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MCDONALD'S CEO OUT AMID DECLINE

C3 • CEO Don Thompson is leaving as company struggles with worst U.S. sales slump in a decade.

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FDA TIGHTENS RULES FOR DEFIBRILLATORS

REUTERS & AP

Defibrillators, such as this one made by Philips, can jolt the heart back to normal in an emergency. AP

The Food and Drug Administration said Wednesday that it is tightening the requirements for approval of emergency defibrillators after thousands of reports of malfunctioning devices.

Once used exclusively in emergency rooms, the defibrillators, also known as AED's, are found in schools, office buildings and other public places. They use electric shocks to jolt the heart back to normal after cardiac arrest or other cardiovascular problems. The FDA says it has received 72,000 reports of defibrillator problems between 2005 and September 2014. Since 2005, manufacturers have issued 111 recalls involving more than 2 million defibrillators.

Under the new rules, companies will need to provide clinical data or other evidence proving the devices, including batteries, adapters and electrodes, are safe and effective in order to be approved or remain on the market. The agency will also inspect their manufacturing facilities before approval.

The rules take effect for new defibrillators July 2016. Accessories already on the market will have until January 2020 to meet the new requirements. Companies who make AEDs include Zoll Medical, Physio-Control and Royal Philips Electronics.

"These changes to the way these devices are reviewed will allow us to more closely monitor how they are designed and manufactured,"said Dr. William Maisel, deputy director for science in the FDA's center for devices and radiological health. Most problems involved the design or manufacture of the device, or inadequate control of components purchased from other suppliers, the FDA said.