

Attachment D

CORRECTION INSTRUCTIONS – FOR FORMULA MACHINES WITHOUT BATTERY BACKUP (CHARGE BOARD REMOVAL)

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



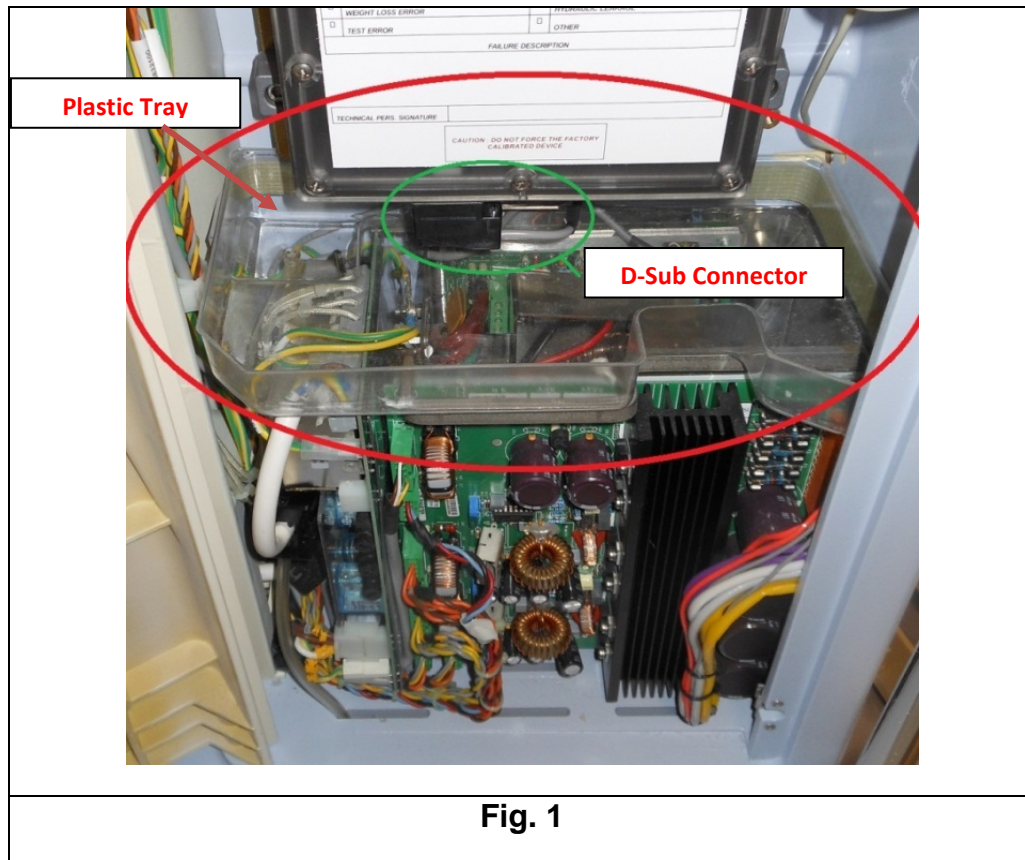
Unplug the mains power cable from the wall outlet



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

Inspect the Machine

1. Using a size 4 Allen key, open the left access door of the machine.
2. Remove the front plastic cover, then remove the plastic tray (red oval in **Fig.1**) covering the Power Supply Unit (PSU). Finally, disconnect the D-Sub connector (green oval in **Fig. 1**) from the bottom of the Differential Flowmeter.



3. Verify the configuration of the Formula machine:
 - A. If the Formula machine was initially configured for battery backup, **STOP** and refer to **Attachment C: Correction Instructions for Formula Machines with Battery Backup**.
 - B. If the Formula machine was initially configured **without** battery backup, continue on with the instructions in this document.

