Delay in detecting patient lifelessness due to malfunction in telemetry device on 23 October 2024

T2024-01

FOREWORD

Pursuant to section 2, subsection 2 of the Safety Investigation Act (525/2011), the Safety Investigation Authority decided to investigate a malfunction of a telemetry device that led to a delay in detecting patient lifelessness at a hospital located in South Ostrobothnia on 23 October 2024.

The purpose of safety investigations is to promote general safety and to prevent accidents and incidents as well as losses resulting from accidents. A safety investigation is not conducted in order to allocate legal liability.

Jukka Seppänen was appointed as Head of the Investigation team, and Expert Krista Lyyra, Expert Päivi Porkka and Expert Sanna Ranta were appointed as its members. The Investigator in Charge was Chief Safety Investigator Hanna Tiirinki.

Petri Pommelin was appointed as a specialist with regard to the patient safety incident reporting system. Anna Aspelund was appointed as a specialist in the area of human-technology interaction.

Chief Safety Investigator Lasse Laatta, Senior Safety Investigator Leo Evijärvi and Senior Safety Investigator Vaishnave Mohanathas also participated in the investigation.

A safety investigation examines the sequence, causes and consequences of events as well as the rescue operations undertaken and the actions of the authorities. In particular, the investigation seeks to establish if safety was adequately addressed in the activities that led to the accident and in the design, manufacture, construction and use of the equipment and structures that caused the accident or incident or that were affected by it. The investigation also determines if direction, supervision and inspection activities were organised and taken care of appropriately. If necessary, any shortcomings in provisions and regulations applicable to safety and the authorities must also be investigated.

The investigation report describes the chain of events, the factors leading to the accident and its consequences as well as safety recommendations addressed to the appropriate authorities and other instances regarding actions that are necessary in order to promote general safety, prevent further accidents and incidents, prevent losses and improve the effectiveness of the operations of search and rescue and other authorities.

The parties involved in the accident and the authorities responsible for supervision in the sector of the accident under investigation are given an opportunity to comment on the draft investigation report. Their comments were taken into account when finalising the investigation report. A summary of the comments is provided at the end of the investigation report. Pursuant to the Safety Investigation Act of Finland, comments given by private individuals are not published.

The investigation report was translated into English by Lingsoft.

The investigation report, its summary and appendices were published on 30.01.2026 on the Safety Investigation Authority's website at *www.turvallisuustutkinta.fi*.

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1 EVENTS

1.1 Chain of events

A patient in an inpatient ward at Seinäjoki Central Hospital died on 23 October 2024. The patient became lifeless, and the detection of the patient's lifelessness was delayed due to a malfunction in a telemetry device.[1]

The 78-year-old person in question presented to the wellbeing services county's urgent care clinic[2] due to coughing and shortness of breath on 13 October 2024. At the appointment, the person's abnormally high heart rate caused concern, and as a result they were transferred to the inpatient ward of the health centre for further treatment. Shortness of breath and chest sensations continued during the treatment period. A few days later, the patient was transported to the joint emergency clinic of the wellbeing services county for further assessment due to tachycardia that did not respond to pharmacotherapy[3] . The patient was transferred from the emergency clinic to the hospital inpatient ward for further treatment. The patient was connected to telemetry monitoring[4] in the ward on 18 October 2024. The tachycardia continued despite intensified pharmacotherapy, and electrical cardioversion[5] was performed on the patient on 22 October in intermediate care. After the procedure, the patient was transferred back to the inpatient ward for further monitoring. No abnormalities were observed in the heart rhythm during telemetry monitoring in the inpatient ward, and sinus rhythm continued[6]. The patient was in good condition and had experienced no symptoms. The patient's condition was assessed as stable.

An ECG examination[7] was performed on the patient at about 8:20 in the morning of 23 October 2024. No acute changes were observed in the ECG examination. After the examination, the nurse who performed the ECG left the patient room and the patient remained alone in the room to perform their morning routines. The patient sent a message to a loved one at 9:14, saying that they felt well. During the physician's rounds at about 9:50, the patient was found lifeless in their own room. The patient's heart had stopped[8]. In-hospital resuscitation[9]was administered to the patient, but the patient died despite these attempts.

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[1] At the start of the investigation, the term "malfunction" was used to describe the telemetry device's failure associated with the accident. In this investigation, a malfunction means that the device does not function as intended, regardless of whether the cause is related to the user, the system, or the device itself.

[2] Urgent care appointments may be sought due to sudden illness, injury, acute worsening of a long-term illness or reduced functional capacity. Urgent care is intended for treating health problems that do not require emergency treatment but must be treated within 1 to 3 days.

[3] Elevated heart rate (tachycardia) refers to a situation in which the heart rate is above the normal resting heart rate. The normal resting heart rate in adults is usually 60-100 bpm. In tachycardia, the heart rate exceeds 100 beats per minute at rest.

[4] During telemetry monitoring, a telemetry device measures different patient values and sends them wirelessly to central monitoring.

[5] Electrical cardioversion can be used as a treatment method for arrhythmias involving high heart rates. Electrical cardioversion uses a pain-free electric shock to restore the heart rhythm during a short period of anaesthesia lasting for a few minutes.

[6] A normal heart rhythm is called the sinus rhythm. The sinus node is a rhythm centre located in the upper part of the heart that normally produces an order to initiate each heartbeat. This is why it is called the sinus rhythm.

[7] An ECG, or electrocardiogram, is an examination that records the electrical activity of the heart as a graphical representation.

[8] The patient's heart rhythm was asystole, which means complete cardiac arrest, with no electrical or mechanical activity in the heart.

[9] In-hospital resuscitation is a type of resuscitation performed by healthcare professionals using medicines and medical devices.

The patient was connected to a telemetry device at the time of the event, but lifelessness was not observed when it began. The telemetry's patient cables and battery were in place when the patient was found lifeless in the bed. The device had shut down, which is why central monitoring did not receive an alarm of arrhythmia. The device was sent from the ward to the hospital's medical technology unit[10] for investigation and from there to the device manufacturer. It was not possible to accurately determine the time when lifelessness began. There was no surveillance camera in the patient room, and the patient did not send a request for assistance through the ward's nurse call system. The nurse later discovered from central monitoring that the device had already shut down at 9:01 and that the central monitoring unit contained a "No Data Tele" alarm indicating that the connection had been interrupted.

On the day of the event, the nurse who was caring for the patient submitted a patient safety incident report to the hospital's HaiPro system[11] and to the Finnish Medicines Agency Fimea. Fimea reported the event to the Safety Investigation Authority. The wellbeing services county reported the event to the Regional State Administrative Agency and the National Supervisory Authority for Welfare and Health Valvira.

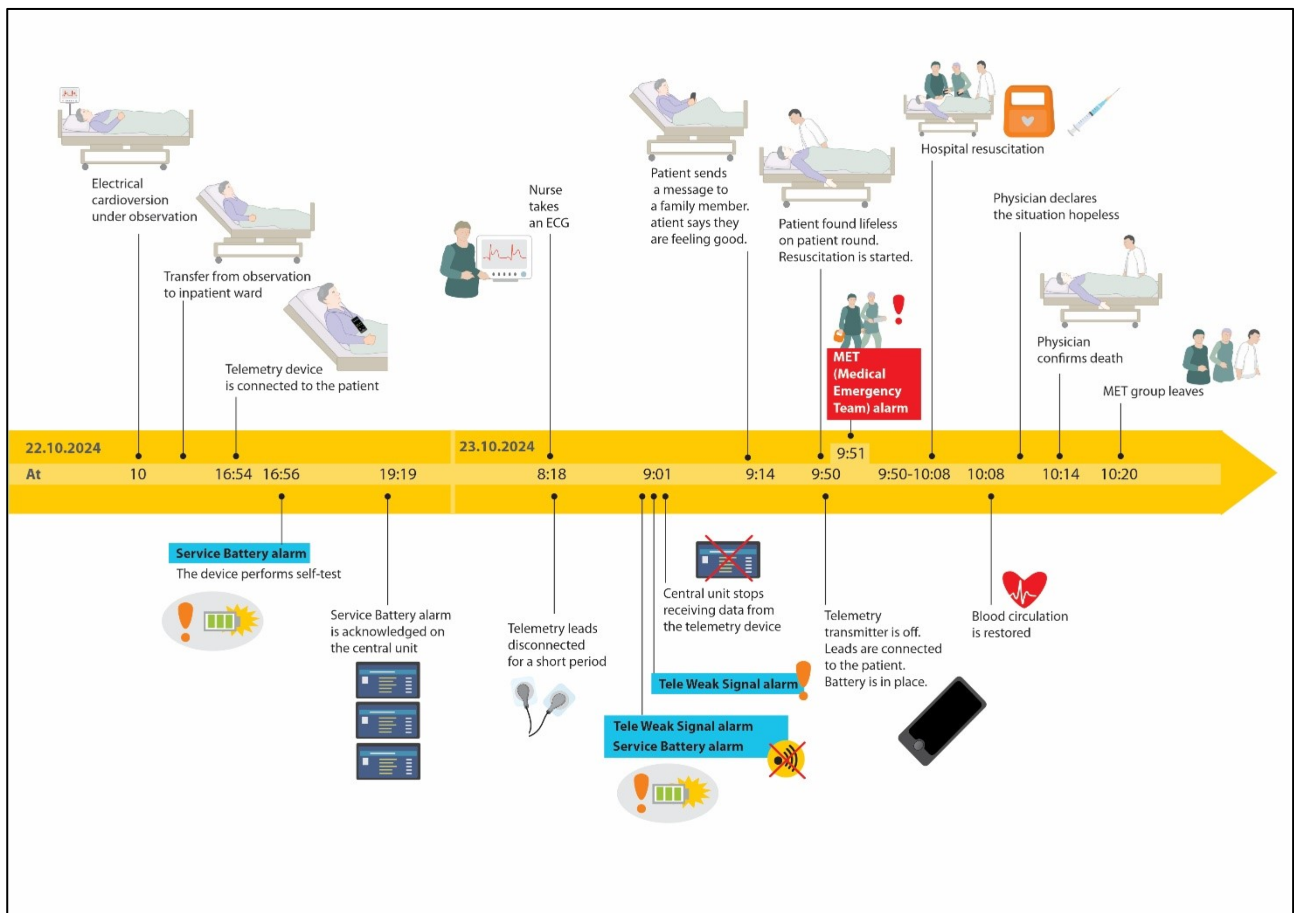

Figure 1. Chain of events. (Figure: SIAF)

10 Medical technology, or healthcare technology, covers the equipment, systems and technical solutions used to diagnose, treat and monitor patients.

11 HaiPro (Reporting System for Safety Incidents in Healthcare Organizations).

1.2 Alarms and rescue operations

After lifelessness was detected, cardiopulmonary resuscitation was started and the patient was connected to a defibrillator[12] to analyse the heart rhythm. The hospital's MET team[13] was called to the site. The patient was resuscitated for approximately 18 minutes, after which the overall situation was declared hopeless and the treatment procedures were discontinued.

1.3 Consequences

The patient was declared dead at 10:13. A forensic investigation of the cause of death concluded that the death was caused by disease. The death was classified as disease-related.

2 BACKGROUND INFORMATION

2.1 Environment, equipment and systems

2.1.1 Seinäjoki Central Hospital Inpatient Ward

Seinäjoki Central Hospital is the central hospital of the Wellbeing Services County of South Ostrobothnia. It has 24-hour emergency services for specialised medical care and non-urgent care provided by specialists in all key medical specialities.

The inpatient ward at Seinäjoki Central Hospital has 27 beds. The ward treats adult patients with illnesses that require hospitalisation. Patient turnover in the ward is high. All patient rooms are equipped for telemetry monitoring of the patient's status and cardiac rhythm. The ward office has a central monitoring unit at which the nursing staff monitor alarms and review earlier events. The auditory alarms issued by the central monitoring unit via a speaker connected to it can only be heard in the office. The central monitoring unit is connected to a printer, which the nursing staff use to print out any abnormal cardiac rhythm periods observed on the screen. A secondary monitoring unit is located in the department's break room, allowing staff to observe the central monitoring display without audible alarms. Another ward located on the same floor only uses telemetry monitoring on an occasional basis, and this monitoring is performed using the equipment in the inpatient ward.

Telemetry monitoring can be performed in certain rooms of the inpatient ward located above the ward within the limits of the network carrying capacity. However, the telemetry data from this ward is only transmitted to the central monitoring unit in the inpatient ward located below it. In addition to the patients in their ward, the nursing staff are responsible for monitoring the status of patients in the ward located upstairs and any alarms on the monitor. If necessary, the staff upstairs is contacted by phone regarding the observed abnormalities.

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[12] A defibrillator is a medical device that can be used to administer a shock, or defibrillation, to the heart of a person who has life-threatening cardiac arrhythmia. The goal of defibrillation is to restore a normal cardiac rhythm.

[13] The MET (Medical Emergency Team) is a multiprofessional emergency care team operating in the hospital. The MET team is called to a patient who is experiencing a disruption or threat of disruption in their basic vital signs. The goal of these activities is to ensure that the patient has quick access to intensive care if necessary. The MET group usually includes intensive care and acute medicine professionals.

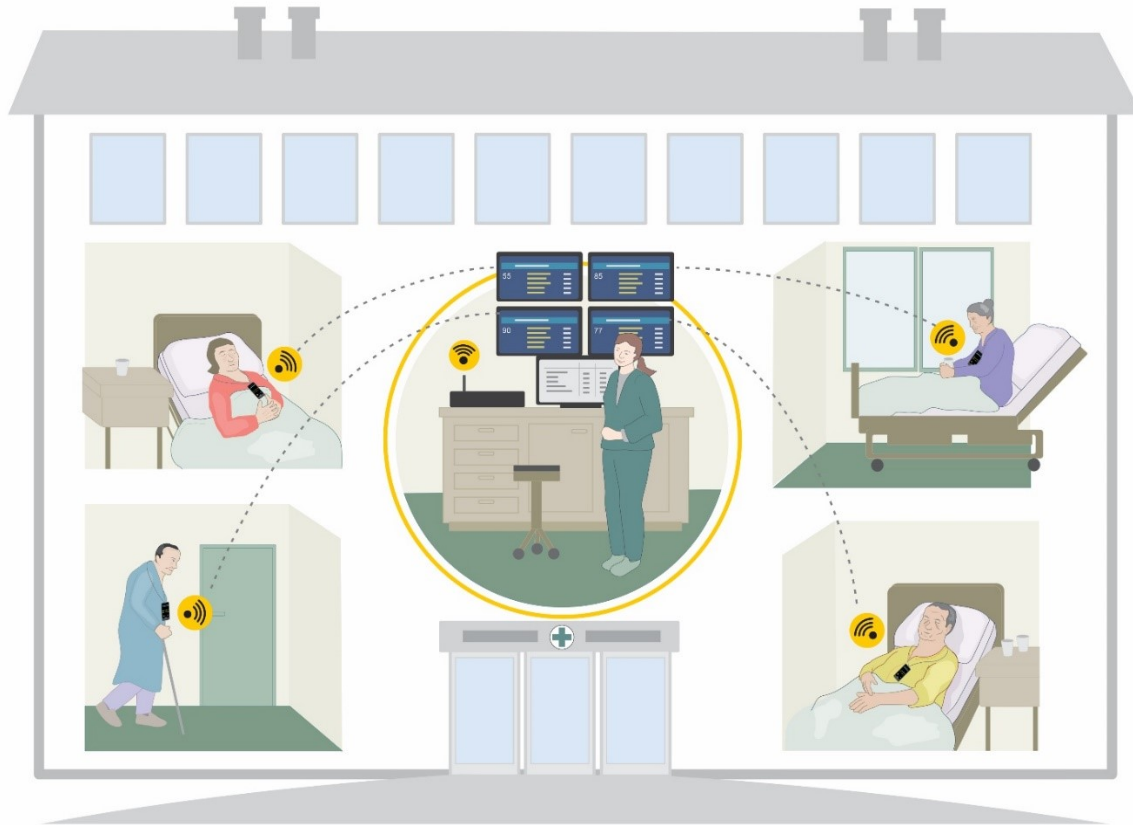

Figure 2. Telemetry system at the hospital. (Figure: SIAF)

The inpatient ward usually has seven nurses working on the morning shifts, six of whom are responsible for their own patients. One of the nurses acts as a coordinating nurse. Personnel resources have generally been considered adequate in the ward. Patients are transferred from the ward to their homes, health centres, home hospitals or further treatment locations.

