A Silent ICU for Improved Patient Care

An interoperability showcase for a true healing environment

Noise pollution in intensive care units (ICUs) interferes with the optimal conditions required for a healing environment; and it is suspected of being a high risk for patient delirium, which is associated with longer lengths of stay, increased readmission rates, cognitive and functional impairment as well as increased mortality.[1,2] Having a silent patient room with alarm forwarding technology can support patient healing, potentially prevents the development of delirium, and improves workflows for ICU care providers.

This interoperability showcase from Ascom, B. Braun and Dräger demonstrates how open interoperability technology based on the ISO/IEEE 11073 SDC standard enables safe distribution of medical alarms from different vendors while bedside medical devices stay silent for a true healing environment.

Disclaimer: The information about the solution in the showcase is preliminary. The solution is under development and for demonstration purposes only. It is not for clinical use and is not commercially available. Its future availability cannot be ensured. This solution does not have CE approval, is not cleared nor approved by the FDA and has not been submitted for FDA 510k clearance.

Intensive care units – a noisy and stressful environment

Clinical alarms in ICUs are necessary to alert healthcare providers to changes in a patient's condition and to help prevent adverse events. Alarms can indicate problems such as arrhythmias, apnea, high or low blood pressure, and low oxygen saturation or technical issues such as an occlusion of an infusion line. Early detection of these problems can lead to prompt interventions, which can improve patient outcomes.

However, the extensive and inappropriate use of alarms in ICUs can contribute to overwhelming levels of noise. Peak levels can exceed 85 dB multiple times an hour while WHO guidelines suggest noise levels shouldn't exceed 35 dB for patient care areas.[1]

The equipment used in ICUs, such as patient monitors, ventilators, infusion pumps, and others, all generate technical and clinical alarms. Daily alarm quantities from these devices can add up to 350 alarms per ICU bed.[3] Up to 85 – 95 % of these alarms are false positive, might not require urgent clinical intervention and can cause alarm fatigue.[3,4] Clinical staff might become desensitized to alarms and may miss important alerts. This can lead to delayed or missed interventions, which can have serious consequences for patients.

Noise in ICUs can have several negative effects on both patients and healthcare providers. Some of the problems associated with noise in ICUs include[1,5,6,7]:

- **Sleep disturbance:** Patients in ICUs require restful sleep to promote healing and recovery. However, noise levels in ICUs are often high, making it difficult for patients to sleep. Sleep disturbances can lead to delirium, increased pain, and prolonged hospital stays.
- **Stress and anxiety:** High noise levels can cause stress and anxiety for both patients and healthcare providers. This can lead to increased blood pressure, heart rate, and respiratory rate, which can negatively impact patient outcomes.
- **Communication difficulties:** High levels of noise in ICUs can make it difficult for healthcare providers to communicate with each other, which can lead to errors and delays in care.
- **Decreased patient satisfaction:** Noise can negatively impact the overall patient experience in the ICU, leading to decreased patient satisfaction.
- **Occupational hazards:** Prolonged exposure to high levels of noise in the ICU can lead to hearing impairment and other occupational hazards for healthcare providers.

Therefore, reducing noise levels in ICUs can help improve patient outcomes and create a more comfortable and safer environment for patients, their relatives and healthcare providers alike.

How interoperability can help improve alarm handling

Interoperability can improve managing clinical alarms in an ICU by facilitating the integration and communication between different medical devices and information systems. Analyzing the occurring alarms to reduce their quantity and distributing the remaining alarms away from the patient to the responsible caregivers should be an integral part of a comprehensive alarm management strategy.

Interoperability

...is the ability to **seamlessly, automatically and securely exchange interpretable data** between devices and systems within an information technology network in a **standardised way** without technical restrictions.[8,9]

Alarm analytics:

Retrieving data from medical devices allows to assess the alarm occurrence in a unit. This allows the identification of the root causes of excessive alarms, and the development of strategies to significantly decrease the number of clinically irrelevant alarms. Solutions, like Dräger Alarm History Analytics, exist to perform an extensive analysis of clinical alarms.

Alarm distribution with audio-off:

Interoperability enables to safely forward alerts from the patient room to the responsible caregiver in the unit while simultaneously silencing the source devices in the patient vicinity. Caregivers could respond to critical changes in a patient's condition in a timely manner while the patient room itself would stay silent. The HIMSS Interoperability Showcase™ from Ascom, B. Braun and Dräger focuses on advancements for the safe distribution of clinical alarms to caregivers while simultaneously enabling to silence the source devices.