Remove the PSU From the Machine

4. Unscrew PSU mounting screws (**Fig. 2**).

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

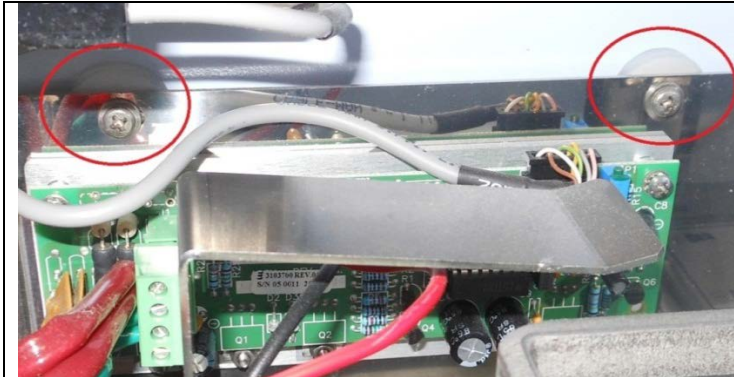


Fig. 2

5. Unplug the following connectors: PS2, PS3, PS4, PS5, PS6, PS7, PS8 and the two ground cables positioned below PS8 (**Fig. 3**).

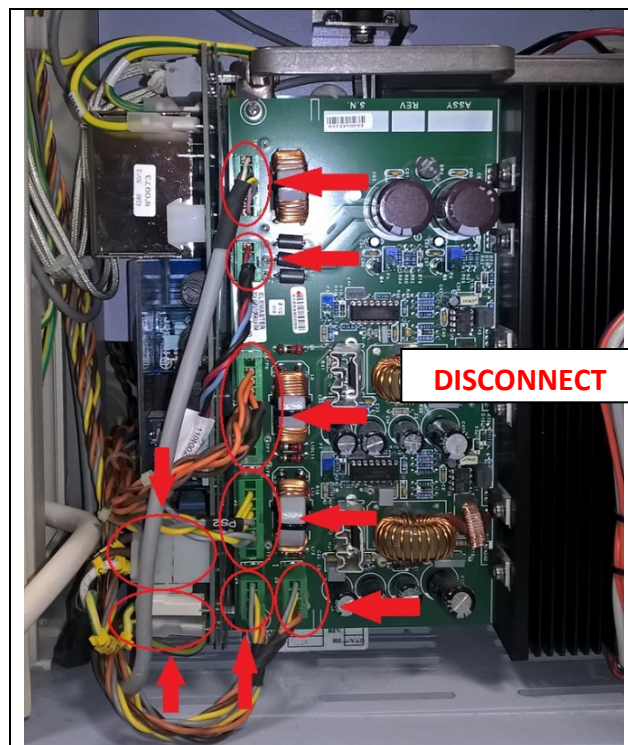


Fig. 3

6. Disconnect power supply cable by pressing on the terminal release levers (Fig. 4 & Fig. 5).

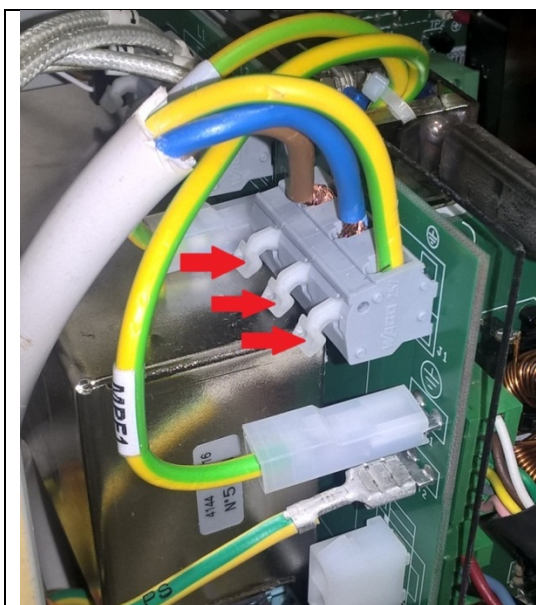


Fig. 4

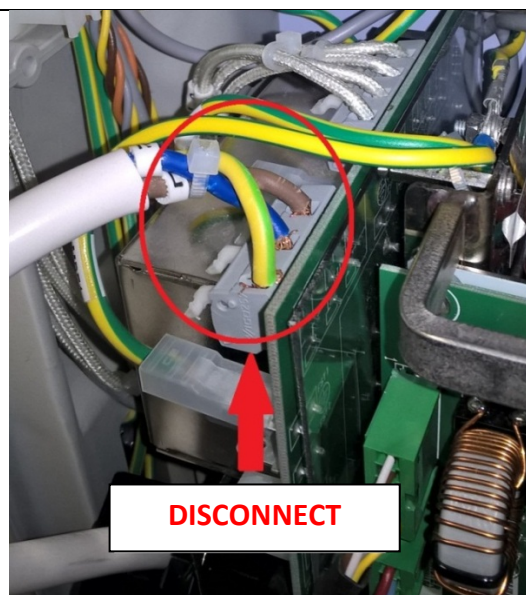


Fig. 5

7. 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. 6**).

