

Attachment C

CORRECTION INSTRUCTIONS FOR FORMULA MACHINES WITH BATTERY BACKUP

UPDATE TO OCTOBER 2016 FIELD SAFETY CORRECTIVE ACTION – Formula® Hemodialysis Machines:
Formula®, Formula® 2000, Formula® PLUS, Formula® 2000 PLUS, Formula® Therapy, and Formula® Domus

WARNING! – BEFORE STARTING

All operations must be carried out by Bellco/Medtronic personnel or authorized technical staff.

PERFORM THE FOLLOWING BEFORE STARTING SERVICE:



Power off the machine



Unplug the mains power cable from the wall outlet



Lock the wheels of the machine so it does not move during servicing

1. Ensure the correction kit (**Fig. 1**) is available and complete per the component list below.



Correction Kit Components		
Part Number	Description	Quantity
IB5022800	Battery	1
IB1448800	Battery Installation Date Sticker	2
IB1500370	Battery Protective Cover	1
IB3103700	Battery Charge Board	1
IB5455033	Screws - M4x8	2
IB5455035	Screws - M4x12	2

Inspect the Machine

2. Using a size 4 Allen key, open the left access door of the machine.
3. Remove the front plastic cover, then remove the plastic tray (red oval in **Fig. 2**) covering the Power Supply Unit (PSU). Finally, disconnect the D-Sub connector (green oval in **Fig. 2**) from the bottom of the Differential Flowmeter.

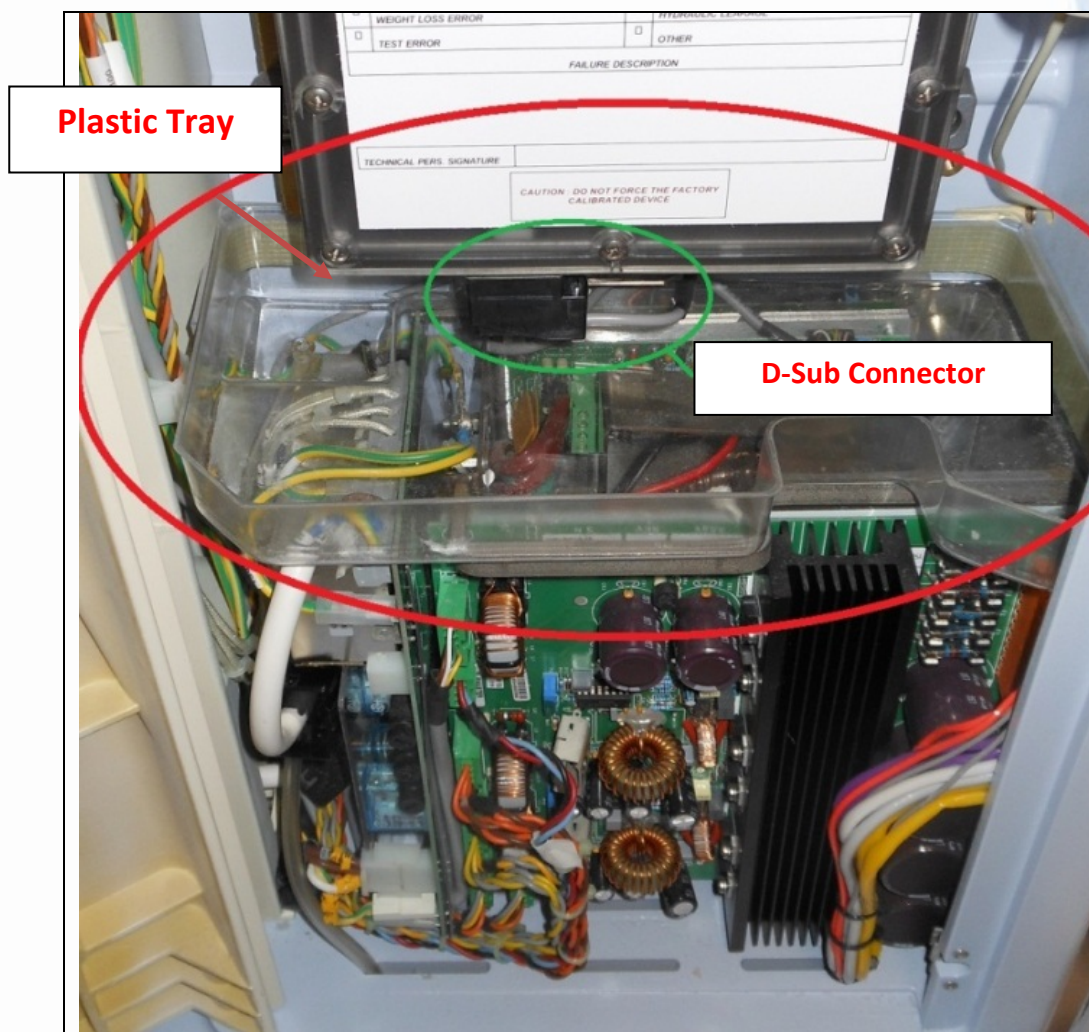


Fig. 2

4. Verify the configuration of the Formula machine:
 - A. If the Formula machine was **NOT** initially configured for battery backup, **STOP** and refer to **Attachment D: Correction Instructions for Formula Machines without Battery Backup**.
 - B. If the Formula machine was initially configured for battery backup, **continue** with the steps in this instruction set.

Remove the PSU From the Machine

5. Unscrew PSU mounting screws (**Fig. 3**).



WARNING! ACCOUNT FOR THE TWO (2) PSU MOUNTING SCREWS REMOVED DURING THE PROCEDURE. IF MISSING SCREWS, VERIFY THAT THEY HAVE NOT FALLEN INSIDE THE PSU

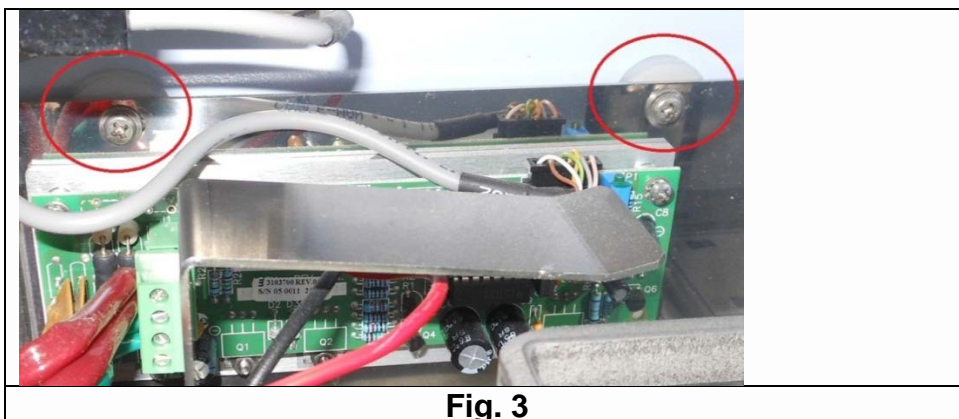
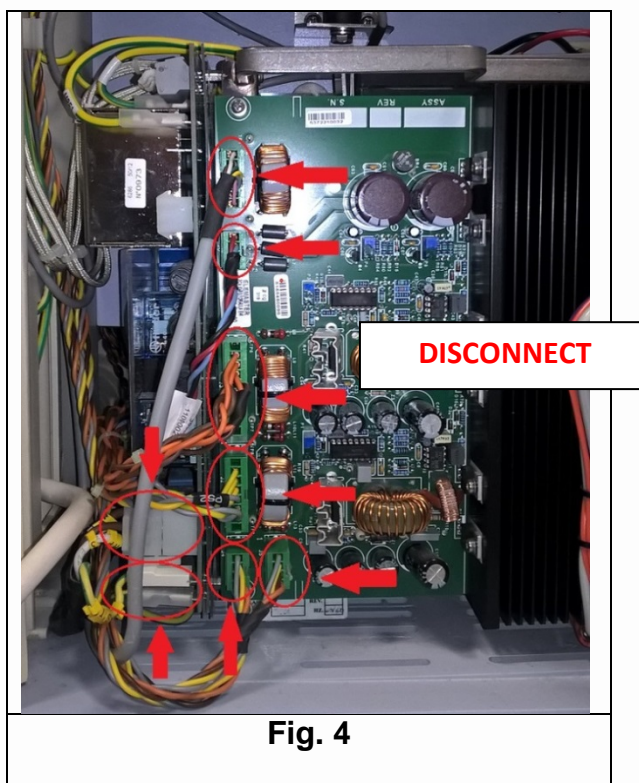


Fig. 3

6. Unplug the following connectors: PS2, PS3, PS4, PS5, PS6, PS7, PS8 and the two ground cables positioned below PS8 (**Fig. 4**).



