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Compilation About Adverse Events Recorded in FDA/USA and ANVISA/Brazil Databases Through Models Available in the Literature Concerning Analysis and Prioritization of Actions for Medical Devices

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ABSTRACT

The development and application of medical technologies have grown steadily in all health fields, offering numerous benefits to users. However, adverse events, which may cause severe consequences for patients, also have increased. Technical and human factors that provoke dangers are related to the complexity of the devices, quality control in manufacturing, software, maintenance procedures, materials, and mode of use. This work aims to present the main alerts, dangers, and failures and some ways to mitigate them related to the following medical devices: Defibrillators, Infusion Pumps, Physiological Monitors, Pulmonary Ventilators, and Ultrasonic Scalpels. For that, we performed an analysis of adverse events reported in the Food and Drug Administration (FDA/USA) and the Brazilian Health Surveillance Agency (ANVISA) databases since 2016. Finally, we classified the events into different categories, according to their similarity. The results show a total of 3,100 cases registered in the FDA for the six types of medical devices addressed in this work and 75 cases registered in the ANVISA/Brazil for two of them. Based on the top ten health hazards provided by ECRI (2016-2020), this work contributes to understanding the most significant hazards of the previously mentioned devices and the main ways to mitigate these risks. Throughout our research, we found that the risks addressed in this work are common to several medical devices; therefore, there preventative measures to avoid them must be established, for example, training users to use and maintain the equipment, improving their quality, and also reporting adverse events to manufacturers.

Keywords – Adverse Events, ANVISA, ECRI, FDA, Medical Devices, Manufacturing, Training, Maintenance.

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INTRODUCTION

According to the World Health Organization (WHO), a medical device is an “apparatus, instrument, machine, software, material or another similar article, intended for a medical purpose” as monitor treatments, help people with disabilities, diagnose and treat illnesses¹. In the current COVID-19 pandemic, measures of prevention and control of health services have been defined by the Brazilian Association of Clinical Engineering, whose guidelines include checking the configuration and availability of Intensive Care Unit (ICU) beds and their primary devices: mechanical ventilator, multi-parameter monitor, defibrillator, and infusion pumps, noting the need for staff training to use them. In addition, it is also necessary to identify defective or unused equipment due to a lack of parts or inadequate maintenance.² In this sense, clinical engineers play an essential role in managing fundamental medical devices for treating patients affected by the disease.³

Despite the importance and benefits of medical equipment in health care, adverse events are also associated with them. In Brazil, the National Health Surveillance Agency (ANVISA) classifies adverse events like health problems caused to the patient by a device subject to a health surveillance regime, even used under recommendation from the manufacturer.⁴ These events can occur because the medical device environment is a complex system of human-machine interaction that requires understanding the environment and identify risk factors.⁵

Every year, the Food and Drug Administration (FDA/ USA) receives many thousand reports of suspected medical device-associated injuries, deaths, and malfunctions.⁶ The FDA uses these reports to detect potentially related safety issues, monitor device performance, and contribute to benefit-risk assessments of these products.⁷ Since 1991, FDA has received more than 4.4 million adverse event reports.⁸ In addition, the ECRI/USA publishes the annual top ten of health hazards that assist in understanding risks in health procedures worldwide.

This work addresses risks associated with six pieces of equipment commonly used in ICUs. The first is the Automated External Defibrillator (AED, non-wearable), which uses external electrodes to analyze the patient's electrocardiogram (ECG) and automatically deliver an

electrical shock to treat ventricular fibrillation on victims of sudden cardiac arrest.⁹ The second, Direct-Current Defibrillator (low energy), delivers an electrical shock of up to 360J through paddles placed either directly across the heart or on the surface of the body, which is used for restoring normal heart rhythm in pediatric defibrillation or cardiac surgery.^{10,11}

The third piece of equipment is the Infusion Pump (IP), which perfuses medications or nutrients to the patient at a controlled amount; a health professional programs the rate and duration of fluid delivery using the equipment's software.^{5,12} Fourth is the Physiological Monitor (PM), which is a device connected to the patient, able to identify clinical emergencies when vital signs like heart rate, blood pressure, and oxygenation exceed preset thresholds; in this case, alarms are activated.¹³

