Adverse Events in Medical Devices used in Home Care

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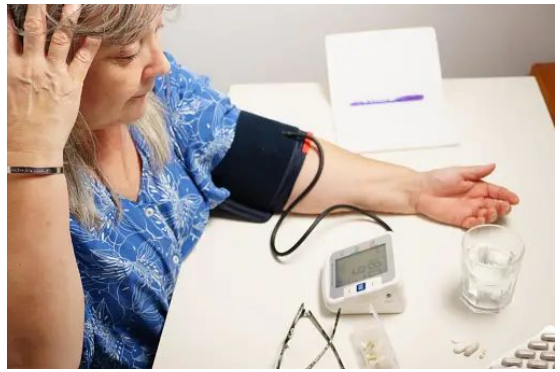
Institute of Biomedical Engineering (IEB-UFSC) - Florianópolis/Brazil

Main areas:

- Clinical Engineering;
- Biomedical Instrumentation;
- Bioengineering;
- Informatics in Health

Medical Devices in Home Care

- Presence of Medical Devices **beyond hospital environments**
- Many users are new using the Health Technologies, **no previous experience**
- Incorrect use can lead to **inappropriate decision-making,** causing **adverse event**
  - *According to WHO, 2023, around "1 in every 10 patients is harmed in health care and more than 3 million deaths occur annually due to unsafe care. In low-to-middle income countries, as many as 4 in 100 people die from unsafe care. Above 50% of harm (1 in every 20 patients) is preventable."*
- Management of adverse events is essential to **patient safety using Medical Devices** such as pacemakers, stents, blood pressure monitors, glucometers, insulin pumps, respirators, nebulizers, thermometers, oximeters, among others.
- **<u>Clinical Engineering in the Health Technology Management (HTM)</u>**



Executive Brief

ECRI is providing this Executive Brief describing its 2024 Top 10 list of health technology hazards to inform the healthcare community about key safety issues involving the use of medical devices and systems.

The List for 2024

1. Medical Devices May Pose Usability Challenges for Home Users, Risking Misuse and Patient Harm
2. Inadequate or Onerous Device Cleaning Instructions Endanger Patients
3. Sterile Drug Compounding without the Use of Technological Safeguards Increases the Risk of Medication Errors
4. Overlooked Environmental Impacts of Patient Care Endanger Public Health
5. Insufficient Governance of AI Used in Medical Technologies Risks Inappropriate Care Decisions
6. Ransomware Targeting the Healthcare Sector Remains a Critical Threat
7. Increased Burn Risk with Single-Foil Electrosurgical Return Electrodes
8. Infusion Pump Damage Remains a Medication Safety Concern
9. Poor QC of Implantable Orthopedic Products Can Lead to Surgical Delays and Patient Harm
10. Third-Party Web Analytics Software Can Compromise Patient Confidentiality

Executive Brief

ECRI's 2025 Top 10 Health Technology Hazards report identifies potential sources of danger involving the use of medical devices and systems. Further, the report offers practical recommendations for reducing the identified risks, all with the goal of preventing harm. ECRI is providing this Executive Brief version of the report to inform the healthcare community about these key safety issues.

The List for 2025

1. Risks with AI-Enabled Health Technologies
2. Unmet Technology Support Needs for Home Care Patients
3. Vulnerable Technology Vendors and Cybersecurity Threats
4. Substandard or Fraudulent Medical Devices and Supplies
5. Fire Risk in Areas Where Supplemental Oxygen Is in Use
6. Dangerously Low Default Alarm Limits on Anesthesia Units
7. Mishandled Temporary Holds on Medication Orders
8. Infection Risks and Tripping Hazards from Poorly Managed Infusion Lines
9. Skin Injuries from Medical Adhesive Products
10. Incomplete Investigations of Infusion System Incidents