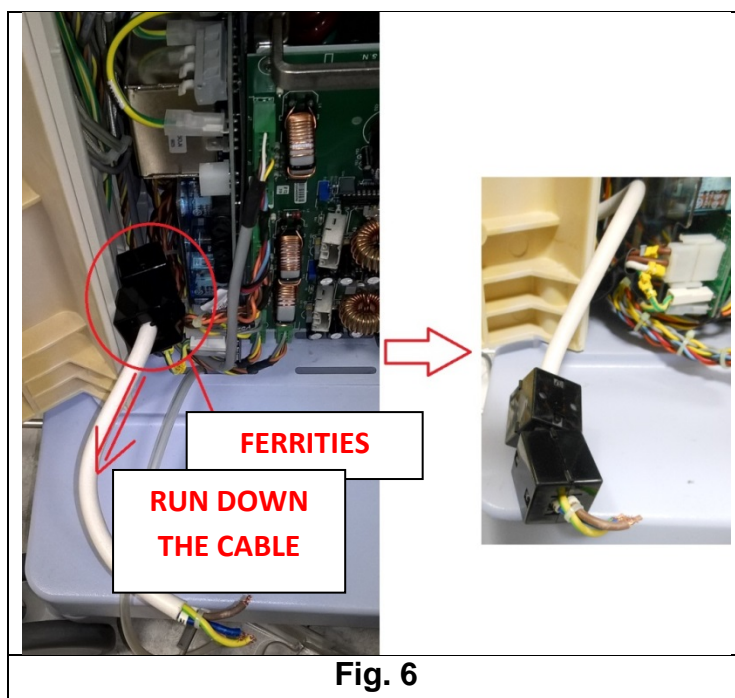


Fig. 6

8. Extract the PSU from the equipment:
- Grab the PSU using the metal handle welded to the box (**Fig. 7**);
 - Lift it up and rotate PSU to the front (**Fig. 8**).

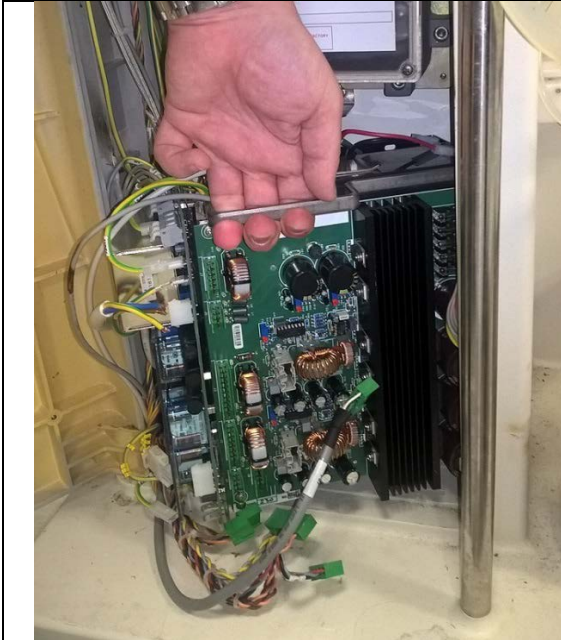


Fig. 7

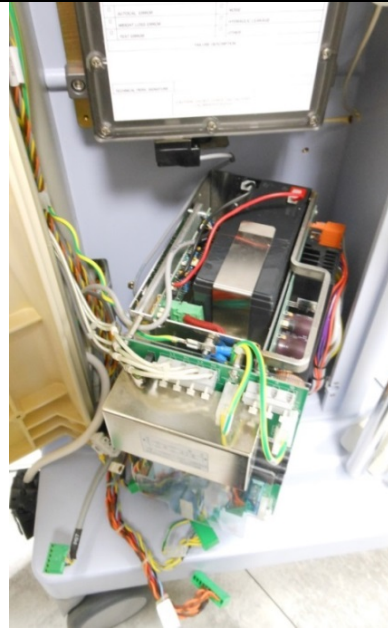


Fig. 8

(NOTE: battery will not be present as displayed in this picture)

