

Appendix C

Use Case 1: SDPi-R Standalone OR Dashboard Use Case - SORD

Use Case 2: SDPi-R/A/xC Standalone OR Cockpit Use Case – SORC

Use Case 3: SDPi-R/xC ICU Isolation PoC Use Case - IIPoC

Use Case 4: SDPi-A Silent PoC Use Case - SPoC

Use Case 5: SDPi-A Silent ICU Use Case - SI

Use Case 6: SDPi-A/xC Remote Alarm Management Use Case – RAM

Use Case 7: SDPi-A Smart Alert System Use Case - SAS

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Overview of the 60601-1-8 Concepts for DIS, DAS and CDAS

The following is a quick guide to the functionality of DIS, CDIS, DAS and CDAS systems. Please refer to the Annex for relevant excerpts from 60601-1-8:2020 for normative text.

DIS – Distributed Information System

- DIS is a system for reporting alarm signals with no technical confirmation (of receipt).
 - Cannot rely on it for alarm signaling as a risk control
 - Optional support operator alarm management* response locally
 - Example - patient remote display, hallway display, one-way pager

CDIS – Distributed Information System with Confirmation

- CDIS is a system for reporting alarm signals with no technical confirmation and operator confirmation (accept/reject). (Note it is not recognized in 60601-1-8)
 - Cannot rely on it for alarm signaling as a risk control
 - Optional support operator alarm management* response locally and remotely
 - Example – two-way pager (open loop)

DAS – Distributed Alarm System

- DAS is a system for reporting alarm signals with technical confirmation (of receipt).
 - Can rely on it for alarm signaling as a risk control
 - Optionally supports local alarm management (alarm acknowledgement)
 - A communications failure or failure in any remote component of the DAS must initiate a technical alarm.
 - Example - Central Station

CDAS - Distributed Information System with Confirmation

- CDAS is a system for reporting alarm signals with technical and operator confirmation (accept/reject) (of receipt).
 - Can rely on it for alarm signaling as a risk control
 - Supports operator confirmation (accept/reject); It may redirect...
 - Optionally support local/remote alarm management (acknowledgement)
 - A communications failure or failure in any remote component of the DAS must initiate a technical alarm.
 - Example - System that sends alarm to caregiver mobile device with accept / reject. Integrator may redirect

The following table summarizes the various types of information/alarm systems.

Description	Type	Technical Delivery Confirmation ¹	Operator Delivery Confirmation ²	Optional Alarm Management	Examples
Reports alerts from a Single Patient (sp)	DISsp	No	No	Local	Single-Pt. information Dashboard
	CDISsp	No	Yes ³	Remote ³	Single-Pt. Remote View w/ accept/reject
	DASsp	Yes	No	Local	Single Pt. Cockpit w/audible alarms
	CDASsp	Yes	Yes	Remote	Single Pt. Cockpit w/ accept/reject
Reports alerts from Multiple Patients (mp)	DISmp	No	No	Local	Multiple-Pt. info. Dashboard or View Station
	CDISmp	No	Yes ³	Remote ³	Multiple-Pt. info. View Station w/ accept/reject
	DASmp	Yes	No	Local	Multiple Pt. Central Station w/ audible alarms
	CDASmp	Yes	Yes	Remote	Multiple Pt. Central Station w/ accept/reject
Reports and directs alerts to responsible Caregiver (cg)	DIScg	No	No	Local	Alerts to caregiver pager, Mobile viewer
	CDIScg	No	Yes ³	Remote ³	Alerts to caregiver pager, w/ accept/reject
	DAScg	Yes	No	Local	Alerts to caregiver w/ audible/haptic alarms
	CDAScg	Yes	Yes	Remote	Alerts to caregiver w/ accept/reject
¹ In each communication step the receiving device provides a technical response to the sending device that it received and is taking responsibility for the alert ² Operator can, at their choice, use the receiving device (communicator) UI to accept or reject responsibility for the alert ³ Not recommended since there is no confirmation that the Source has received the commands					

Use Case/Feature 1: SDPi-R Standalone OR Dashboard - SORD

Narrative:

Dr. Presky is in the Operating Room performing an operation to remove cancerous tumors from the patient's abdominal area. He can view previous radiology results, electrosurgical equipment settings, patient readings such as HR, Blood Pressure, SpO2 and associated waveforms integrated on his real-time 'Dashboard' display. The dashboard display can display visual alarms but does not sound alerts or provide any remote-control capabilities. (This display can be considered an xDISp.)