Seinäjoki Central Hospital also has an intermediate care ward. The intermediate care ward has facilities suitable for that purpose. The investigation revealed that due to a shortage of personnel, the number of monitoring beds does not correspond to the need, which is why patients in increasingly poor condition are transferred to the inpatient ward.

2.1.2 Telemetry monitoring

Telemetry monitoring is a system used in hospitals that allows wireless and real-time monitoring of the electrical activity of a patient's heart. Monitoring is performed using a device that transmits information about heart function to a central monitoring unit. Cables are used to connect the device to electrode pad stickers, which are applied to the patient's chest. Telemetry is used particularly for cardiac patients in situations where it is important to continuously monitor cardiac function but the patient does not need intermediate care-level treatment. Wireless monitoring allows the patient to move around the ward without interrupting cardiac monitoring. The purpose of the telemetry system is to detect changes in the electrical function of the heart that are significant and life-threatening in real time and to issue alarms about

them. The system includes electrodes[14], a telemetry device carried by the patient, and a central monitoring unit. The ECG signal is obtained from electrodes attached to the patient's skin and transmitted via the device to central monitoring.

The telemetry device used in the inpatient ward at Seinäjoki Central Hospital is a **Philips IntelliVue MX40** model that is controlled using a touch screen. The inpatient ward at Seinäjoki Central Hospital had a total of 14 MX40 devices at the time of the event.

Figure 3. The touch screen on the Philips IntelliVue MX40 device displays measurement numerics, information fields, alarm fields, waveforms, SmartKeys and menus. (Picture: Philips)[15]

The MX40 operates with a rechargeable lithium-ion battery or disposable batteries. At the time of the incident, there were 28 device batteries in the ward. The ward does not use disposable batteries. The batteries are not device-specific. Procurement of batteries for telemetry equipment was handled by the medical technology unit, which ordered new batteries on average a few times a year as needed. The medical technology unit usually also had replacement batteries in its own storage. According to the medical technology unit, the availability of batteries was good.

The inpatient ward monitors the battery charge status of devices being used by patients. The charging stations are located in a cabinet in the ward office. The Safety Investigation Authority's on-site investigation found that some of the devices in the ward were missing battery compartment doors. A cabinet in the office contained a box with a handwritten message that read "broken battery". A Post-it note with the text "A blue light at the charging point means that the battery is nearing the end of its useful life. Decommission the battery" was attached to the other side. At the time of the investigation, there were no decommissioned batteries in the box.

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[14] Electrodes are pads placed on the skin that measure electrical impulses. In medical science, ECG electrodes measure the electrical activity of the heart.

[15] Philips IntelliVue MX40 quick guide. 2013 Koninklijke Philips N.V.

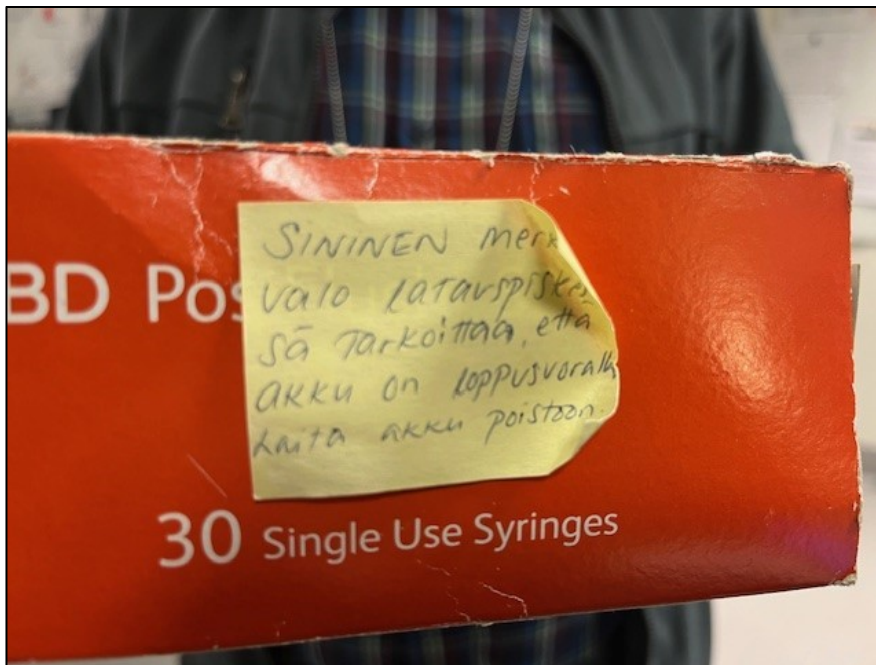

Figure 4. A box in the ward cabinet intended for telemetry device batteries to be decommissioned. (Photo: SIAF)

Rather than having a separate power switch, the MX40 device turns on when the battery is inserted. The device then automatically performs a self-test. The device is equipped with a pouch that allows the patient to carry the device around their neck. There is an opening on the side of the pouch for the sensor cables. The patient may not touch the display or open the battery compartment while the device is in use. When the electrodes and patient cables are in place and connected, an ECG wave and numeric values are displayed. When the device is connected to the central monitoring unit, the device screen remains off unless it is activated separately.

The MX40 battery(s) must be replaced if the device alerts the user with INOP messages[16]. If these errors are not resolved, the unit will shut down and monitoring will be interrupted.[17]

16 INOP (inoperative) messages indicate technical errors or system failure. Among other things, messages are produced about battery charge status and disconnected electrodes. In conventional INOP alarms, the system produces an alert sound that is repeated every two seconds.

17 Philips IntelliVue MX40 Instructions for Use. Version C.01. p. 26.

Table 1. Example of MX40 INOP alarms. (Source: Philips).

Decommission the battery	When any of the following INOPs are displayed on the MX40: **TELE SERVICE BATTERY** **TELE BATTERY TEMP** **TELE REMOVE BATT** **Note** — When the above INOPs occur, the Tele Battery Low INOP is suppressed.

The service life of a lithium-ion battery is determined by the number of times it charges and discharges, and by the duration of use. The average life of a well-maintained battery is approximately 500 full charge cycles. Battery age is calculated from the date of manufacture marked on the side of the battery.[18]

The telemetry system used in the hospital inpatient ward includes a central monitoring unit, which is the **Philips Patient Information Center iX** model. The unit allows real-time monitoring of patient status in the hospital environment. It collects and displays patient data from various sources, such as monitoring and surveillance devices. The central monitoring unit helps the nursing staff monitor patient status, respond to alarms, and analyse patient data. It enables the monitoring of physiological measurements such as ECG, blood pressure and respiration. The telemetry devices send the measurement data to the central monitoring unit and database, where it can be examined in real-time or retrospectively as graphs and waves. The unit also makes it possible to perform more in-depth analysis of data, print reports and transfer data to other systems.[19]

The telemetry system generates alarms related to cardiac rhythm and technical alarms that are displayed in the central monitoring unit. A patient alarm gives alerts of changes in the patient's condition with a message on the screen and an auditory alarm. The highest priority alarm level, which may involve a risk to the patient's life, is indicated by three stars and an alarm repeated once a second. The telemetry device stores the 50 most recent alarms. The patient's telemetry events are stored in the system for seven days.

The alarm limits for patient alarms were set in the telemetry system of the Seinäjoki inpatient ward in conjunction with system deployment. Alarm limit values are not usually adjusted for each patient. The alarm limits are therefore the same for all patients. The alarm limits for individual patient telemetry were only changed in exceptional cases, for which the nurse always requested a physician's permission.

In the case under investigation, the patient's cardiac rhythm data during inpatient care was no longer in the telemetry system when the investigation started. After the event, the ward staff printed out from the telemetry system the patient's cardiac rhythm data for the hours preced-

[18] Philips IntelliVue MX40 Instructions for Use. Version C.01. p. 163.
[19] Philips Patient Information Center iX Instructions for Use. Version C.03.

ing death. The printouts were saved in the hospital's electronic archive. The telemetry system's technical log data on alarms and their acknowledgements were obtained with the support of the device manufacturer.

The telemetry system at Seinäjoki Central Hospital uses Philips Smart Hopping network designed for use with the IntelliVue patient monitoring system. The network functions as a separate and closed network, alongside the hospital's open Wi-Fi network. The Smart Hopping network is based on Frequency Hopping Spread Spectrum, where data transfer takes place in rapidly changing frequencies in the 2.4 GHz frequency band. This allows the network to adapt to congestion and disruptions in the environment. The system analyses signal quality, loss and delays in real time and automatically selects the optimal frequency. For information security purposes, the system is designed not to transfer patient IDs or other identifying information over a wireless network.

2.2 Conditions

2.2.1 Conditions during the event

On the day of the event, seven nurses were working on the morning shift, which was the normal staffing in the ward. One of them acted as a coordinating nurse. The coordinating nurse was not responsible for specific patients.

The ward had 27 beds. On the morning of the event, 20 patients were being treated in the ward. A responsible nurse had been appointed for each patient. One nurse was responsible for 3-4 patients. Following an established practice, the information of individual patients was not processed or reported orally in the morning, and the nurses read the patient information directly in the patient information system.

In the case under investigation, the nurse responsible for the patient first read the patient information for the patients assigned to them. Next, the nurse checked the cardiac rhythms, the battery charge status of the telemetry equipment and the alarm information in the central monitoring unit. After this, the nurse started morning rounds in the patient rooms. The nurse used a separate device to perform an ECG examination on the patient who is the subject of this investigation. The telemetry device was disconnected during the examination to allow connection of the ECG device. After the examination, the telemetry device was reconnected. The nurse returned the ECG device and the supplies to the office and went to the break room. After the break, they helped another nurse perform a procedure on a different patient.

The nurse was informed that the physician was going to the patient's room for the physician's round. In preparation for the physician's round, the nurse checked the patient's telemetry data in the ward office. The nurse noticed that the telemetry connection was not working. For this reason, the nurse immediately accompanied the physician to the patient room, where the patient was found lifeless in the bed. According to the staff, all patient cables were properly attached to the patient and the device battery appeared to be in place. However, the device had shut down and stopped sending data to the central monitoring unit. No power outages were observed during the event, and there were no disruptions in the hospital's telecommunications networks that interfered with operation.

2.3 Recordings

The log data stored in the ward's central monitoring unit concerning the time of the event and the days preceding it was utilised in the investigation. At the request of the Safety

Investigation Authority, the device manufacturer retrieved the log data using a remote connection. The log data contains information on alarms and alarm acknowledgements.

The nurse who treated the patient on the day of the event printed out periods of cardiac rhythm data for the hours preceding the event that had been recorded in the telemetry system. The paper printouts were scanned and stored in the hospital's electronic archive. The central monitoring unit only stores the data of an individual patient for seven days.

Data from the hospital's patient information system was utilised in the investigation.

The patient also had an Apple Watch Series 3 smart watch that, among other things, recorded the patient's heart rate data.[20] Comparison of the heart rate data provided by the smart watch with the corresponding data in the patient information system and telemetry revealed that the heart rate data recorded by the smart watch during the patient's hospitalisation was unreliable in some respects. In addition, the investigation was unable to verify the times when the watch had been on or off the patient's wrist. For this reason, the heart rate data obtained from the smart watch was not considered reliable for determining how the event progressed.

2.4 Organisations associated with the accident and safety management

2.4.1 Wellbeing services county of South Ostrobothnia

The Wellbeing Services County of South Ostrobothnia is responsible for organising social services, healthcare and rescue services in its region. The wellbeing services county of South Ostrobothnia comprises 18 municipalities. The wellbeing services county provides services to approximately 190,000 residents in South Ostrobothnia and has more than 10,000 employees.

The wellbeing services county's self-supervision plan specifies how the Wellbeing Services County of South Ostrobothnia supervises and guides the organisation and provision of social services and healthcare. The wellbeing services county has a statutory responsibility to ensure that its residents receive high-quality, safe and equal services. The purpose of the supervision is to ensure that the rights of clients and patients are realised, that the services meet the requirements set for them, and that client and patient safety is appropriately handled. The supervision targets both public and private actors and was carried out using a variety of methods, such as proactive guidance, systematic visits, document monitoring and agreement monitoring. All supervision activities are reported and evaluated annually. The objective is to ensure the rights of clients and safe services throughout the region.[21]

2.4.2 Seinäjoki Central Hospital

According to the ward's **self-supervision plan**, ward activities are based on client orientation, safety and individual care. The activities of the ward are led by a designated person responsible for medical and nursing work. The staff are qualified and their sufficiency is ensured on a daily basis. New employees and students receive orientation regarding practices in

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[20] Heart rate measurement in an Apple Watch is based on medical photoplethysmography (PPG), which is used to detect changes in blood volume. In practice, an optical sensor in the back of the smart watch is in contact with the skin. This sensor uses infrared and LED lights and light-sensitive photodiodes to measure the heart rate. When the smart watch user's heart beats, the amount of blood in the wrist increases and causes an increase in light absorption. The blood volume and light absorption decrease between beats. The smart watch measures the user's heart rate based on the variation in this absorption. According to the manufacturer, Apple Watch heart rate measurement is accurate to within 5 bpm (beats per minute) 87-98% of the time, depending on whether the user is at rest or in motion. (Apple (2024) Using Apple Watch to Measure Heart Rate, Calorimetry, and Activity). [https://www.apple.com/health/pdf/Heart_Rate_Calorimetry_Activity_on_Apple_Watch_November_2024.pdf]

[21] Wellbeing Services County of South Ostrobothnia. Valvontasuunnitelma 2024. https://www.hyvaep.fi/uploads/2024/02/valvontasuunnitelma2024.pdf.

the unit. The services involve multi-professional cooperation, and the facilities have been updated to meet modern requirements. Data protection and pharmacotherapy are implemented in accordance with the legislation and instructions. Risk management is performed regularly and any incidents are processed quickly. Client feedback is collected and utilised to develop the activities.

The nurse manager is responsible for activities in the inpatient ward. The nurse manager had been in their position for approximately one year as a substitute. At the time of the incident, the nurse manager was not on duty. The nurse manager of the neighbouring ward acted as the designated substitute.

The unit uses a training plan according to which continuing education is implemented systematically and targeted to meet the needs of the ward. All staff working on the ward complete a medical device safety course in Oppiportti[22]. The nurse manager monitored the realisation of the continuing education. The personnel resource allocation determined that seven nurses worked on the morning shift, six on the evening shift and three on the night shift on weekdays. On weekends and public holidays, six nurses worked on the morning shift. At least one half of the nurses on the shift were registered nurses. A shift coordinator, i.e. a coordinating nurse, was designated for each shift. Staff planning and a deputy system were in place in order to ensure sufficient resources.

The patient's personal nurse had worked as a registered nurse in the ward for three years. The coordinating nurse on the morning shift had worked in the ward for three years. Their duties included coordinating the activities and information flow in the ward and assisting with patient work. Rather than assigning specific patients to each nurse, on the night shift all nurses assumed joint responsibility for all patients.

The specialising physician had started working in the ward as a specialising physician at the beginning of September. The acting chief physician had been a specialist in the ward for more than two decades.

The chief physician and 2-3 specialising physicians generally worked in the ward. On weekday mornings, the physicians usually started by reviewing the information of all ward patients together. The physicians then went round to see the patients, either together or separately, depending on patient numbers and the number of physicians and their work experience.

The long-standing practice of the ward was that each patient's nurse checked the cardiac rhythm periods of their patients that caused alarms in the telemetry system during their shift. The nurse printed out the trend waves for the physicians, as well as the time periods during which abnormal findings were observed in cardiac rhythms. This operating model dated back to a time when only one specialist worked in the ward and there were 40 beds. The nurses in the ward had greater than normal responsibility for monitoring the patients' telemetry data as well as screening for and analysing arrhythmias. The physicians only rarely checked the patient data directly in the central monitoring unit of the telemetry system, and there was no telemetry monitor in the physicians' office. When visiting patient rooms, the physicians checked the patient's current cardiac rhythm by activating the telemetry transmitter display if necessary.