Remove the Charge Board From the PSU

9. If not already performed, disconnect J1 and GC2 from charge board (**Fig. 9**).
10. Using a PH1 screwdriver, unscrew charge board mounting screws (located on the back side of the PSU) (**Fig.10**). Remove the charge board, and **discard the charge board according to your facility policies.**

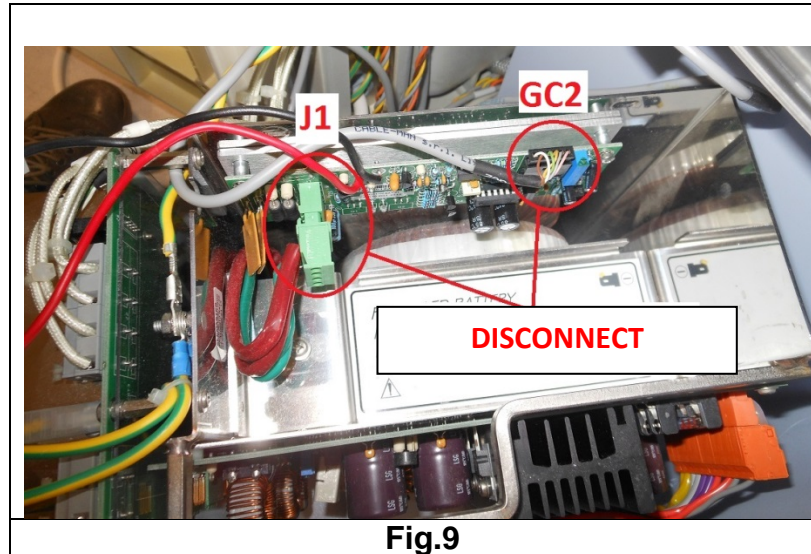


Fig.9

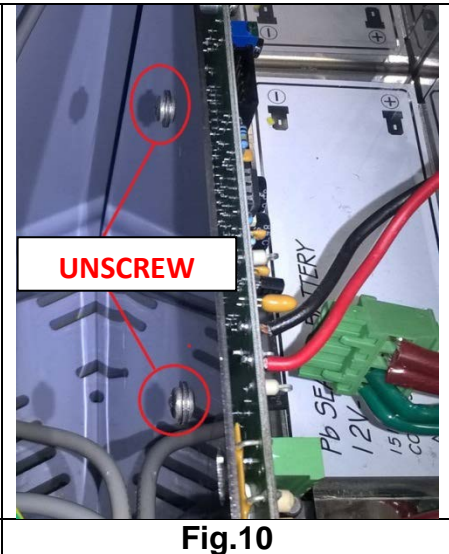


Fig.10

Reinstall the PSU Into the Machine

11. Insert the two (2) M4x12 PSU mounting screws previously removed in Step 4 into their corresponding cutouts on PSU box (**Fig. 11**).



Fig. 11

(NOTE: battery will not be present as displayed in this picture)

12. Place the silicone washers previously removed from the PSU onto the protruding ends of the two installation screws (**Fig. 12**).