Technical Pre-Conditions:

- All devices communicate using SDC
- At least one OR Dashboard display

SORD Scenario 1.1: OR Devices are Accessible to the Dashboard

Given Dashboard has detected at least one accessible OR device

When the OR Devices are "On"

Then the Cockpit will display parameter, waveform, setting, alarm, imaging, etc. information from those devices (based on configuration)

SORD Scenario 1.2: OR Devices are Inaccessible to the Dashboard

Given Dashboard cannot detect any accessible OR devices

Then the Dashboard will display an error message

SORD Scenario 1.3: One or more OR Devices are Inaccessible to the Dashboard

Given Dashboard cannot detect configured OR devices (based on configuration)

Then the Dashboard will display an error message

Use Case/Feature 2: SDPi-R/A/xC Standalone OR Cockpit - SORC

Narrative:

John Miller (13yrs, m) has chronic rhinosinusitis, which is an inflammatory condition in which the nose and his left maxillary sinus is swollen and the drainage of the mucus is prevented. John's chronic rhinosinusitis doesn't respond to medication anymore. After consulting with his physician, he and his parents decide to resolve the issue with Functional Endoscopic Sinus Surgery (FESS). The FESS will be done as a day surgery, so that John can get home in the evening.

Before the day of the surgery, a CT scan is taken that is used to guide the surgeon during the surgery.

In order for the surgery to start, John is put under general anesthesia and monitored with a patient monitor by a pediatric anesthesiologist, especially his mean arterial blood pressure which has been lowered in order to reduce capillary bleeding to provide optimal visibility of the surgical field.

During the intervention, the Surgeon has a constant view, using his Surgical Cockpit of the patient's vitals (including MABP), CT imaging results, real-time endoscope camera output and has access to the control functions to execute the intervention. The anesthesiologist can also view relevant patient real-time information such as ECG, blood pressure, anesthesia agent, depth of anesthesia, allergies, etc. using the Anesthesia Cockpit where he/she can manage alarms and control device settings as needed.

{During the procedure one of the surgical devices has a technical issue. It generates a technical alert which notifies the responsible biomedical technician. He/she decides to replace the device and connects it to the network where it is automatically discovered and configured allowing the intervention to continue.}

There are no additional technical or clinical problems, the surgery is a success and John can go home with his parents.

Technical Pre-Conditions:

- All devices communicate using SDC
- At least one Anesthesia Cockpit and/or Surgical Cockpit

SORC Scenario 2.1: OR Devices are Accessible to the Cockpit

Given Cockpit has detected at least one accessible OR device

When the OR Devices are "On"

Then the Cockpit will display parameter, waveform, setting, alarm, etc. information from those devices (based on configuration)

When audio alarms are enabled on the Cockpit

Then the audio alarm shall be disabled on the source devices associated with the Cockpit (based on configuration)

When remote control is enabled on the Cockpit

Then the user can control device settings at the source device or at the Cockpit

SORC Scenario 2.2: OR Devices are Inaccessible to the Cockpit

Given Cockpit cannot detect any accessible OR devices

Then the Cockpit will display an error message

When any OR Device detects an alert condition

Then the audio alarm shall be signaled at that source device in the OR

SORC Scenario 2.3: Some OR Devices are Inaccessible to the Cockpit

Given Cockpit cannot detect some configured OR devices (based on configuration)

Then the Cockpit will display an error message

When the OR Device detects an alert condition

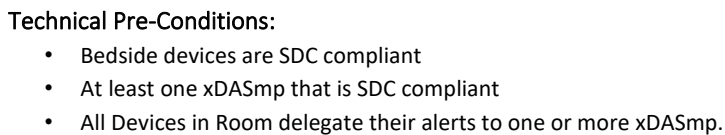
Then the audio alarm shall be signaled at that source device in the OR

Use Case/Feature 3: SDPi-R/xC ICU Isolation PoC Use Case - IIPoC
Narrative:

Technical Pre-Conditions:

Coming soon...

Linda is an ICU nurse responsible for 4 patients. While she is updating documentation at the nursing station Jack's (one of her patients) condition deteriorates and his ventilator goes into an alarm state (#1). The ventilator alarm sounds are quite loud and jarring which usually disturbs the patient in the room and nearby rooms. In this case the alert only generates visual alerts and does not generate an audible tone in the patient room (#2). It does generate an alarm tone at the central station (xDASmp) (#3) and her mobile device (xDAScg) (#4). As a result, Linda must acknowledge or otherwise handle the alert at the bedside (#5).