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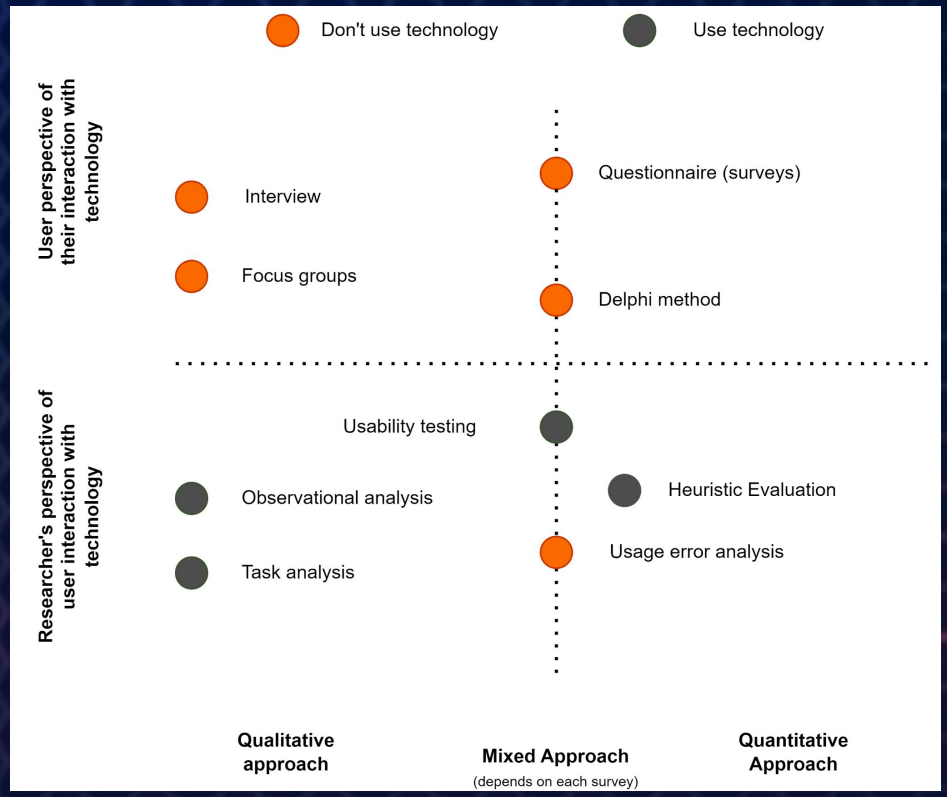
Usability Techniques to identify the main problems involving Medical Devices



Reference: (Brandão, 2024)

FDA U.S. FOOD & DRUG ADMINISTRATION

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Manufacturer and User Facility Device Experience (MAUDE) Database

FDA Home › Medical Devices › Databases

The MAUDE database houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

Learn More

Search Database Help Download Files

Product Problem

Product Class

Event Type | Manufacturer

Model Number | Report Number

Brand Name | Product Code | Summary Report

Exemption Number | UDI-Device Identifier

Date Report Received by FDA *(mm/dd/yyyy)* 02/01/20 to 02/28/20 | PMA/510K Number

Go to Simple Search | 10 Records per Report Page | Clear Form | Search

Other Databases

- 510(k)s
- De Novo
- CDRH Export Certificate Validation (CECV)
- CDRH FOIA Electronic Reading Room
- CFR Title 21
- CLIA
- Device Classification
- FDA Guidance Documents
- Humanitarian Device Exemption
- Medsun Reports
- Premarket Approvals (PMAs)
- Post-Approval Studies
- Postmarket Surveillance Studies
- Radiation-Emitting Products
- Radiation-Emitting Electronic Products Corrective Actions
- Recalls
- Registration & Listing
- Standards
- Total Product Life Cycle
- X-Ray Assembler