The fifth is the Pulmonary Ventilator (PV), which involves a breathing tube placed in the patient's windpipe, connected to the mechanical ventilator, which delivers oxygenated air.¹⁴ PV is used during surgeries or treatment for lung disease, essential to treat respiratory failure caused by COVID-19. Sixth is the Ultrasonic Scalpel (US), which generates harmonic vibrations in a metal rod that denatures proteins, cuts tissues, and coagulates them simultaneously.¹⁵

Unfortunately, there are harms associated with the use of these medical devices. Estimates from 2008 to 2017 have shown alarming results: defective medical devices may have caused more than 1.7 million injured patients and approximately 83000 deaths worldwide.¹⁶ These data denote the importance of identifying types of failures, hazards, and their causes, as what can be done to reduce them. Thus, this work aims to present the main alerts, dangers, and failures related to the use of PV, IP, AED, DC-Defibrillator, PM, and the US. This overview of their main events can guide users for their most appropriate management and best practices when using these medical devices.

METHODS

The ECRI's top ten health technology hazards ranked annually (from 2016 to 2020) have guided our research

regarding the types of equipment that most offer danger to patients and the main ways to mitigate them. On the other hand, a review of documents published (since 2016) by FDA/USA and ANVISA/Brazil was also analyzed here, which report adverse events related to medical equipment. Several papers from the literature about that subject were analyzed too in our research.

The FDA database contains medical device reports submitted by mandatory reporters, manufacturers, importers, and facilities, in addition to voluntary reports by consumers, health care professionals, and patients.⁷ The medical devices addressed in our research (AED - non-wearable and DC-Defibrillator - low energy; IP; Non-Continuous PV; PM - without arrhythmia detection or alarms; and the US) were searched in the FDA database within the period from January 1st, 2016 to April 30th, 2020. The cases from the FDA were classified into six categories defined in this study, which are shown in Table 3. It is worth mentioning that only reports of death and injuries for these devices were considered. The information found on the ANVISA databases is shown in Table 4. The searches for PV and AED were conducted considering the same period, and the alerts found were classified into three categories.

RESULTS

Main causes of failures in medical devices

In their historical development, medical devices have an increasing degree of complexity, with the development of new components and materials. This complexity impacted the maintenance and performance of the devices and their reliability,¹⁷ which is directly related to the increased failure rate (Fig. 1).

The analysis of contributing factors in the appearance of faults demonstrates that causes are varied. Tables 1 and 2 respectively show the classification of incidents according to studies by Amoore using ECRI database and Shepherd.^{18,19} In these tables, aspects as "device" are repeated, including manufacturing, materials, and maintenance. Another common factor is the "user" or "operator," i.e., ignorance, inadequate technical training, and staff negligence.¹⁷

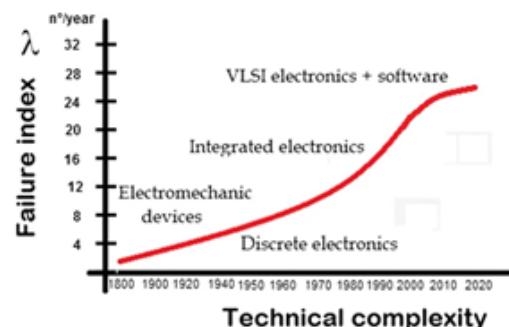


FIGURE 1. Reliability conditioned by technical complexity¹⁷

TABLE 1. ECRI Classification of medical device incidents¹⁷

| | |
|----------|--|
| Device | 1) Human factor design 2) Parts design unexpected failure 3) Deterioration failure that requires preventive maintenance (e.g., Battery) |
| Operator | 1) Training and use error 2) Diverted attention 3) Criminal intent |
| Facility | 1) Human factor design 2) Parts design; unexpected failure 3) Deterioration that requires preventive maintenance 4) Maintenance error |
| Patient | 1) Active patient action affected the outcome 2) Patient's condition affected the outcome |