Rule: Single xDASmp or combination xDASmp and xDISmp/xDIScg/xDASmp

Note: xDAScg is not included since this can lead to a Silent ICU scenario

SPoC Scenario Outline: Detect and Communicate Alert at Bedside Device

SPoC Scenario 4.1: Medical device detects an alert situation and at least one distributed alarm system xDASmp is accessible

Given alert event was detected by a medical device attached to the patient

When at least one remote alert system is accessible

Then the alert shall be shown on all accessible remote alerting devices

And the audio alarm shall be enabled on all accessible remote alerting devices

And active device alert events shall be shown on the medical devices locally

And the audio alarm shall be disabled on all medical devices in the patient room

SPoC Scenario 4.2: Medical device detects an alert situation and all distributed alarm systems (xDASxx) are inaccessible or become inaccessible

Given alert event was detected by a medical device attached to the patient

When distributed alarm systems (DAS/DIS) are inaccessible or become inaccessible

Then active device alert events shall be shown on the medical devices locally

And the audio alarm shall be enabled on all medical devices in the patient room

SPoC Scenario 4.3: Alert situation has been resolved and at least one distributed alarm system (xDASxx) is accessible

Given medical device detected that the alert situation has been resolved

When at least one distributed alarm system (DAS/DIS) is accessible

Then the alert shall be shown as inactive/ended at the medical device locally

And the audio alarm shall be disabled on the medical device in the patient room

And the alert shall be shown as inactive/ended on all accessible remote alerting devices

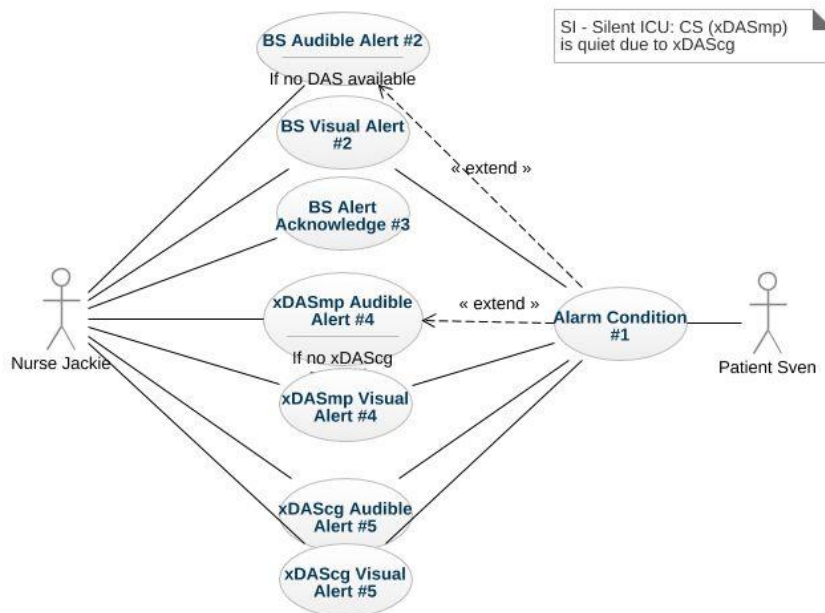
And the audio alarm shall be disabled on all accessible remote alerting device for this alert event

SPoC Scenario 4.4: Medical device detects an alert situation, initially DAS is accessible but fails

Use Case/Feature 5: SDPi-A: Silent ICU Alert Distribution - SICU

Narrative:

Jackie is an ICU nurse responsible for 4 patients. While she is updating documentation at the nursing station Sven's (one of her patients) condition deteriorates and his ventilator goes into an alarm state (#1). The ventilator alarm sounds are quite loud and jarring which usually disturbs the patient in the room and nearby rooms. Jackie's ICU uses personal mobile devices to alert the nurses about patient alarms so in this case the alert only generates visual alerts in the patient room (#2) and central station (#3). It does generate an audible alert on her mobile device (xDAScg) (#4).



Technical Pre-Conditions:

- Bedside devices are SDC compliant
- A DAScg that is SDC compliant
- All Devices in Room delegate their alerts to one or more DASxx or CDASxx.