7. Disconnect power supply cable by pressing on the terminal release levers (**Fig. 5 & Fig. 6**).

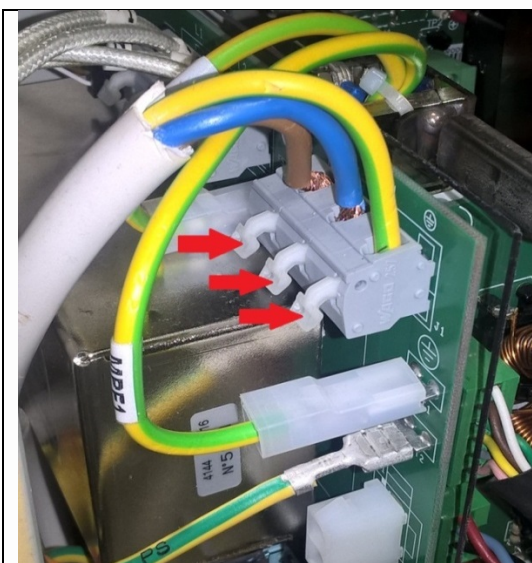


Fig. 5

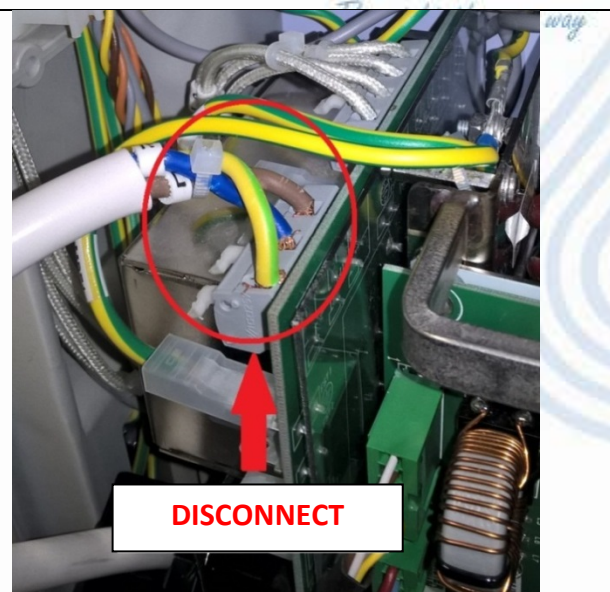


Fig. 6

8. If your Formula machine has black ferrites, slide the black ferrites on the power supply cable down the power supply cable (toward the PSU attachment wires). Place the power supply cable with attached ferrites out of the machine and to the side so it does not interfere with the removal of the PSU (**Fig. 7**).

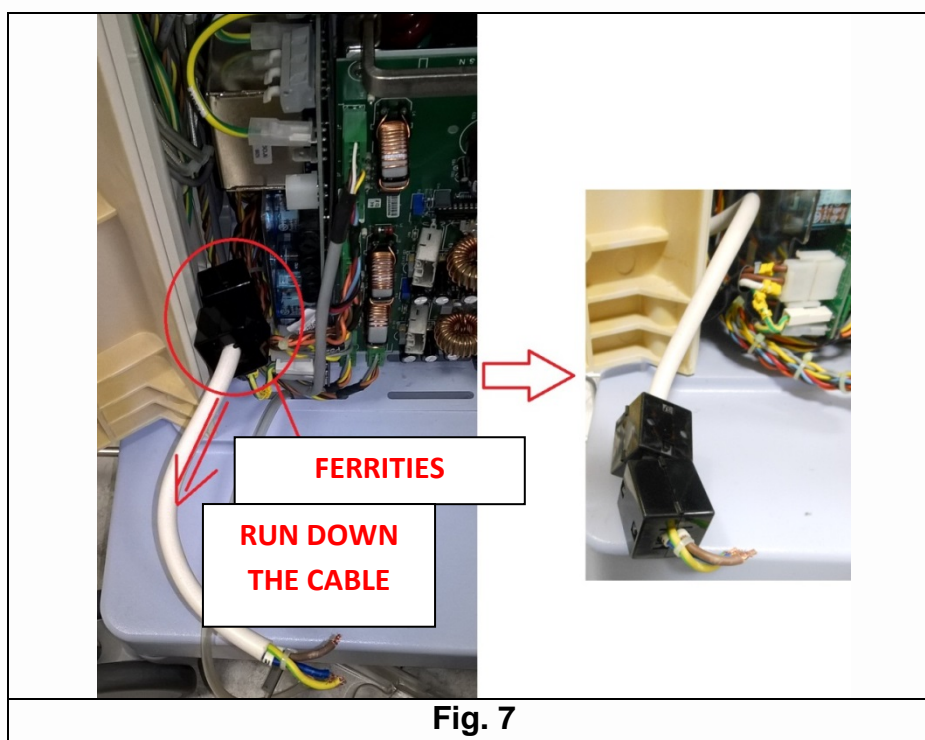


Fig. 7

9. Extract the PSU from the equipment:

- Grab the PSU using the metal handle welded to the box (**Fig. 8**);
- Lift it up and rotate PSU to the front (**Fig. 9**).

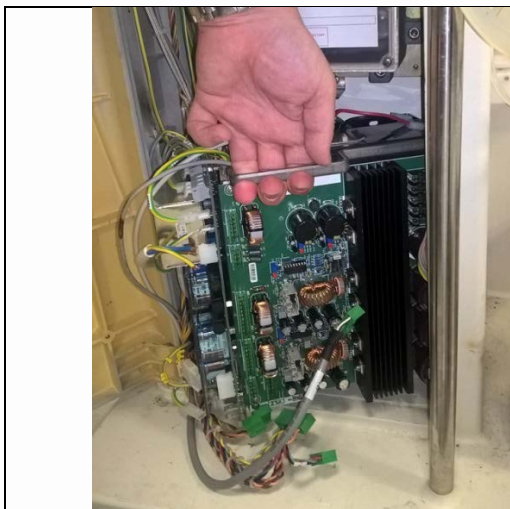


Fig. 8



Fig. 9

Remove the Battery From the PSU

10. Loosen the battery retention bracket screw (**Fig. 10**).

11. Remove the battery retention bracket.

12. If not already performed, disconnect power cables from battery (**Fig. 11**).

13. If not already performed, remove the battery and **dispose of the battery according to your facility policies.**

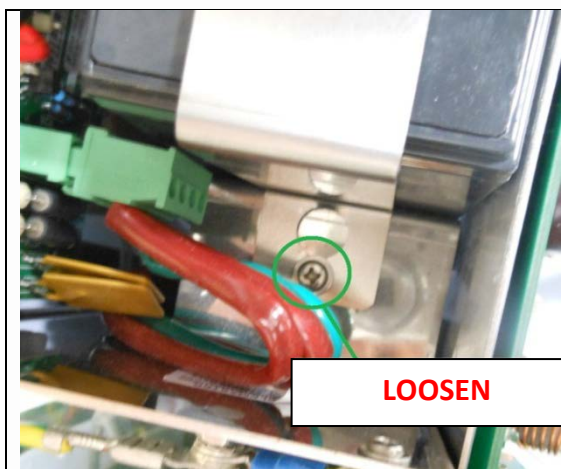


Fig. 10

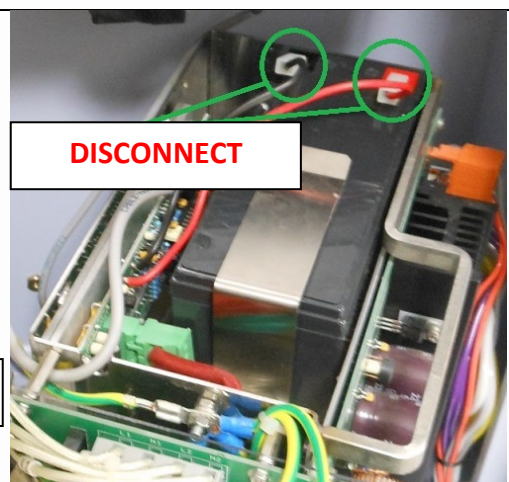


Fig. 11

Remove the Charge Board From the PSU

14. If not already performed, disconnect J1 and GC2 from charge board (**Fig. 12**).
15. Using a PH1 screwdriver, unscrew charge board mounting screws (located on the back side of the PSU) (**Fig. 13**). Remove the charge board, and **discard the charge board according to your facility policies**.