TABLE 2. Shepherd's Classification of medical device incidents¹⁷

| | |
|-------------------------|--|
| Device | 1) Design error 2) Device or accessory failure 3) Improper maintenance / testing / modification 4) Manufacturing error |
| User | 1) Device miss-assembly 2) Failure in pre-use inspections 3) Improper connection 4) Improper reliance on an automated feature 5) Incorrect clinical use and control settings |
| External | 1) Electromagnetic or radiofrequency interference 2) Power Supplies (including gas) |
| Support System Failures | 1) Error in hospital policy 2) Failure to train 3) Improper storage 4) Lack of competent accident investigation 5) Poor pre-purchase evaluation |

In the scientific literature, it is possible to identify models such as the Swiss cheese, proposed by Orlandella and Reason, which allow understanding the system failures, which arise when protection measures are overcome (Fig. 2).²⁰ In that model, the human aspect is highlighted, which occurs when the error originates from inadequate actions from health personnel due to fatigue, stress, inattention, and negligence. Regarding the system, it is possible to standardize the security measures taken from design, quality control, safety testing, maintenance throughout the life cycle, and adequate user training. Each aspect is equivalent to a cheese layer, representing barriers to errors and present fragilities. Therefore, it is crucial to scientifically determine which layers are involved in medical device failures and ensure that these "cheese holes" are not aligned, creating problems.¹⁷

Another model is Pareto analysis, which shows that many failures occur in critical devices, being possible to determine the causes, allowing focusing professional attention on the most relevant situations and corrective actions. This model showed that misuse, lack of maintenance, and use by untrained personnel are the leading causes of medical equipment failures.¹⁷

Both models contain promising elements, which were applied in our research, detailed in the sections that follow.

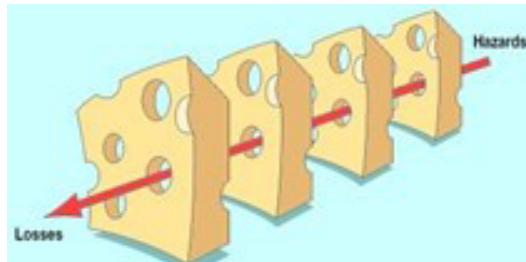


FIGURE 2. The Swiss cheese model for events occurrence²⁰

FDA Adverse Events

The data in Table 3 shows adverse events related to devices of general clinical use (with important application in ICUs), such as the equipment addressed in our research: PM, IP, AED, and PV. In addition, Table 3 also shows the US equipment used in surgical procedures. Several cases were reported in the USA, totaling 3,100 events between 2016 and 2020. The highlights are the equipment AED and IP, which have 1,382 and more than 1,424 reports. The

PV, US, and PM have, in that order, 187, 60, and 40 cases, respectively, whereas the DC-Defibrillator has only 7 cases.

The AED presented 831 cases of operating issues associated with malfunction and shock problems and problems in defibrillation and alarm errors. For this equipment, 77 cases were related to monitoring problems with incorrect messages, and 58 cases of assembly or structural defects due to the defective connection and impedance problems. Cases of incorrect procedures were 59 due to inappropriate actions that lead to burns. Hazards were 20 events of shock and burn to nurses and physicians. Finally, unknown reasons were 337 events. Regarding the DC-Defibrillator, which is activated manually, the seven cases were related to device operating issues generated by inappropriate shock. All events were related to severe cases, with four deaths and three injuries (Fig. 3).

For IP, we analyzed a total of 1,424 events related to injury and death. Most of them were related to device operating issues (913) due to stop working and failure to deliver medication. Still, flow obstruction and alarm error were also reported. The assembly or structural defects had 124 cases reported due to the component disconnection and broken devices. The monitoring problems, with 30 cases, occurred due to incorrect messages on display. Unknown reasons were 306 events.

PV covers 187 events, with 73 being device operating issues that correspond to airway pressure and oxygen saturation defects. The 65 hazard cases were linked to loss of smell sense and respiratory distress. Assembly or structural defects were 43 cases related to broken pieces, connection of tubing problems, and inadequate humidification. The PM comprised 40 cases, ten device operating issues related to alarm problems, software, and electronic motherboard problems. Incorrect procedures were due to inadequate or insufficient training. Seventeen monitoring problems were due to inappropriate electrocardiograms and incorrect display messages. The US had 60 cases, 43 due to device operating issues linked to failure to cut, malfunction during surgery, and energy output problems. The remaining cases were divided into assembly or structural defects and hazards, with 10 and 7 cases, respectively, including disconnecting components and fragmented material.