Rule: Single DAScg or combination of xDAScg and xDxSxx

SICU Scenario Outline: Audible Alert at CDAScg Nurse Device

SICU Scenario 5.1: Medical device detects an alert situation and the distributed alarm system CDAScg is accessible and announces the alert at the caregiver device

Given alert event was detected by a medical device attached to the patient

When at least one remote alert system is accessible

Then the alert shall be shown on all accessible remote alerting devices

And the audio alarm shall be enabled on the caregiver's accessible CDAScg remote alerting devices

And the audio alarm shall be disabled on all accessible non-CDAScg remote alerting devices

And active device alert events shall be shown on the medical devices locally

And the audio alarm shall be disabled on all medical devices in the patient room

SICU Scenario 5.2: Medical device detects an alert situation and the distributed alarm system CDAScg is inaccessible

Given alert event was detected by a medical device attached to the patient

When at least one remote alert system is accessible

Then the alert shall be shown on all accessible remote alerting devices

And the audio alarm shall be enabled on all accessible remote alerting devices

And active device alert events shall be shown on the medical devices locally

And the audio alarm shall be disabled on all medical devices in the patient room

SICU Scenario 5.3: Medical device detects an alert situation and all distributed alarm systems (xDASxx) are inaccessible or become inaccessible

Given alert event was detected by a medical device attached to the patient

When distributed alarm systems (DAS/DIS) are inaccessible or become inaccessible

Then active device alert events shall be shown on the medical devices locally

And the audio alarm shall be enabled on all medical devices in the patient room

SICU Scenario 5.4: Alert situation has been resolved and at least one distributed alarm system (DASxx) is accessible

Given medical device detected that the alert situation has been resolved

When at least one distributed alarm system (DAS/DIS) is accessible

Then the alert shall be shown as inactive/ended at the medical device locally

And the audio alarm shall be disabled on the medical device in the patient room

And the alert shall be shown as inactive/ended on all accessible remote alerting devices

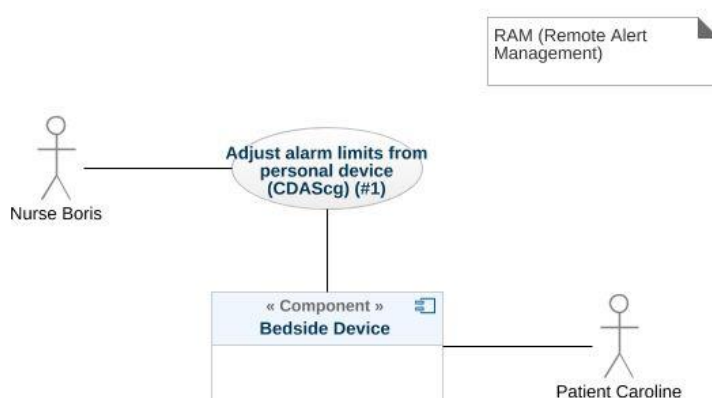
And the audio alarm shall be disabled on all accessible remote alerting device for this alert event

SICU Scenario 5.5: Medical device detects an alert situation, initially DAS is accessible but fails

Use Case/Feature 6: SDPi-A/xC: Remote Alert Management - RAM

Narrative

Boris is an ICU nurse responsible for 4 patients. His ICU has a central station but also uses personal devices for alert notification and management. He needs to adjust the upper heart rate limit for Caroline, one of his patients. Even though Boris is near the central station, he decides to use his personal device to adjust the limit (#1).



Technical Pre-Conditions:

- Bedside devices are SDC compliant
- A CDAScG that is SDC compliant
- All Devices in Room enable remote setting adjustment

Rule: Single CDAScG or combination CDAScG/xDxS

RAM Scenario Outline 1: Adjust Alert Limit Setting at CDAScG Nurse Device

RAM Scenario 6.1: Caregiver adjusts alarm limit at their Mobile Device

Given alert event was detected by a medical device attached to the patient

And remote alerting device is part of the CDAScG

When caregiver confirms the alert at a remote alerting device

And CDAScG is accessible

Then the alert shall be shown as acknowledged at the medical device

And the audio alarm shall be disabled on the medical device

And the alert shall be shown as acknowledged on all accessible remote alerting devices

RAM Scenario 6.2: Caregiver attempts to adjust alarm limit at their CDAScg mobile device but the respective CDAScg is not accessible

Given alert event was detected by a medical device attached to the patient

And remote alerting device is part of the DIS

When caregiver confirms the alert at a remote alerting device

But DAS is inaccessible

Then ???