An interoperability concept for a true healing environment

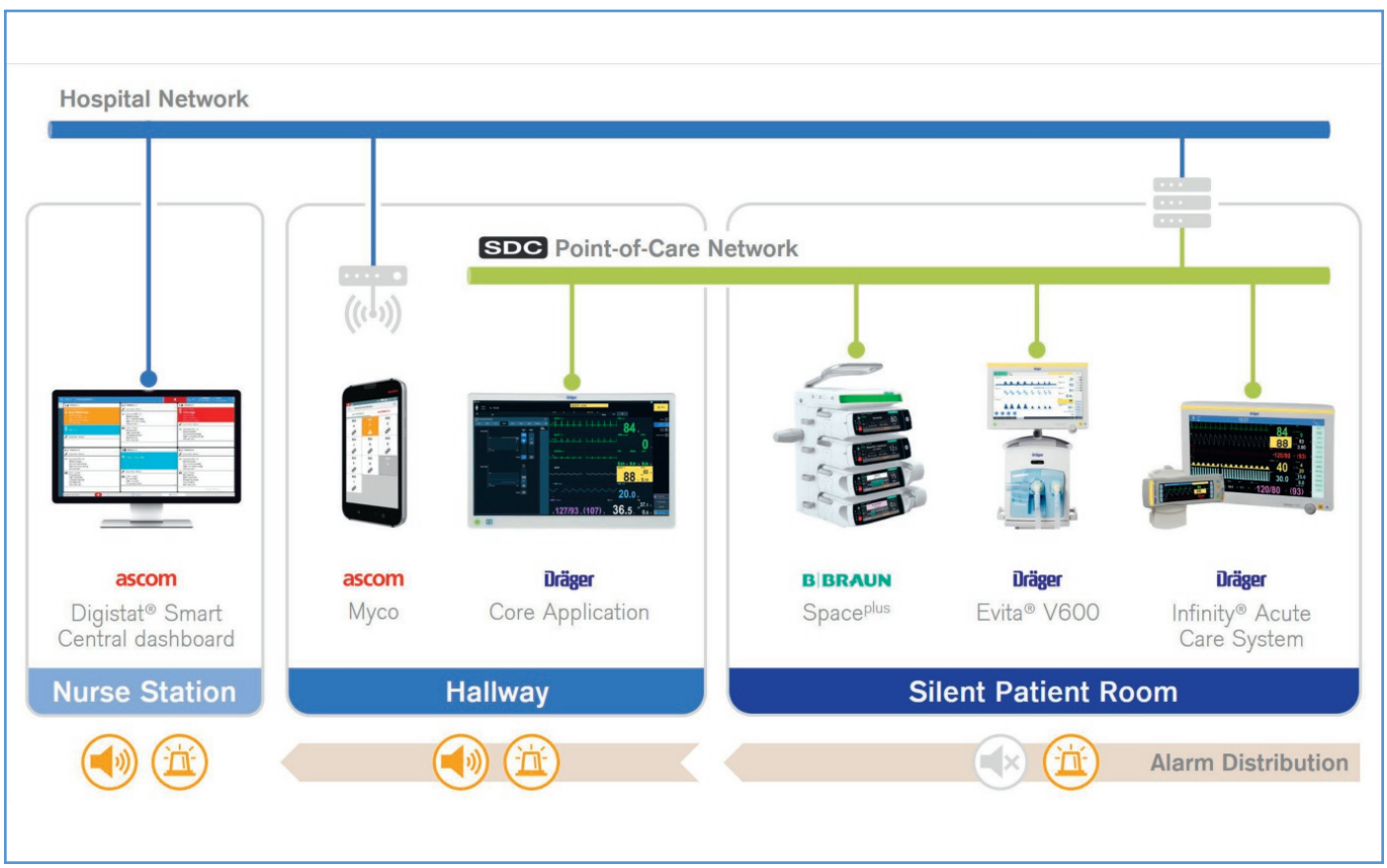
Based on the open industry standards ISO/IEEE 11073 SDC for vendor-independent interoperability, the joint HIMSS Interoperability Showcase™ by Ascom, B. Braun and Dräger demonstrates a visionary silent ICU concept for improved patient care.

The ICU patient room is equipped with a multi-modality system consisting of B. Braun Spaceplus infusion pumps, a Dräger Evita® V600 patient ventilator and a Dräger Infinity® Acute Care System to deliver high-quality medical therapy and monitoring. Additionally, the Dräger Access and Control Package allows staff to access medical device data from outside the patient room for a next level of patient surveillance. Alarms generated at the bedside are forwarded reliably via the network infrastructure and are visually and acoustically annunciated on the Ascom Digistat® Smart Central dashboard located in the central nurses' station and on mobile Ascom Myco® devices while the medical devices inside the patient room are in a steady audio-off mode.

Having a silent patient room with alarm forwarding technology supports patient healing through relieving the patient from the unnecessary burden of alarms. Furthermore, it potentially prevents the development of delirium, and improves workflows for ICU care providers.

