Urgent Safety Communication

Urgent Field Safety Notice of LIFEPAK 20e Defibrillator Manufactured by Physio-Control

Device/ Product Name:	LIFEPAK 20e Defibrillator/Monitors
Lot numbers/Serials:	Units manufactured between September 2016 and June 2017 **(See Serial Number below)**
Manufacturer:	Physio-Control Inc.
Problem:	Saudi FDA would like to bring to your attention that Physio-Control states that it has received reports of the above devices exhibiting power-related failures as the user prepared the device for initial deployment or during use within the first year of distribution. The failures may include unexpected power on and power off, device lockup, or failure to power on or off. Any of these failures could result in a failure to deliver therapy to the patient and serious injury or death.
Recommendation/Actions:	• Identify any affected product in your inventory. • If you have affected product, verify that you have received the January 2018 Urgent Medical Device Correction letter and Confirmation Sheet from Physio-Control's authorized representative. • Physio-Control's Authorized representative (mentioned below) will contact your facility to arrange for a device correction that will include replacement of the power PCBA.

Devices/Products photo:	

Authorized Representative Details	**Company name:**	**Al-Jeel Medical & Trading Co. LTD**
	Contact Person:	**Alaa Mohamed**
	Phone:	**+966 11 2168222 Ext:253 , 234**
	Email:	aljeel.sfda@aljeel.com or amohamed@elajougroup.com

For further information, please **see the Urgent FSN from** Physio-Control **(attached below).**

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2412
Fax: +966 (11) 2757245

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely,
NCMDR Team

Affected Devices

- **Units manufactured between September 2016 and June 2017**

45953044, 45953128, 45953198, 45309136, 45310175, 45310178, 45376546, 45378865, 45379055, 45383054, 45383585, 45383685, 45383795, 45384615, 45811059, 45828696, 45407747, 45873973, 45874304, 45874315, 45663358, 45145943, 45596499, 45519440, 45882555, 45889251, 45807259, 45145822, 45886431, 45412677, 45415033, 45871645, 45938750, 45938758, 45941171, 45941173, 45471854, 45757159, 45384818, 45408333, 45408568, 45408664, 45052248, 45052441, 45068218, 45068223, 45158775, 45269624, 45272549, 45272601, 45063297, 45066561, 45457806, 45472449, 45472637, 45476382, 45476970, 45482729, 45482822, 45489434, 45464356, 45597868, 45600646, 45030658, 45110841, 45146038, 45147871, 45147962, 45153397, 45153490, 45153586, 45153726, 45153816, 45154274, 45154282, 45156355, 45158192, 45543239, 45545019, 45552488, 45556804, 45557283, 45557391, 45557871, 45558643, 45558755, 45569831, 45569904, 45570130, 45572265, 45572331, 45572404, 45572517, 45572648, 45572708, 45572844, 45572889, 45572947, 45573094, 45573203, 45573263, 45573363, 45573491, 45573589, 45573653, 45573839, 45573900, 45573978, 45574028, 45574236, 45578498, 45578582, 45578821, 45578925, 45579267, 45579691, 45580114, 45953426, 45953998, 45955706, 45955745, 45955836, 45955947, 45956162, 45956410, 45956619, 45957138, 45599345, 45073473, 45604320, 45623947, 45412794, 45383153, 45431457, 45256519, 45259218, 45259443, 45259531, 45259741, 45485161, 45046372, 45309388, 45320101, 45320107, 45940979, 45941505, 45626102, 45632311, 45045806, 45612388, 45613638, 45277258, 45278004, 45581695, 45581886, 45166942, 45777814, 45245606, 45246748, 45246972, 45247040, 45665463, 45068214, 45270019, 45046189, 45070011, 45073957, 45073961, 45259668, 45544347, 45158240, 45412224, 45073967, 45041441, 45044606, 45044773, 45052333, 45584673, 45882699, 45324663, 45888842, 45167299, 45408201, 45521321, 45882791, 45519274, 45936915, 45622924, 45303933, 45888442, 45777606, 45223952, 45315964, 45846766, 45846811, 45846876, 45848401, 45544037, 45544908, 45545115, 45568865, 45568951, 45569023, 45859768, 45464142, 45881362, 45604532, 45777417, 45777493, 45307555, 45758023, 45070589, 45274469, 45873947, 45874261, 45874277, 45269247, 45485974, 45545559, 45797822, 45438489, 45439902, 45623456, 45662703, 45662816, 45662954, 45663159, 45625621, 45845336, 45845436, 45438475, 45073753, 45391526, 45394728, 45398502, 45398635, 45398905, 45398960, 45399011, 45407996, 45408114, 45599052, 45599171, 45600306, 45665536, 45880907, 45881700, 45881893, 45882127, 45882299, 45883066, 45883191, 45884622, 45045093, 45664714, 45158378, 45937941, 45255763, 45259855, 45268244, 45482383, 45485168, 45490232, 45490441, 45883093, 45883152, 45888410, 45935577, 45483605, 45613637, 45277794, 45485366, 45032948, 45037565, 45039386, 45039546, 45039665, 45039728, 45040051, 45040421, 45040579, 45040639, 45040672, 45073277, 45103284, 45103499, 45103802, 45103959, 45104052, 45104589, 45104688, 45104986, 45260695, 45260812, 45260830, 45260839, 45277250, 45301001, 45301113, 45301195, 45301350, 45307766, 45307993, 45309765, 45310087, 45312841, 45313253, 45313803, 45314254, 45314438, 45314555, 45315733, 45315897, 45319608, 45321276, 45321565, 45321584, 45321712, 45321744, 45321816, 45321899, 45321986, 45322030, 45322097, 45324335, 45324429, 45329939, 45367949, 45368097, 45368130, 45368180, 45368545, 45368830, 45368839, 45368867, 45370948, 45370960, 45371496, 45374093, 45374368, 45374449, 45374732, 45375661, 45376138, 45376446, 45377198, 45578401, 45587025, 45593348, 45593364, 45593590, 45597054, 45597176, 45597441, 45597448, 45597453, 45580228, 45580399, 45301317, 45301333, 45301343, 45301359, 45302298, 45302308, 45304069, 45307048, 45307369, 45308861, 45552237, 45597708, 45600015, 45600030, 45603349, 45603391, 45603434, 45603465, 45603585, 45603640, 45603717, 45603808, 45603870, 45603876, 45603900, 45603918, 45604017, 45604075, 45605198, 45605231, 45611072, 45611079, 45611080, 45611155, 45611261, 45611264, 45611419, 45611611, 45611612, 45612385, 45612387, 45612622.

