Patient Monitor Defibrillator Proposal

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Overview

Patient monitor defibrillators provide the functions of both a patient monitor and a defibrillator in a single medical device. Patient monitor functions include monitoring electrocardiogram waveforms, heart rate, blood pressure, and oxygen saturation. The interface of the device displays the patient monitor values. Defibrillator functions include detecting arrhythmias and cardiac arrest, and sending electrical shocks to the heart to restore a normal heart rhythm. Combining the functionality of patient monitors and defibrillators into a singular device is enormously helpful in emergency medical situations, such as in hospital emergency rooms, ambulance vehicles, and intensive care units because medical personnel are able to quickly and efficiently monitor and intervene during cardiac emergencies. However, numerous problem reports are received each year by the Emergency Care Research Institute (ECRI) and Food and Drug Administration (FDA) about user errors, display issues, and device failures associated with the devices.[1] Due to the life-saving potential of patient monitor defibrillator devices in emergency medical settings, it is necessary to identify and address key issues to improve the safety, efficiency, and usability of these devices.

User Needs

Defibrillation Functionality

1. Include both pads and paddles for defibrillation
2. Provide adjustable energy settings for defibrillation
3. Provide continuous monitoring of ECG, heart rate and rhythm
4. Include option for synchronized cardioversion
5. Ensure accurate detection of shockable rhythms
6. Offer rapid charging and energy delivery for faster defibrillation

Monitoring Capability

7. Provide continuous monitoring of ECG, heart rate, and heart rhythm
8. Monitor oxygen saturation levels (SpO2)
9. Monitor end-tidal CO2 levels
10. Display arterial blood pressure waveforms (ABP)

Notifications & Alerts

11. Incorporate audible and visual indicators for critical events
12. Allow users to customize alert settings for various situations
13. Provide alerts for low battery percentage
14. Provide alerts for software updates or detected bugs
15. Provide alerts for device malfunction of calibration issues
16. Alert users when electrode or pad detachment occurs during monitoring

[1] (PubMed, 1993)

Interface Design

17. Provide intuitive touchscreen interface for easy operation
18. Include main navigation menu for frequently accessed functions
19. Allow users to customize display layouts based on individual preferences
20. Ensure legible fonts and text size
21. Incorporate backlighting to increase legibility in dark environments
22. Include easily recognizable symbols and icons
23. Allow customization for device settings

Physical Design

24. Design a compact and lightweight device for easy transport
25. Design device to be easily cleanable
26. Include handles or straps to be easily transportable
27. Incorporate shock-resistant materials to withstand accidental drops or sudden movement
28. Design device to minimize noise and vibration while in use
29. Design electrode pads to be comfortable and hypoallergenic
30. Design ergonomic controls and supports for the physical buttons

Data Integration & Management

31. Record and store patient data
32. Allow connectivity for data transfer to electronic medical records (EMR) and health information systems (HIS)
33. Allow trend analysis to analyze vital signs over time
34. Allow remote monitoring and data access for medical personnel
35. Ensure data encryption to support patient privacy and security with sensitive medical information

Training

36. Include built-in interactive training modules for operating the device
37. Provide user instructions and documentation in multiple languages and accessibility options
38. Include educational materials on CPR and defibrillation techniques that can be accessed as needed
39. Include online training videos and resources that can be accessed as needed
40. Include simulation modes for testing and practice

Safety Features

41. Include built-in self-testing and self-diagnostics to validate reliability
42. Provide manual override option incase of emergency events
43. Maintain electrical safety compliance with industry standards

44. Design pediatric settings and safeguards intended for children

Top 10 User Needs

1. Provide continuous monitoring of ECG, heart rate and rhythm
2. Incorporate audible and visual indicators for critical events
3. Record and store patient data
4. Provide an intuitive touchscreen interface for easy operation
5. Design a compact and lightweight device for easy transport
6. Include built-in interactive training modules for operating the device
7. Allow customization for device settings
8. Design electrode pads to be comfortable and hypoallergenic
9. Design device to be easily cleanable
10. Design device to minimize noise and vibration while in use

Market Competition

Mindray BeneVision N22

The Mindray BeneVision N22 is a combined monitor/defibrillator usually sold for around $18,000. This device is noted for the modular platform design that allows for customization based on certain clinical needs, multi-parameter monitoring capabilities, and ease of use when integrating into hospital environments during emergency medical settings. The modular platform design enhances flexibility and customization by enabling medical personnel to configure the device based on the needs of the present situation. The Mindray BeneVision 22 also boasts seamless data integration with healthcare information systems (HIS) and emergency medical record (EMR) to effectively manage and document patient information. User reviews positively highlight the intuitive interface of the touchscreen display and the modular design.[2] However, some users report connectivity issues hindering the data integration capabilities.