The safe forwarding of alarms allows to operate the system with closed patient room doors. If this is applied, there will be even less disturbance for patients from busy hallways and more privacy, while the overall noise in the unit is going to decrease.

Multi-modality system concept of the showcase "Silent ICU for Improved Patient Care"

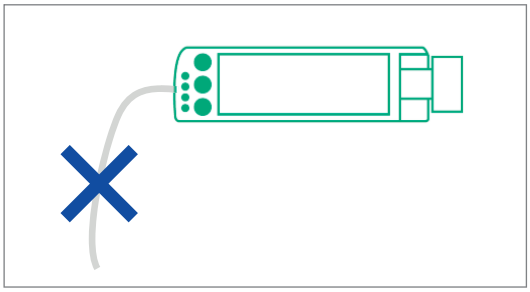


D-5345-2023

Selected use cases to demonstrate the system's value

The following three use cases demonstrate the behavior and value of the multi-modality system when handling lifesaving alarms from the infusion pumps, ventilator and monitor as well as a fallback scenario in the event of loss of network connection.

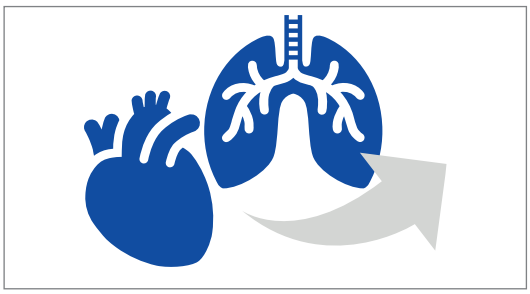
High priority occlusion alarm



What if an occlusion alarm appears on the Spaceplus infusion pump? The system would allow to safely forward the alarm from the pump in the patient room to the responsible caregiver's Myco phone and the Digistat® Smart Central dashboard. While the Spaceplus infusion pump in the room stays silent, both the Myco Myco and Digistat® Smart Central and Smart Central dashboard will annunciate visually and acoustically. Dedicated nurses can react in a timely manner to remove the occlusion from the infusion line keeping the patient safe.

- ✓ Fewer unnecessary disturbances for the patient in a quieter room.
- ✓ Increased situational awareness with immediate alarm notifications to the dedicated caregiver.
- ✓ Safe distribution of alarms even allows a closed-door scenario.

Heart rate and respiratory rate high alarm

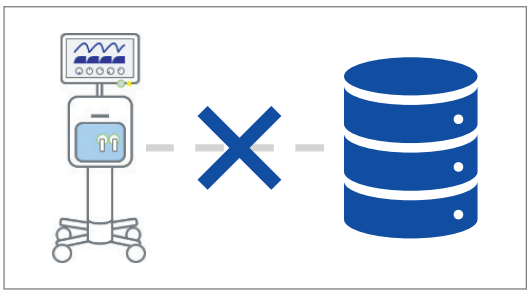


What if critical alarms occur on the ventilator and patient monitor? When a change in the patient's condition triggers a heart rate and respiratory rate alarm, the alarm is forwarded to the dedicated caregiver's Myco and the Digistat® Smart Central dashboard. The Evita® 600 and Infinity® Acute Care System in the room stay silent to not further distress the patient. The caregiver can immediately intervene and e.g. change the medication and control the wakeup process.

A medical-grade PC running the Dräger Core software application further enhances the staff's workflow by enabling to check the patient's vital signs and medical device data from outside the patient room. This helps to further reduce unnecessary patient disruption and provides staff with flexible access to patient status information.

- ✓ Fewer unnecessary disturbances for the patient in a quieter room.
- ✓ Increased situational awareness with immediate alarm notifications to the dedicated caregiver.
- ✓ Safe distribution of alarms even allows a closed-door scenario.

Infrastructure error and fallback



What if any of the medical devices lose their connection to the alarm system? In such a case, the devices will immediately fall back to annunciate upcoming alarms acoustically and visually. The disconnection notification of the system is displayed on the medical device and simultaneously on the alarm system end devices. Caregivers are notified that the alarm distribution is currently disabled and that re-opening the patient room doors is recommended. Nurses can now react to audible alarms from the source devices as a fallback workflow. This safely bridges the time until the silent mode is reactivated after the alarm system connection has been reestablished.

- ✓ Notification of staff that connection is lost to take appropriate action.
- ✓ Fallback to acoustic alarming on source devices to keep patients safe.
- ✓ Reactivation of audio-off state and alarm forwarding when connection is reestablished.