TABLE 3. Adverse events reported in FDA databases during January 1st 2016 to April 30th 2020⁽¹⁾.

| Medical Devices | Assembly or structural defects | Device operating issues | Hazards | Incorrect procedures | Monitoring problems | Unknown reasons | Total |
|--------------------|--------------------------------|-------------------------|----------|----------------------|---------------------|-----------------|-----------------------|
| AED (non-wearable) | 58 (4%) | 831 (60%) | 20 (1%) | 59 (5%) | 77 (6%) | 337 (24%) | 1,382 |
| DC-Defibrillator | - | 7 (100%) | - | - | - | - | 7 |
| IP | 124 (9%) | 913 (64%) | 10 (1%) | 41 (3%) | 30 (2%) | 306 (21%) | 1,424+ ⁽¹⁾ |
| PM | - | 10 (25%) | 10 (25%) | 3 (7,5%) | 17 (42,5%) | - | 40 |
| PV | 43 (23%) | 73 (39%) | 65 (35%) | - | 6 (3%) | - | 187 |
| US | 10 (17%) | 43 (72%) | 7 (11%) | - | - | - | 60 |
| Total | 235 | 1877 | 112 | 103 | 130 | 643 | 3,100 |

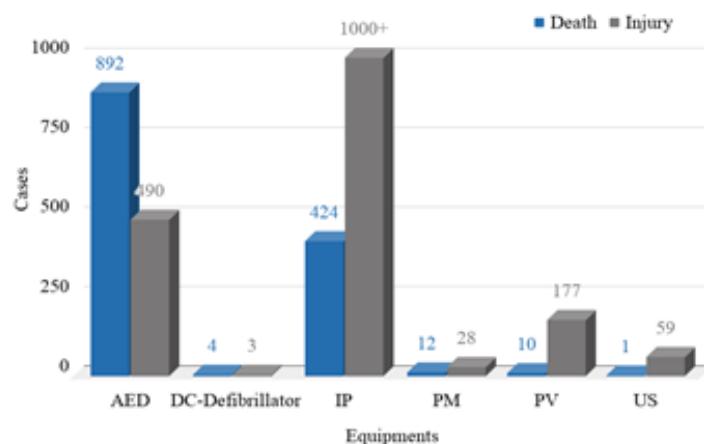


FIGURE 3. Graph of death and injury found in FDA referring to Table 3⁽¹⁾

The FDA's adverse events are again shown in Fig. 3, but in this case, separating death and injury provoked by the device. Again, the data are alarming for AED, with 892 deaths and 490 injuries related to events. IP has 424 deaths and more than 1,000 injury cases. Injuries were also more common than death for PV, PM, and the US.

ANVISA Adverse Events

The data from ANVISA/Brazil is restricted to national and international events with medical devices used in Brazil. The search on this public agency official page offers gross values, often unrelated to the device. Thus, we identified 38 alerts for PV and 37 alerts for AED (Table 4).

TABLE 4. Adverse events reported in the ANVISA/Brazil databases during January 1st 2016 to April 30th 2020.

| Medical devices | Device operating issues | Assembly or structural defects | Manipulation or installation problems | Total |
|-----------------|-------------------------|--------------------------------|---------------------------------------|-------|
| PV | 26 (68%) | 8 (21%) | 4 (11%) | 38 |
| AED | 29 (78%) | 8 (22%) | - | 37 |
| Total | 55 | 16 | 4 | 75 |

PV presents most cases of device operating issues, totaling 26. Of these, 24 are related to display and oxygen sensor failure, incorrect ventilation, and stop working; and two cases were caused by problems with equipment alarm, such as sound-related problems. The assembly or structural defects were eight cases due to lack of soldering on the plate, leading to loss of power and short circuit interrupting the ventilation. Manipulation or installation problems (four cases) occurred due to problems in the power panel of the ventilators. For this type of device, three alerts contained records of death and 11 cases of patient hypoxia, which could cause sequelae and lead to death.

AED presented 29 cases of operational problems, such as electric shock error, cable failure, attenuated discharge in defibrillation, and alarm error, which could lead to death and injury of the patient. For assembly or structural defects, there were 8 cases of battery drainage and component failures.