Use Case/Feature 7: SDPi-A: Smart Alerting System - SAS

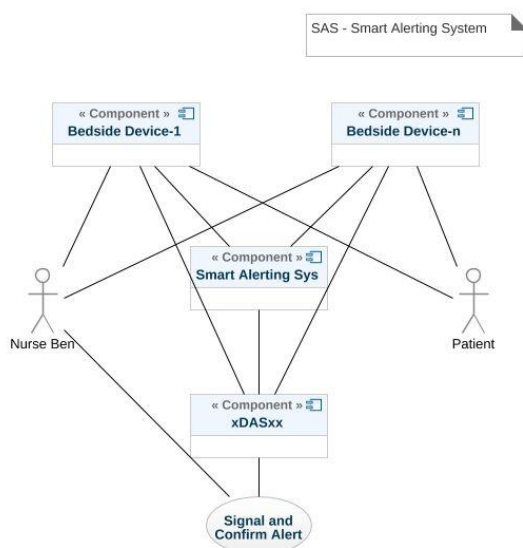
Narrative:

Ben is an ICU nurse. Suddenly, he gets a “Check Ventilation Hose!” alert for one of the patients he is responsible for. In addition, the alert suggests possible root causes to the caregiver (i.e. obstruction (sputum/kinked hose)). This leads to a quicker, more adequate intervention.

The alert was generated by a smart alerting system that collects all the data from the point-of-care devices such as vital signs, alerts, settings, waves, etc., and combines them to create more actionable information for the care giver to guide care, intervention and treatment. In the example above, an algorithm combines a “Low SPO2” alarm from the patient monitor and a “Peak Pressure” alarm and “Minute Volume low” alarm from the ventilator into one alarm superseding the individual alarms.

The original alerts generated by the patient monitor and the ventilator are shown at the devices but the audio alarm is enabled or disabled on both devices dependent on other rules such as configuration or presence of caregiver in patient room.

Note that the smart alerting system is seen as a separate entity independent of an xDxSxx in this Feature. However, a combination of a xDxSxx with a smart alerting system is a typical configuration.



Technical Pre-Conditions:

- Bedside devices are SDC compliant
- A single smart alert system that is SDC compliant
- All devices in the room can delegate their alerts to the Smart Alert System.
- The SAS is a “box” with no visual or audible alert output. It communicates its alerts to an xDASmp and/or xDAScg.

SAS Scenario Outline: Local device generates alerts and Smart Alerting System is accessible

Given local device audio alarm state was set to <state>

When there is an alert event on one or more medical devices in the patient room

And smart alerting system is accessible

Then the alerts on the medical devices in the patient room shall be delegated to the SAS

And active device alert events shall be shown on the medical devices locally

And the audio alarm shall be <action> on all medical devices in the patient room

Examples:

state	action	
disabled	disabled	
enabled	enabled	

SAS Scenario 7.1: Local device alerts and Smart Alerting System is inaccessible

When there is an alert event on one or more medical devices in the patient room

And smart alerting system is inaccessible

Then the audio alarm shall be enabled on all medical devices which have an alert event

And active device alert events shall be shown on the medical devices locally

Situation: Smart Alerting System is accessible from devices, generates an alert and an xDASxx is potentially accessible

SAS Scenario 7.2: Smart Alerting generates an alert and an xDASxx is accessible

When SAS is accessible

And there is an alert event detected by the SAS

And an xDASxx is accessible

Then the alerts on the SAS shall be delegated to the xDASxx

And the xDASxx shall signal the SAS audio and visual alerts

And a CDASxx can confirm the alert back to the SAS

SAS Scenario 7.3: Smart Alerting generates an alert and an xDASxx is inaccessible

When SAS is accessible

And there is an alert event detected by the SAS

Commented [KF1]: Pretty sure this isn't Gherkin – meant to be a summary of the next scenarios. Maybe Gherkin has an equivalent? Could just be a comment.

And an xDASxx is inaccessible
Then any device alert signal delegation shall be disabled
And any active alerts (audio and visual) shall be signaled on the originating device

Situation: Smart Alerting System is inaccessible from devices and an xDASxx is potentially accessible

SAS Scenario 7.4: Smart Alerting System is inaccessible from devices and an xDASxx is accessible

When SAS is inaccessible
And an alert event was detected by a bedside device
And an xDASxx is accessible
Then the alerts on the device shall be delegated to the xDASxx
And the xDASxx shall signal the device audio and visual alerts
And a CDASxx can confirm the alert back to the device

SAS Scenario 7.5: Smart Alerting System is inaccessible from devices and an xDASxx is inaccessible