Physio-Control LIFEPAK 15

The Physio-Control/Stryker LIFEPAK 15 is a combined monitor/defibrillator typically sold for around $18,500. This device has six main operating modes: AED Mode for automated electrocardiogram analysis and prompted treatment for cardiac arrest, Manual Mode for performing manual defibrillation, synchronized cardioversion, noninvasive pacing, electrocardiogram and vital sign monitoring, Archive Mode for accessing stored patient data, Setup Mode for changing default settings of operating functions, Service Mode for authorized users to perform diagnostic tests and calibrations, and Demonstration Mode for simulating waveforms and trend graphs. Additional features include invasive pressure monitoring, pulse oximetry technology, and advanced data review software. User reviews overwhelming highlight the user-friendly interface, with options for customization and color-coded controls to easily

[2] (Kim, 2023)

access certain functions. However, user reviews also mention issues with poor battery life and software bugs.[3]

ZOLL X Series

The ZOLL X series combined monitor/defibrillator is typically sold for around $23,000. This device features extensive monitoring capabilities, defibrillation capabilities, and real-time CPR feedback. Advanced monitoring features include capnography, pulse oximetry, invasive pressures, temperature channels, non-invasive blood pressure, and 12-lead capabilities.[4] The touchscreen display includes customizable layouts and quick-access buttons, along with built-in checklists and automated prompts to guide new users through operational protocols. User reviews positively mention how the lightweight design of the device (weighing 11.7 pounds) makes it very portable, along with the availability of both hands-free pads and external paddles for adult and pediatric use. Additional reviews highlight the improved safety features, such as integrated monitoring for continuous patient assessment during an emergency situation and utilizing rectilinear biphasic waveform technology to ensure effective defibrillation of the device.[5]However, some users report technical issues with connectivity in addition to expressing frustration with the complexity of the touchscreen display having an overwhelming amount of advanced features and customization options to navigate through.

Interviews

Interview Participant #1

The first interview participant is a 25 year old male who works as a paramedic in Thousand Oaks, CA for American Medical Response (AMR). AMR is a private ambulance company that provides emergency medical services, managed and non-emergency transportation and air ambulance services and disaster response services. The participant has worked as a paramedic for 2 years and 4 months.

Interview Participant #2

The second interview participant is a 22 year old female who works as a paramedic in Thousand Oaks, CA for AMR. The participant has worked as a paramedic for 1 year and 8 months.

Interview Participant #3

The third interview participant is a 26 year old male who works as a paramedic in Boston, MA for Cataldo Ambulance Service. Cataldo Ambulance Service is a private emergency medical services company that provides 911 and interfacility transportation ambulance services to the Greater Boston and North Shore areas of Massachusetts. The participant has worked as a paramedic for 7 years.

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[3] (AED Professionals, 2024)
[4] (ZOLL Medical Corporation, 2024)
[5] (Schumann, 2024)

References

Defibrillator/monitor/pacemakers. (1993). PubMed. https://pubmed.ncbi.nlm.nih.gov/8253590/#:~:text=Combined%20defibrillator%2Fmonitors%20enable%20the,fibrillation%20during%20a%20cardiac%20arrest.

Kim, Y., Son, J., & Jang, W. S. (2023). Usability Study on Patient Monitoring Systems: An evaluation of a user interface based on user experience and preference. *Medical Science Monitor*, *29*. https://doi.org/10.12659/msm.938570

Physio-Control/Stryker LIFEPAK 15 Defibrillator | AED Professionals. (2024). AED Professionals. https://aedprofessionals.com/products/physio-control-stryker-lifepak-15-defibrillator

Schumann, S., Schmutz, A., Feger, K., & Spaeth, J. (2024). Comparative usability of manual defibrillators – A human factors study. *Resuscitation Plus*, *17*, 100526. https://doi.org/10.1016/j.resplu.2023.100526

ZOLL Medical Corporation. (2024). https://www.zoll.com/products/defibrillators/x-series-for-hospital