To ensure everyday safety, the ward has a defibrillator that is located in the ward's office. Adrenaline that could be administered intravenously is also available in the ward. On average, the ward has had a resuscitation situation approximately once a month in recent years. If

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[22] An online continuing education service for healthcare professionals provided by Kustannus Oy Duodecim.

lifelessness or a life-threatening disturbance in vital signs is detected in the ward, a resuscitation or MET alarm is triggered by calling the MET number on the phone. Regular resuscitation training is organised for the ward personnel.

The purpose of **the medical technology unit** is to ensure that medical devices work well and are safe. Nine people worked in the medical technology unit, and their responsibilities were divided by different device groups. The medical technology unit personnel and resources have not increased in recent years, even though the number of devices in the hospital has been growing all the time.

At the time of the event, the team manager of the medical technology unit was serving as the designated responsible person. They had approximately 20 years of work experience in the field.

In autumn 2024, the medical technology unit's team manager organised training for central hospital staff on the responsibilities and duties of a professional user as a user of a medical device.

A service technician with approximately seven years of experience in the field worked in the medical technology unit. The technician was responsible for patient monitoring devices, ECG devices and ultrasound devices. In total, the service technician was responsible for 60 to 80 different device groups. Some of the devices for which the technician was responsible were critical devices used in the intensive care unit or operating room, which meant that their tasks had to be prioritised according to urgency.

Monitoring of the medical devices used in the hospital was centralised to an information system managed by the medical technology unit. All medical devices acquired for the hospital were marked with a unique nine-character identifier and registered in the information system. Scheduled maintenance of the devices, other maintenance measures and the related maintenance documentation were also recorded in the system.

Professional users placed work orders for medical devices through the hospital's internal information system or by contacting the medical technology unit by telephone.

The telemetry equipment was procured for the ward as a public procurement in 2014. The equipment was intended for the continuous monitoring of basic vital signs in critically ill adult patients. During 2018, there were recurring and unpredictable disruptions in the use of the telemetry equipment. During the disruptions, the monitoring of the patient's vital signs was interrupted. A complaint was submitted in writing to the device manufacturer. According to the complaint, the operational disruptions caused serious situations that endangered patient safety in the ward. The matter was investigated drawing on device log data and the competence of the manufacturer's experts. In cooperation, the investigations were also expanded to cover port settings for switches, cabling and possible telecommunication problems. According to the device manufacturer's assessment, the printer in the ward could have caused the reported disruptions, during which all telemetry waves were interrupted for several minutes. On the other hand, interruptions in individual bedside telemetry devices may, for example, be caused if the device is taken outside the operating range.

In the June, a system update was carried out on the central monitoring unit. In connection with the update, training on the operation of the central monitoring unit was arranged at the initiative of the device manufacturer. The training covered basic operation of the central monitoring system, review and adjustment of monitoring parameters, and instructions for safe use, maintenance, minor servicing, and cleaning of the system.

Several years earlier, one of the registered nurses in the ward had been appointed as the responsible user of the telemetry system. The responsible user had no task description or concrete responsibility for the system. The nurse manager was responsible for ordering new batteries or parts and for contacts with the medical technology unit in practice. The ward and the medical technology unit had not agreed separately on any specific responsibilities related to telemetry.

The nurse's manual, quick guide for telemetry and the orientation form for new employees were used as orientation material in the ward. The nurse's manual did not contain instructions on the use of telemetry devices. The orientation form for new employees included sections on device safety, starting and ending telemetry, and telemetry equipment labelling. The date on which the employee had received the orientation was recorded on the orientation form. The same orientation format had been in use for a long time, and its content had not been reviewed or updated in recent years. The telemetry quick guide compiled in the ward was not the official quick guide issued by the device manufacturer. The instructions compiled in the ward provided visual and verbal instructions for attaching electrodes to the patient, installing the device, checking the rhythm, unlocking the device, replacing the battery, and delivering a new battery to another ward by pneumatic tube post. The guide also included instructions for cleaning the device after use. The instructions compiled in the ward did not address the content of alarms, acknowledgement of alarms in the central monitoring unit or action in case of disruptions.

HaiPro is an electronic reporting system designed for reporting and processing events that pose a threat to patient and client safety. HaiPro is also used at Seinäjoki Central Hospital in the Wellbeing Services County of South Ostrobothnia. Its aim is to promote patient safety, improve safety and develop risk management. HaiPro is a key tool in Finnish healthcare and it supports the development of quality and safety. Professionals report adverse events and incidents internally but usually not to the supervisory authority.

The investigation revealed that the staff do not always have time to record all events that pose a risk to device safety due to their heavy workload.

2.4.3 Philips Healthcare

Philips is one of the world's largest manufacturers of healthcare technology. Philips manufactures a variety of medical devices, such as patient monitoring systems, that are used in hospitals and other healthcare environments. These patient monitoring systems enable remote monitoring of patients, a quick alarm system, and early diagnosis. Philips IntelliVue Telemetry System is a telemetry solution that allows patients to move around in a hospital environment while their vital signs are monitored in real time. In early 2025, nearly 900 Philips IntelliVue MX40 devices were in use in Finland. At the beginning of 2025, Philips IntelliVue MX40 devices were in use across nearly all wellbeing services counties in Finland. The device is also widely used in several other countries.

In connection with the procurement of telemetry equipment, the device manufacturer provides the staff with deployment training prior to the commissioning of the system. In addition, the manufacturer has prepared a user guide for the device. According to the Act on Medical Devices[23], a professional user must ensure that medical devices are used in accordance with the intended purpose and instructions specified by the manufacturer. The

[23] 719/2021.

Medical Devices Act contains provisions on the obligation of healthcare operators to ensure the proper use, safety and traceability of devices.

2.4.4 Role and supervision of the Finnish Medicines Agency Fimea

The Medical Devices Act obliges professional users to notify the Finnish Medicines Agency (Fimea) of any existing and potential incidents involving medical devices. Statutory notifications or applications are key tools in terms of monitoring. A total of 5,000–6,000 patient safety incident reports are submitted to Fimea each year. Professional users report patient safety incidents to Fimea through an electronic interface used by the organisation or using a separate form that is available on the Fimea website. Medical device manufacturers submit their incident reports to Fimea as separate files by e-mail. These reports are transferred to the national CERE register[24].

The manufacturer's notifications include MIR reports[25] designed to ensure rapid information flow, risk assessment and implementation of corrective actions in the case of serious incidents. The report types include initial report, combined initial and final report, follow-up report and final report. The initial report is submitted for the first abnormality or incident. The combined initial and final report is used if the incident can be processed and completed with a single report. The follow-up report complements an earlier report, and the final report describes the processing of the event and the corrective actions that were implemented. The final report is submitted to the supervisory authority when the medical device has caused or could have caused a serious incident.

If the manufacturer considers that corrective actions are necessary, it submits an FSCA form[26] to Fimea stating the actions to be taken. In most cases, this is also accompanied by an FSN notice[27] that provides instructions on actions related to the safe use of the device. The manufacturer is responsible for implementing the actions and Fimea monitors their adequacy. The manufacturer also compiles periodic PSUR reports[28]. In addition, the manufacturer may report recurring and similar incidents using a PSR report[29]. Implementation of Eudamed's Vigilance module[30] will improve and harmonise reporting practices at the EU level. For more detailed information on Eudamed, see section 2.5.5.

Fimea does not provide regular feedback on the processing of patient safety incident reports or corrective actions, but it may require additional information on a case-by-case basis before the matter is concluded.

Fimea does not disclose patient safety incident reports to a professional user. Neither does the manufacturer send reports to professional users or medical technology units. In the case under investigation, Fimea requested additional information from the professional user concerning the handling of the device. The medical technology unit confirmed that the device had been sent to the manufacturer.

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[24] CERE is the name of the national register of medical device operators and their devices maintained by Fimea.

[25] MIR, Manufacturer Incident Report, is a notification submitted to the authority regarding an incident or adverse event related to a medical device.

[26] FSCA, Field Safety Corrective Action.

[27] FSN, Field Safety Notice.

[28] PSUR, Periodic Safety Update Report, is a report produced by device manufacturers. The PSUR includes post-market surveillance information, safety analyses and preventive and corrective actions.

[29] PSR, Periodic Summary Report.

[30] EUDAMED Vigilance is part of the EUDAMED system. The Vigilance module focuses on patient safety incident reports and safety reporting for medical devices. Vigilance will help manufacturers and authorities monitor and manage the safety of medical devices in line with the EU's Medical Device Regulation.

It is up to the professional user to assess whether use of the device in question can continue after an incident. Fimea notifies other authorities – such as the National Supervisory Authority for Welfare and Health, the Regional State Administrative Agency, the Radiation and Nuclear Safety Authority, the Finnish Safety and Chemicals Agency Tukes or the Safety Investigation Authority – of incidents as required by the regulations. As a rule, the information is delivered by Secure Mail to the address specified by the authority in question. Information on their delivery is recorded in the incident register.

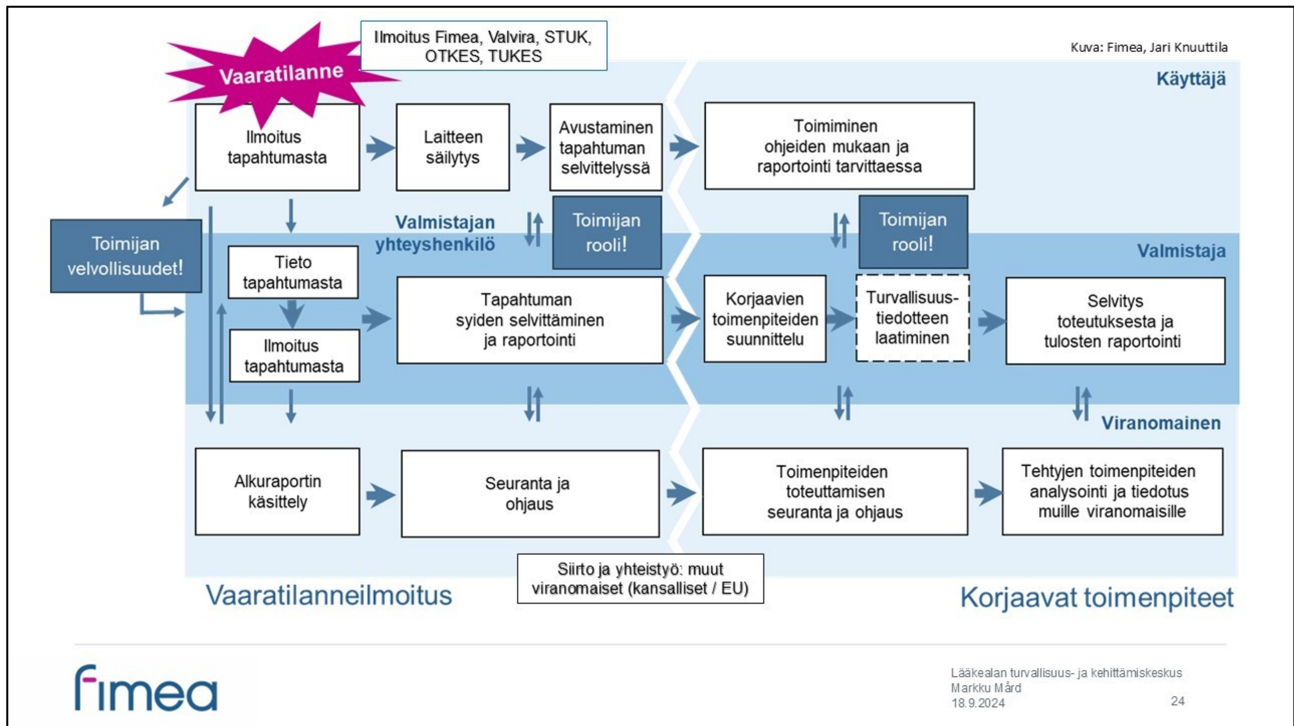

Figure 5. Fimea's description of the procedure for processing patient safety incident reports. (Picture: Fimea)[31]

The medical device manufacturer is responsible for reporting, investigation, risk assessment, conclusions and corrective actions related to a serious incident. In connection with the case under investigation, the manufacturer has submitted its final report to Fimea. Based on the conclusions of the investigation, Fimea finds the manufacturer's actions as sufficient. Fimea waited for the investigation of the Safety Investigation Authority to progress.

The manufacturer's final report submitted to Fimea concluded that the exact cause of the reported problem could not be determined on the basis of the available information and the tests that were performed. According to the report, possible causes were detachment of the battery due to a broken clip on the battery compartment or a decrease in battery charge because, based on log data, the battery had exceeded 500 charge cycles.

During the investigation, **Fimea also provided the Accident Investigation Authority** with Excel summaries of other telemetry device-related incidents reported to Fimea that did not involve the case under investigation or Seinäjoki Central Hospital. No other telemetry-related incidents leading to the death of a patient were reported during the investigation.

[31] Fimea's description of the procedure related to patient safety incident reports at a mini-seminar involving Fimea and the Safety Investigation Authority held on 18 September 2024.

2.5 Preventive action by the authorities

2.5.1 Ministry of Social Affairs and Health

Under section 21 of the Act on Organising Healthcare and Social Welfare Services (612/2021), the Ministry of Social Affairs and Health is responsible for the general guidance, planning, development and supervision of social welfare and healthcare. The Ministry of Social Affairs and Health is responsible for national health and social policy and thus for drafting and presenting legislative proposals concerning social welfare and healthcare services in the Government. The Ministry of Social Affairs and Health delivers its guidance in close cooperation with the wellbeing services counties. The Ministry of Social Affairs and Health also manages the client and patient safety strategy by defining the objectives and monitoring its implementation.[32]

The **Finnish Centre for Client and Patient Safety**, which operates under the Ministry of Social Affairs and Health, supports the development, planning, monitoring and evaluation of client and patient safety in Finland.[33] Funding for the Centre comes from the Ministry of Social Affairs and Health and the Wellbeing Services County of Ostrobothnia as well as through projects. The Centre produces various tools – such as operating models, checklists and indicators – for wellbeing services counties, professionals, clients and patients. In 2024, the Centre's national coordination tasks included coordinating and supporting implementation of the national Client and Patient Safety Strategy and Implementation Plan 2022–2026, drawing up an action plan for the remainder of the strategy period 2025–2026, and launching preparation of the new strategy period 2027–2031.

The Finnish Centre for Client and Patient Safety has prepared a tool called "General task description for the responsible person for medical devices"[34]. The definition of the general task description for a responsible person for medical devices is based on the objectives set out in the client and patient safety strategy. The responsible person for medical devices ensures the safe and appropriate use of the unit's medical devices.

2.5.2 Wellbeing services county

A wellbeing services county is a self-governing region that is responsible for organising social welfare, healthcare and rescue services in its region. The wellbeing services county is responsible for the realisation of client and patient safety in its services. It ensures equality for clients and the availability, continuity, safety and quality of services through self-supervision. Self-supervision refers to the means and actions by which the service organiser and service provider supervise, monitor and assess their activities. Self-supervision is the primary form of monitoring. In healthcare, a person who is dissatisfied with the care they receive or the way they are treated in connection with it may submit an objection to the healthcare unit responsible for the care.

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[32] Ministry of Social Affairs and Health (2022) The Client and Patient Safety Strategy and Implementation Plan 2022–2026, Publications of the Ministry of Social Affairs and Health 2022:12.

[33] In an assessment published in 2025 by the Finnish Centre for Client and Patient Safety (*Matkalla mallimaaksi*, Publications of the Finnish Centre for Client and Patient Safety 2025:1), the level of preparedness for tasks defined in the earlier Client and Patient Safety Strategy (*Publications of the Ministry of Social Affairs and Health 2022:2*) was examined using self-assessment questions. The preparedness level assessed by the South Ostrobothnia Wellbeing Services County for objectives related to the safe use of medical devices and information systems was 22%, which was the lowest among all wellbeing services counties. The national average for this indicator was 69%.

[34] Finnish Centre for Client and Patient Safety: Tool. Laitevastuuhenkilön yleinen toimenkuva. Laitevastuuhenkilön yleinen toimenkuva - Asiakas- ja potilasturvallisuuskeskus (only available in Finnish).