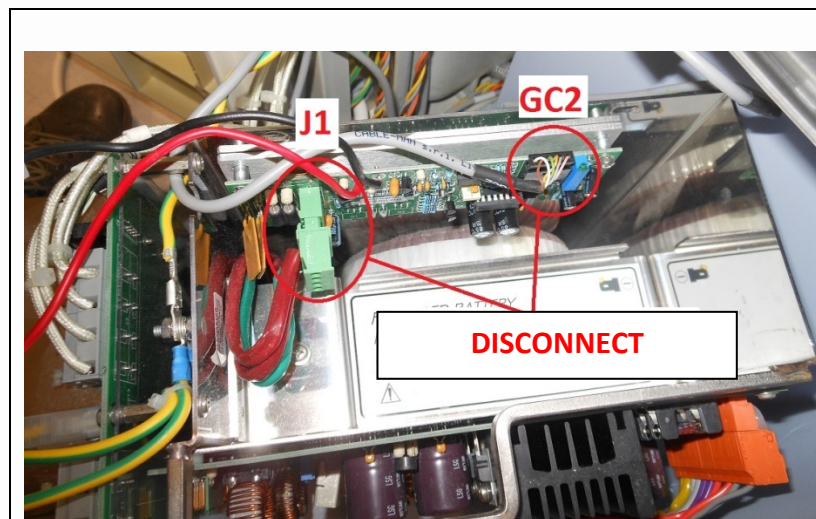


Fig. 12

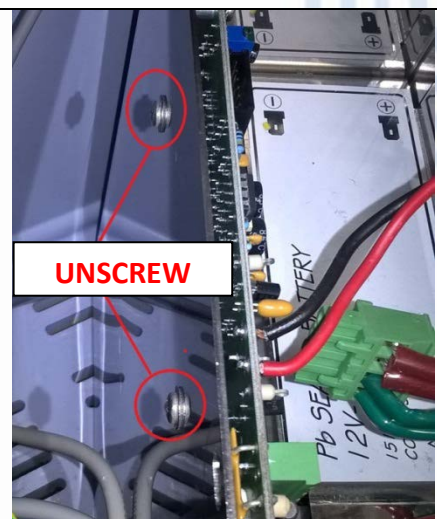


Fig. 13

Install the New Charge Board and Battery Into the PSU

16. Install the new charge board (cod. IB3103700) found in the re-work kit into the PSU using the two (2) M4x8 screws previously removed in Step 15 or new ones supplied in the correction kit. Then reconnect the connectors J1 and GC2 to the new charge board.
17. Apply ID sticker, contained in the correction kit, (cod. IB1448800) to the new battery found in the correction kit (cod. IB5022800) then blacken the installation month and year on the sticker (**Fig. 14**).

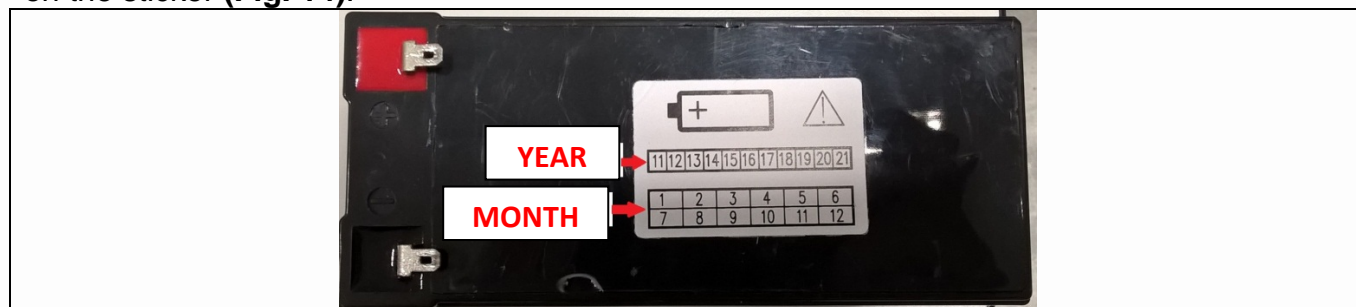
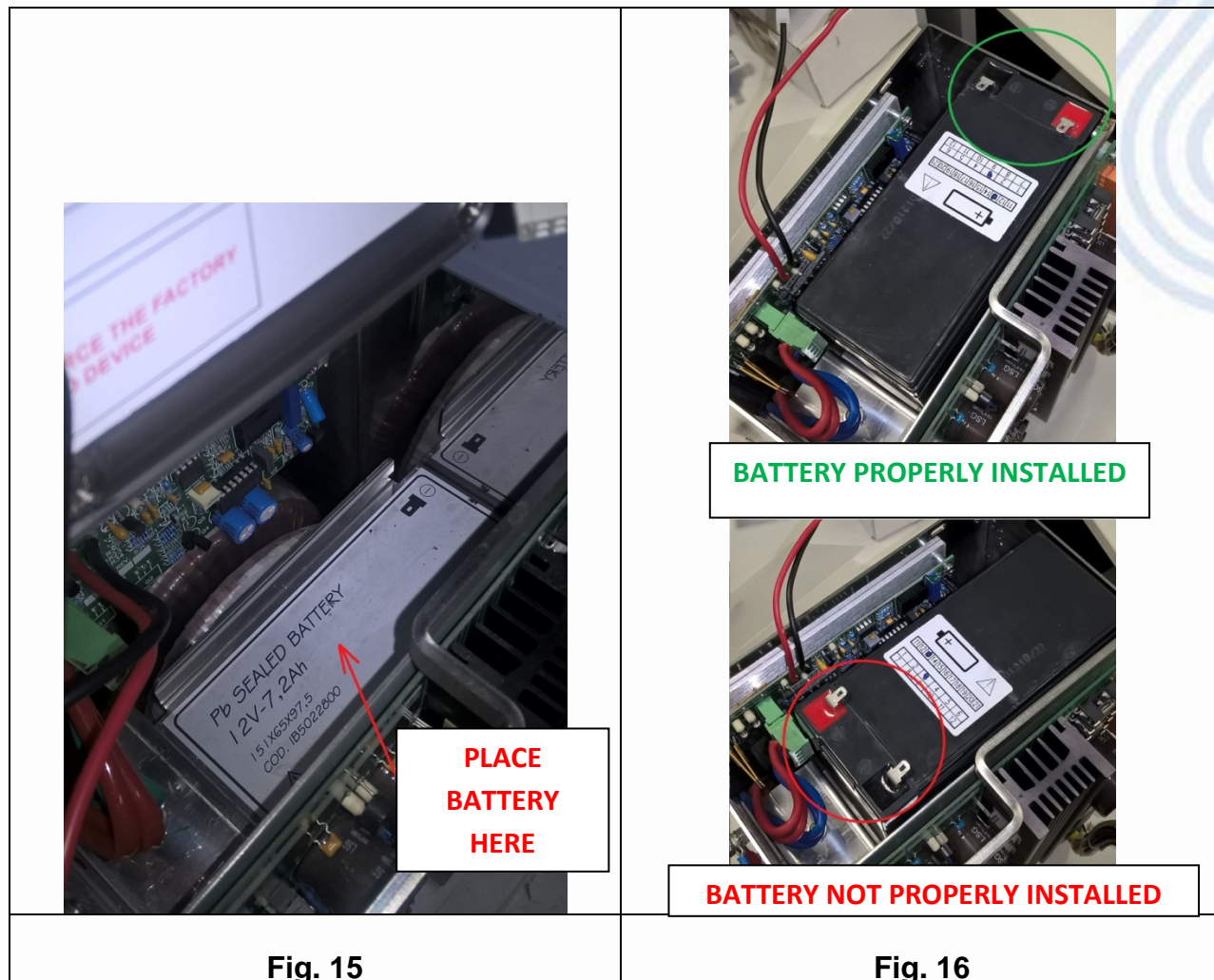