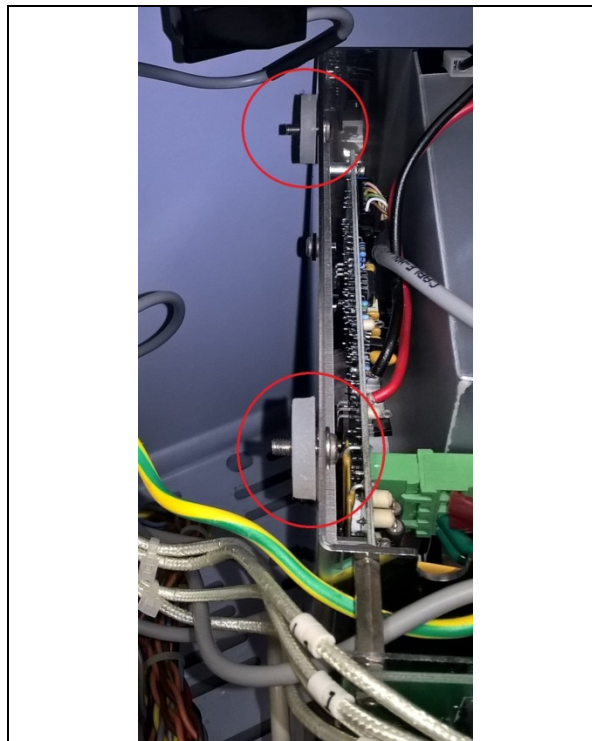


Fig.12

(NOTE: battery will not be present as displayed in this picture)

13. Mount the PSU inside the equipment:

- Grab the PSU using the metal handle welded on the PSU box (**Fig. 13**);
- Lift up the PSU and reinsert it inside the machine (**Fig.13**).

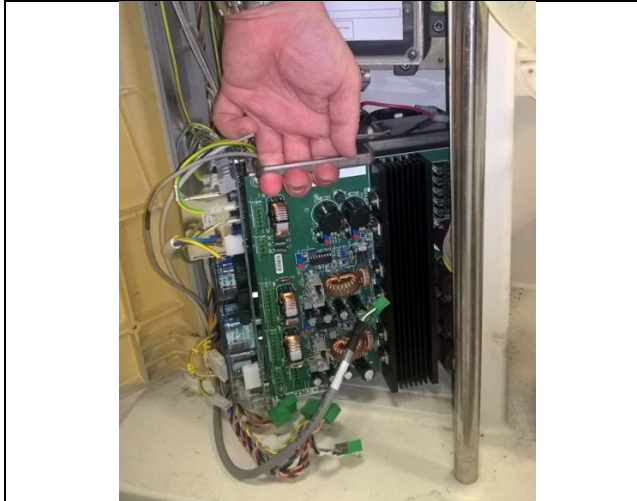


Fig. 13

14. Fix the PSU to the machine chassis using the two (2) M4x12 screws previously placed in Step 11 (**Fig. 14 & Fig. 15**).

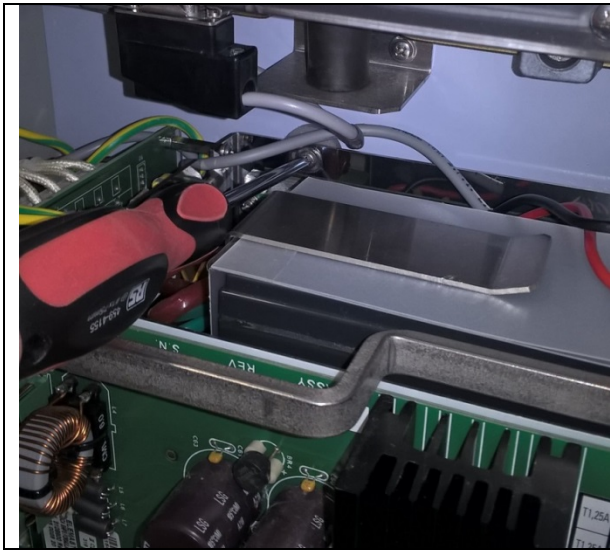
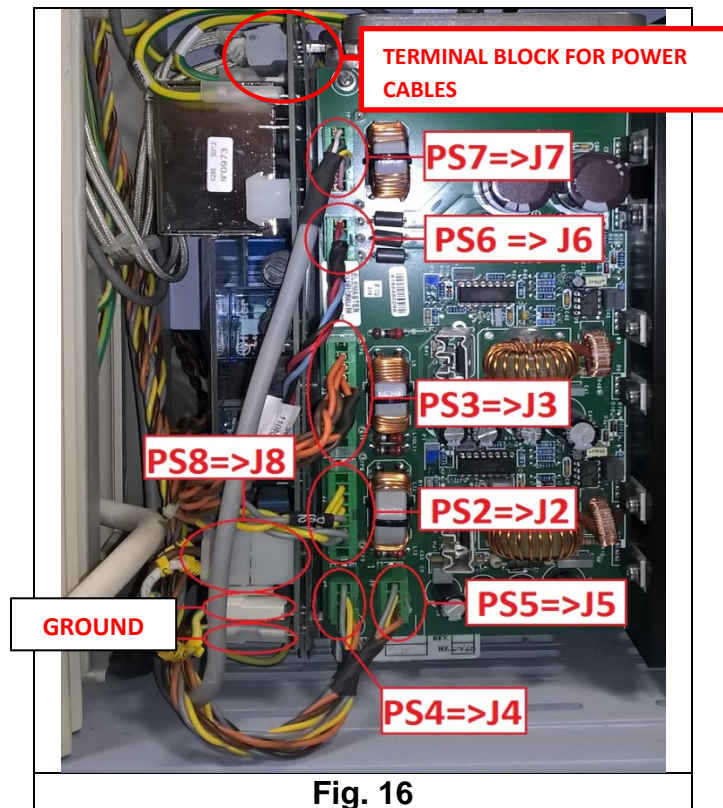


