Physio-Control—LIFEPAK 20 Defibrillator/Monitors: May Misrepresent Critical Failures as Incomplete Self-Test

**Product Identifier:** LIFEPAK 20 Defibrillator/Monitors [Capital Equipment]
**Manufacturer:** Physio Control Inc Div Metronic Inc [452575], 11811 Willows Rd NE, Redmond, WA 98052, United States

**Summary:** ECRI Institute is concerned that the Physio-Control LIFEPAK 20 defibrillator/monitor’s display of “Self-test did not complete” does not adequately alert users that the device may be inoperative. Users need to be aware that the message may indicate a more serious problem and must be trained on how to respond to the message when encountered during routine inspection and during emergency use. In addition, users should configure their LIFEPAK 20 units to print self-test results to provide a permanent indicator if a problem occurs.

**Problem:** ECRI Institute has recently become aware of an incident in which a LIFEPAK 20 defibrillator/monitor was found to be inoperative, yet failed to provide any audible or visual messages indicating that the device was not working. The unit would not monitor an electrocardiogram, deliver a shock in either the automated external defibrillator or manual mode, or deliver pacing pulses. The only notification of any kind found by clinicians was a “Self-test did not complete/Connect to test plug” message on the printout from the unit’s most recent automated self-test. Based on the details of this incident and our research, we determined that upon detecting certain critical failures that render the device inoperative, the LIFEPAK 20 defibrillator/monitor may issue this seemingly innocuous message instead of a more appropriate alert.

Our concern is that this message may result in an inoperative unit going undiscovered; with a more appropriate warning, the unit could be identified and the condition resolved (or an alternative unit put in place). In the event of an emergency, clinicians might attempt to use the device despite seeing the message, not realizing that the device may not function at all. In such scenarios, life-sustaining therapy could be delayed—with potentially fatal results—while clinicians attempt to locate a new defibrillator/monitor.

**BACKGROUND**

Each day, the LIFEPAK 20 defibrillator/monitor performs an automated self-test (Physio-Control refers to it as an auto test) that checks the defibrillator and pacer circuitry and the defibrillator component of the therapy cables. The product instructions specify that the self-test can take the place of a manual daily charging and discharging protocol. Thus, instead of manually testing the device every day, users often configure the device to print out the results of the self-tests so that they can quickly determine whether the device is operating properly.

Generally, if the self-test detects a critical failure, the unit will print a “Self-test failed” message, illuminate the service light-emitting diode (LED), and display a prominent message on the screen, making it easy for clinicians to tell that the device is inoperative and should not be used. However, in certain circumstances, the unit will generate a “Self-test did not complete/Connect to test plug” message, which will appear on the test strip printout and will be briefly displayed on the screen. The supplier states that this message could occur if the therapy cable is not properly seated, which is a relatively minor problem that can be quickly and easily resolved. But it could also happen if there is a problem with the cable or with the defibrillator, either of which could be serious enough to prevent the unit from performing properly.

Other than on the test strip printout, the LIFEPAK 20 defibrillator/monitor does not generate any kind of permanent message to alert clinicians to the problem. The supplier states that when the “Self-test did not complete” message occurs, the device is not ready for use, and users must perform manual verification tests to determine whether there is a problem with the therapy cable or the defibrillator.

**DISCUSSION**

The LIFEPAK 20 defibrillator/monitor’s “Self-test did not complete” message may...
misrepresent the seriousness of the underlying problem. If the message was triggered by problems with the defibrillator or cable, the device may be unable to function—a fact that is not conveyed by the relatively benign tone of the message. We agree with the supplier’s instruction that clinicians should manually check the unit upon discovering an incomplete self-test; this is an easy step to take during daily shift checks and other nonurgent times. However, in an emergency, quick action is critical. For this reason, a clinician may, thinking that the device is functional, decide to skip the manual testing step and attempt to use the unit on a patient.

Exacerbating the problem is the fact that some units may not be set up to print the results of self-tests, in which case there would be no permanent indicator that the self-test was not completed and, consequently, that a manual test of the device is required. Unless clinicians are near the device to see the briefly displayed message at the time the device detects the problem, they would not receive any indication of the potential problem or the need to manually check the device.

The company states that it is evaluating whether current user messages and labeling adequately convey inspection and testing requirements; however, it made no indication that a design change is imminent.

CONCLUSIONS

Generally, most medical device self-tests improve patient safety; they help ensure that the device and its components are in working order. A self-test should reliably alert users—with obvious audible and visual indicators—when it detects a component failure that is significant enough to impair functionality of the device, and it should unambiguously convey the nature and seriousness of the problem. Self-tests that fail to properly indicate critical device failures—such as the LIFEPAK 20 defibrillator/monitor’s self-test—may leave users with a false sense of confidence, placing patients at greater risk.

ECRI Institute Recommendations:

1. Alert the code team, nursing staff, and biomedical engineers to the problem and this report.
2. Verify that all LIFEPAK 20 units are configured to print out self-test results. Otherwise, there is no lasting indication to inform users when the self-test does not complete and a manual check is needed.
3. During daily shift checks, if a LIFEPAK 20 defibrillator/monitor prints the “Self-test did not complete” message, verify that the therapy cable is securely connected, and perform the manual check according to the operator’s instructions. If it does not clearly pass manual verification, remove the unit from service and arrange for repair and interim replacement if needed.
4. If the LIFEPAK 20 defibrillator/monitor is required for immediate use on a patient but (a) there is an indication that the self-test was not completed (the unit has printed or displayed “Self-test did not complete” and/or “Connect to test plug”) and (b) there is no replacement unit readily available, immediately send for a backup unit, check that the cable connector on the suspect unit is completely inserted, and use the suspect device. If it does not deliver the anticipated therapy, attend to the patient according to your hospital protocols until the backup unit arrives.

Source:


Comment:

- This Hazard Report has been adapted for inclusion in Health Devices Alerts. The original version of the article is available in the May 2009 issue of Health Devices.