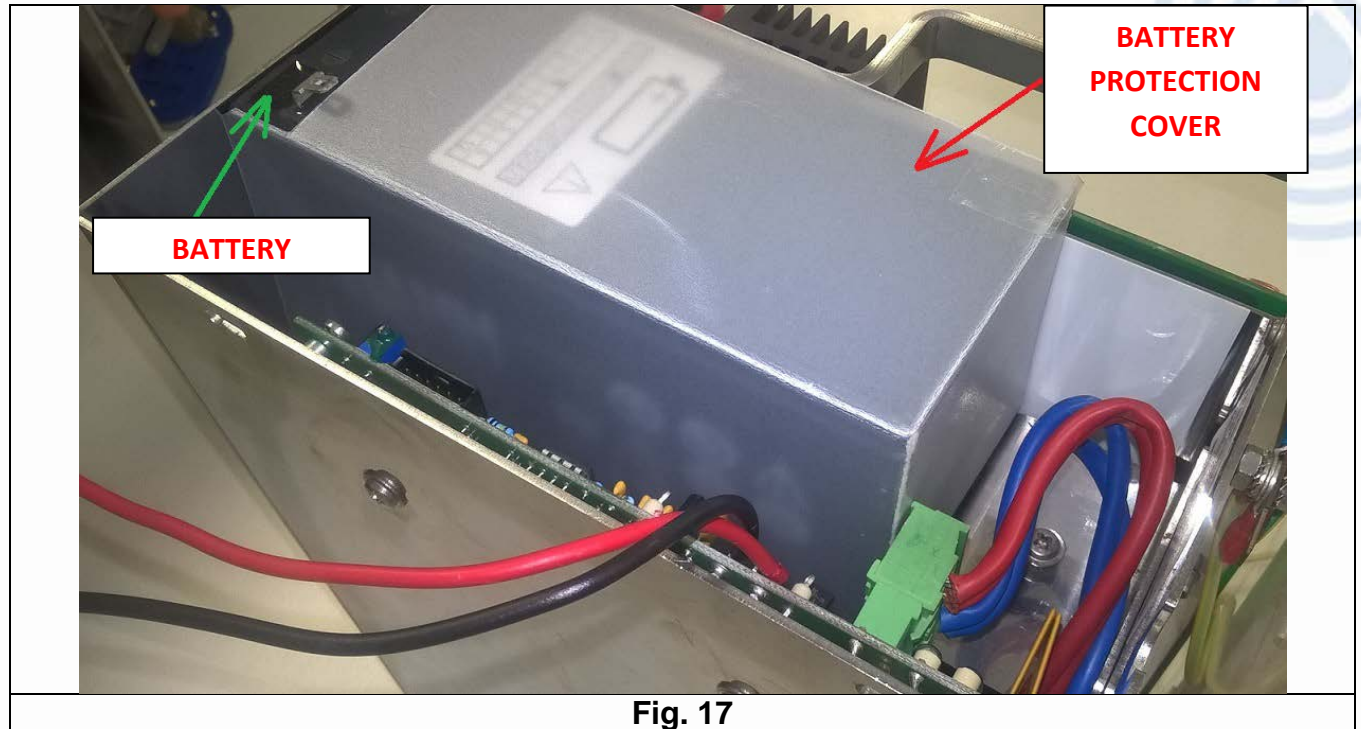
Fig. 14

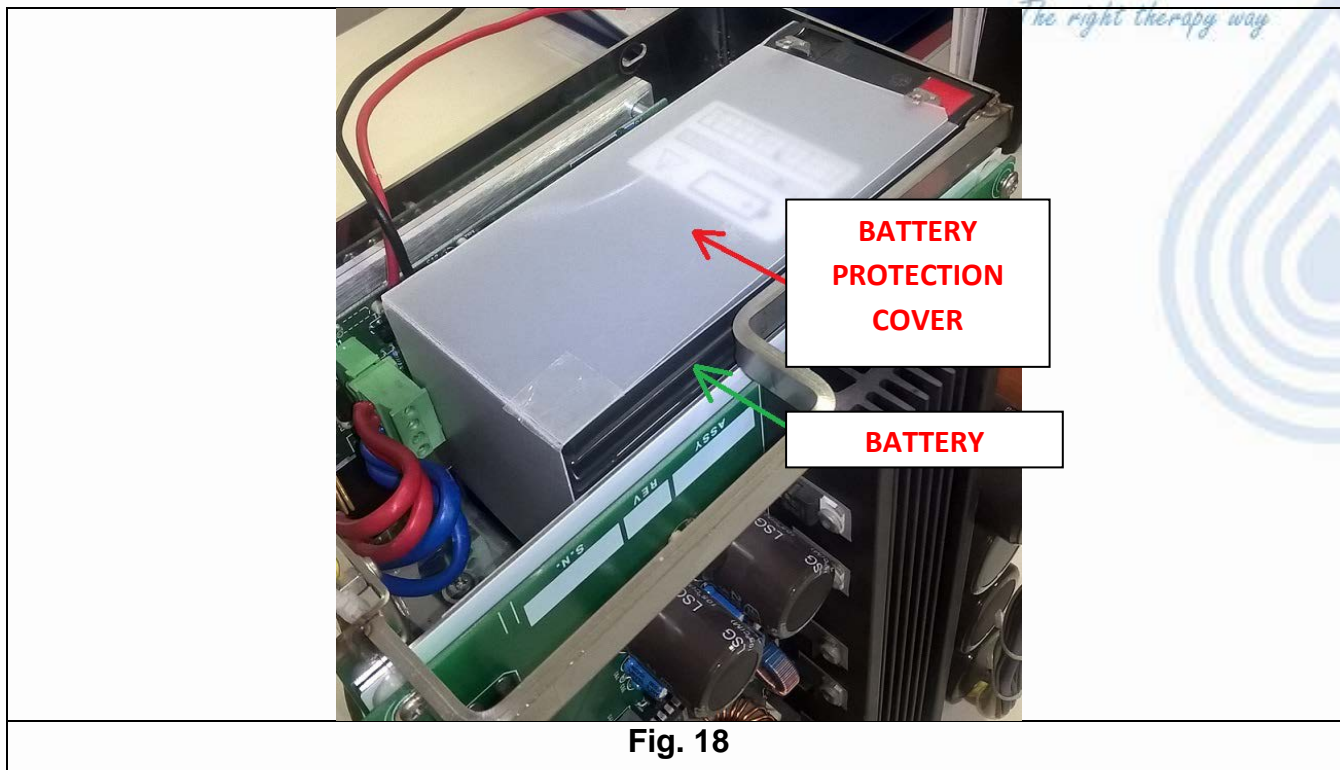
18. Insert new battery inside the PSU in the correct mounting direction, ensuring that the battery terminals face the PSU outer wall. (Fig. 15 & Fig. 16).



Install the Battery Protection Cover Over the Battery *The right therapy way*

19. Place the battery protection cover (cod. IB1500370) over the battery. Ensure the side of the battery facing the charge board is covered by the protective cover (**Fig. 17 & Fig. 18**).