2.5.3 National Supervisory Authority for Welfare and Health

The National Supervisory Authority for Welfare and Health (Valvira) is a central agency operating in the administrative sector of the Ministry of Social Affairs and Health. It is responsible for providing guidance to the Regional State Administrative Agencies and wellbeing services counties in healthcare-related duties. Valvira also monitors the legality of social welfare and healthcare service provision and the services which the wellbeing services counties are responsible for organising. It provides supervision-related guidance in matters that are of importance in terms of principle or have broad implications, such as issues that concern two or more Regional State Administrative Agencies or the entire country. Valvira is also responsible for supervising the activities of social welfare and healthcare professionals and organisations as well as compliance with the essential requirements of patient and client information systems. Valvira processes healthcare complaints if there is suspicion that malpractice has resulted in a patient's death or serious permanent injury.

2.5.4 Regional State Administrative Agency

In its area of operation, the Regional State Administrative Agency supervises the legality of the provision of social welfare and healthcare and the services for which the wellbeing services counties are responsible for organising. It also provides guidance related to supervision. The Regional State Administrative Agencies guide and supervise both public and private social welfare and healthcare service providers. Among other things, the work of the Regional State Administrative Agencies aims at ensuring client and patient safety. The Regional State Administrative Agencies process nearly all complaints concerning social welfare or healthcare. Complaints most commonly deal with individual matters, such as those concerning the care, service or treatment of a specific client or patient. A Regional State Administrative Agency may refer a complaint to the operating unit concerned for processing as an objection.

2.5.5 Finnish Medicines Agency

In Finland, the manufacture, marketing and use of medical devices is supervised by the Finnish Medicines Agency (Fimea). Fimea's Medical Devices unit is responsible for supervising the regulatory compliance of medical devices and for promoting their safe use. Supervision of the regulatory compliance of devices applies to medical devices placed on the market as well as their professional use and maintenance The supervision is carried out in collaboration with other EU authorities. Fimea handles the patient safety incident reports that it receives. In addition, it issues certificates of free sale, and grants clinical trial investigation and derogations for medical devices.

Fimea performed an inspection of a professional user at Seinäjoki Central Hospital in May 2024. The inspection focused on activities in a total of nine hospital units. Fimea had requested and received advance material on the procurement of medical devices, the guidance of a professional user as a user of medical devices, and incidents. The information was supplemented during the on-site inspection. Nine deviations were detected during the inspection of a professional user. Fimea ordered the hospital to correct the deviations observed during the inspection. The hospital had to submit a plan describing the corrective and preventive actions to Fimea by the end of August 2024.

Table 2. Observations made and actions taken during Fimea's inspection of a professional user at Seinäjoki Central Hospital in May 2024.

Observations made during the inspection	Actions taken
The designated responsible person had not been clearly appointed, and there was no evidence to demonstrate that the obligations of that role were met.	The staff received training on the duties of a professional user and a responsible person. The South Ostrobothnia Wellbeing Services County appointed a responsible person (2023). The duties of the responsible person were also recorded in the decision.
Incidents related to medical devices were not identified or reported as required by law. The staff did not have sufficient knowledge about the obligations and procedures. No patient safety incident reports were submitted to Fimea in 2024.	After the inspection, an operating procedure for and process description of patient safety incident reports were prepared for Fimea. The procedure was linked to orientation programmes and self-supervision plans. The staff received training on the duties of a professional user and a responsible person.
Instructions drawn up in the hospital on the use of medical devices were being followed, and there was no certainty of compliance with the manufacturer's instructions.	The management of the units removed the instructions drawn up in the units and ensured that the manufacturer's operating instructions were used by the staff.

The patient safety incident reports submitted to Fimea are a key part of monitoring the safety of medical devices in healthcare. Patient safety incident reports provide the authority with information on incidents observed by both professional users and device manufacturers. These notifications can be used to assess the safety of medical device use and, if necessary, to initiate further investigations and actions to ensure patient safety.

Fimea had received patient safety incident reports related to MX40 devices from both professional users and the manufacturer. The incidents were divided into three categories:

- incident,
- serious incident, and
- death.

In an incident, the use of a medical device involves a deviation or risk without serious consequences. In a serious incident, the incident causes or could have caused a significant risk to the patient's safety. In a case of death, a deviation in the use of the device results in the death of the patient.

Prior to the case under investigation, a total of six cases related to the MX40 device or its malfunction in which the patient had died had been reported to Fimea between 1 July 2022 and 31 September 2023.

Table 3. Event descriptions of malfunctions in the telemetry system 1 July 2022–31 September 2023.

Date	Location	Disturbance related to telemetry
July 2022	North Karelia	The alarm system of a telemetry device did not function as expected
September 2022	Central Ostrobothnia	Technical failure of the telemetry system.
September 2022	Central Ostrobothnia	Interruption in the telemetry system connection.
October 2022	Central Ostrobothnia	Disconnected telemetry device cable.
January 2023	North Savo	The so-called red alarm of a telemetry device was not transmitted to the nurses due to a connection problem.
September 2023	Central Ostrobothnia	The alarm system of a telemetry device did not function as expected.

During the investigation, patient safety incident reports related to the MX40 device from professional users and the device manufacturer were submitted to Fimea. Five serious incidents were reported between October 2024 and August 2025. A total of 33 serious incidents were reported in 2024.

EUDAMED[35] is a European database on medical devices, which is a key part of new EU legislation. The database compiles information on manufacturers, devices and the different stages of their life cycle. In the future, medical device manufacturers will submit patient safety incident reports directly to EUDAMED, from where the data will be transferred to the national CERE register. Reports from professional users will not be transferred to the EUDAMED database.

The launch of EUDAMED has been delayed and the Vigilance (incident) module is expected to be introduced in 2026. The database combines several information systems, enhances the exchange of information between EU countries and improves market openness and transparency. It consists of six modules, which are actor registration, UDIs/device registration[36], notified bodies and certificates, clinical investigations and performance studies, vigilance and post-market surveillance, and market surveillance. The objective of EUDAMED is to ensure that the medical devices available in the EU are safe and effective.[37]

The CERE register is a database maintained nationally by Fimea on medical device operators and their devices. The register has been in use since 2020. The register is developed continuously, depending on the available funding. Fimea makes the details of operators registered in the CERE register publicly available in list format. Fimea updates the downloadable file on its website on the first business day of each month. Fimea receives, analyses and processes the incidents related to medical devices that are reported to the register. Each report

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[35] European Database on Medical Devices.

[36] UDI (Unique Device Identification) is a unique code used to identify and improve the traceability of medical devices.

[37] European Commission. [https://commission.europa.eu/index_fi]

entered in the register receives its own report number. The system may contain several reports with different numbers concerning a single case. Reports related to the same device and event may appear in the register under the names of different device components as indicated by the party submitting the report. The reports are assessed on the basis of the severity of the events. If necessary, additional information is requested and a risk assessment is performed. If the medical device poses a safety risk, a recommendation is issued to review the instructions for use, initiate recall procedures or impose other restrictions. The decisions are entered in the register and, if necessary, the information is shared with national and international authorities. Fimea also monitors the impacts of the actions and ensures that medical devices meet safety requirements. The CERE register is an important tool in terms of ensuring patient safety and market surveillance.

2.5.6 Finnish Safety and Chemicals Agency (Tukes)

The Finnish Safety and Chemicals Agency (Tukes) monitors compliance with the REACH[38] and CLP[39] regulations for chemicals used in medical devices.

Tukes works closely together with Fimea in the monitoring of medical devices. Fimea focuses on the general safety and suitability of medical devices for their intended use, while Tukes emphasises the aspects related to chemicals.

Tukes monitors the safety and compliance of medical devices, but Fimea has the main responsibility for monitoring the actual medical devices.

2.5.7 Other actors

Rather than an authority, the Medical Device Safety Network is a cooperation body of experts that focuses on improving the safety of medical devices in Finland. The network consists of expert volunteers who work together to develop device safety in social welfare and healthcare organisations. The network's activities include the specification of national criteria for device competence, the preparation of competence demonstration criteria and the development of harmonised device permit application forms. The aim is to ensure that the use of medical devices is safe and that users have the necessary skills to operate them appropriately. In cooperation with the Finnish Centre for Client and Patient Safety, Fimea and STUK, the network has prepared a user guide for ensuring competence related to devices. The Medical Device Safety Network produced a guide on the safe use of devices and ensuring device competence[40], which it submitted to the Ministry of Social Affairs and Health in June 2022. The Ministry of Social Affairs and Health published the guide in January 2024. The guide provides instructions on the safe use of medical devices and the legislation related to it.

The aim of the guide was to contribute to ensuring competence in units using the devices and to create a nationally harmonised model for device permit application forms and approval of device permits. Another aim was to help specify risk assessments for devices in individual operating units that would be used as the foundation for creating competence requirements. The guide discusses device safety deviations and reporting them, with an emphasis on the importance of monitoring and analysing patient safety incident reports with regard to learning and targeting corrective actions. The guide provides recommendations for ensuring device

[38] REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals.

[39] CLP, or Classification, Labelling and Packaging, regulates the classification, labelling and packaging of chemicals.

[40] Publications of the Ministry of Social Affairs and Health 2024:3, "Safe use of medical devices – a guide to ensuring device competence" (only available in Finnish).

competence, such as the use of device passports, which has been found to be a good way of ensuring staff competence. The publication is particularly intended for the management and staff of social welfare and healthcare organisations, and its aim is to promote device safety and client and patient safety by ensuring that competence related to the use of devices is up to date and sufficient.[41]

2.6 Organisations that participated in the rescue operation and their standby readiness

The hospital has an MET team that can be alerted to any hospital location in the event of a patient's lifelessness or a life-threatening disturbance in their vital signs. The alert is made by calling a specific telephone number. The MET team usually includes an intensive care unit physician or on-call anaesthesiologist and 1 to 2 nurses who are familiar with acute care. The group brings the equipment and medications needed to deal with the emergency from the intensive care unit.

2.7 Statutes, regulations and instructions

2.7.1 Acts and regulations

Pursuant to the **Health Care Act**[42], healthcare activities must be based on evidence and recognised treatment and operational practices. The healthcare provided must be high quality, safe, and appropriately organised.

The purpose of the **Act on Organising Social Welfare and Health Care**[43] is to promote and maintain the well-being and health of the population and to ensure equal, interoperable and cost-effective social welfare and healthcare services throughout the country.

The purpose of the **Act on the Supervision of Social Welfare and Health Care**[44] is to ensure client and patient safety and high-quality social welfare and healthcare services. The service provider must supervise the quality and appropriateness of the operations as well as client and patient safety. The service provider must draw up a self-supervision plan for each service unit, including a description of the reporting and learning procedure for incidents. The implementation of the activities described in the self-supervision plan must be monitored and any shortcomings observed during that monitoring corrected.

The **Health Care Professionals Act**[45] contains provisions on the obligation to provide further training and continuous professional development. Healthcare professionals must maintain and improve their professional knowledge and skills required to carry on their professional activity and familiarise themselves with the provisions and regulations concerning them. Employers of healthcare professionals must monitor the professional development of the healthcare professionals working for them. In addition, employers must create opportunities for healthcare professionals to participate in necessary further training for the profession and use other professional development methods to maintain and develop their knowledge and skills so that they can practice their profession in a safe and appropriate manner.

[41] Publications of the Ministry of Social Affairs and Health 2024:3.
[42] 1326/2010.
[43] 612/2021.
[44] 741/2023.
[45] 559/1994.

Provisions on the entire life cycle of medical devices from manufacturing to withdrawal are laid down in the **MD Regulation**[46] and in the **IVDR** [47]. The objective of the MD Regulation is to improve patient safety by tightening the requirements for the safety, quality and supervision of devices. In addition, the regulation contains provisions on the EUDAMED information system, which collects key information on medical devices and their safety.

Article 19 of the MD Regulation contains provisions on the EU declaration of conformity. Under Article 19.1, the manufacturer must compile and update an EU declaration of conformity. The manufacturer must ensure that the device remains safe and maintains its performance while being used in compliance with the instructions for use. The instructions for use must include information on the limitations of the device and the time for discontinuing its use.

In Finland, the MDR is supplemented by the **Medical Devices Act**[48]. The purpose of the Act is to ensure that medical devices are safe and effective. The Act protects the health and safety of patients, users and other persons and contains provisions on the placement on the market, deployment, use, maintenance and supervision of devices. The Act also promotes the traceability of devices and aims to ensure that they are monitored throughout their life cycle. Under the Act, Fimea is responsible for the general steering and supervision of the activities referred to in the Act.

Medical devices must be CE marked or otherwise legally approved medical devices. The device must have or be accompanied by labelling and instructions for use required for their safe use. The device must be used for the purpose stated by the manufacturer and in accordance with the manufacturer's instructions. The device must be adjusted, maintained and serviced according to the manufacturer's instructions and otherwise appropriately. The place of use must be suitable for the safe use of the device. Other medical devices and systems connected to the device or in its immediate vicinity may not compromise device performance or the health of the users. The device may be installed, serviced and repaired only by a person who has the required proficiency and expertise.

The Medical Devices Act provides a definition of a **professional user**. A professional user is a healthcare professional who uses a medical device in their work or hands it over for use by a patient. The user must have sufficient training and experience in the safe use of the device. A professional user must have a designated responsible person who ensures that the user's activities comply with the requirements. The **designated responsible person** must ensure the safety and appropriate use of the devices by means of a monitoring system. All information related to the use of the device and any incidents are entered in the monitoring system.

A professional user is required to report **adverse incidents** to Fimea and to the device manufacturer, authorised representative, importer, or distributor. For example, a report is submitted when the features, performance, disturbances or insufficient instructions for use related to the medical device have or could have caused a dangerous situation.

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[46] MD Regulation, Medical Device Regulation. Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

[47] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

[48] 719/2021.

Patient safety incident reports submitted by professional users and manufacturers are stored in the incident register maintained by Fimea. In addition, reports of incident filed by professionals responsible for service and installation, other users and patients may also be stored in the incident register.

Under the **Act on the Status and Rights of Patients**[49], every person who is permanently resident in Finland is entitled to health and medical care without discrimination within the resources available to healthcare at the time in question.

2.7.2 Standards

Alarm systems on medical electrical devices must be designed and implemented in accordance with standard IEC 60601-1-8[50]. For telemetry equipment, the standard places particular emphasis on the clarity, prioritisation and operating logic of alarms so that users can identify incidents in a timely manner and respond to them appropriately. The starting point for the standard is that each alarm is part of risk management. Based on a risk analysis, the manufacturer must determine the situations in which the device issues an alarm and with what priority.

The alarm systems for telemetry equipment are based on standardised prioritisation categories, where alarms are divided into low, medium and high-risk categories based on whether the situation causes immediate danger, threat to life or potential harm. The standard emphasises that alarm systems must not only be technically functional, but also understandable and consistent for users. As a result, both visual and auditory alarms must be designed in a way that makes it easy to identify their significance and level of urgency.

High priority alarms are always expressed in red, medium priority alarms in yellow, and low priority alarms in cyan or yellow. Priority-coded sounds must be used for the auditory signals, and they must be clearly distinguishable based on urgency.

Technical alarms in telemetry device alarm systems are usually classified as low priority notifications because they do not indicate an immediate threat to the patient's life.[51] According to the standard, such notifications can also be non-alarming advisory notifications that do not require an immediate response, but communicate about a future need, such as the replacement of a battery within the next 24 hours.

The standard defines so-called latched and non-latched alarms. A latched alarm continues until it is acknowledged, even if the situation that caused it has already been resolved, whereas a non-latching alarm automatically stops when the situation has been resolved. In terms of telemetry equipment, it is particularly important that, for example, a disconnection from the central monitoring unit is reported as a locking alarm. This ensures that the situation is not overlooked even if the connection is temporarily restored. It ensures that the user is made aware of an interruption in monitoring that may endanger patient safety.

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[49] 785/1992.

[50] International Electrotechnical Commission. (2020). *IEC 60601-1-8:2020 medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*. International Electrotechnical Commission.

[51] Patterson, E. S., Rayo, M. F., Edworthy, J. R., & Moffatt-Bruce, S. D. (2022). Applying human factors engineering to address the telemetry alarm problem in a large medical center. *Human Factors*, *64*(1), s. 126–142.