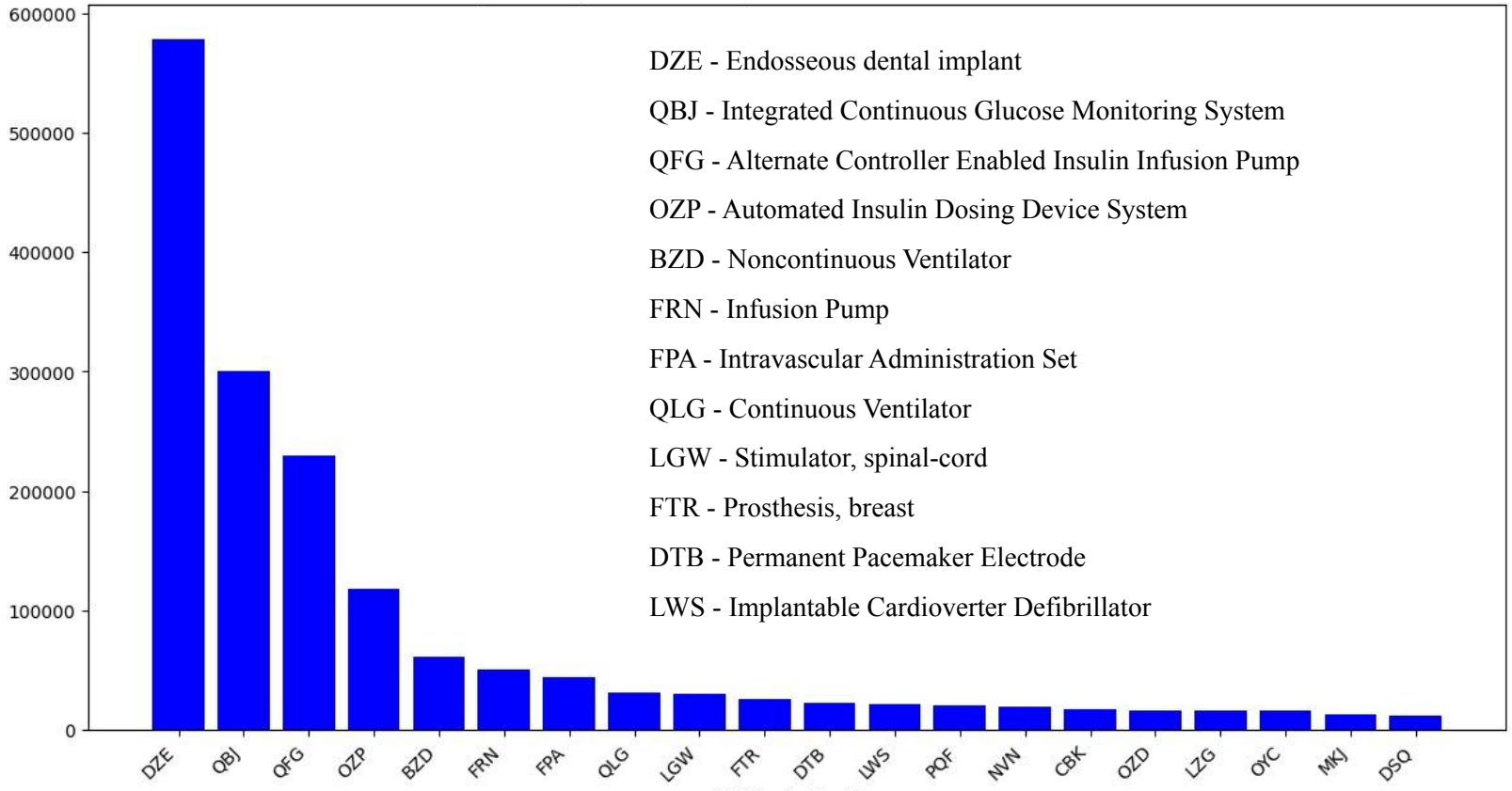
Conducting searches in the MAUDE Database

The Manufacturer and User Facility Device Experience (MAUDE) database is a searchable database of medical device reports (MDRs) of adverse events involving medical devices over the last ten years. Reports older than ten years are provided on the FDA's MDR Data Files webpage.

