

Field Safety Notice Monitor / Defibrillator DEFIGARD Touch7

Description :

The DEFIGARD Touch7 performs periodic self-tests. The frequency of these is weekly (configurable daily by the user). To these tests, the monthly test, performed manually by the operator, is added.

It has been detected that a software error causes a blocking of the device, in Autotest mode, on every 51st test.

Risk:

The device can be blocked during the scheduled maintenance operation. This problem doesn't occur when the device is switched on by the ON / OFF button.

The most important risk is therefore to discharge the battery of the device apart from medical use: blocked in self-test mode, and only if the device is not connected to the mains, its battery reaches the low charge level in 6 hours, then emits the alarm "battery empty" (auditory and visual alarm which lasts for several hours to alert the user).


Affected Devices:

All devices with software version up to "SOFT 4" are affected by this Fields Safety Notice.

Interim Measures:

Waiting the update of your DEFIGARD Touch 7, you can continue to use it without restriction.

If your device is in this blocking situation, you have to switch off by pressing and holding the Start /

Stop button: . It remains completely functional again.

Waiting for a new software version, resetting the maintenance counter once a month by the procedure described below eliminates the risk of blockage.


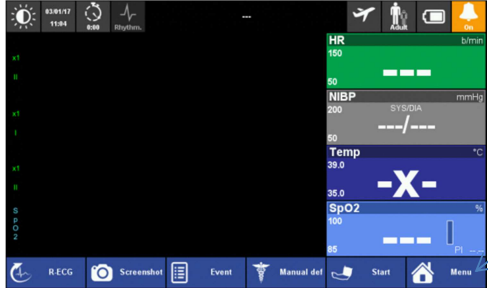
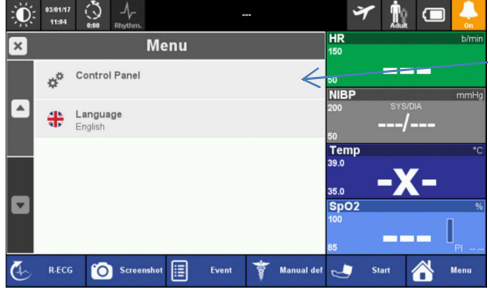
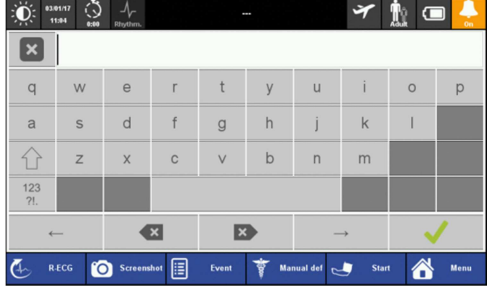
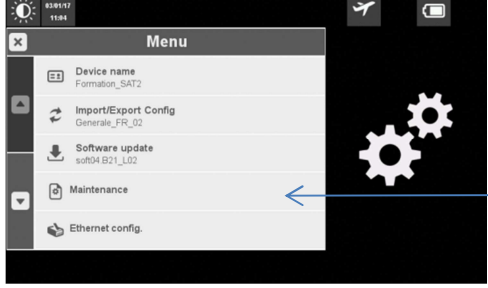
Caution: Be sure to retrieve the interventions in memory before resetting. It is also necessary to pair the printer after resetting.

It is reminded that paragraph 1.4 of the user guide also indicates to have a second battery.

Solution:

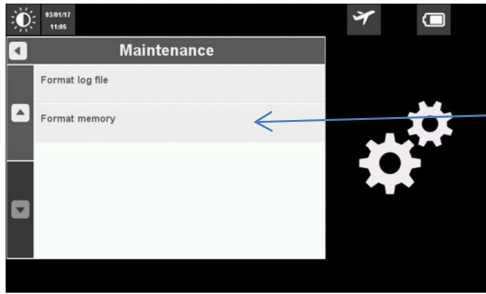
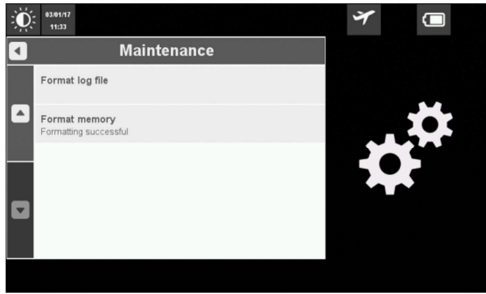

A new software version "Soft 5" will correct this problem. It will be transmitted to you as soon as available.




<p>1. Turn on the device in monitoring mode</p>	<p>Key </p>
<p>2. Go to « Menu »</p>	
<p>3. Then « Control Panel »</p>	
<p>4. Enter the password to confirm the entry in the configuration mode (default password: "schiller")</p>	
<p>5. Go to « Maintenance »</p>	



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<p>6. Then « Format memory »</p>	
<p>7. Wait for "Formatting Successful" on the display</p>	
<p>8. Switch off the device.</p>	<p>Key </p>

Wissembourg, January 20, 2017



Alain Weissinger
Quality Manager



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