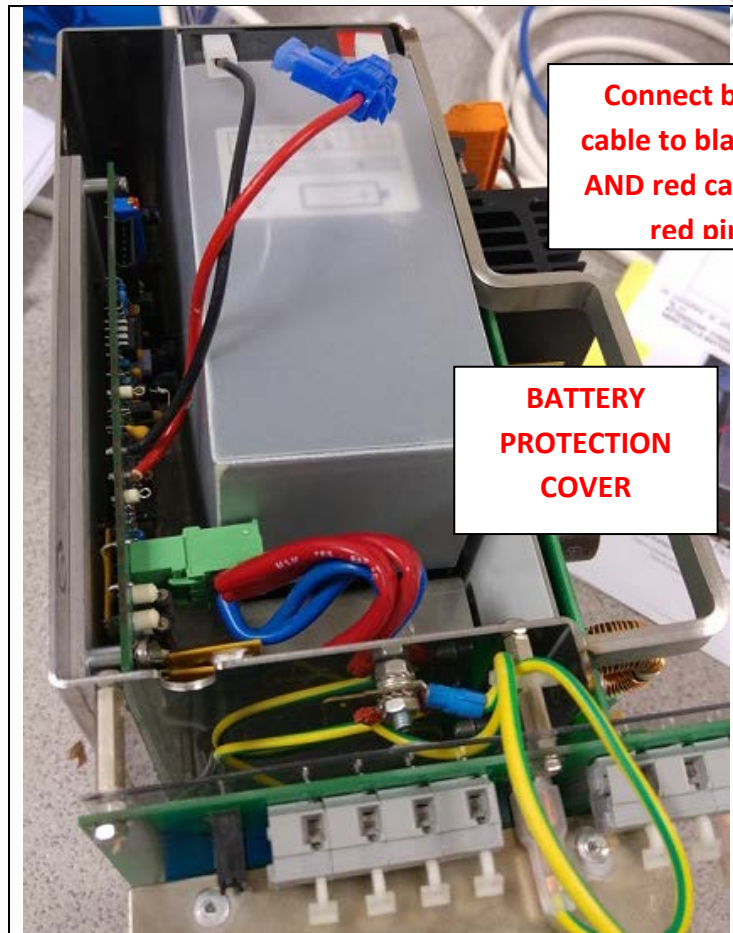


Reconnect the Battery

20. Reconnect the battery to the charge board ensuring the battery cables are placed on the corresponding color battery terminal. **(Fig. 19).**



WARNING: CONNECT BLACK CABLE TO BLACK PIN AND RED CABLE TO RED PIN



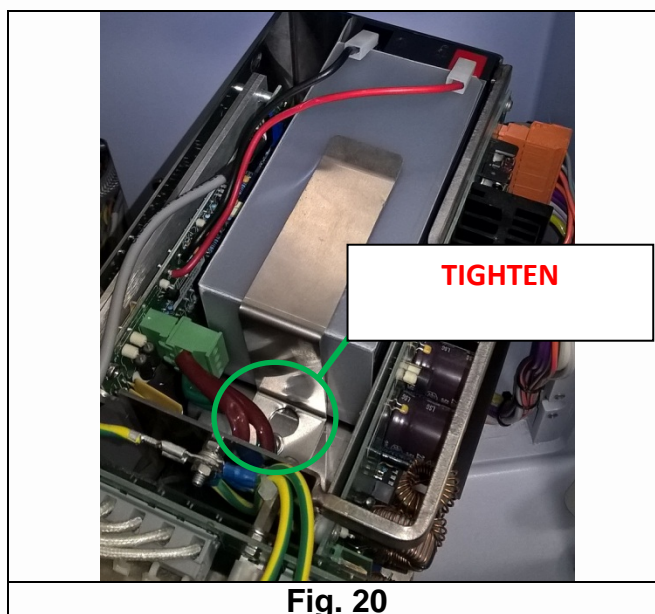
The right therapy way

**Connect black
cable to black pin
AND red cable to
red pin**

**BATTERY
PROTECTION
COVER**

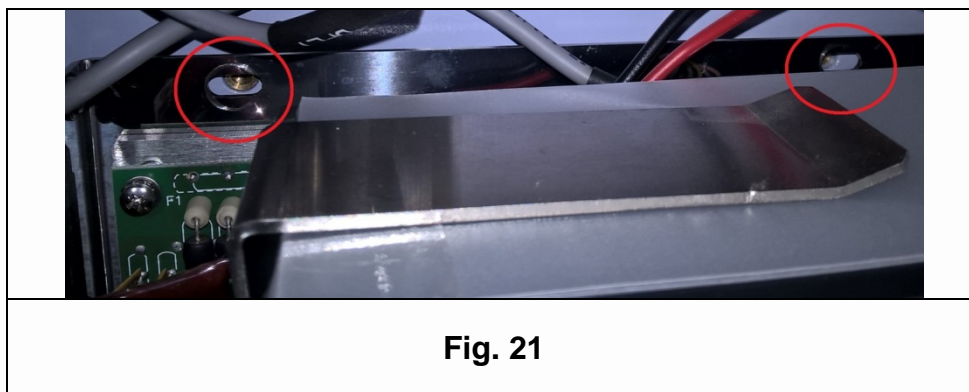
Fig. 19

21. Reinstall the battery retention bracket over the battery/battery cover and tighten the screw (**Fig. 20**).

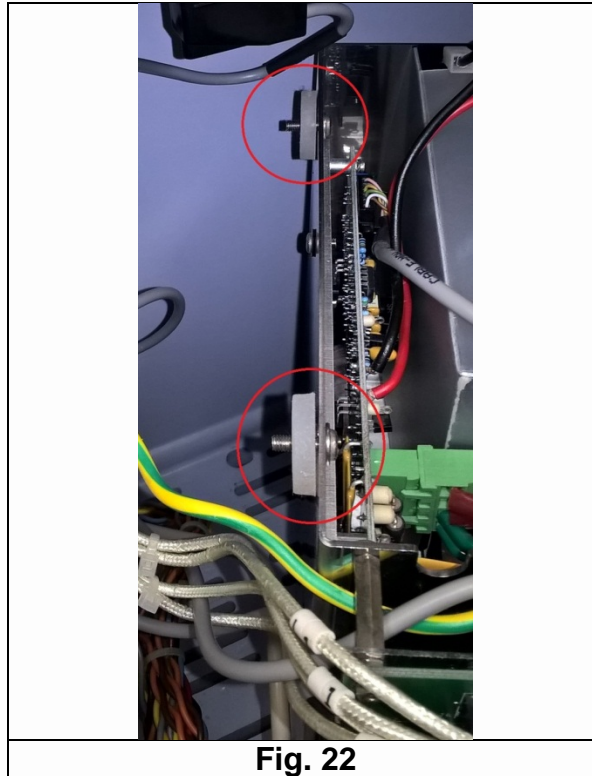


Reinstall the PSU Into the Machine

22. Insert the two (2) M4x12 PSU mounting screws previously removed in Step 5 or new ones supplied in the correction kit into their corresponding cutouts on PSU box (**Fig. 21**).

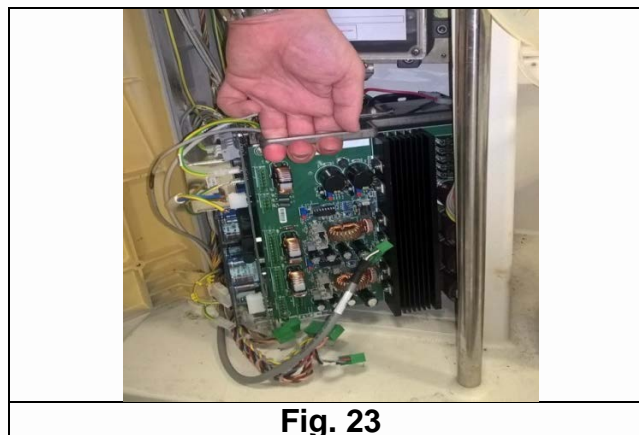


23. Place the silicone washers previously removed from the PSU onto the protruding ends of the two installation screws (**Fig. 22**).



24. Mount the PSU inside the equipment:

- Grab the PSU using the metal handle welded on the PSU box (**Fig. 23**);
- Lift up the PSU and reinsert it inside the machine (**Fig. 23**).



