: Viamed

X-Mailer: GoldMine [6.00.30403]

Dear Samuel,

Thank you for your reply to my questions. My comments are:

¹ Please add 2 screws in the asymetrical position (4 screws.jpg).

2, 3, 4, 5, 6 All ok.

7 Can the knob be removed from the pot if the pot has to be replaced?

8,9 ok.

10 Please add the spring latches to hold the battery firmly in its correct position.

11 ok.

12, 13 ok but it needs to be impossible for the battery to make contact with the battery contacts when it is electrically reversed.

14, 15, 16 ok.

The camera mount is there to allow a neck cord to be used for hands free whilst the Microstim is not in use. Currently, Microstims lie on the patient's bed and sometimes fall off onto the concrete floor and break.

We look forward to seeing your next sample so that we can see how the assemblies go together.

Could you please give me approximate prices for 100 off of each of the following spare parts?

Complete spare cases
Spare PCB assemblies
Battery contacts
Lead connector assemblies
Knobs
Any other custom design parts

יst wishes,

Peter

Design review with John Lamb and Peter Anderson on the 16th March 2005. Reply from Samuel Sham to our document "Microstim Case II Comments".

Our comments on Samuel's replies to my questions are:

- 1 Please add 2 screws in the asymetrical position (4 screws.jpg).
- 2, 3, 4, 5, 6 All ok.
- 7 Can the knob be removed from the pot if the pot has to be replaced?
- 8, 9 ok.
- 10 Please add the spring latches to hold the battery firmly in its correct position.
- 11 ok.
- 12, 13 ok but it needs to be impossible for the battery to make contact with the battery contacts when it is electrically reversed.
- 14, 15, 16 ok.
- 17 The camera mount is there to allow a neck cord to be used for hands free whilst the Microstim is not in use. Currently, Microstims lie on the patient's bed and sometimes fall off onto the concrete floor and break.

We look forward to seeing your next sample so that we can see how the assemblies go together.

Could you please give me approximate prices for 100 off of each of the following spare parts?

Complete spare cases Spare PCB assemblies Battery contacts Lead connector assemblies Knobs Any other custom design parts

There are no changes to the risk assessment.

Peter Anderson 16th March 2005