⁽¹⁾ Considering up to 1,000 cases for IP related to injuries and all 424 cases related to death

Top Ten Health Hazards of the ECRI

The ECRI is a nonprofit organization, which develops guidance for improving the safety and quality of care across all healthcare environments worldwide. Every year they produce a report of the top 10 health technology hazards, whose items represent hazards that managing technologies can minimize. ECRI's engineers, scientists, and clinicians select topics based on insight gained through investigating, testing, observing operations, reviewing the literature, and speaking with clinicians, clinical engineers, administrators, and device suppliers.²¹⁻²⁵

Comparing our results to ECRI lists, we noticed a convergence regarding problems and errors presented by the six devices evaluated. Devices alarm problems were present in all five lists considered. For PV and IP, alarm malfunction, overload, and loss of alarms could induce severe consequences in patients. Infusion errors appear in the 2017 and 2019 lists. Problems with device operation by the medical team were listed in 2016 and 2019; however, many other cases were related to inadequate procedures.²¹⁻²⁵ Regarding device cleaning, alerts were on the five lists due to patient infection or technical problems arising from incorrect cleaning. Structural problems appeared in 2020 (such as the risk of loose nuts and bolts to device failures) and 2019 (about device battery charging defects). From 2017 to 2020, cybersecurity risks were emphasized due to system exploitation by hackers, causing health care disruption.²¹⁻²⁵

DISCUSSION

Nowadays, practically all health specialties need modern technologies, going beyond health establishments to patients' homes. However, the risk of adverse events concerning these technologies is growing rapidly. These events can result from a single cause or the simultaneous occurrence of several factors, with the clinical team generally being held responsible. However, we identified several causes to be considered in all processes: the choice of technology, proper installation, technical maintenance throughout the life cycle, and correct use in relation to the patient.

The results shown in Tables 3 and 4 suggest high reliability. However, it is worth commenting that In this sense, Table 3 shows adverse events recorded at the FDA/USA whereas Table 4 presents alerts from ANVISA/Brazil.

The hazard for patients occurs when: an alarm condition is not detected by a medical device (such as IP, PM, or PV); the condition is detected but not communicated to a staff member, or the condition is communicated but not appropriately addressed.²⁰ Regarding the PV, injuries occur mainly in the respiratory tract because the patient depends on this equipment for ventilation. Errors in the air supply, if not rectified, can lead to damage like hypoxic brain or lung injury and death, as shown in some records in this study. These devices have alarms that indicate inadequate ventilation, so proper configuration is needed. However, the challenge is to manage the alarms, which are usually missed due to alarm fatigue (when the team is overloaded), lack of sound sensitivity, or failure in the notification of alarms, in which they are not effectively communicated to staff.²⁶

Other factors contributing to the inadequate ventilation implementation include insufficient knowledge of the best practices for ventilation and ventilator functionality.²¹ Healthcare facilities need policies on setting ventilator alarms and protocols for verifying components. In addition, too often, lung-protective strategies and advanced ventilator tools are not commonly used, and best practices are not adopted.^{22,24} Mitigate these problems by verifying that all staff members dealing with mechanical ventilation have a good understanding of how these devices work.²¹

PM is used in physiological monitoring. The improper customization of the alarms could make it more difficult for the operator to understand changes in the patient's physiological conditions or problems with the device. These systems must be configured not to act too many alarms or too few alarms, as this involves settings based on the needs of a care area and the patient's condition. In addition, establishing policies and educating staff about optimal alarm-customization practices can help reduce the risks of loss sounds and harm to the patient.^{13,24,27}

A total of 424 deaths and up to 1,000 injuries (Fig. 3) related to IP were recorded in this study. The incorrect programming procedure performed by the medical team occurs even with smart pumps that have a dose error reduction system. In this case, the patient can receive either too much or too little solution. The complex programming display and the absence of procedures to verify the programming can contribute to these errors. Thus, the surest way to eliminate them is to use auto and double-checks programming. Still, the staff needs to notice signs of damage to the IP components to guarantee the correct flow of medication.^{22,24}

The AED has high values of death and injury, respectively 892 and 490 cases in FDA. The relationship to the death of patients undergoing resuscitation is mainly linked to the operational failure of the device, for example, not providing an adequate charge or discharge. Successful defibrillation depends on delivering the shock to the myocardium, as the longer brain and heart are deprived of oxygen, the more damage suffers.^{10,11}

The US is reported to be quick for the cutting and coagulation of tissue.²⁸ Studies claim the benefits of this equipment, including allowing faster and safe surgical procedures.²⁹ However, the alerts show that no device is exempt from technical and human failures; for example, there might be improper cutting.