The MAUDE database:

- Is updated every month to include reports received through the last day of the previous month.
- May not include reports made according to exemptions, variances, or alternative reporting requirements granted under 21 CFR 803.19 prior to June 2019. However, these reports, as well as reports older than ten years, can be found on the MDR Data Files webpage.
- Includes a **simple search** and an **advanced search**.
  - **Simple search** allows the user to search on any terms that appear in an MDR received by the FDA in a selected year.

Top 20 Medical Devices with more notifications in MAUDE/FDA



Agência Nacional de Vigilância Sanitária - Anvisa

O que você procura?

Notificações em Tecnovigilância

Total de Notificações	Evento Adverso	Queixa Técnica	Artigo Médico Hospitalar	Equipamento Médico Hospitalar	Produto para Diagnóstico *in vitro*
220.167	34.959	185.208	196.653	19.667	3.847
	15,88%	84,12%	89,32%	8,93%	1,75%

Total de notificações por ano

Ano	Notificações	%	% Ano a ano
2024	447	0,20%	-97,64%
2023	18.968	8,61%	7,42%
2022	17.657	8,02%	18,60%
2021	14.888	6,76%	0,34%
2020	14.838	6,74%	-19,76%
2019	18.492	8,40%	11,59%
2018	16.571	7,53%	-0,40%
2017	16.637	7,56%	5,66%
2016	15.746	7,15%	-5,06%

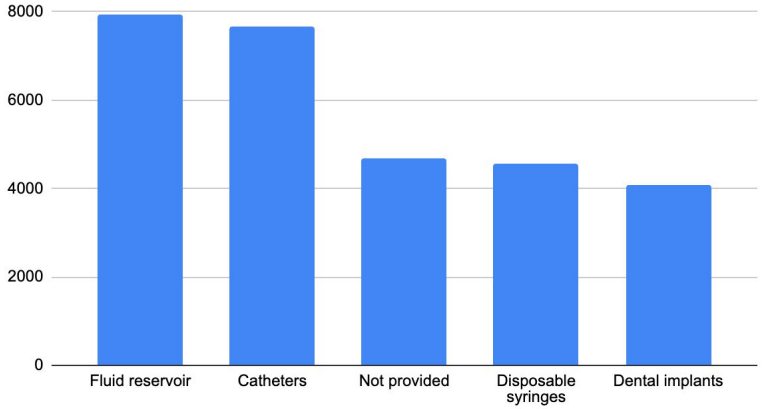
Tipo de notificações

Ano	Evento Adverso	%	Queixa Técnica	%
2024	65	0,19%	382	0,21%
2023	3.359	9,61%	15.609	8,43%
2022	3.454	9,88%	14.203	7,67%
2021	2.556	7,31%	12.332	6,66%
2020	2.580	7,38%	12.258	6,62%
2019	3.277	9,37%	15.215	8,21%
2018	3.795	10,86%	12.776	6,90%
2017	3.119	8,92%	13.518	7,30%
2016	2.383	6,82%	13.363	7,21%