Fig. 14



Fig. 15

15. Connect following connectors: PS2, PS3, PS4, PS5, PS6, PS7, PS8 and the ground cables below PS8 (**Fig. 16**).



16. Insert the power supply cable into the equipment and, if applicable, slide the ferrites back to their original position on the cable (**Fig. 17 & Fig. 18**).

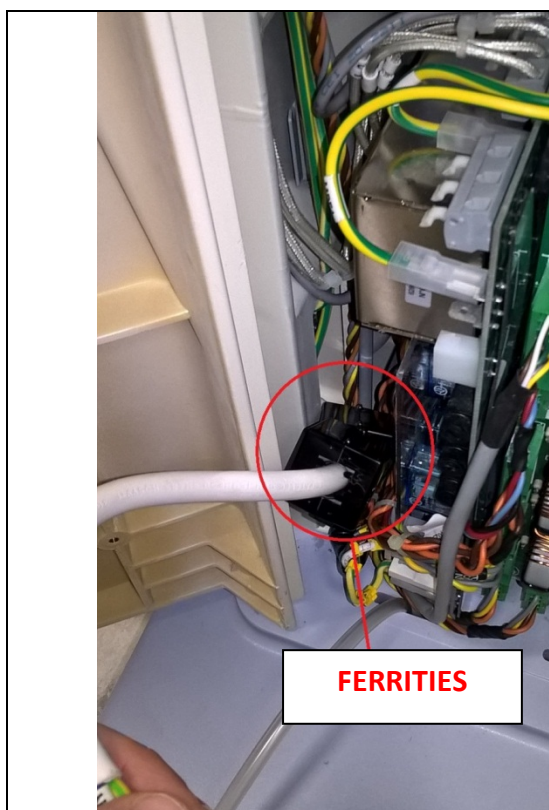


Fig. 17



Fig. 18

17. Connect the three single wires of the power supply cable to the terminal block by depressing the levers and inserting the wires. **(Fig. 19 & Fig. 20)**. 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.