Achieved results indicate the essential need for better protocols on activity verification and medical equipment quality control, especially for high-risk instruments. It is also necessary to provide medical staff training about the operation and execution parameters of all equipment to get good accuracy.¹¹

Another critical point is the medical equipment maintenance carried out by clinical engineers. Thus, the predictive maintenance that accompanies equipment performance parameters, aiming to define the right moment of the intervention, with the maximum use of the asset, proves to be profitable, combining operational safety of the equipment and cost.³⁰ On the other hand, preventive maintenance, according to NBR 5462-1994, "is carried out at predetermined intervals, or according

to prescribed criteria, designed to reduce the probability of failure or degradation of the functioning of an item"³¹, therefore offering more safety.

In Brazil, to guarantee the safety and the values measured within the reliability standards of medical equipment and to obtain the Brazilian certification by the National Institute of Metrology, Quality and Technology (INMETRO), the clinical engineering team management performs testing and calibration of equipment following Brazilian standards, such as RDC number 02 and NBR15943.^{4,32} The manufacturers and distributors have a great responsibility in producing equipment in compliance with regulations and quality requirements.

On the other hand, health authorities must follow regulations, conduct technological surveillance, and collect information about events. In health establishments, the clinical and biomedical engineers are professionally trained to relate scientifically to devices, being increasingly important in product certification, choosing technologies and training of personnel, and thus helping to avoid serious failures.¹⁷

To evaluate the events addressed in our research, we used Pareto's analysis to prioritize corrective actions and quantify the causes of problems in medical devices, allowing focusing the professional's attention on the most relevant causes. The Swiss cheese model was used when protective measures of systems were overcome by circumstantial factors that combined them and produced an undesirable result. This model encompasses human aspects, such as faulty actions and the system, which need barriers against errors (cheese layers). The layers represent points in developing and using a device that can have weaknesses, so these layers cannot align.¹⁷

Finally, the alerts, hazards, and adverse events registered allowed us to identify the best practices to be adopted concerning the highlighted medical devices. This included increasing the training of operators and technicians in maintenance, expanding predictive maintenance, changing the corrective maintenance modus operandi, adapting the infrastructure of the health care establishment (hospital, clinic, polyclinic, etc.), identifying the need

to replace obsolete technologies, providing feedback to manufacturers and suppliers of medical technologies, and suggesting new public policies for the management of medical devices among other actions.

CONCLUSIONS

The common faults in AED, DC-Defibrillator, IP, PM, PV, and US are related to alarm conditions not being issued by the medical device or not being adequately addressed by the team of professionals. In addition, these professionals are often not adequately trained to deal with the devices, the scarcity of system verification protocols, errors in the automatic execution of standard processes, lack of maintenance and programming according to the patient's needs.

All medical devices can fail; however, the failures must be avoided by adequately selecting and maintaining these devices. For that purpose, it is necessary to pay attention to medical devices' clinical and technical needs, perform regular equipment tests and maintenance, and medical team training. In addition, the medical devices must have adequate incorporation with an extensive search for suppliers, involving technical, clinical, budgetary, and infrastructure areas, allowing for a specification that meets the clinical, operational, and cost.

To understand and mitigate adverse events, this work shows that it is essential to apply models to analyze their causes, for example, Pareto's analysis, which prioritizes corrective actions. In addition, it is necessary to stratify the types of adverse events for medical equipment, for example, using the layers of the Swiss cheese model to help understand which stages of development and use of the device contributed to the failures.

Indeed, future research and studies with other international databases are necessary to widen the outcomes obtained in our research. Nevertheless, we believe that all aspects brought through applying models from Pareto's analysis and Swiss cheese can impact the mitigation of these adverse events and, consequently, offer end-users safer medical devices and more effective health care.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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