Physiological alarms are often susceptible to misinterpretation, but technical alarms are usually accurate and reliable. They include battery depletion, loss of signal or disconnection of sensor. These events may leave the patient completely without monitoring.[52]

2.8 Other information

2.8.1 Testing of the MX40 device

On 13 November 2024, the Safety Investigation Authority and the device manufacturer tested the MX40 device that was in use at the time of the incident. During the testing, the device was inspected externally and its functionality was tested with batteries received from the device manufacturer while it was connected to the central monitoring unit. In addition, log data available covering the time of the event was examined with an expert employed of the device manufacturer. The external inspection revealed that the device was physically damaged. The battery remained in place during the tests, but it detached easily when tapped against the palm of a person's hand or the edge of a table.

Figure 6. Broken hinges on the battery compartment door and a broken clip in the compartment. (Photo: SIAF)

For testing purposes, the manufacturer had arranged a corresponding central monitoring unit with the same settings as those at the site of the incident. The tests showed that the telemetry device was operating normally during the day of the test. The device manufacturer's demo system was set up and the device was connected for six hours. During testing, the device was restarted several times and it started each time without any problems. The distance from the base station that the device could be taken to before the connection was lost was also tested. In an open space, the connection was only lost at a distance of 30 metres. No problems with battery life or alarms issued by the device were detected during testing.

In connection with the testing, the log data was reviewed with an expert from the device manufacturer's German office.

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[52] Edworthy, J. R., Talbot, N., & Martin, N. (2025). Responding to clinical alarms in unfolding simulated clinical scenarios: auditory icons perform better than tonal alarms. *British Journal of Anaesthesia*. https://doi.org/10.1016/j.bja.2024.12.047.

The log data analysis revealed that, since the night before the event and during it, a battery that had exceeded the maximum number of charge cycles had been in the device. The log data also revealed that the device had issued an INOP message when it was attached to the patient at 16.56: "Tele: Service battery". The INOP message's auditory alarm was acknowledged by the nurses at 19:19 from the central monitoring unit. The log data showed that the battery had not been replaced after that, and the same battery was connected to the telemetry device until the telemetry device stopped operating the next morning.

The manufacturer of the telemetry device received the telemetry device sent by the medical technology unit of Seinäjoki Central Hospital without the battery that was in use at the time of the event. The battery had been removed from the device and returned to the charging station at the hospital. It was not later possible to identify this battery as the one installed in the device at the time of the event.

The Safety Investigation Authority instructed the device manufacturer to refrain from examining the device until the examination could be performed in the presence of representatives of the Safety Investigation Authority. The device manufacturer did not perform any actions on the device before the testing agreed with the Safety Investigation Authority on 13 November 2024. At that time, the box in which the device had been delivered to the manufacturer from the site of the event was opened.

The medical technology unit at Seinäjoki Central Hospital informed the Safety Investigation Authority on 7 November 2024 that it had inspected all batteries that were in use or in the ward's charging station on 6 November 2024. The inspection revealed that two of the batteries that were in use at Seinäjoki at the time of the event had exceeded the two-year service life recommended by the manufacturer.[53] The batteries had been manufactured in week 4 of 2022. In addition, five batteries were decommissioned in Seinäjoki because they did not charge during the inspection even though the blue light was on in the charging station. These five batteries had been manufactured in week 49 of 2022, which means that some of the two-year service life recommended by the manufacturer remained at the time of decommissioning. The medical technology unit at Seinäjoki handed over all seven batteries that had been decommissioned in connection with the inspection to the Safety Investigation Authority.

Examination of telemetry alarm log data revealed that at least three batteries that had issued a "Service Battery" alarm to the central monitoring unit while attached to the telemetry sensor were in use in the ward at the time of the event.

The **Safety Investigation Authority** tested the decommissioned batteries on 3 December 2024. The test revealed that two of the seven batteries that were in use at the site charged normally in a device corresponding to the charging station. These batteries had been manufactured in week 4 of 2022. Five of the batteries completely failed to charge, which is why their charge cycles could not be checked. The batteries that did not charge could not start the telemetry device. These batteries had been manufactured in week 49 of 2022.

[53] Philips Installation and Service IntelliVue MX40. Service Guide 6/2011, p. 68.

Situation at 9:08:

Batteries 1 and 2 almost fully charged.

Situation at 10.33:

Batteries 1 and 2 fully charged, batteries 3, 4, 5, 6 and 7 completely failed to charge.

Situation at 10.35:

Battery 2 removed from charging station and inserted into the telemetry device. Batteries 3, 4, 5, 6 and 7 repositioned in the station, causing the blue (cyan) light to go on.

Situation at 10.38:

Batteries 3,4,5,6 and 7 gradually change to blue (cyan). The batteries fail to charge, and the charging station fails to recognise them.

Figure 7. Testing of telemetry device batteries on 3 December 2024. (Photo: SIAF)

The test was terminated at 14:45 p.m. Batteries 1 and 2 charged normally. Batteries 3, 4, 5, 6 and 7 completely failed to charge. It was not possible to check the charge cycles for the batteries because they could not start the telemetry device.

In cooperation with the device manufacturer, the **Safety Investigation Authority** retested the batteries and alarms of the MX40 device on 14 March 2025. Two Philips MX40 devices were used in the test, one of which was a Philips demo device and the other the device under investigation. For the purposes of the test, the device manufacturer had been asked to obtain batteries that were of different ages and in different conditions. The charge cycles of the batteries used in the test ranged from 0 to 549. The devices were connected to a demo monitoring system using the Philips Patient Information Center iX system equipped with the settings used by Seinäjoki Central Hospital. The demo monitoring system included a dual-

screen computer, network devices and a Smart-Hopping base station. The telemetry devices were connected to the wireless LAN. Alarms were directed through a speaker connected to the computer.

The testing revealed that the system's alarm listing could not be accessed with the system's normal user IDs, and accessing it required switching to the system's diagnostics and maintenance functions and logging in with the system administrator's user IDs. System users did not have the possibility to view the status of system alarms as a whole.

Based on observations made during testing, the alarm names mentioned in the instructions for use prepared by the MX40 device manufacturer were not identical to those used in the system at Seinäjoki Central Hospital.

Table 4. The indicator that expressed the battery charge in the monitoring room system was found to function in steps during testing, displaying the values 100%, 80%, 60%, 40%, 20% and 0%. The corresponding actual battery charges were:

Indikaatio	Akun todellinen varaus
100 %	81–100 %
80 %	61–80 %
60 %	41–60 %
40 %	21–40 %
20 %	0–20 %

Table 5. The MX40 units functioned as described in the instructions for use in all tests performed on 14 March 2025. As the battery charge decreased, the devices issued INOP messages as follows:

Akun varaus	INOP-viesti
alle 20 %	"AKKU LOPUSSA TELE"
alle 10 %	"TELE AKKU TYHJÄ"

If a battery with more than 500 charge cycles was inserted, the device issued a "Service Battery" INOP message. The "Service Battery" INOP message prevents visibility and logging of the "Tele Battery Low" INOP message in the system. However, the "Tele Battery Empty" INOP message is displayed normally. At Seinäjoki Central Hospital, the configuration of the "Tele Battery Empty" INOP message had been upgraded to yellow when the system was deployed. During the test, the device operated for more than one hour after issuing the "Tele Battery Empty" INOP message. In successive technical alarms, the previous INOP message was always replaced by a new INOP message on the central monitoring unit screen.

In its own tests, the manufacturer also performed discharge tests on batteries that had been charged more than 500 times. In two cases, they managed to repeat a situation where the device shut down without an INOP warning about low battery. The battery charge was over 20% in the initial situation. When the battery charge decreased to less than 20%, the charge level dropped suddenly. Based on the alarm logs, device behaviour in these situations corresponded to the situation at Seinäjoki Central Hospital in the case under investigation. In this type of a situation, the central monitoring unit only reported the situation with a "No Data Tele" INOP message and the connection was lost.

2.8.2 Measurements of Smart-Hopping network reliability

The reliability of the Smart-Hopping wireless network used for telemetry device data transmission in different patient rooms was measured with the hospital's medical technology unit during the investigation. The measurement was performed using the built-in network measurement function of the MX40 following instructions given in the Philips Service Guide. The network measurement function analyses the connection based on three criteria: signal strength, connection quality and duration of interruptions. The service guide specifies limit values for a good connection for all of these criteria.

The values for signal strength were slightly lower than the limit value in about one third of the patient rooms. The quality of the network connection was generally good in the ward, and satisfactory in one patient room only. There were no interruptions during the measurement.

The signal strength in the patient room where the accident occurred was at the limit value and the connection was good. When viewed from the room where the accident occurred, the nearest Smart-Hopping network antenna was in the corridor right beside the door to the room.

2.8.3 Survey on Telemetry Devices for Medical Technology Professionals

The Safety Investigation Authority conducted a Webropol survey for people working in medical technology units in Finland. The survey mapped telemetry device operation, prevalence of disturbances related to them, and device maintenance practices. A total of 23 people, all of whom worked in public healthcare, responded to the survey anonymously. As the number of responses received to the survey was limited, it is not possible to draw reliable generalisable conclusions on problems related to the use of telemetry devices based on the responses, which must be seen as anecdotal findings.

The majority of the respondents reported problems with the operation of telemetry devices in their organisation. One half of the respondents estimated that problems or disturbances related to telemetry devices occur less than once every three months, while one third reported problems every 1 to 3 months. The most common cause of disturbances was disconnection from the central monitoring unit.

According to respondents, the staff has good competence in both using telemetry devices and assessing their operating condition. Respondents estimated that most of the problems were caused by technical faults, while user errors were considered rare. The features of the telemetry devices in use were mainly assessed as corresponding well to the current requirements for use.

Regular inspections of the devices are performed to a certain extent, especially annually or weekly, but nearly a half of the respondents could not say how often inspections were carried out. This suggests that practices are not clear to everyone or that inspections are not documented consistently. The responses reveal that employees do not know if telemetry devices are tested regularly, for example with test alarms, or if the number of charge cycles in telemetry device batteries is checked following the manufacturer's instructions. The most common reason for the decommissioning of batteries was poor battery life, which indicates that its capacity is declining and its service life is coming to an end.

Approximately one half of the respondents reported that their unit had designated a responsible person to ensure the safe operation of telemetry devices. This position was primarily considered to be the responsibility of the medical technology unit, but care unit supervisors, external service providers and device manufacturers were also mentioned as responsible parties. This suggests that responsibility arrangements may vary from one organisation to another, and that not all employees are completely certain of who is ultimately responsible for device safety.

2.8.4 Patient safety incident reports related to telemetry devices in wellbeing services counties and the HUS Group

During the investigation, the Safety Investigation Authority examined patient safety incident reports related to telemetry devices (HaiPro and Laatuportti) submitted by a total of 17 wellbeing services counties and the HUS Group. According to the information provided by the device manufacturer, these organisations used the same telemetry device models as in the case under investigation.

A total of 147 client and patient safety incident reports related to telemetry were submitted to the patient safety incident reporting systems in wellbeing services counties between 1 January 2023 and 31 December 2024. A total of 69% of the reports concerned patients. In six cases, the patient was found lifeless or they had died despite resuscitation.

Table 6. Client and patient safety incident reports related to telemetry in the wellbeing services counties' patient safety incident reporting systems from 1 January 2023 to 31 December 2024. The classification is based on the view of the event held by the person processing the report.

Nature of event	Consequence to patient			
	No harm	Slight harm	Moderate harm	Serious harm
Happened to the patient	21	61	19	6
Near miss	29			
Other observation/development proposal	11			

The data was divided into themes using the risk management model and applying the BowTie method.[54]

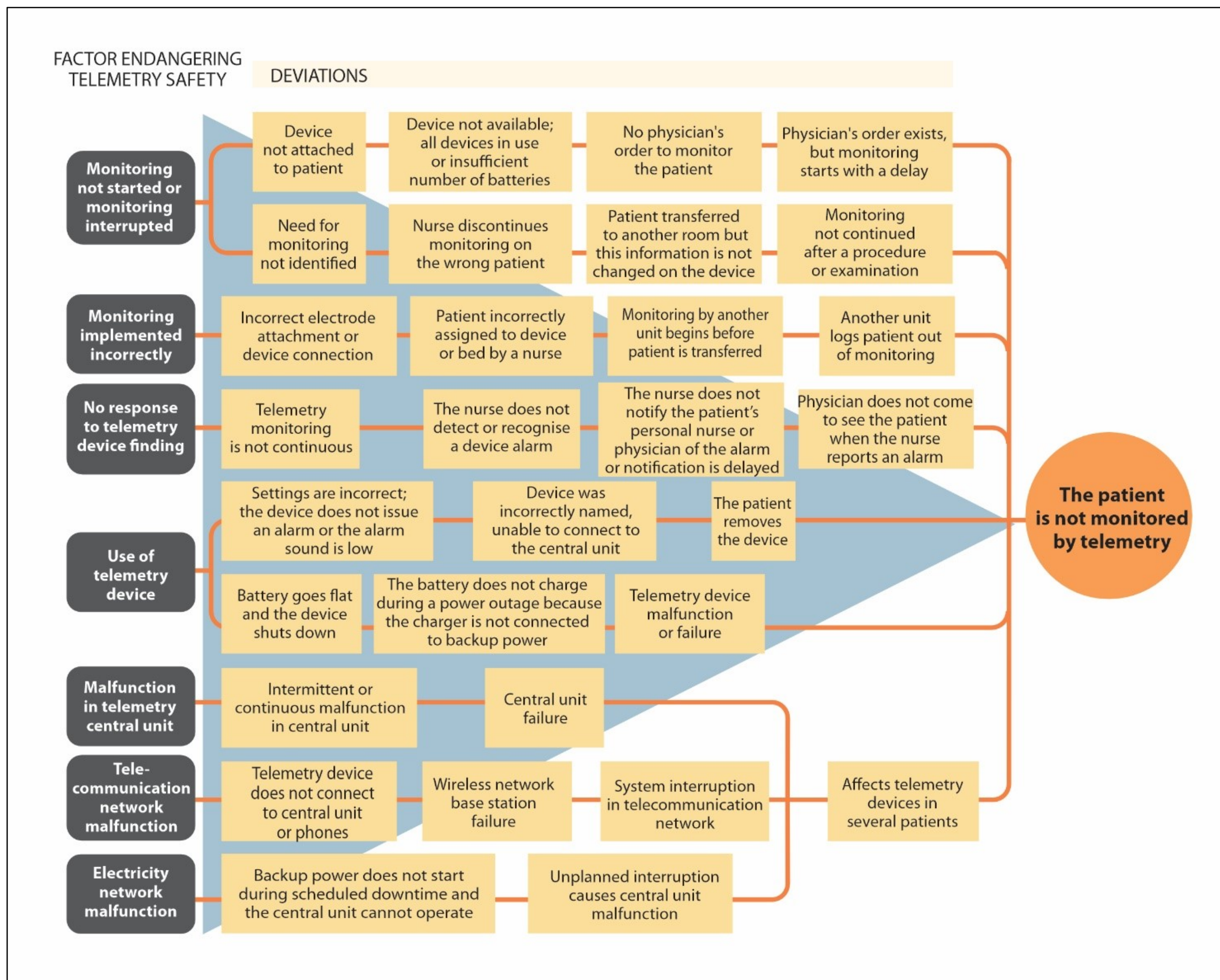

Figure 8. Deviations related to telemetry and their causes that may, based on the patient safety incidents reported to the wellbeing services counties' reporting systems, endanger patient safety. The main reasons affecting the event are grouped on a general level. (Figure: SIAF)

54 BowTie is a method used to describe different scenarios in risk management. It derives its name from the fact that the diagram resembles a bowtie in shape. At the centre of the diagram is a top event in which loss of control occurs. On the left are sequences of events triggered by threats that can lead to the top event. The sequences of events can be interrupted by barriers that prevent the top event. On the right side are potential consequences that can be prevented or mitigated by proactive barriers.