When SAS is inaccessible
And an alert event was detected by a bedside device
And an xDASxx is inaccessible
Then any device alert signal delegation shall be disabled
And any active alerts (audio and visual) shall be signaled on the originating device

Situation: CDASxx receives and confirms Smart Alerting System alert

SAS Scenario 7.6: Devices, CDASxx and Smart Alerting System are accessible, and SAS generates an alert

When a CDASxx is accessible
And an alert event was detected by the SAS
And the operator confirms the alert at the CDASxx
Then the confirmation will be sent to the SAS
And the SAS will send the confirmation to the appropriate Devices

~~Scenario Outline: Smart alerting system is inaccessible and distributed alarm system (DAS/DIS) is accessible~~

~~**Given** local device audio alarm state was set to <state>
When there is an alert event on one or more medical devices in the patient room
And distributed alarm system is accessible
And smart alerting system is inaccessible
Then the alerts on the medical devices in the patient room shall be shown on the remote alerting devices
And the audio alarm shall be enabled on the remote alerting devices for these alert events
And active device alert events shall be shown on the medical devices locally~~

Commented [KF2]: The strikethrough text can be deleted if no longer necessary. Feeling is that it duplicates the previous content.

~~And the audio alarm shall be <action> on all medical devices in the patient room~~

Examples:

_____	state _____	action _____	
_____	disabled _____	disabled _____	
_____	enabled _____	enabled _____	

~~Scenario: Smart alerting system is accessible and distributed alarm system (DAS/DIS) is inaccessible~~

~~When there is an alert event on one or more medical devices in the patient room~~

~~And distributed alarm system is inaccessible~~

~~And smart alerting system is accessible~~

~~Then the audio alarm shall be enabled on all medical devices which have an alert event~~

~~And active device alert events shall be shown on the medical devices locally~~

~~Scenario: Smart alerting system is inaccessible and distributed alarm system (DAS/DIS) is inaccessible~~

~~When there is an alert event on one or more medical devices in the patient room~~

~~And distributed alarm system is inaccessible~~

~~And smart alerting system is inaccessible~~

~~Then the audio alarm shall be enabled on all medical devices which have an alert event~~

~~And active device alert events shall be shown on the medical devices locally~~

~~Rule: Only smart alert event distribution is configured~~

~~Per configuration, only the smart alert event from the smart alerting system shall be sent to the distributed alarm system (DAS/DIS).~~

~~Scenario Outline: Smart alerting system waits for additional inputs such as alert events from other devices and distributed alarm system (DAS/DIS) is accessible~~

~~Given smart alert system was receiving vital signs, device settings, alert events, etc. from medical devices assigned to the patient~~

~~And local device audio alarm state was set to <state>~~

~~When smart alerting system waits for additional inputs~~

~~And there is an alert event on one or more medical devices in the patient room~~

~~And distributed alarm system is accessible~~

~~Then active device alert events shall be shown on the medical devices locally~~

~~And the audio alarm shall be <action> on all medical devices in the patient room~~

~~But no device alert events shall be shown on the remote alerting devices~~

Examples:

_____	state _____	action _____	
_____	disabled _____	disabled _____	
_____	enabled _____	enabled _____	

Scenario Outline: Smart alert event from the smart alerting system is available and distributed alarm system (DAS/DIS) is accessible

Given smart alert system was receiving vital signs, device settings, alert events, etc. from medical devices assigned to the patient

And local device audio alarm state was set to <state>

When there is an alert event from the smart alerting system

And distributed alarm system is accessible

Then the smart alert event shall be shown on the remote alerting devices

And the audio alarm shall be enabled on the remote alerting devices for these smart alert events

And active device alert events shall be shown on the medical devices locally

And the audio alarm shall be <action> on all medical devices in the patient room

Examples:

_____	state _____	action _____	
_____	disabled _____	disabled _____	
_____	enabled _____	enabled _____	

Rule: Smart and device alert event distribution is configured

Per configuration, the smart alert events from the smart alerting system as well as all the local device alert events shall be sent to the distributed alarm system (DAS/DIS).