25. Fix the PSU to the machine chassis using the two (2) M4x12 screws previously placed in Step 22 (**Fig. 24 & Fig. 25**).

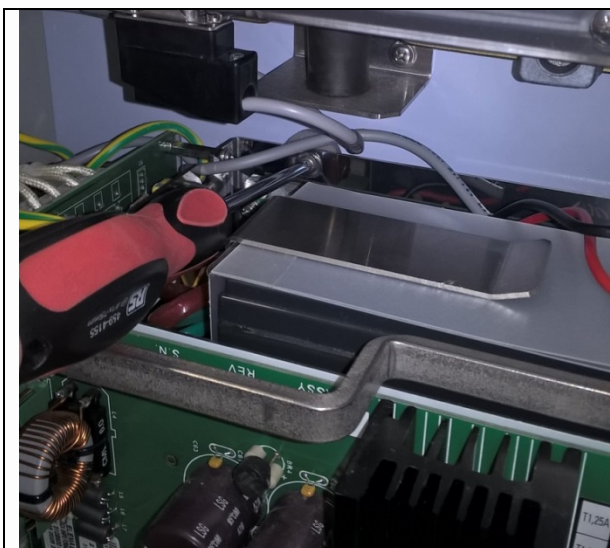


Fig. 24

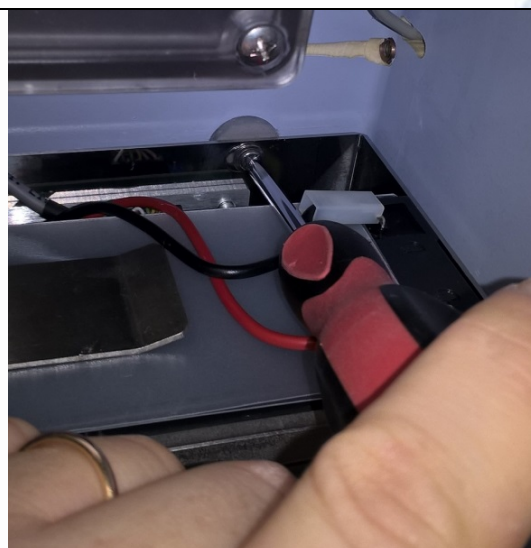


Fig. 25

26. Connect following connectors: PS2, PS3, PS4, PS5, PS6, PS7, PS8 and the ground cables below PS8 (**Fig. 26**).

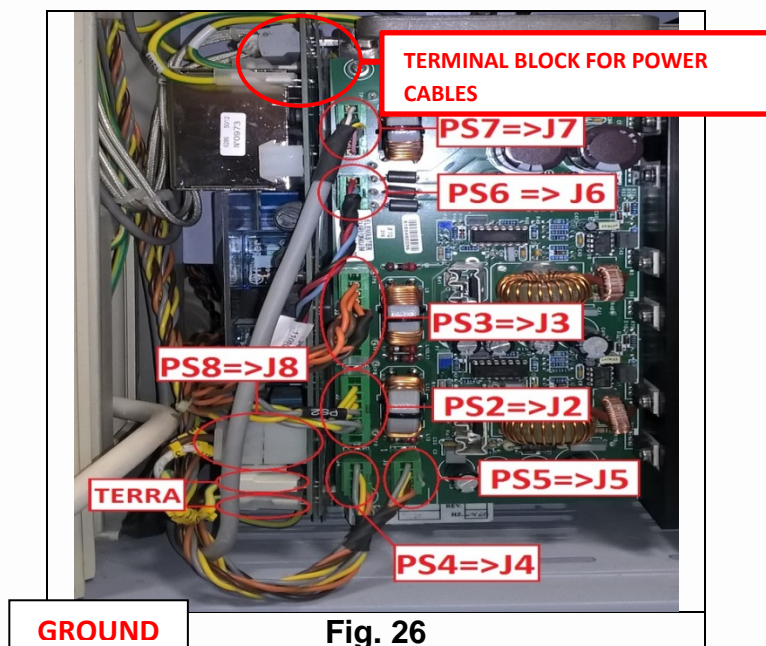


Fig. 26

27. Insert the power supply cable into the equipment and, if applicable, slide the ferrites back to their original position on the cable (**Fig. 27 & Fig. 28**).

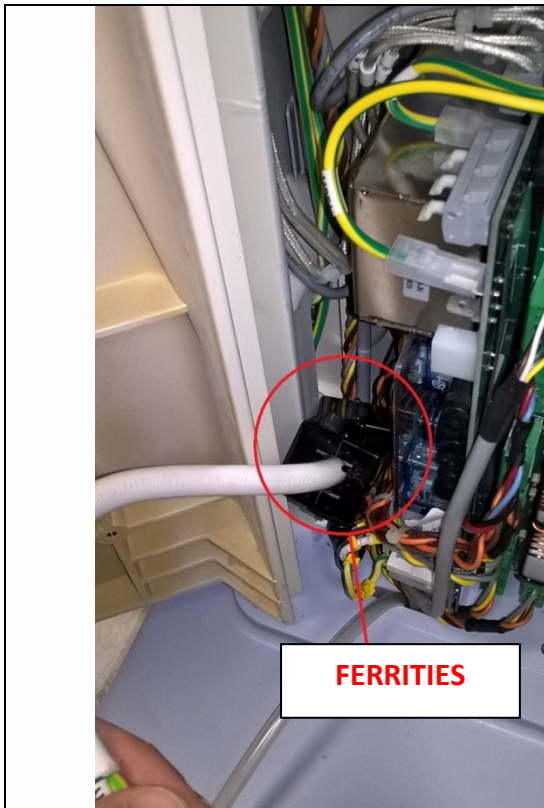


Fig. 27



Fig. 28

28. Connect the three single wires of the power supply cable to the terminal block by depressing the levers and inserting the wires. **(Fig. 29 & Fig. 30)**. Verify that the wires are correctly installed and secured in terminals by gently pulling back on each wire to ensure it's retained by the terminal block.

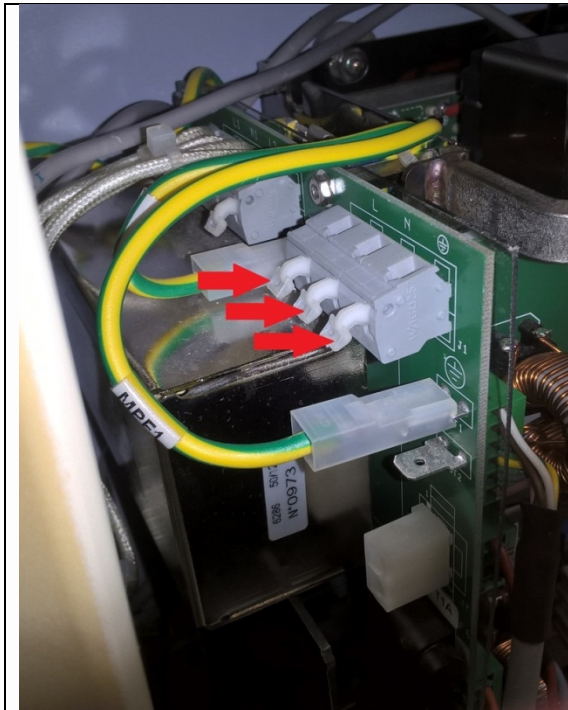


Fig. 29

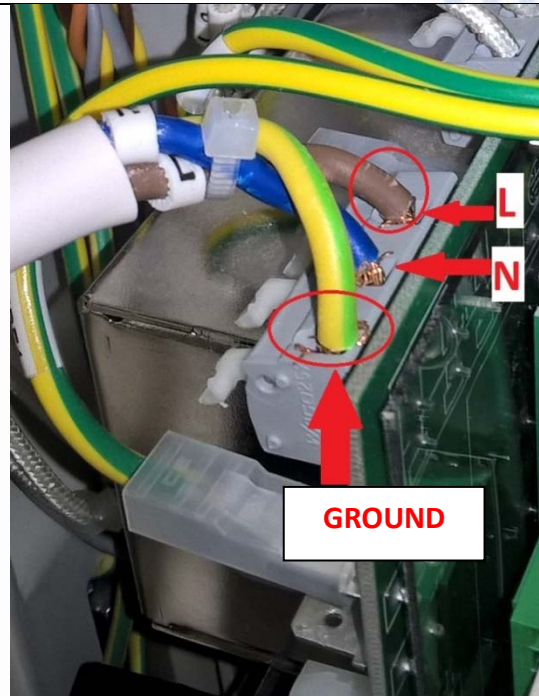


Fig. 30

29. Place the plastic protection tray over the PSU and route the drain pipe to the bottom of the machine (**Fig. 31**).
30. Connect the D-Sub connector to the differential flowmeter (**Fig. 31**).