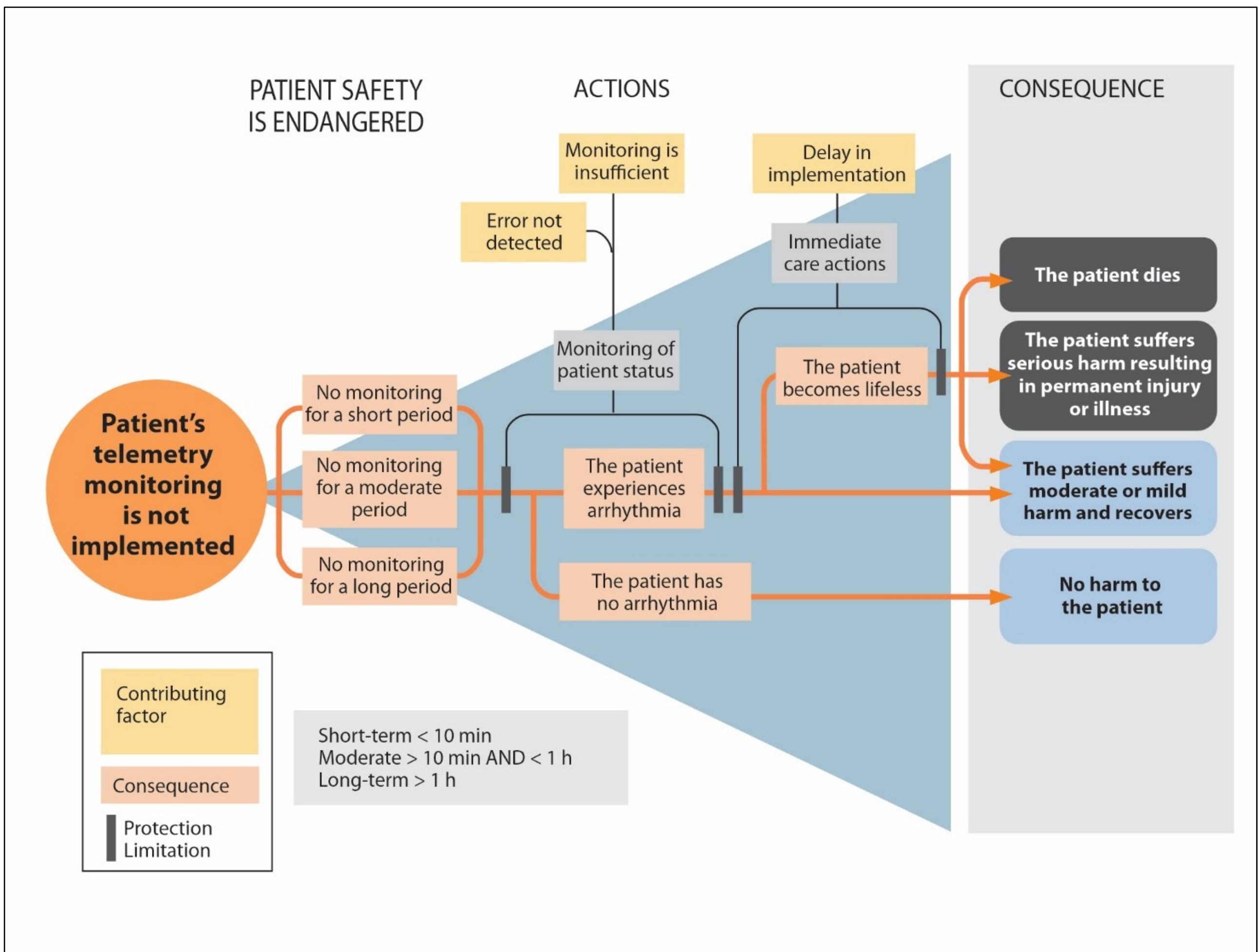

Figure 9. Consequences for the patient of telemetry-related patient safety incidents reported to the wellbeing services counties' reporting systems if the safety risk related to telemetry is realised and patient safety is compromised. The consequences of the patient safety incident and the methods for managing them are described on a general level. (Figure: SIAF)

Table 7. Telemetry-related patient safety incident reports submitted to the wellbeing services counties' patient safety incident reporting systems 1 January 2023–31 December 2024.

Factor endangering the safety of telemetry	The patient's telemetry monitoring is not implemented			
	Short-term < 10 min	Moderate > 10 min and < 1 h	Long-term > 1 h	Total
Monitoring not started or monitoring interrupted	0	9	17	**26**
Device not attached to patient		3	5	**8**
Device not available; all devices in use or insufficient number of batteries		1	2	**3**
No order to monitor the patient issued by a physician			2	**2**
Physician's order has been issued but monitoring starts with a delay		1	2	**3**
Need for monitoring not identified		1	1	**2**
Nurse stops monitoring on the wrong patient		1	1	**2**
Patient transferred to another room but this information is not changed on the device			2	**2**
Monitoring not continued after a procedure or examination		2	2	**4**
Monitoring carried out incorrectly	4	6	1	**21**
Incorrect electrode attachment or device connection		1	4	**5**
Patient incorrectly assigned to device or bed by the nurse	2	2	6	**10**
Monitoring by another unit begins before patient is moved	2	1		**3**
Another unit logs patient out of monitoring		2	1	**3**
No reaction to telemetry device finding	4	8	6	**18**
Telemetry monitoring is not continuous		2		**2**
Nurse does not detect or recognise the device alarm	2	3	1	**6**
The nurse does not notify the patient's personal nurse or physician of the alarm, or notification is delayed	2	3	3	**8**
Physician does not come to see the patient when the nurse reports an alarm			2	**2**
Use of telemetry device	6	1	1	**8**
Settings are incorrect; the device does not issue an alarm or the alarm sound is low	6			**6**
Device is incorrectly named, unable to connect to the central unit			1	**1**
The patient removes the device		1		**1**
Telemetry equipment malfunction	11	6	4	**21**
Battery goes flat and device shuts down	2	3	4	**9**
Battery fails to charge during scheduled power outage; charger not connected to backup power		1		**1**
Telemetry device malfunction or failure	9	2		**11**
Malfunction in telemetry central unit	2	0	3	**5**
Brief or recurring intermittent malfunction in central unit	2			**2**
Central unit failure			3	**3**
Electricity network malfunction	1	0	1	**2**
Backup power does not start during scheduled downtime and the central unit cannot function	1			**1**

Unplanned interruption causes central unit malfunction			1	**1**
Telecommunication network malfunction	32	7	7	**46**
Telemetry device does not connect to central unit or phones	29	3	2	**34**
Wireless network base station failure	3	1		**4**
System interruption affecting several telemetry devices		3	5	**8**
Total	**60**	**37**	**50**	**147**

2.8.5 Human factors related to telemetry device alarms

Studies show that working with telemetry equipment places five key cognitive demands on healthcare professionals: attention and vigilance, multitasking, mental workload, memory and situation awareness.[55] The related limitations expose people to errors and alarm fatigue if the systems are not designed to support human information processing.

Studies show that up to 85-99% of telemetry alarms are false positives or clinically insignificant, in other words alarms that do not require a reaction involving treatment actions[56] Over time, this type of situation may lead to an inappropriate working culture in which, rather than immediately reviewing alarms in detail, they are only acknowledged en masse when the nurse has time to view the central monitoring unit screen.

Alarm fatigue occurs in situations where a high number of unnecessary alarms[57] increases the load on staff to the point that they unconsciously begin to ignore or silence alarms. This may lead to failure to notice clinically significant alarms, which reduces patient safety.

Social welfare and healthcare staff usually have complete trust in technology, such as telemetry equipment, and do not consider it necessary to check the operation of monitors and equipment if there are no alarms. This is reflected in the phrase that emerged in the hearings, “the device will surely issue an alarm if something happens”. Patient monitoring is based on the assumption that the device is reliable.[58]

The illusion of safety, or excessive confidence in device operation, may lead to hazardous situations involving problems with the functioning of the device or alarm system. A paradox arises: if a device constantly issues alarms for insignificant reasons, the staff will not react, but will still rely on it in critical situations. If the device battery is flat, the sensor is disconnected or the signal is interrupted, the disturbance may be missed as the staff do not immediately react to all alarms due to the work culture or the alarms are not noticed due to alarm fatigue. If the telemetry device does not transmit or issue an alarm, the patient is not being monitored. If the patient's condition deteriorates, the staff has no knowledge of the situation.

Studies have also found that many units, such as the Seinäjoki Central Hospital ward, use the factory settings of the devices and do not adjust them individually for each patient. In practice,

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[55] Korentsides J, Miller ZN, Lazzara EH., Fernandez R & Keebler JR (2025) The perils of modern telemetry: A human factors perspective. *Human Factors in Healthcare*, *7*, 100102. https://doi.org/10.1016/j.hfh.2025.100102.

[56] Lewandowska K, Weisbrot M, Cieloszyk A, Mędrzycka-Dąbrowska W, Krupa S, & Ozga D (2020) Impact of alarm fatigue on the work of nurses in an intensive care environment—a systematic review. *International Journal of Environmental Research and Public Health*, *17*(22), 8409. https://doi.org/10.3390/ijerph17228409.

[57] Jämsä JO, Uutela KH, Tapper AM, Lehtonen L. Clinical alarms and alarm fatigue in a University Hospital Emergency Department-A retrospective data analysis. Acta Anaesthesiol Scand. 2021 Aug;65(7):979-985. doi: 10.1111/aas.13824. Epub 2021 May 4. PMID: 33786815.

[58] Bach TA, Berglund L-M, Turk E. Managing alarm systems for quality and safety in the hospital setting.BMJ Open Quality 2018;7:e000202. doi:10.1136/bmjoq-2017-000202. https://doi.org/10.1136/bmjoq-2017-000202

this means that alarm limits often remain very sensitive and that minor and clinically insignificant variations in the patient's vital signs can trigger alarms. This results in a large number of non-functional alarms that increase the workload of healthcare professionals and expose them to an inappropriate work culture and alarm fatigue.[59]

Studies have also addressed the importance of the quality and distinctiveness of alarm sounds. Alarm sounds that are confusing and difficult to identify increase the likelihood of errors.[60] The concept of a "normal alarm" emerged in the hearings, which refers to a fairly common INOP alarm issued by the telemetry monitor. The alarm sound generated by the system was the same for all different INOP alarms. According to recommendations in the new IEC 60601-1-8 standard, the use of auditory icons should be introduced.[61] These are alarms that resemble the sounds of the real world and are quicker to learn and easier to identify. They also cause less cognitive load.[62]

The significance of alarms is not solely determined by their priority category, as some of the technical INOP alarms are vital and critical for telemetry system operation. The decisive factor is how people respond to them in practice. This is why knowledge of the alarm system logic and alarm management play a key role. Reducing the number of false higher-priority positive alarms, for example by actively using patient-specific alarm limits, can also contribute to a more sensitive response to INOP alarms. In addition, instructions on acknowledging alarms can also help to change the working culture.

2.8.6 Impact of patient safety incident reporting systems

The patient safety incident reporting systems used in Finnish healthcare, such as HaiPro and Laatuportti, have been in use for more than a decade. Their primary objective is to improve patient safety by enabling the reporting and analysis of adverse events and near misses and implementation of the necessary corrective actions.

Although the number of reports has increased over the years, only a very small proportion of them result in concrete actions. Studies indicate that written development recommendations are prepared in few cases, and the inefficiency of processing in the reporting systems has been considered a significant deficiency. Although the basic logic of the systems and user competence are assessed as positive, their ability to produce concrete improvements has remained limited, which has led to dissatisfaction among staff.[63] [64]One key issue is the lack of a reporting feedback loop. The employee who submitted the report often does not receive information on what happened after the report. This one-way communication is perceived as frus-

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[59] Cvach M. (2012). Monitor alarm fatigue: an integrative review. *Biomedical instrumentation & technology*, *46*(4), 268-277. https://doi.org/10.2345/0899-8205-46.4.268

[60] Lin YL, Guerguerian AM, Tomasi J, Laussen P & Trbovich P (2017) Usability of data integration and visualization software for multidisciplinary pediatric intensive care: Human factors approach to assessing technology. *BMC medical informatics and decision making, 17*, 1–19. https://doi.org/10.1186/s12911-017-0520-7

[61] IEC 60601-1-8:2006+A1:2012+A2:2020, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*

[62] Auditory icon alarms can include a heart symptom alarm that resembles the sound of the heart or a medication alarm that resembles the sound of shaking a jar of tablets. Auditory icons give the nurse an auditory signal that mimics the real world and immediately describes the treatment area it is related to, thus reducing the load.

[63] Liukka M, Hupli M, Turunen H. Problems with incident reporting: Reports lead rarely to recommendations. J Clin Nurs. 2019; 28: 1607–1613. https://doi.org/10.1111/jocn.14765.

[64] Koskiniemi S, Syyrilä T, Mikkonen S, Hämeen-Anttila K, & Härkänen M (2024). Käyttäjien näkemykset sähköisistä potilasturvallisuuteen liittyvistä vaaratapahtumien ilmoitusjärjestelmistä. *Finnish Journal of eHealth and eWelfare*, *16*(3), 309–321.

trating, and it reduces the motivation to submit another report in the future. Without a feedback loop, reporting remains a separate process that does not give the reporting person the impression that their experience or concerns would be taken seriously. This is problematic, as earlier international studies have shown that feedback and visible impact perceived by staff are the most important motivating factors in terms of reporting.[65]

The processing of reports also involves organisational challenges. Supervisors' responsibility for reviewing reports and development actions varies significantly. In some units, reports are processed systematically and development plans are drawn up for them, while in others the processing may be delayed by months or not done at all. The problem is exacerbated by the fact that the systems often do not monitor whether the recommendations have actually been implemented. Monitoring and impact assessment remain inadequate, which reduces the credibility of the system.

The technical implementation of reporting systems has a significant impact on how easy and meaningful reporting is. Based on extensive survey data, nurses feel that the systems support cooperation and information flow inside the organisation. However, there are still significant problems related to their usability and technical functionality, especially in client and patient information systems. The systems used for reporting patient safety incidents, such as HaiPro and Laatuportti, work better in a technical sense but there is still a need for development in other information systems. Poorly functioning systems waste time, increase the workload and reduce willingness to submit reports.[66] [67]

Finnish systems for reporting patient safety incidents have developed over the years, but their actual impact has so far remained modest. The number of reports continues to increase, but they rarely result in documented development actions. This jeopardises the credibility of the entire system and reduces staff motivation to actively participate in patient safety work. In order for the system to genuinely function as a tool for learning and development, changes are needed at the technical, organisational and cultural levels.

The Finnish Institute for Health and Welfare (THL) is conducting continuous research and working on a project to develop this matter: “Monitoring Digital Healthcare and Social Welfare”. The monitoring work covers the implementation of national information system services, the experiences of professional users, the population’s use of digital services and experiences obtained through surveys conducted at different times.

2.8.7 Human errors and reporting them

Social welfare and healthcare continuously strive to move towards a more open and safe care environment, but the fact that people are still reluctant to discuss errors made by people in the same way they discuss faults in technical systems remains a major challenge. Although patient safety is everyone’s goal, reporting practices continue to favour technical problems that

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65 Wawersik D M, Boutin ER, Gore T & Palaganas J C (2023) Individual Characteristics That Promote or Prevent Psychological Safety and Error Reporting in Healthcare: A Systematic Review. Journal of Healthcare Leadership, Volume 15, 59–70. https://doi.org/10.2147/jhl.s369242.