Scenario Outline: Smart alerting system waits for additional inputs such as alert events from other devices and distributed alarm system (DAS/DIS) is accessible

Given smart alert system was receiving vital signs, device settings, alert events, etc. from medical devices assigned to the patient

And local device audio alarm state was set to <state>

When smart alerting system waits for additional inputs

And there is an alert event on one or more medical devices in the patient room

And distributed alarm system is accessible

Then active device alert events shall be shown on the medical devices locally

And the audio alarm shall be <action> on all medical devices in the patient room

And device alert events shall be shown on the remote alerting devices

And the audio alarm shall be enabled on the remote alerting devices for these alert events

Examples:

_____	state _____	action _____	
_____	disabled _____	disabled _____	
_____	enabled _____	enabled _____	

Scenario Outline: Smart alert event from the smart alert system is available and distributed alarm system (DAS/DIS) is accessible

Given smart alert system receives vital signs, device settings, alert events, etc. from medical devices assigned to patient

And local device audio alarm state was set to <state>

When there is an alert event from the smart alerting system

And there is an alert event on one or more medical devices in the patient room

And distributed alarm system is accessible

Then all alert events shall be shown on the remote alerting devices

And the audio alarm shall be enabled on the remote alerting devices for these alert events

And active device alert events shall be shown at the medical device locally

And the audio alarm shall be <action> on all medical devices in the patient room

Examples:

_____	state _____	action _____	
_____	disabled _____	disabled _____	
_____	enabled _____	enabled _____	

Annex – References from 60601-1-8:2020 for DIS, DAS and CDAS

DIS - * DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS

system that involves more than one item of equipment in a ME SYSTEM intended to provide information about ALARM CONDITIONS but does not guarantee delivery of that information

NOTE 1 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended to notify OPERATORS of the existence of an ALARM CONDITION as a RISK CONTROL measure. A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is intended to provide information about an ALARM CONDITION while the OPERATOR is aware of the existence of the ALARM CONDITION by an ALARM SYSTEM.

NOTE 2 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended for confirmed delivery of ALARM CONDITIONS

Examples could be:

Sometimes referred to as secondary alerting devices: Hallway display of active alarms; Hallway light over room door; Caregiver worn device;

DAS - * DISTRIBUTED ALARM SYSTEM

ALARM SYSTEM that involves more than one item of equipment in a ME SYSTEM intended for delivery of ALARM CONDITIONS with technical confirmation

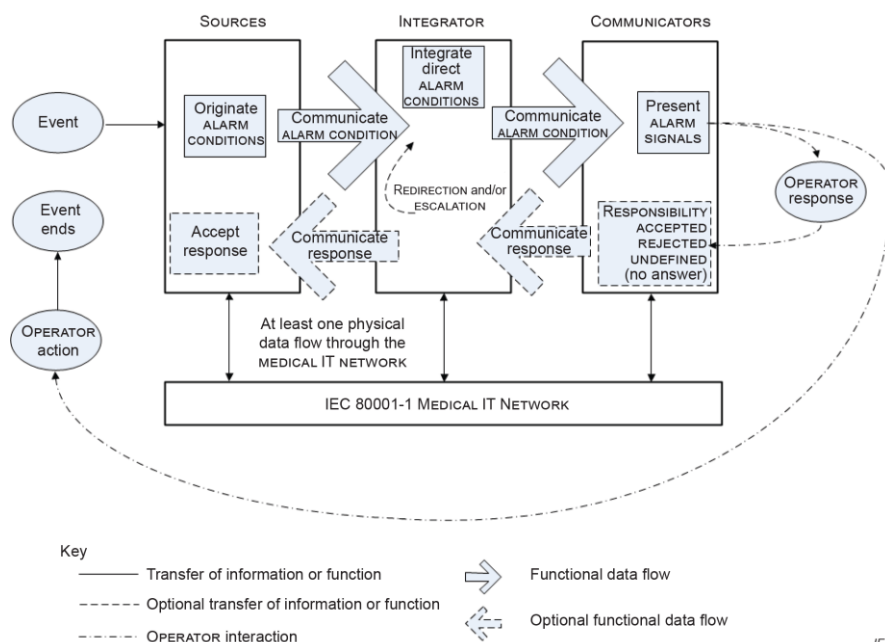
NOTE 1 The parts of a DISTRIBUTED ALARM SYSTEM can be widely separated in distance.

NOTE 2 A DISTRIBUTED ALARM SYSTEM is intended to notify OPERATORS of the existence of an ALARM CONDITION.

NOTE 3 For the purposes of this document, technical confirmation means that each element of a DISTRIBUTED ALARM SYSTEM confirms or guarantees the successful delivery of the ALARM CONDITION to the next element or appropriate TECHNICAL ALARM CONDITIONS are created as described in 6.11.2.2.1.

Examples could be:

Central Station without alarm accept/reject.