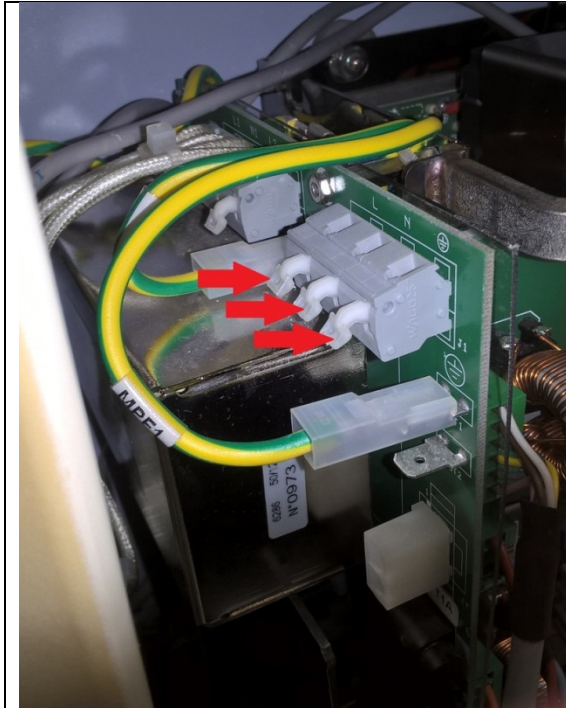


Fig. 19

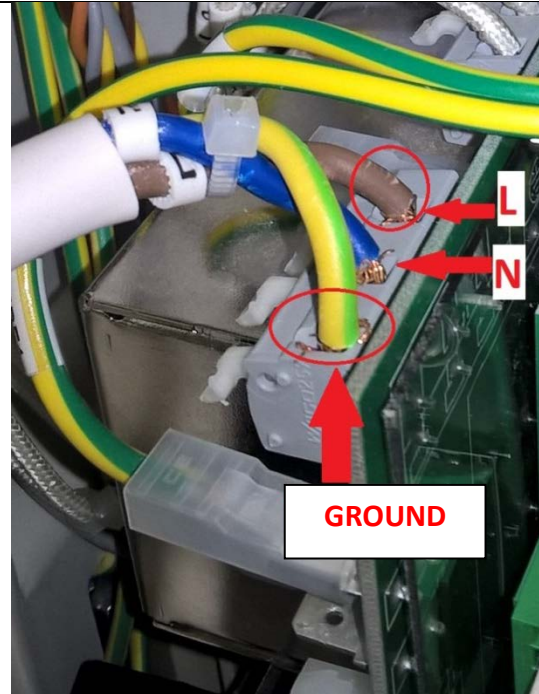


Fig. 20

18. Place the plastic protection tray over the PSU and route the drain pipe to the bottom of the machine (**Fig. 21**).
19. Connect the D-Sub connector to the differential flowmeter (**Fig. 21**).