URGENT MEDICAL DEVICE CORRECTION – ACTION REQUIRED
LIFEPAK® 20e Defibrillator/Monitor

ADRES
HQ Europe, Middle East & Africa
Herikerbergweg 110
1101 CM Amsterdam
The Netherlands
www.physio-control.nl

Please bring this letter to the immediate attention of the person(s) responsible for maintaining/monitoring your LIFEPAK® 20e Defibrillator/Monitors.

January 2018

Dear Valued Customer,

Physio-Control is conducting a voluntary Field Correction for specific units of the LIFEPAK 20e Defibrillator/Monitor built between September 2016 and June 2017. This communication is intended to provide critical information regarding the readiness of your device.

The attached Confirmation Sheet includes a list of device serial numbers that our records show are in your possession and are impacted by this Field Correction.

Description of Issue

Physio-Control is aware that some devices have had power-related failures as customers prepared their device for initial deployment or during use within the first year of distribution. The symptoms of these failures may include unexpected power on and power off, device lock-up, or a failure to power on or off, any of which has the potential to result in a failure to deliver therapy to the patient and serious injury or death.

These failures are the result of manufacturing process residue located beneath a component mounted on the Power printed circuit board assembly (PCBA).

There have been no adverse events reported as a result of this issue.

Physio-Control's Planned Actions

Physio-Control will contact customers with LIFEPAK 20e devices who are potentially affected to arrange for a device correction. This correction will include the replacement of the Power PCBA.

Required Customer Actions

1. Please forward this letter to all of your sites, trainers, and users that have an affected LIFEPAK 20e device(s) as identified on the attached Confirmation Sheet.
2. Promptly return the completed Confirmation Sheet to Physio-Control.
3. Follow the recommended daily Operator's Checklist steps in accordance with LIFEPAK 20e defibrillator/monitor Operating Instructions – Section 7 – Maintaining the Equipment. The checklist can be found in Appendix D of the Operating Instructions.
4. If you experience any of the symptoms described above, contact Physio-Control immediately to arrange servicing of your device.

If your LIFEPAK 20e defibrillator/monitor exhibits any power issues that cannot be resolved, then please contact your local Physio-Control distributor.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

Sincerely,

Kathryn E. Janecke

Kathryn Janecke
Senior Director, Quality
Physio-Control, now part of Stryker

LIFEPAK® 20e Defibrillator/Monitor
CONFIRMATION SHEET

By signing below and returning to Physio-Control, you have acknowledged that you have received the notification letter titled "URGENT MEDICAL DEVICE CORRECTION – ACTION REQUIRED, LIFEPAK® 20e Defibrillator/Monitor" and that it has been delivered to sites, trainers and users of the LIFEPAK 20e device at your facility.

Account #: _____ {End User} _____ {Name} _____ {City, State, Zip} _____ Attention: Risk Management	Completed By (Print Name): _____ Signature: _____ Phone #: (_____) _____ Date: _____ Email: _____	Please return completed form: • By fax to: +31 43 808 0003 • By email to: rsEMEAFA278@stryker.com • Or by mail to: Physio-Control Operations Netherlands B.V. Galjoenweg 68 6222 NV Maastricht The Netherlands

Serial Number	Confirmed Possession	Never possessed the device	Device permanently disposed (scrapped) or retired from use	Device cannot be located	Device transferred to another location*	*Please provide the new address and new contact information
{EXAMPLE}	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	
	☐	☐	☐	☐	☐	