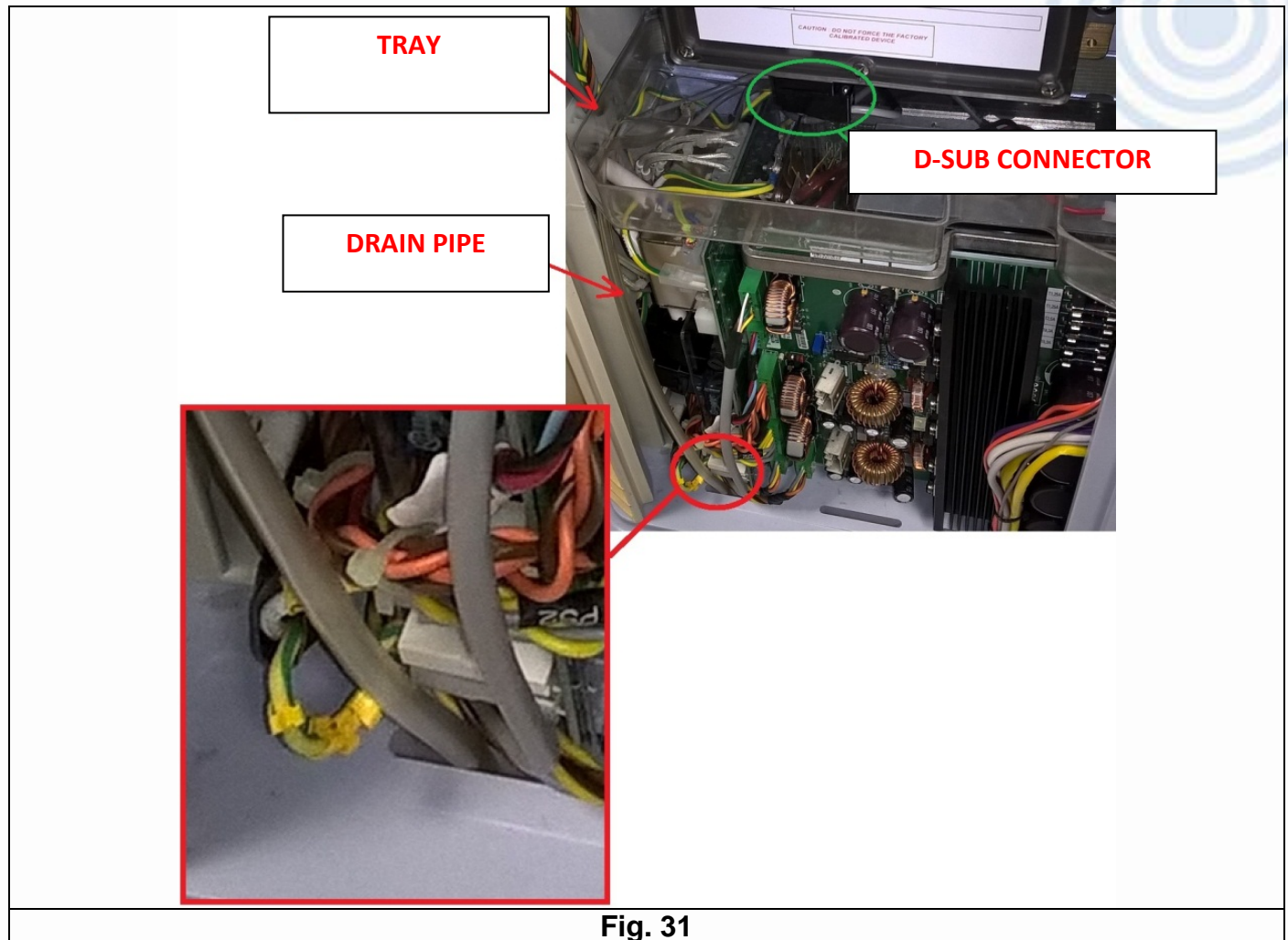


Fig. 31

31. Place the plastic cover on to the differential flowmeter.
32. Close the left door, lock it using a size 4 Allen key.

Configure the Machine

The right therapy way

33. Using a size 4 Allen key, open the right access door of the machine.
34. If not already connected, connect the cable marked as AN28 onto the analogic board, **(Fig. 32)**.
35. On to the back of the machine, apply the battery identification sticker, included in the correction kit, (cod.IB1448800). Blacken month and year of battery installation **(Fig. 33)**.