- EXAMPLE 1 – A central station
- EXAMPLE 2 – An electronic record-keeping device
- EXAMPLE 3 – Remote viewing from home or office
- EXAMPLE 4 – Bed-to-bed viewing of ALARM CONDITIONS (e.g. one nurse for two beds).
- EXAMPLE 5 – Transmission of ALARM CONDITIONS to pagers, cell phones, hand-held computers, etc.

CDAS - DISTRIBUTED ALARM SYSTEM WITH OPERATOR CONFIRMATION

DISTRIBUTED ALARM SYSTEM that includes the capability to receive an OPERATOR response

Examples could be:

Traditional Central Station; Bed to Bed alarm feature supporting alarm acknowledge;
Caregiver worn device supporting alarm acknowledge

6.11.2.4 * CDAS

In a CDAS, the COMMUNICATOR that receives an ALARM CONDITION shall have means to create the OPERATOR responses (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) and transfer them to the INTEGRATOR.

- In a CDAS, the COMMUNICATOR that receives an ALARM CONDITION and initiates an OPERATOR response (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED) shall indicate the OPERATOR response state (RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED).

The means of control used to initiate an OPERATOR response or indication of state may be marked with:

- a) symbol ISO 7000-6334A (2015-06) (see Symbol 13 of Table C.1) for RESPONSIBILITY ACCEPTED; or
- b) symbol ISO 7000-6335A (2015-06) (see Symbol 16 of Table C.1) for RESPONSIBILITY REJECTED.

Means shall be provided for the OPERATOR to terminate RESPONSIBILITY ACCEPTED or RESPONSIBILITY REJECTED while the related ALARM CONDITION is active.

Initiating RESPONSIBILITY REJECTED may be used to terminate RESPONSIBILITY ACCEPTED.

Initiating RESPONSIBILITY ACCEPTED may be used to terminate RESPONSIBILITY REJECTED.

In a CDAS, RESPONSIBILITY ACCEPTED may initiate an ALARM SIGNAL inactivation state.

NOTE RESPONSIBILITY ACCEPTED is a different function than an ALARM SIGNAL inactivation state.

In a CDAS, the INTEGRATOR shall have means to accept OPERATOR responses from the COMMUNICATOR.

In a CDAS, the SOURCE may receive OPERATOR responses from the INTEGRATOR.

Subclause 6.11.2.4 – CDAS

The terms RESPONSIBILITY ACCEPTED, RESPONSIBILITY REJECTED, and RESPONSIBILITY UNDEFINED are new to this document. They are most often applicable to a DISTRIBUTED ALARM SYSTEM for use in an intensive care setting or a hospital ward setting, in which each OPERATOR has a COMMUNICATOR (example: pocket pager or phone) that provides an ALARM CONDITION to a specific OPERATOR. If the DISTRIBUTED ALARM SYSTEM presents an ALARM CONDITION to a specific OPERATOR, then there can be three possibilities:

- the specific OPERATOR accepts responsibility for the ALARM CONDITION, and the state RESPONSIBILITY ACCEPTED becomes true;
- the specific OPERATOR is busy and therefore rejects responsibility, the state RESPONSIBILITY REJECTED becomes true, and the DISTRIBUTED ALARM SYSTEM redirects the ALARM CONDITION to a different COMMUNICATOR, hence OPERATOR;
- the OPERATOR does not respond to the ALARM SIGNAL within the timeframe established by the RESPONSIBLE ORGANIZATION in the INTEGRATOR, the state RESPONSIBILITY UNDEFINED becomes true, and the INTEGRATOR redirects the ALARM CONDITION to a different COMMUNICATOR, hence OPERATOR in this instance also.

A similar configuration might be provided for other DISTRIBUTED ALARM SYSTEMS, for instance, from a bedside monitor to a different bedside monitor, or from a bedside monitor to a central station.

Care is needed in the design of a CDAS when there is a non-homogenous set of SOURCES. The logic (REDIRECTION and ESCALATION) behind the processing of RESPONSIBILITY UNDEFINED can become very complex and needs to take into account how each SOURCE responds to the resulting states. These complex systems can inadvertently cause ALARM FLOOD or 'lost' ALARM CONDITIONS (i.e. no assigned COMMUNICATOR).

Such a configuration would not be expected in ME EQUIPMENT without a DISTRIBUTED ALARM SYSTEM. For example, an anaesthesia workstation, for which an OPERATOR is normally present during all PATIENT care, would not be expected to provide these functions.