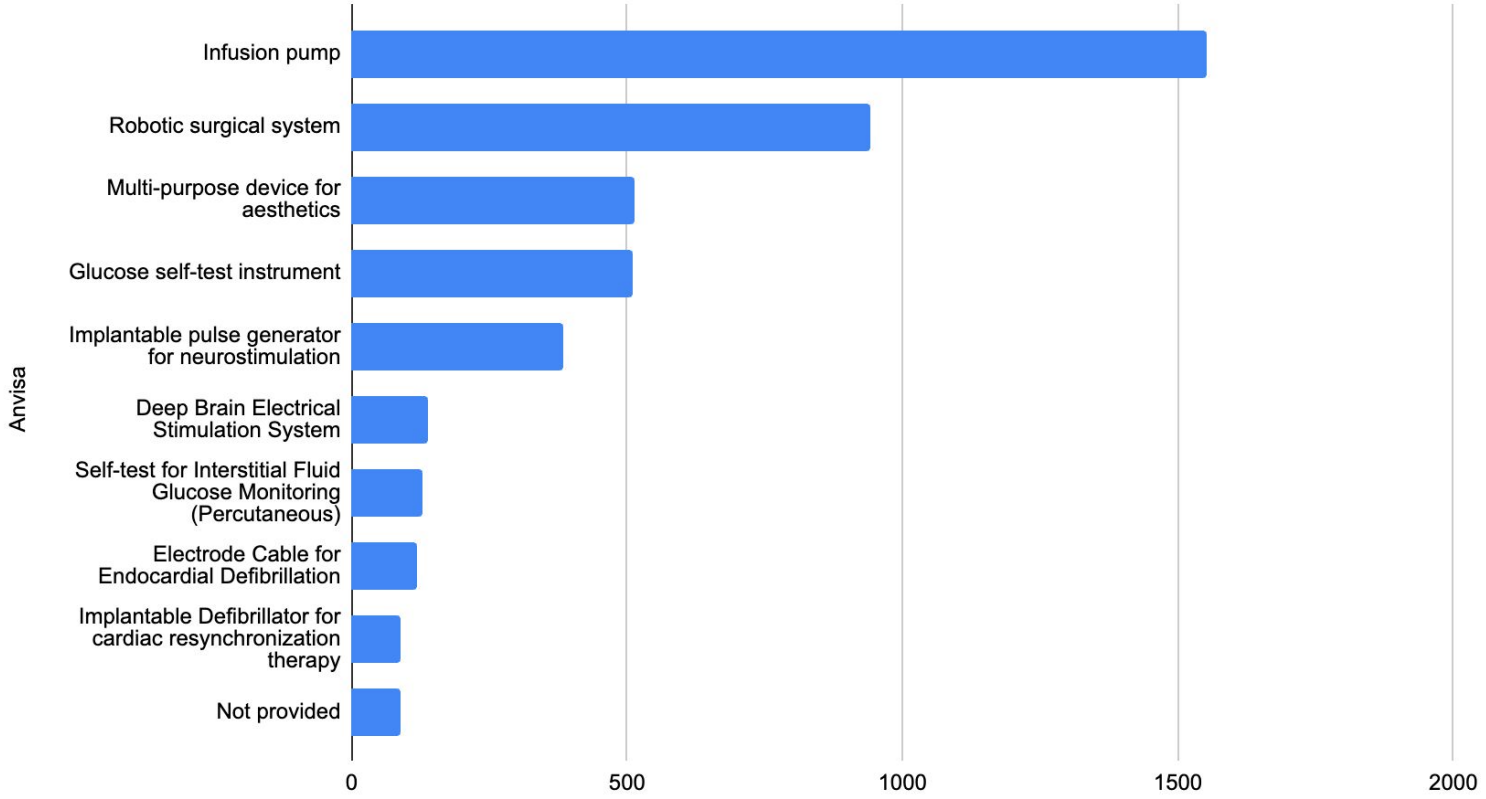
Produto motivo

Ano	Artigo Médico Hospitalar	%	Equipamento Médico Hospitalar	%	Produto para Diagnóstico "in vitro"	%
2024	363	0,18%	77	0,39%	7	0,18%
2023	15.925	8,10%	2.541	12,92%	502	13,05%
2022	14.545	7,40%	2.623	13,34%	489	12,71%
2021	12.606	6,41%	1.878	9,55%	404	10,50%
2020	13.194	6,71%	1.249	6,35%	395	10,27%
2019	16.343	8,31%	1.681	8,55%	468	12,17%
2018	14.751	7,50%	1.617	8,22%	203	5,28%
2017	15.136	7,70%	1.270	6,46%	231	6,00%
2016	14.470	7,36%	1.054	5,36%	222	5,77%