66 Kyytsönen M, Hyppönen H, Koponen S, Kinnunen UM, Saranto K, Kivekäs E & Vehko T. (2020). Information systems as supporters of nurses' work: experiences by system brand. doi:10.23996/fjhw.95704

67 Yusof MM, Takeda T, Shimai Y, Mihara N & Matsumura Y (2024) Evaluating health information systems-related errors using the human, organization, process, technology-fit (HOPT-fit) framework. Health Informatics Journal, 30(2). https://doi.org/10.1177/14604582241252763.

are easier to observe and less likely to attach blame. This has a direct impact on how much is learned from the system and how well it works.[68]

Many social welfare and healthcare professionals hesitate to report situations in which they have been involved in an error or when the case involves a colleague's actions. A qualitative study of nurses' experiences shows that reporting an error may seem like a personal threat, especially if it involves a colleague with whom they work closely. In such situations, fear of reactions in the work community or a negative attitude on the part of management may silence important information before it ever reaches the system.[68]

This is one of the reasons why technical errors, such as device malfunctions or information system failures, are reported more readily. A technical error is often clear, verifiable and separate from personal responsibility. The study shows that reporting technology-related errors is perceived as safer, the source of the error being the "system" rather than a "human". As a result, technological deviations are more easily recorded in the systems and more is learned from them. However, this distorts the idea of the roots of the problems: systems indicate that technological errors are the greatest challenge, while less attention is paid to problems related to behaviour and operating principles. This reduces the ability of reporting systems to identify actual development areas in healthcare.[69]

An individual's perception of psychological safety has a significant impact on whether or not they report their mistakes. If an employee believes that reporting an error does not result in punishment or stigmatisation, it is much more likely that they will be prepared to report it. On the other hand, errors are often left unreported in situations where the atmosphere involves fear of accusations or shame. In particular, this is emphasised in organisations where people are blamed for errors and attention focuses on the individual and not on system development.[70]

The idea that errors are an inevitable part of a complex operating environment is a well-functioning approach. Rather than as an individual's failures, errors should be seen as opportunities to improve activities and learn. This so-called "just culture" approach[71] makes it possible to openly process errors and supports reporting. For example, this approach has been successfully used in the aviation sector, where one of the criteria for assessing reporting system effectiveness is how often people report their own errors. A similar approach in healthcare could significantly improve patient safety and the organisation's learning capacity.[72]

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[68] Namadi F, Alilu L & Habibzadeh H (2024) Nurses' experiences of reporting the medical errors of their colleagues: A qualitative study. BMC Nursing, 23(1). https://doi.org/10.1186/s12912-024-02092-8.

[69] Ndabu T, Mulgund P, Sharman R & Singh R (2021) Perceptual Gaps Between Clinicians and Technologists on Health Information Technology-Related Errors in Hospitals: Observational Study. JMIR Human Factors, 8(1), e21884. https://doi.org/10.2196/21884.

[70] Wawersik DM, Boutin ER, Gore T & Palaganas JC (2023) Individual Characteristics That Promote or Prevent Psychological Safety and Error Reporting in Healthcare: A Systematic Review. Journal of Healthcare Leadership, Volume 15, 59–70. https://doi.org/10.2147/jhl.s369242.

[71] Just culture approach to safety.

[72] Yusof MM, Takeda T, Shimai Y, Mihara N & Matsumura Y (2024) Evaluating health information systems-related errors using the human, organization, process, technology-fit (HOPT-fit) framework. Health Informatics Journal, 30(2). https://doi.org/10.1177/14604582241252763.

3 ANALYSIS

To analyse the event, the Accimap[73] method developed further by the Safety Investigation Authority was used. The analysis text is structured based on an Accimap diagram prepared during the course of the investigation. At the bottom of the diagram, the accident is described as a chain of events. Factors emerging in the background of the chain of events are analysed in the diagram at different levels.

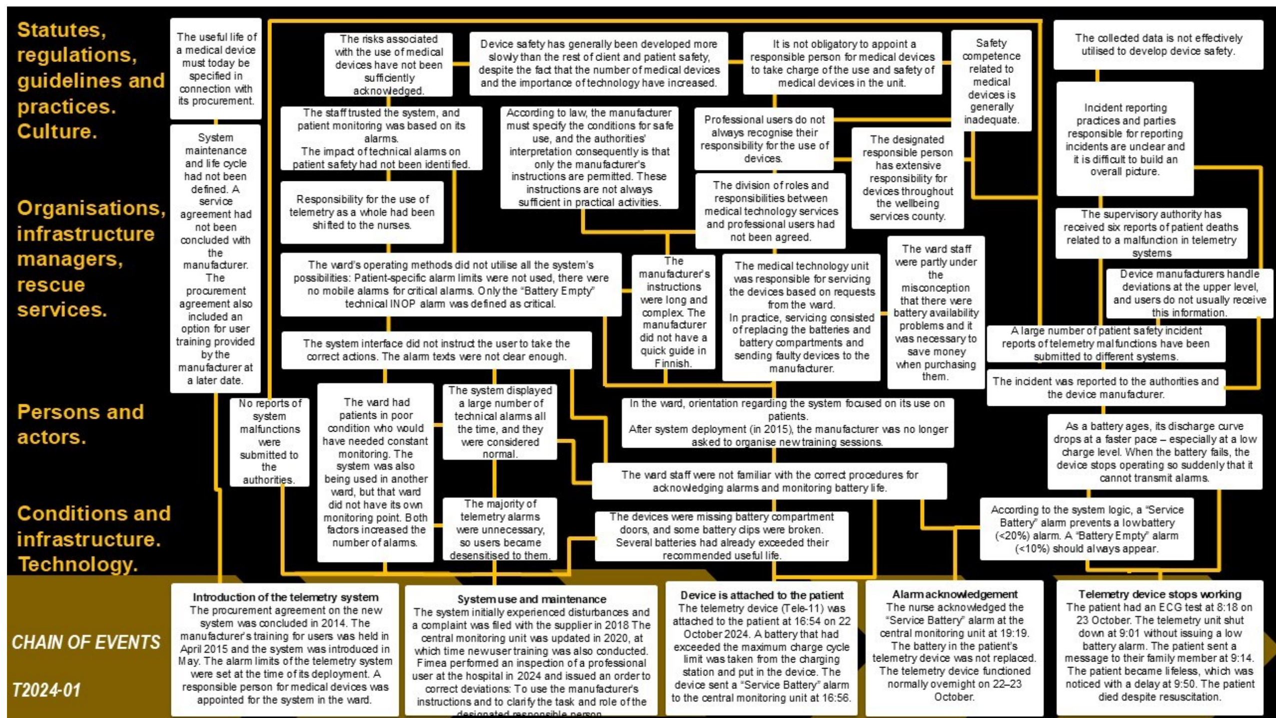

Figure 10. ACCIMAP analysis diagram T2024-01. (Picture: SIAF)

3.1 Analysis of the event

A patient who was being treated in an inpatient ward at Seinäjoki Central Hospital died on 23 October 2024. The patient became lifeless, and this was detected with a delay as a telemetry device had stopped working.

3.1.1 Deployment of the telemetry system

A decision was made to replace the old telemetry system used in the ward in conjunction with a renovation of the hospital. The procurement decision on the new system was made in 2014, and training related to system deployment was organised by the device manufacturer in April 2015. The new system was completed shortly afterwards and deployed in May. In June 2020, a system update was implemented for the central monitoring unit, in connection with which training on the operation of the central monitoring unit was provided at the initiative of the device manufacturer. Furthermore, no service agreement concerning the telemetry system was concluded with the device manufacturer.

In 2015, the ward prepared its own quick guide to the system to support the staff. The physicians in the ward trained the nurses in such tasks as interpreting the patient's heart rate

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[73] Rasmussen, J. & Svedung, I. (2000) *Proactive Risk Management in a Dynamic Society*. Karlstad, Sweden: Swedish Rescue Services Agency.

waves. The alarm limits for patient alarms were also configured and set in conjunction with system deployment. Some technical INOP alarms could have been configured as critical, but with the exception of one alarm, this was not done during commissioning or at any later stage.

After system deployment, disruptions in its operation were observed, and a complaint was filed with the device manufacturer in January 2018. However, no reports concerning system operation were made to the supervisory authority despite the disruptions that led to the complaint.

At the time of its deployment, no life cycle was defined for the telemetry system installed in the ward, nor was a date set for expiry of the declaration of conformity. At the time of the event, the staff had no knowledge of how long the intended use of the system in question was expected to continue.

The MD Regulation entered into force when the Seinäjoki Central Hospital telemetry system was already in use. Medical devices introduced after the Regulation took effect had to have a specific life cycle defined in conjunction with the device procurement.

3.1.2 Use and maintenance of the telemetry system

The orientation of new employees mainly focused on how to place telemetry devices on patients and on the basic use of the device in patient care, such as identification of various arrhythmias. The orientation guide for new nurses contained a general statement of the fact that new employees must receive orientation regarding telemetry devices. The orientation only dealt with the ways in which the staff was accustomed to use the system. More extensive learning of how to use the system was largely based on the employees' own activity level and interest. As a result, the staff in the ward were not widely aware of such possibilities as increasing the priority of technical alarms. In addition, the orientation did not address the limitations of the system or the risks associated with its use.

The safe use of medical devices is a key element in terms of ensuring client and patient safety. For this, sufficient device safety competence is required. Continuous staff training and upkeep of competence are essential, especially due to the rapid development of medical devices and technology as well as staff turnover.

Legislation obliges persons using medical devices to have training and experience that enable them to use the devices safely. The management of the organisation is responsible for the fulfilment of and compliance with these requirements, and each social welfare and healthcare professional is also responsible for maintaining their personal competence. The national Client and Patient Safety Strategy and Implementation Plan 2022–2026 also emphasises the importance of device safety, safety competence and appropriate orientation.

The telemetry system was trusted in the daily work of the ward, and the system was generally perceived as easy to use. The monitoring of patients' condition was largely based on the data recorded by the system and the alarms received through it. As this was not an intensive care unit, the number of nursing staff members was not dimensioned for real-time monitoring of patients. This increased the importance of telemetry in monitoring patients' condition. Although the uninterrupted operation of the telemetry system is a key prerequisite for patient safety, the risks related to system operation had not been assessed and, for example, the impact of technical alarms on patient safety had not been identified.

The entire responsibility for using the telemetry system had been shifted to the nursing staff. The physicians working in the ward asked nurses to print the information collected by the

system from the central monitoring unit, but they rarely investigated system alarms themselves.

It is technically possible to adjust the alarm limits of the system for each patient, but in practice, adjustments were rarely made. In this case, the nurse first asked the physician for permission to change the alarm limits. Using the same alarm limits for all patients instead of patient-specific alarm limits is likely to increase the number of alarms. The higher the number of alarms, the more difficult it is for staff to distinguish alarms that actually require attention from those that do not require action by the staff. The inpatient ward at Seinäjoki Central Hospital had not prepared separate instructions for handling and acknowledging alarms issued by telemetry devices.

Alarms were perceived as a normal event in the ward, which may have resulted in healthcare professionals becoming accustomed to the alarm sounds. The number of alarms was also increased by the fact that the telemetry monitoring data and alarms of patients on an upstairs floor were transmitted to the central monitoring unit screen in the inpatient ward. This increased the risk of missing actual alarms or failing to acknowledge them for a longer period of time.

Patients whose condition would have required continuous monitoring and treatment in a monitoring unit were transferred to the inpatient ward. The placement of patients in the hospital was influenced by a shortage of staff resources in the intermediate care unit. The treatment of patients in poor condition requires a great deal of resources in an inpatient ward. Patients in poor condition also typically cause more critical alarms in the telemetry system than those who are in good condition. Patients in good condition may be more mobile than those in poor condition, which can cause more technical alarms, for example when the device is taken out of the network's range.

The staff was under the impression that the devices were old. This was interpreted as meaning that the long service life of the devices caused them to function uncertainly at times. In other words, situations caused by incorrect use might also be attributed to the age of the devices.

The legislation states that the medical device manufacturer specifies the conditions for safe use of the device. Accordingly, for example, all instructions for use should be prepared or approved by the device manufacturers. However, the ward was using a quick guide to the telemetry system that had been prepared in the ward, which the supervisory authority does not permit. The only quick guide provided by the device manufacturer was insufficient. It only described the structure of the device, not the risks associated with using the system or issues that are essential to its reliable operation, such as correct procedures for acknowledging alarms or decommissioning batteries that have exceeded the maximum lifetime or number of charge cycles.

The current legislation and its interpretation are based on the assumption that each employee thoroughly familiarises themselves with dozens of different devices and reads instructions for their use that are hundreds of pages long. This is not realistic in practice, because nurses use several devices in their work and may work in several different units. There is usually no time reserved for reading device instructions during working hours.

Fimea performed a professional user inspection at the hospital in May 2024. During the inspection, an order was issued to correct deviations. Although only instructions for use approved by the manufacturer were to be used in the ward, a quick guide prepared in the ward was still being used at the time of the event. The inspection also drew attention to the fact that

the designated responsible person in the wellbeing services county had not been clearly appointed and their role had not been appropriately specified.[74]

Some parts of the user interface of the telemetry system were unclear. It was not intuitive in terms of its informatics and did not guide users to act correctly. The alarm texts in the device were misleading. In many cases, the original English wording was already unclear, and the Finnish translation repeated the same error. For example, the "Service Battery" message gave the wrong impression in a situation where a more accurate and instructive message would have been "Replace Battery".

Battery compartment doors were missing from several of the telemetry devices used in the ward, and the battery clips were broken in some devices. The condition of the devices was not systematically monitored and inspected at regular intervals, and the people working in the ward were not aware of the criteria for decommissioning the batteries. The LED lights on the battery charging station of the telemetry devices were not monitored systematically. The charging station was placed on a shelf in an office cabinet behind the door, making it difficult to monitor the charging station lights. The nursing staff in the ward were under the misconception that there were problems with the availability of telemetry device batteries and that savings should be made regarding their procurement.

The hospital's medical technology unit was responsible for servicing the telemetry system. In practice, their tasks involved replacing batteries and battery compartment doors and sending faulty devices to the manufacturer. The medical technology unit did not monitor the charge cycles of the batteries in the telemetry devices or the dates of battery manufacture even though the instructions for device use stated that batteries should be decommissioned after 500 charge cycles or two years after the date of manufacture.

The division of roles and responsibilities between the medical technology unit and the ward staff was unclear in terms of telemetry system maintenance. The medical technology unit was responsible for managing a large and continuously growing number of different device groups, which meant that very little time might be available for a single device.

3.1.3 Placement of the telemetry device on the patient

The telemetry device was placed on the patient as soon as the patient was transferred to the ward. A battery for which 500 charge cycles had already been exceeded was taken from the charging station and inserted into the device. The device being used was not in perfect condition either, as the battery clips and battery compartment door were broken.

Once the device was placed on the patient, the nurse checked the device screen to ensure that the data being measured was formally correct and the battery charge level was sufficient. All alarms issued by the device can also be acknowledged from the device on the patient, but this option was not part of the ward's operating practices. Ward practice involved checking and acknowledging all alarms on the central monitoring unit screen.

The "Service Battery" message was displayed immediately after the telemetry device was turned on. Normal practice did not involve checking any technical alarms related to the start-up of telemetry devices on the central monitoring unit screen in real time in connection with the process of starting to use the device.

[74] In an assessment published in 2025 by the Finnish Centre for Client and Patient Safety (*Matkalla mallimaaksi*, Publications of the Finnish Centre for Client and Patient Safety 2025:1), it was found that almost all wellbeing services counties had designated a person responsible for the professional user role.

The people working in the ward did not recognise their responsibility as professional users of telemetry devices. The personnel did not have sufficient competence for the correct and safe use of the device. The technical alarms issued by the device, such as those related to battery condition or battery charge, were not recognised as important alarms.

The ward had appointed a responsible person for the telemetry system, but no job description had been drawn up for them. As a result, responsibility for this task was mainly symbolic. The appointment of a responsible person for medical devices is based on recommendations as it is not required by legislation.

In wellbeing services counties, the designated responsible person has responsibility for all medical devices in the entire wellbeing services county. There is often a large gap in the flow of information between professional users of medical devices and the designated responsible person, which complicates cooperation and the realisation of responsibility in practice.

3.1.4 Acknowledging a telemetry device alarm

The nurse acknowledged the "Service Battery" alarm sent by the patient's telemetry device more than two hours after the device had issued the alarm. At the time of acknowledgement, the nurse did not react to the alarm content. The device users did not understand the purpose of the alarm and were not aware of the actions required by it. However, an appropriate reaction to technical alarms concerning system operation is an essential part of ensuring the reliability of the system.

It was common practice in the ward to monitor the battery charge and replace the batteries used in patient devices, especially in the evenings, with fully charged batteries. Since the battery in the device still contained a charge, the nurses did not replace the battery in conjunction with the evening routines. The patient's telemetry device continued to operate continuously overnight.

Older batteries may discharge more quickly than new ones, particularly at low charge levels, meaning that the discharge curve of an aged battery can drop sharply. In practice, the charge of old batteries can decrease rapidly any time their charge status drops to 20% or less. In the case under investigation, the battery charge level dropped faster during the morning than the nurses had expected.

Since the "Service Battery" alarm had not been reacted to, monitoring of the battery charge level was not sufficient in this situation. The voltage of the battery in the patient's telemetry device dropped so suddenly that the device did not have time to sound a low charge alarm. The same observation has also been made in tests carried out by the device importer: when an old battery fails, the device may shut down without giving warnings of the battery charge level.