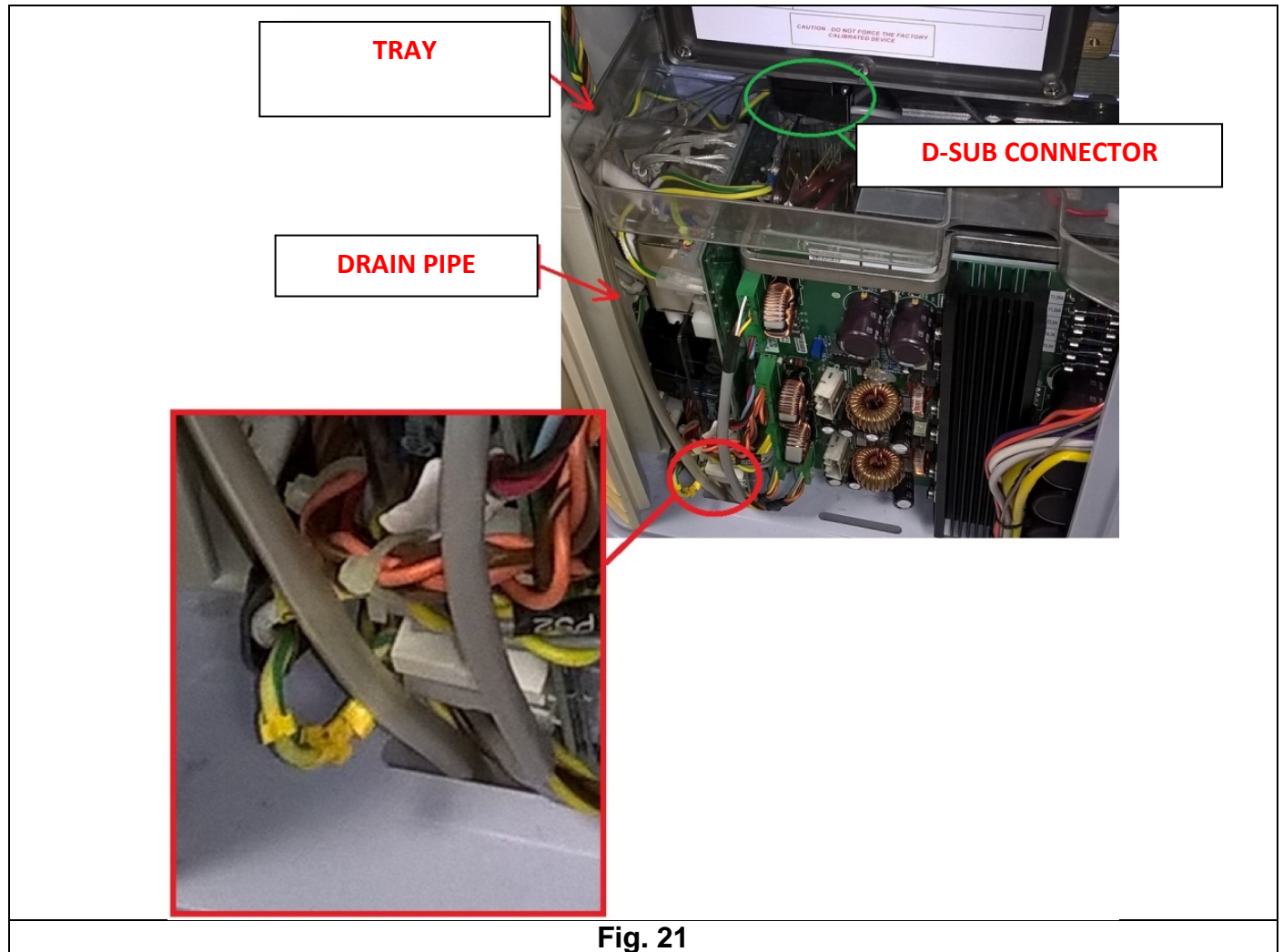


Fig. 21

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

Configure the Machine

22. Using a size 4 Allen key, open the right access door of the machine.
23. If not already disconnected, disconnect connect the cable marked as AN28 from the analogic board (**Fig. 22 & Fig. 23**).

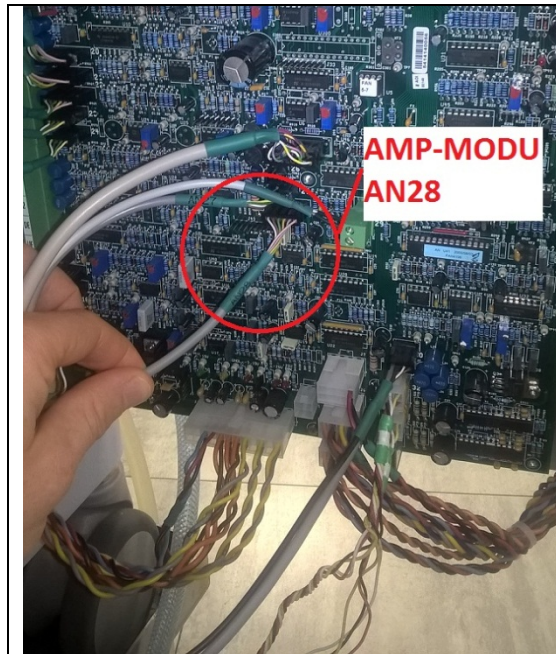


Fig. 22

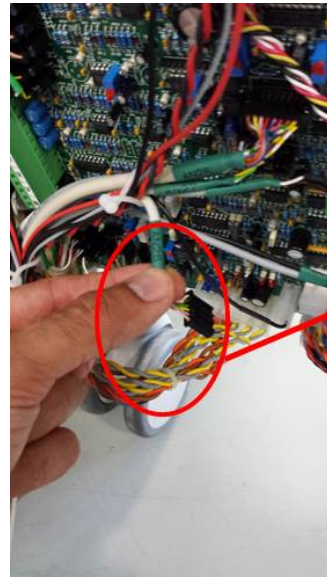


Fig. 23

24. Close the right access door and secure it using a size 4 Allen key.

Test the Machine

25. Plug the mains power cable into a working wall outlet.
26. Turn on machine and wait for the machine to run the self-tests (T1 tests). Verify that all T1 tests pass
27. Perform all the electrical safety tests, as defined in the Formula Technical Manual.
28. Complete **Attachment E: Correction Acknowledgement Form** and return it to Bellco according to the instructions on the form.