Anvisa Top 5 Notifications in Medical Devices (2019 - 2024)



Anvisa Top 10 - Notifications in Medical Equipment (2019 - 2024)



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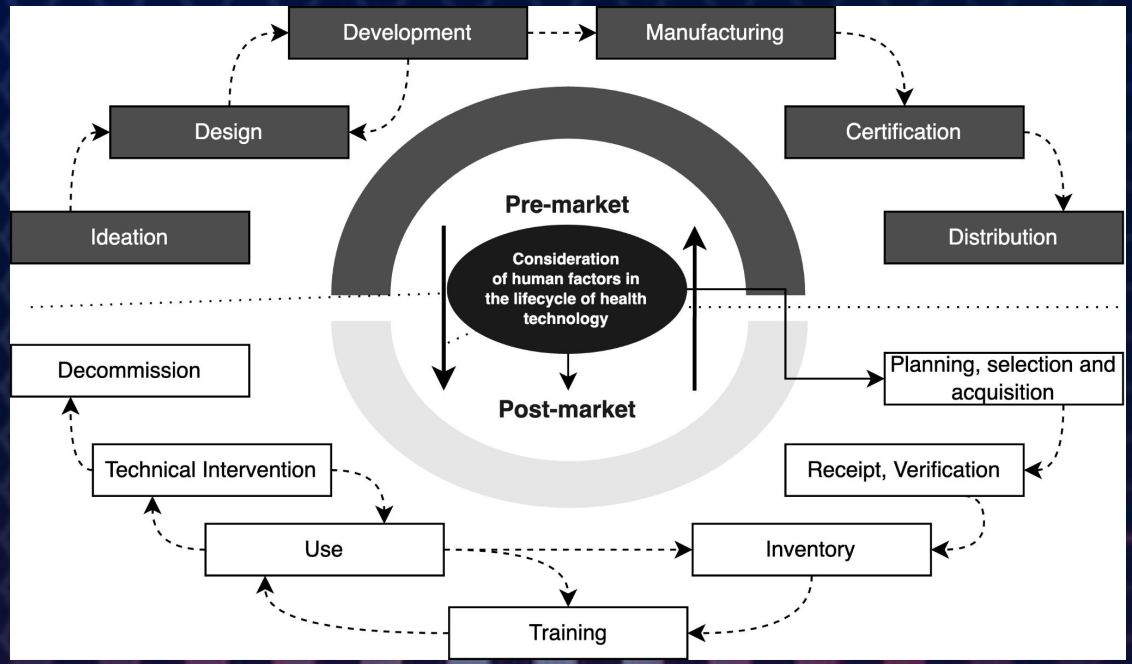
Analyzing Adverse Events associated with medical devices used in home care throughout the life cycle is essential to identify problems and establish strategies to mitigate risks and make healthcare environments safer.



Reference: (Brandão, 2024)

Finals Considerations

Clinical Engineering in Medical Devices used in Home Care:

- **Real-world data (RWD) in Technovigilance**: To identify problems involving Medical Devices
- **Living Lab:** Interaction with differents actors (health professionals, users, university, industry, government)
- **Develop User-centered technologies**
- **Usability and Accessibility:** Considering different users
- **Metrology**: Ensure reliability
- **Subnotification:** Highlights the need to encourage the reporting adverse events to generate evidence
- **Analysing the causes and effects** is a relevant tool for the HTM to create preventive actions.
- **Education / training:** Develop guidance resources to meet different user profiles
- **Connectivity, Cybersecurity and data security**
- **Predictive Management of Health Technology Process in all lifecycle: Ubiquitous scenarios**

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Importance to analyze adverse events in medical devices used in Home care to mitigate risks and improve health safety.

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Thank you!

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