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IMPLEMENTATION SCIENCE & OPERATIONS MANAGEMENT

System for Storage, Dispensing, and Tracking Expiration of Electrocardiography Electrodes

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Abstract
Electrocardiography electrodes have expiration dates that are foreshortened once the manufacturer's packaging is opened. A system is described for storing and dispensing these perishable electrodes while tracking their new expiration date for safety and regulatory purposes.

Keywords Electrocardiography · Electrodes · Expiration dating · Regulatory compliance

Introduction

Electrocardiography electrodes are perishable and so are packaged with an expiration date to comply with FDA regulations[1, 2]. Their shelf life is limited by the presence of adhesive and conductive gels that may desiccate over time and eventually fail, resulting in unreliable electrocardiography. To preserve the electrodes until expiration, they are typically packaged in foil-lined packages to retain moisture. However, once the package is opened and the electrodes are exposed to the environment, their shelf life is dramatically reduced (typically to 30 days). Therefore, regulations require that open packages be labeled with the date they were opened so that freshness can be assured, since the expiration date printed by the manufacturer on the packaging no longer applies once opened. Non-compliance with such labeling can lead to citations by inspectors.

Healthcare providers are faced with a choice of either stocking bulk-packaged electrodes or individually-wrapped electrodes. The former are easier to handle, are half the cost, and generate a fifth of the packaging waste, but they put the facility at risk for non-compliance if staff fail to write the opening date on the package, or a loose electrode is found without any packaging. The latter take more time to open when needed, are twice as expensive, and generate five times the packaging waste, but improve compliance. Multipacks of different quantities are available, but any more than one per package creates a chance of leftovers without an expiration date recorded - a serious violation.

The device described herein provides a solution to this problem, allowing purchase/usage of bulk-packaged electrodes while tracking their expiration date after opening for safety and regulatory purposes.

Design & Function

The device consists of a transparent bin, or gravity-fed hopper with dispensing lever, with a lid (Fig. 1). It has a microcontroller (Arduino Nano Every for the prototype) with digital and analog I/O, internal clock, and EEPROM, all powered by a USB (5 V) power cable. An OLED display and piezoelectric buzzer are connected to the microcontroller output. An infrared photodiode emitter/receiver array (either direct or reflective) are positioned at the bottom of the bin/hopper and connected to the microcontroller input. The system could be secured table-top, wall-mounted, or integrated into a supply cart. A video demonstration of the bin version of the system can be seen in Electronic Supplementary Material.

Bulk electrodes are added to the bin/hopper from their original, sealed packaging. Once the infrared sensor beams are interrupted by electrodes inside the bin/hopper, a countdown timer of preset duration begins to cycle and is

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Fig. 1 Devices for Storage, Dispensing, and Shelf-Life Tracking of Electrocardiography Electrodes

displayed. Electrodes can be removed from the box or dispensed from the hopper as needed. The countdown continues as long as there are electrodes in the bin/hopper, and the remaining time until expiration is displayed.

Once the countdown is complete, an expiration warning message is displayed and an audible alert is periodically sounded so that the staff will know to discard the remaining electrodes. Completely emptying the bin/hopper will restore the infrared beams and reset the countdown.

Adding electrodes to a partially-filled bin/hopper will not reset the countdown; therefore, the entire supply will expire simultaneously at the expiration time of the electrodes placed earliest, even though some electrodes may have been placed more recently and are not actually expired. Although this may result in premature discard and waste of some inventory, it ensures that no expired electrodes are dispensed without warning, and freshness can be ensured.

Unopened electrode packages could be stored nearby for practitioners to immediately refill an unexpectedly empty bin themselves. Support staff could also top-up the bin between cases or overnight, avoiding overstocking (and premature expiration as above) by determining par levels consistent with predicted volume of use. Although this initial design does not include wireless connectivity, such functionality could be added in future revisions for remote monitoring or automated electronic messaging if needed for real-time inventory control, provided wireless security is ensured.

Restoration of electricity after an interruption of power will result in continuation of the countdown from its last known state (stored in the EEPROM), and indication of a fault to alert users of potentially compromised timing accuracy. Battery backup could be considered in future revisions.

Conclusions

A system was described for storing and dispensing perishable, bulk-packaged electrocardiography electrodes while tracking their expiration date for safety and regulatory purposes. The system may help increase compliance, improve safety, reduce cost, decrease waste, and add convenience.

Supplementary information The online version contains supplementary material available at https://doi.org/10.1007/s10916-022-01818-y.

Declarations

Conflicts of Interest None.

Ethical approval This article does not contain any studies with human participants or animals performed by the author.

References

1. United States Food and Drug Administration. Labeling - Regulatory Requirements for Medical Devices. https://www.fda.gov/media/74034/download (Accessed Jan 2022)
2. United States Food and Drug Administration. Electrocardiograph Electrodes - Class II Special Controls Guidance for Industry and Food and Drug Administration Staff. https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/electrocardiograph-electrodes-class-ii-special-controls-guidance-industry-and-food-and-drug (Accessed Jan 2022)