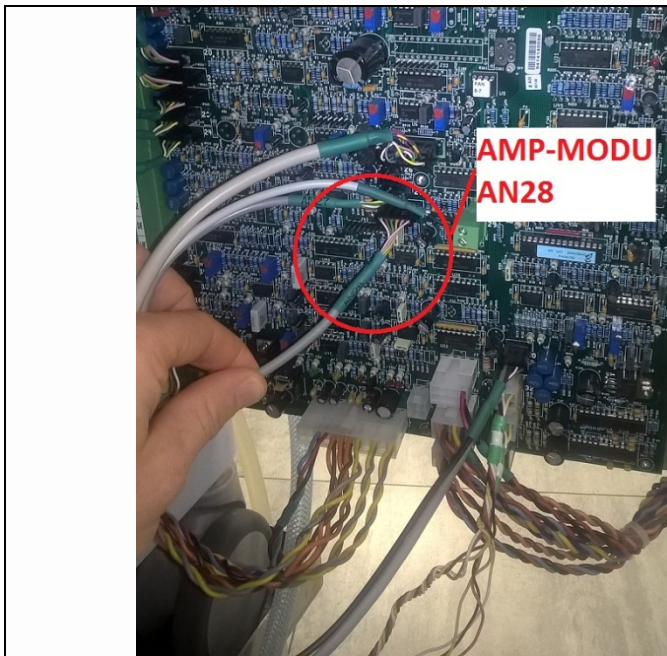


Fig. 32

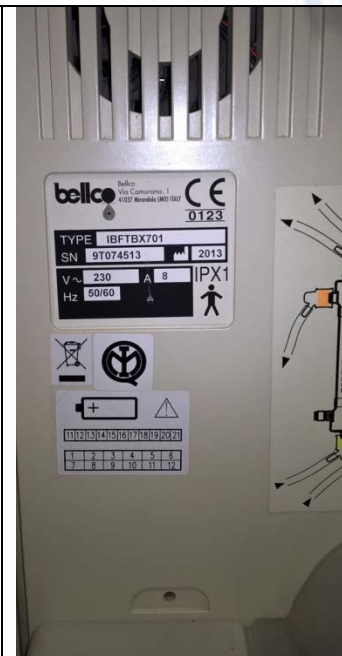
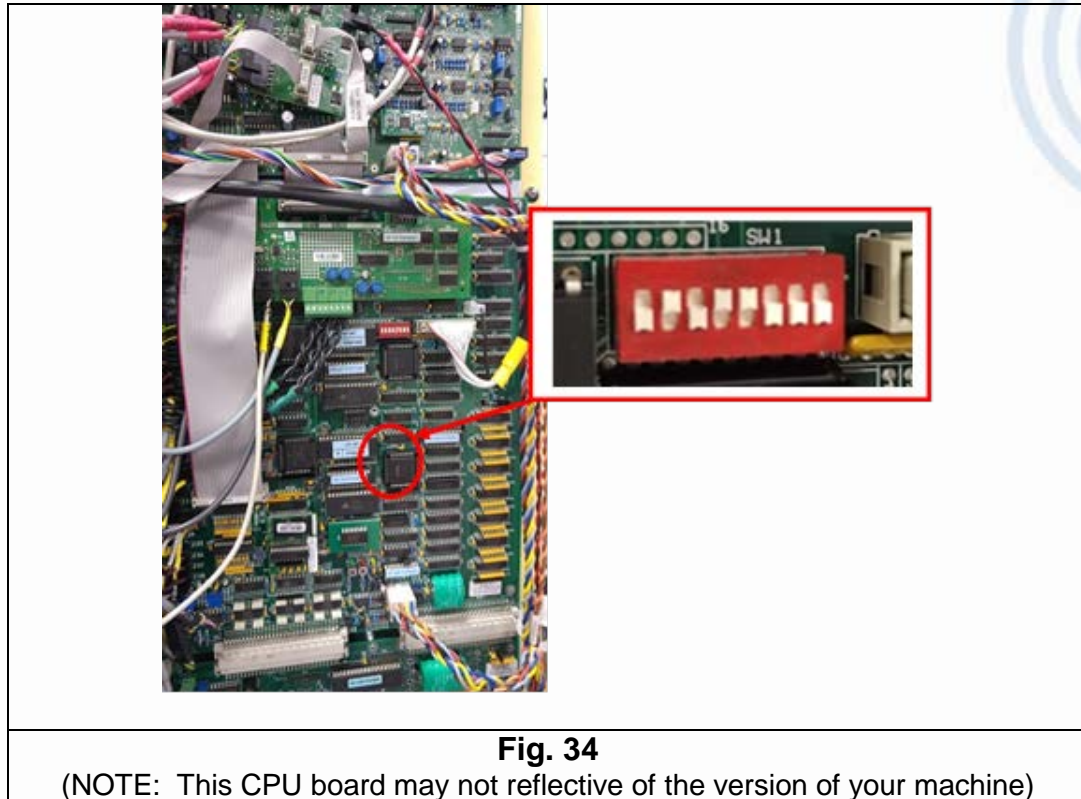


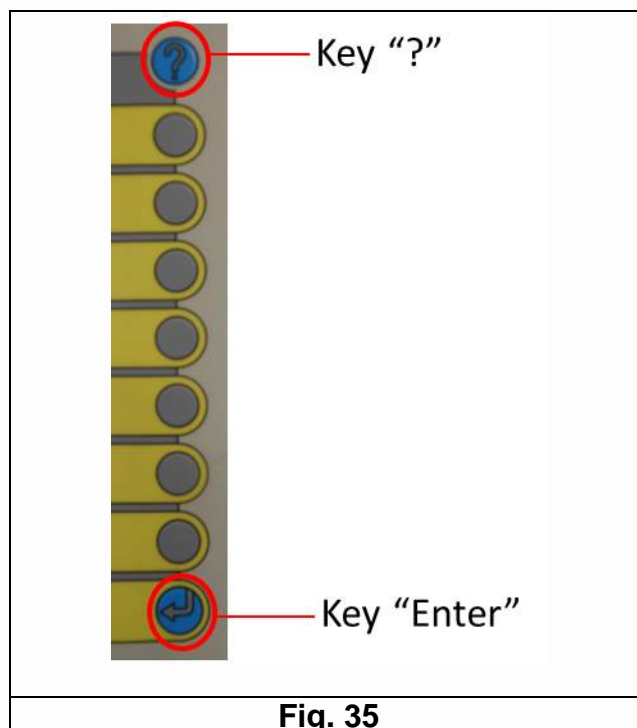
Fig. 33

36. Locate the dip-switch N° 7 on to the CPU board. If it's positioned in lower position, switch it to the upper position. If it's positioned in the upper position, switch it to the lower position (**Fig. 34**).



37. Plug the mains power cable into a working wall outlet
38. Turn on the machine.

39. When the characters “***” appears on the screen, enter the technical configuration mode by using this button combination: “?-Enter” (**Fig. 35**).



40. Using the “**Enter**” button select “**Hardware configuration**”.
41. Modify battery status from **OFF** to **ON** (**Fig. 36 & Fig. 37**).

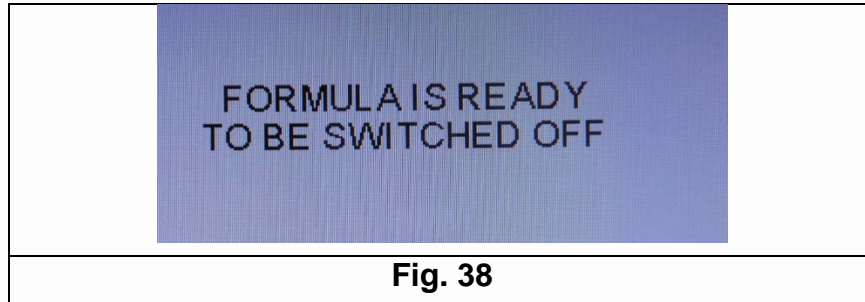
	P	M	X	6
TYPE: IBF	P	M	X	6
SN:	98	16	02	24
CPU (5)		ON	OFF	
HDF kit (3)		OFF	OFF	
Battery (4)		OFF	OFF	
Serial communication		OFF	OFF	
Promies		OFF	OFF	
Disinf. security level		OFF		
Pump volume:P.Cond.(ul)		109	113	
Temperature offset (°C)		0.0	-0.1	
UF null value (g/min)		0.9	0	
Fill. T. bic. cart. perf.(sec)		50		
EV2 Kit		ON	1	

Fig. 36

	P	M	X	6
TYPE: IBF	P	M	X	6
SN:	98	16	02	24
CPU (5)		ON	OFF	
HDF kit (3)		OFF	OFF	
Battery (4)		ON	OFF	
Serial communication		OFF	OFF	
Profiles		OFF	OFF	
Disinf. security level		OFF		
Pump volume:P.Cond.(ul)		109	113	
Temperature offset (°C)		0.0	-0.1	
UF null value (g/min)		0.9	0	
Fill. T. bic. cart. perf.(sec)		50		
EV2 Kit		ON	1	

Fig. 37

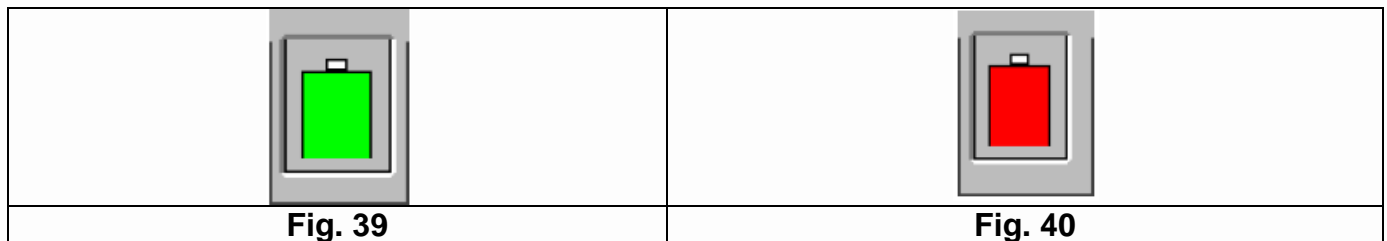
42. Locate the dip-switch N° 4 on to the CPU board. Switch it to the upper position as shown in **Fig. 34 above**.
43. Save the configuration. Wait until “**Formula is ready to be switched off**” message appears on the screen (**Fig. 38**).



44. Switch off the machine.
45. Close the right access door and secure it using a size 4 Allen key.

Test the Machine

46. Turn on machine and wait for the machine to run the electrical self-test.
47. During the electrical self-test, verify the positive completion of the battery test. If installed correctly, a green battery icon will appear (**Fig. 39**). If the battery was not installed correctly, a red battery icon will appear (**Fig. 40**).



48. Wait until the T1 test completion and verify all T1 tests pass.
49. Perform all the electrical safety tests, as defined in the Formula Technical Manual.
50. Complete **Attachment E: Correction Acknowledgement Form** and return it to Bellco/Medtronic according to the instructions on the form.