The ward had no systematic practice for acknowledging technical alarms, which were acknowledged in the central monitoring unit with a delay. Technical alarms had become "normal" alarms for the staff.

Although uninterrupted operation of the telemetry system was a key prerequisite for patient safety, the risks related to system operation had not been assessed, and the impact of technical alarms on patient safety had not been recognised. The ward physicians had provided the nurses with training for such tasks as interpreting the patient's heart rate waves.

In the case being investigated, the "Service Battery" message came immediately after the telemetry transmitter was turned on. It was apparently not common practice to view technical

alarms related to the start-up of a telemetry device in real time in connection with device self-testing.

3.1.5 The telemetry device stops working

The telemetry device powered down without generating the required battery alarm. The shutdown was not immediately detected on the ward. After the nurse had completed their morning round and taken the patient's ECG, the patient was alone in their room and messaged a family member about their condition. Between sending of the message and the physician's round, the patient became lifeless. Lifelessness was only detected with a delay as the staff entered the room in conjunction with the regular physician's round. After lifelessness was observed, resuscitation was started immediately and the MET team alerted to the room. The patient died despite the attempts at treatment.

Patient safety incident reports related to telemetry devices are submitted to the wellbeing services counties' internal patient safety incident reporting systems and to the supervisory authority and device manufacturer. However, incidents related to telemetry devices are not always identified as safety deviations. A patient safety incident involving a medical device that must be reported may be a rare event for an individual professional user. Reporting may be difficult and slow, and the reporting practices are not clear in all respects.

Patient safety incident reports submitted to a wellbeing services county's internal systems are not public, which presents a challenge in terms of forming an overall picture of deviations related to telemetry devices at the national level.

The technical features of Fimea's information systems do not support the process of developing an overall understanding of larger entities. It has not been possible to form a comprehensive overall picture of incidents related to telemetry devices via the CERE register. The information stored in the registers maintained by the authorities is not public, either. Between July 2022 and September 2023, the supervisory authority received reports of six patient deaths in which some type of malfunction in a telemetry device was suspected in association with the death. Patient safety incident reports related to telemetry devices had also been submitted to the HaiPro and Laatuportti systems.

The device manufacturers deal with the incidents on a general level, and professional users are not systematically informed of the background factors and causes of the incidents. Learning from patient safety incidents remains inadequate, and the lack of feedback may also affect the motivation for reporting as a professional user does not understand how reporting affects safety development. The processes and responsibilities for reporting incidents related to medical devices are unclear. The data collected on incidents related to medical devices is not effectively utilised to develop device safety.

No overall picture of incidents related to telemetry devices is available. The wellbeing services country's internal systems may contain information on incidents, but it is not always clear to users how and when reports should be submitted to the supervisory authority.

A precondition for **safe device competence** is that a professional user is aware of their responsibilities and duties as a user of medical devices. However, in practice it is often unclear whether a professional user of the device should submit a report to the authority or whether someone else, such as the medical technology unit or a nurse manager, is responsible for this. The collected data is currently not utilised effectively, which reduces the possibilities for developing device safety. People working in social welfare or healthcare units do not always recognise the fact that they are using medical devices. This is due to the fact that some medical devices, such as a hospital bed, do not correspond to traditional ideas of a device.

Generally speaking, device safety in social welfare and healthcare has developed more slowly than in other areas of client and patient safety, such as medication safety. However, the number of medical devices and the importance of technology have simultaneously increased in social welfare and healthcare.

4 CONCLUSIONS

The conclusions deal with the causes of the accident or incident. The cause refers to the different background factors of the event and the direct and indirect elements that influenced it.

1. The device manufacturer provided training during commissioning and the system update. Staff orientation in the ward did not cover ensuring the safe use of the telemetry device.

   Conclusion: *All user training and orientation must address the competence required for using the device safely and ensuring that it is maintained. Orientation and training should be developed in a systematic manner, and operating practices should be updated when necessary.*

2. A designated responsible person had recently been appointed in the wellbeing services county, but the position and role had not become established.

   Conclusion: *The designated responsible person must ensure that professional users of medical devices have the device safety competence required by law. In practice, this is not always realised appropriately.*

3. No competence or training requirements had been specified for the use of telemetry devices. Learning how to use the system was mainly based on the employees' own level of activity and interest. Technical alarms were not always identified as being important.

   Conclusion: *In practice, competence related to the use of medical devices may vary significantly. In addition, device safety competence is not always ensured systematically.*

4. Monitoring of the patient's condition in the ward was largely based on data recorded by the telemetry system and the alarms received through it. The ward also occasionally treated patients whose condition meant that monitoring by means of telemetry was inadequate.

   Conclusion: *Trust in medical devices is generally strong. Telemetry monitoring of a patient is based on the assumption that the device always works. Insufficient attention is paid to device safety and ensuring it.*

5. The telemetry device had instructions for use provided by the manufacturer. This was an extensive document of hundreds of pages. The manufacturer had also prepared a quick guide, but it did not provide sufficient instructions on the key situations in which the device was used. For this reason, the ward had prepared its own quick guide, even though the supervisory authority had ordered its removal from use.

   Conclusion: *Professional users do not always have access to sufficiently concise and consistent instructions that outline the key principles of safe use of a medical device clearly and appropriately for practical purposes. The instructions for use prepared by the manufacturer are not clearly structured and do not, as such, meet the needs of the social welfare and healthcare operating environment.*

6. The battery used in the patient's device issued a "Service Battery" alarm when the device was placed on the patient. The alarm was acknowledged, but the battery was not replaced. The battery charge dropped during the night and in the morning, the device shut down without issuing a "Tele Battery Empty" alarm. The number of charge cycles had exceeded the recommended level and the battery charge had dropped suddenly.

__Conclusion:__ Safety management in social welfare and healthcare has not fully adapted to the rapid increase in technology use and the number of devices. The meanings of technical alarms are not always understood and they do not guide users towards ensuring safety. Risks increase if batteries are used for longer than specified by the manufacturer.

7. The user interface of the telemetry device was not intuitive in terms of its informatics and did not guide users to act correctly. The text, visual and auditory alarms issued by the device were in some parts unclear and difficult to interpret.

   __Conclusion:__ The user interface does not guide the user to safe practices in all situations, which creates risks to patient safety. The clarity and user-friendliness of the interface are not taken into account as part of device safety assessment.

8. The ward used telemetry devices that were missing a battery compartment door or which had a broken battery clip. The condition of the devices was not monitored systematically, and the people working in the ward were not aware of the criteria for decommissioning batteries. The charging station lights indicating battery charge levels were not monitored systematically.

   __Conclusion:__ The condition of the devices is not always ensured properly. Old devices and those with broken parts may be in use. Shortcomings in the maintenance and servicing of medical devices lead to increased patient safety risks.

9. In wellbeing services counties, the designated responsible person has responsibility for all the medical devices in the entire wellbeing services county. The division of responsibilities between the medical technology unit and the ward concerning maintenance of the telemetry system was unclear. A responsible person for the telemetry system had been appointed, but no task description had been prepared for them.

   __Conclusion:__ There is often a large gap in the flow of information between the professional users of medical devices and the designated responsible person, which complicates cooperation and the implementation of responsibility in practice. The legislation does not require or even recognise the concept of responsible person for medical devices.

10. Patient safety incident reports submitted to a wellbeing services county's internal systems are not public, which presents a challenge in terms of forming an overall picture of incidents related to telemetry devices at the national level. In practice, device manufacturers and supervisory authorities only process incidents on a general level.

    __Conclusion:__ No big picture of incidents related to medical devices is formed. Users are not informed about the background factors associated with the incidents. The tools used by the supervisory authority do not support the formation of an overall picture. People do not learn from these cases and safety management cannot be developed.

5 SAFETY RECOMMENDATIONS

5.1 Promoting device safety in social welfare and healthcare

The batteries of a telemetry device are sometimes used for longer than specified by the manufacturer. Healthcare does not always have effective practices for monitoring battery life. Professional users of medical devices do not necessarily recognise the meaning of technical alarms and the operating units do not have sufficient information on their significance in terms of ensuring client and patient safety. The risks related to medical devices are not identified, and there is not enough competence to maintain the devices.

The tasks, roles and responsibilities related to device safety require clarification. The Finnish Centre for Client and Patient Safety has defined a general task description for the responsible person for medical devices, but the legislation does not require that such a person be appointed. The tasks of the designated responsible person and the responsible person for medical devices, resource allocation to them, and the sufficient competence of professional users are important to ensure client and patient safety.

The Safety Investigation Authority recommends that

> *The Ministry of Social Affairs and Health promote device safety by developing regulation related to medical devices and by steering wellbeing services counties to define the risks and risk management methods related to medical devices.* [2026-S1]

Social welfare and healthcare units should identify the medical devices that are critical in terms of client and patient safety and a responsible person for medical devices should be appointed for them. In addition to their appointment, the responsible person for medical devices should have practical possibilities to promote the improvement of professional users' device competence and intervention in risky operating methods as well as to steer the activities in a direction that is appropriate in terms of safety.

Service provider should take into account medical device safety already during the procurement process and ensure adequate familiarisation with the procured equipment. The training of professional users should take into account medical device safety aspects.

5.2 Developing the safe use of medical devices and instructions

The user interfaces of medical devices that are critical to client and patient safety are not always sufficiently intuitive for the user, and the technical alarms issued by the devices may be misleading in some situations. Safe use of the devices requires thorough familiarisation with their features, which is not always possible in practical social welfare and healthcare work.

The instructions provided by device manufacturers are overly long in terms of page numbers and may also be unclear in terms of content. Extensive instructions are difficult to utilise in units' activities or when providing orientation to new employees. The manufacturer’s own quick guides may comprise illustrations of the device structure, which do not contain any essential information regarding safe operation of the system. The supervisory authority only

accepts the instructions for use provided by manufacturers, not instructions prepared by the actual users. The situation is contradictory and forces professional users to act without appropriate instructions, which increases safety risks.

The Safety Investigation Authority recommends that

> *The Finnish Medicines Agency Fimea investigate the requirements for the safe use of medical devices and their instructions for use and develop them to better meet the needs of professional users and the implementation of safety management related to medical devices.* [2026-S2]

5.3 Developing the processing of patient safety incident reports in the activities of the supervisory authority

The Finnish Medicines Agency Fimea collects information on patient safety incidents related to medical devices in the CERE register maintained by Fimea. However, the reports overlap and the information needed to form an overall picture of national patient safety incident reports related to medical devices is currently collected manually.

It should be possible to find and combine patient safety incident reports submitted to the authority concerning the same medical device or device group without delay so that the situational picture remains up-to-date and potential safety risks can be identified proactively.

The Safety Investigation Authority recommends that

> *The Finnish Medicines Agency Fimea develop data collection concerning patient safety incidents involving medical devices and the processing of patient safety incident reports so that they provide the basis for forming an analysed and up-to-date overview of the situation and for proactive identification of safety risks.* [2026-S3]

5.4 Actions taken

A service technician from the medical technology unit inspected the telemetry transmitter batteries used in the ward. Several old batteries were decommissioned and new batteries were purchased. The external condition of the telemetry devices was checked and several broken battery clips and battery compartment covers were detected. Spare parts were ordered for these.

The Finnish Centre for Client and Patient Safety has published a description of Device Safety Plan preparation. Service organisers can rely on it when preparing their own device safety plans. In addition to service organisers, the description helps service providers to meet the requirements set by legislation and the device safety plan and to observe and promote factors that affect device safety.[75]

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[75] Laiteturvallisuussuunnitelman laatimisen kuvaus. https://asiakasjapotilasturvallisuuskeskus.fi/wp-content/uploads/sites/3/2025/09/Laiteturvallisuussuunnitelman-laatimisen-kuvaus_FINAL_29.8.2025.pdf.

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Investigation material

1) On-site investigation photographs, measurements and other material
2) Hearings
3) Telemetry recordings
4) Testing of telemetry equipment batteries
5) Simulation testing of telemetry device
6) Measurement of network performance
7) Information provided by the Police
8) Information provided by Fimea
9) Information provided by Valvira
10) Information provided by the Regional State Administrative Agency
11) Information provided by the Wellbeing Services County of South Ostrobothnia
12) HaiPro data from the wellbeing services counties and HUS Group
13) Survey for the wellbeing services counties
14) Expert statements
15) Forensic investigation of the cause of death

SUMMARY OF COMMENTS RECEIVED ON THE DRAFT INVESTIGATION REPORT

The draft investigation report was submitted for comments to the Ministry of Social Affairs and Health, the Finnish Institute for Health and Welfare, the Finnish Medicines Agency Fimea, the Finnish Supervisory Agency Valvira, the Regional State Administrative Agency for Western and Inland Finland, the Wellbeing Services County of South Ostrobothnia, Philips Oy and the next of kin of the deceased patient.

In accordance with the Finnish Safety Investigation Act, comments issued by private individuals are not published.

The Ministry of Social Affairs and Health proposes a few additional details to the draft investigation report, which the Safety Investigation Authority has included in the final investigation report.

Regarding the recommendations in the draft investigation report, the Ministry of Social Affairs and Health notes that due to the international regulatory framework, Finland has a fairly limited national discretion with regard to the regulation of medical devices. With regard to the recommendations issued to Fimea, the Ministry of Social Affairs and Health notes that ensuring the obligations of a professional user first requires increasing the capabilities of a professional user, after which the advice and guidance provided by Fimea can also be utilised more extensively. The Ministry of Social Affairs and Health emphasises that Fimea can already provide a substantial amount of information.

The Ministry of Social Affairs and Health also proposes a completely new recommendation and states that considering user-friendliness in device purchases could improve patient safety. According to the Ministry of Social Affairs and Health, it would be justified for the Safety Investigation Authority to issue a recommendation focusing on patient safety to support the procurement process. In summary, the Ministry of Social Affairs and Health notes that the draft investigation report describes development areas that are important for patient safety. Development of self-monitoring by the service organiser and the service provider in the field of medical devices is a precondition for the realisation of patient safety. The Ministry of Social Affairs and Health finds that the Ministry of Social Affairs and Health and Fimea may strive to support the organisation of safe services, even though device safety is primarily the responsibility and duty of the service organiser and service provider.

In its comment, the **Finnish Medicines Agency Fimea** noted that the investigation report contains inaccuracies in the descriptions of and regulation on medical devices. The Safety Investigation Authority has accounted for these observations in the final investigation report. In its comment, Fimea also emphasised that to implement recommendation 5.2, legislative amendments at the EU level would be needed. With regard to recommendation 5.3, Fimea stated that the mandatory introduction of the European EUDAMED database will facilitate the finding and combination of manufacturers' notifications.

The Finnish Institute for Health and Welfare (THL) appreciates the opportunity to comment. THL did not have comments on the investigation report.

In its comment, the **Wellbeing Services County of South Ostrobothnia** provided additional detail for the investigation report concerning the orientation model used in the ward, additional training related to the use of telemetry and the quick guide. According to the Wellbeing Services County, telemetry devices were sent for maintenance if necessary, and they were not generally considered critical. The Wellbeing Services County notes that monitoring the condition of the devices was not systematic, but there was an operating model

for the removal of obsolete batteries. According to the Wellbeing Services County, it is important to look into operating models when a supervisor changes, as there may be old operating models that the new supervisor does not know about.

In its comment, **Philips** states that the term “malfunction” in the title of the investigation and in the various sections of the investigation report should be replaced by the term “due to a damaged device”. Philips bases this statement on the fact that, in their view, the investigations described in the investigation report did not reveal any malfunction of the device itself. Philips was provided with a Finnish version of the investigation report for comments, which Philips had translated into English, and the requested comment was also provided in English.

With the comment, Philips provided a document describing the staff training held in June 2020 in connection with the system update of the central monitoring unit. Based on the comment, the date and content of the training have been added to the investigation report. In its comment, Philips drew attention to the sections of the investigation report referring to the fact that the ward personnel acknowledged the system alarm “Service Battery” in the central monitoring unit. According to the device manufacturer, the personnel identified the message issued by the system but did not act as required by it. Philips also highlights the fact that, in the user’s manual, the user is instructed to inspect the device before use and not to use a broken device.