Standards and profiles

The communication between devices and systems in the showcase is leveraging the IHE Devices' "Service-oriented Device Point-of-care Interoperability" (IHE DEV SDPi) profile. This includes the following standards of the ISO/IEEE 11073 SDC standards family:

SDC

- ISO/IEEE 11073-20702-2018 (MDPWS)
- ISO/IEEE 11073-10207-2019 (BICEPS)
- ISO/IEEE 11073-20701-2020 (SDC)

The architecture defined in the SDC standard is built on the principles of a clinical workplace Service-Oriented Medical Device Architecture (SOMDA). The Medical Devices Communication Profile for Web Services (MDPWS), as well as the Basic Integrated Clinical Environment Protocol Specification (BICEPS) are IEEE 11073 standards for the communication inside a SOMDA system.

In addition, the medical device to IT communication uses IHE PCD DEC (Device Enterprise Communication) profiles that send HL7v2 messages between Device Observation Reporters and Consumers (DOR/DOC).

The incorporated standards enable the bidirectional transfer of information using standardized data formats, structure, and semantics, between systems in medical-grade quality, remote control of device functions, and a high level of cybersecurity, which are limited in today's solutions on the market.

About HIMSS Interoperability Showcases™

Interoperability showcases from the HIMSS are offered as interactive, educational presentations of concepts that "display the exchange, access and use of healthcare data through profiles and standards in real-time."[10] In a combined effort, various market participants such as medical systems manufacturers, healthcare providers and standards development organizations "demonstrate the power of standards-based healthcare interoperability by showcasing systems exchanging and using data in real-time to improve care, outcomes and experience."[10] The demonstrated solutions might be prototypes, approved products, or a mix of both.

Do you want to learn more about SDC?

Watch our webinar where industry experts discuss new approaches on standards-based medical device interoperability for high acuity areas.

Scan the QR-Code or click this link to watch the webinar recording.

Medical Device Interoperability by Dräger

We envision a future of acute care where medical devices effectively support clinicians and caregivers in their daily challenge of efficiently achieving the best possible outcomes for patients. We believe that interoperable medical devices can contribute to this and are passionate about developing new clinical applications based on open data exchange technology.

Interested to learn more about our vision of medical device interoperability and our available connected solutions? Please get into contact with your local Dräger representative or go to **www.draeger.com/contact**

Disclaimer:

The information about the solution in the showcase is preliminary. The solution is under development and for demonstration purposes only. It is not for clinical use and is not commercially available. Its future availability cannot be ensured. This solution does not have CE approval, is not cleared nor approved by the FDA and has not been submitted for FDA 510k clearance.

Mentioned trademarks are only registered in certain countries and not necessarily in the country in which this material is released. Go to www.draeger.com/trademarks to find the current status. Digistat® is a registered trademark of Ascom. Space® is a registered trademark of B. Braun. HIMSS Interoperability Showcases™ is a registered trademark of HIMSS.

Sources

[1] Darbyshire J. L. & Young J. D. (2013). An investigation of sound levels on intensive care units with reference to the WHO guidelines. Critical Care 17:R187.

[2] Hughes, C. G. et al. (2020). American Society for Enhanced Recovery and Perioperative Quality Initiative Joint Consensus Statement on Postoperative Delirium Prevention. Anesth Analg. 130(6), pp. 1572-1590.

[3] Jones, K. (2014). Alarm fatigue a top patient safety hazard. Canadian Medical Association Journal, 186(3), p.178.

[4] Nix M. (2015). Combating Alarm Fatigue. American Journal of Nursing, 115(2), p.16.

[5] Meli A.; Coppola S. & Chiumello D. (2020). The Night in the ICU. ICU Management & Practice (2), pp.125-127.

[6] Özcan E. & Gommers D. (2020). Nine Nurse-Recommended Design Strategies to Improve Alarm Management in the ICU: A Qualitative Study. ICU Management & Practice (2), pp.129-133.

[7] Darbyshire J. L.; Muller-Trapet M.; Cheer J.; Fazi F. M. & Young J. D. (2019). Mapping sources of noise in an intensive care unit. Anaesthesia 2019, 74, pp. 1018-1025.

[8] Pronovost P. et al. (2018). Procuring Interoperability: Achieving High-Quality, Connected, and Person-Centered Care. Washington, DC: National Academy of Medicine.

[9] Taylor, K.; Steedman, M.; Sanghera, A. & Thaxter, M. (2018). Medtech and the Internet of Medical Things. How connected medical devices are transforming healthcare. Deloitte Centre for Health Solutions.

[10] HIMSS (2022). HIMSS Interoperability Showcase. Connections That Transform Health. https://www.himss.org/what-we-doinitiatives/himss-interoperability-showcase

IMPRESSUM
Drägerwerk AG & Co. KGaA
Moislinger Allee 53–55
23558 Lübeck, Germany
Tel +49 (0) 451/882 0
Fax +49 (0) 451/882 2080
Mail: info@draeger.com

www.draeger.com