

Appendix C

SDPi Standalone Operating Room - SOR

SDPi Silent Room Use Case - SR

SDPi Silent ICU Use Case - SI

SDPi Remote Alarm Management Use Case – RAM

SDPi 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. dashboard w/ accept/reject

	DASsp	Yes	No	Local	Single Pt. Remote view w/audible alarms
	CDASsp	Yes	Yes	Remote	Single Pt. Remote View 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					

SDPi-R Feature / Use Case: Standalone Operating Room (SOR)

- Bedside devices are SDC compliant
- At least one xDASmp that is SDC compliant
- All Devices in Room delegate their alerts to one or more xDASmp.

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

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

SR Scenario Outline 1: Detect and Communicate Alert at Bedside Device

Scenario 1.1: 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

Scenario 1.2: 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

Scenario 1.3: 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

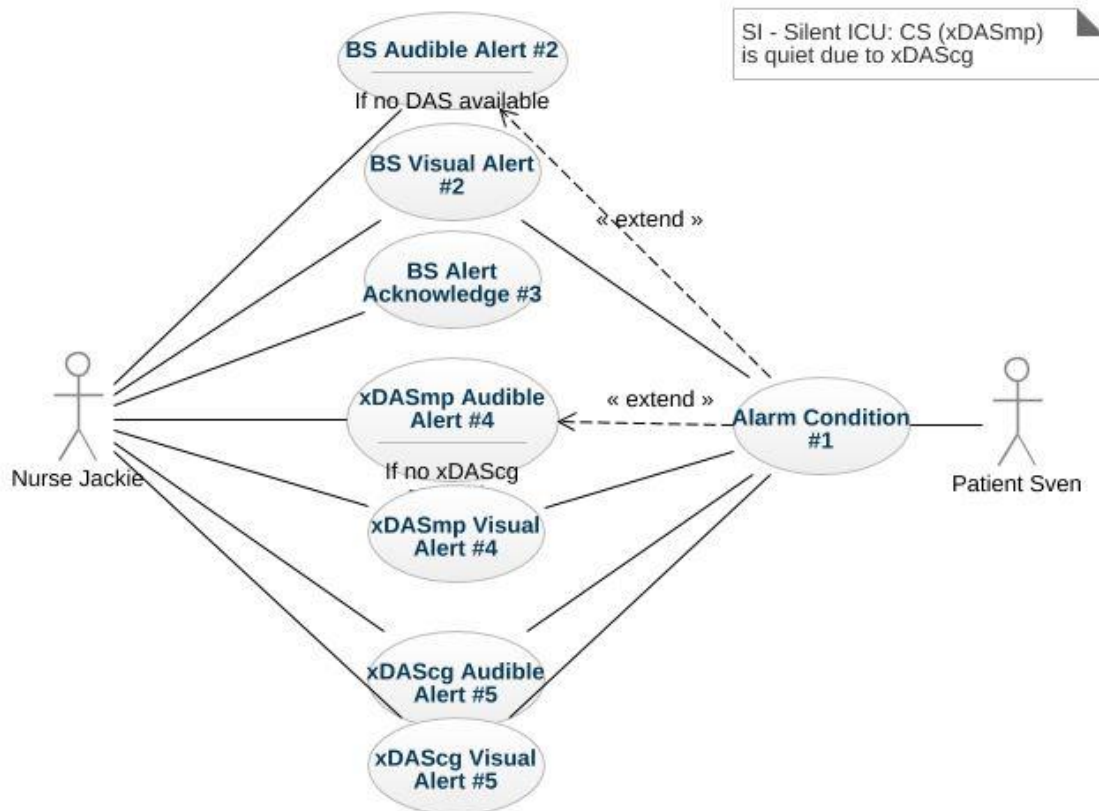
And the audio alarm shall be disabled on all accessible remote alerting device for this alert event

Scenario 1.4: Medical device detects an alert situation, initially DAS is accessible but fails

SDPi-A Feature / Use Case: Silent ICU (SI) Alert Distribution

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 (xDAScgs) (#4).



Technical Pre-Conditions:

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

Rule: Single DAScgs or combination of xDAScgs and xDxSxx

SI Scenario Outline 1: Audible Alert at CDAScg Nurse Device

SI Scenario 1.1: 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

SI Scenario 1.2: 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

SI Scenario 1.3: 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

SI Scenario 1.4: 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

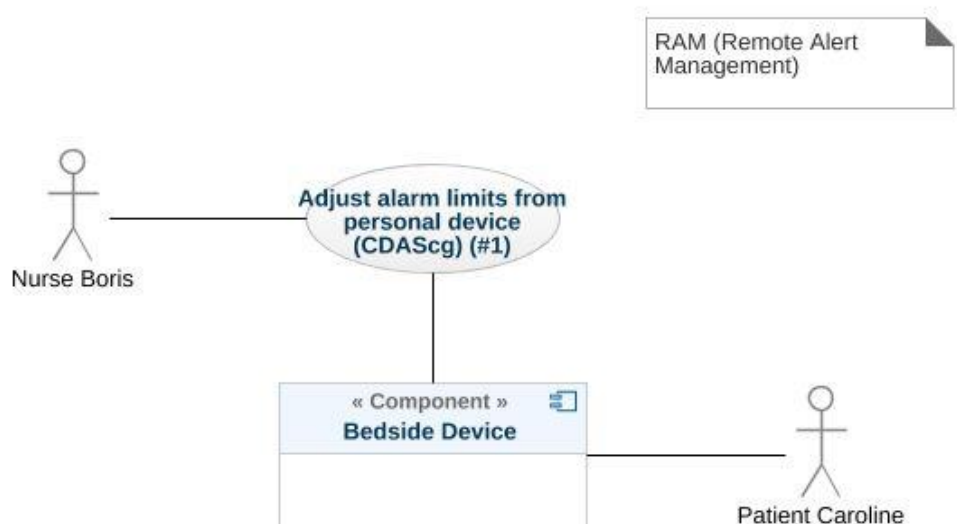
And the audio alarm shall be disabled on all accessible remote alerting device for this alert event

Scenario 1.5: Medical device detects an alert situation, initially DAS is accessible but fails

SDPi-A/xC Feature / Use Case: 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 1.1: 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 1.2: 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 ???

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

Narrative:

Ben is an ICU nurse. Suddenly, he got 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 a DIS/DAS in this feature. However, a combination of a DIS/DAS with a smart alerting system is typical.

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 delegates its alerts to an xDASmp and/or xDAScg.

Scenario Outline: Local device 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	

Scenario: 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

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

When SAS is accessible

And there is an alert event detected by the SAS

And a xDASxx is <dState>

Then <action1>

And <action2>

Examples:

dState	action1	action2
accessible	the alerts on the SAS shall be delegated to the xDASxx	the xDASxx shall signal the SAS audio and visual alert
inaccessible	active device alert events shall be shown on the medical devices locally	the audio alarm shall be signaled on all medical devices which have an alert event

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

When SAS is inaccessible

And a xDASxx is <dState>

Then <action1>

And <action2>

Examples:

dState	action1	action2
accessible	the alerts on the devices shall be delegated to the xDASxx	the xDASxx shall signal the device audio and visual alert
inaccessible	active device alert events shall be shown on the medical devices locally	the audio alarm shall be signaled on all medical devices which have an alert event

~~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~~

~~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

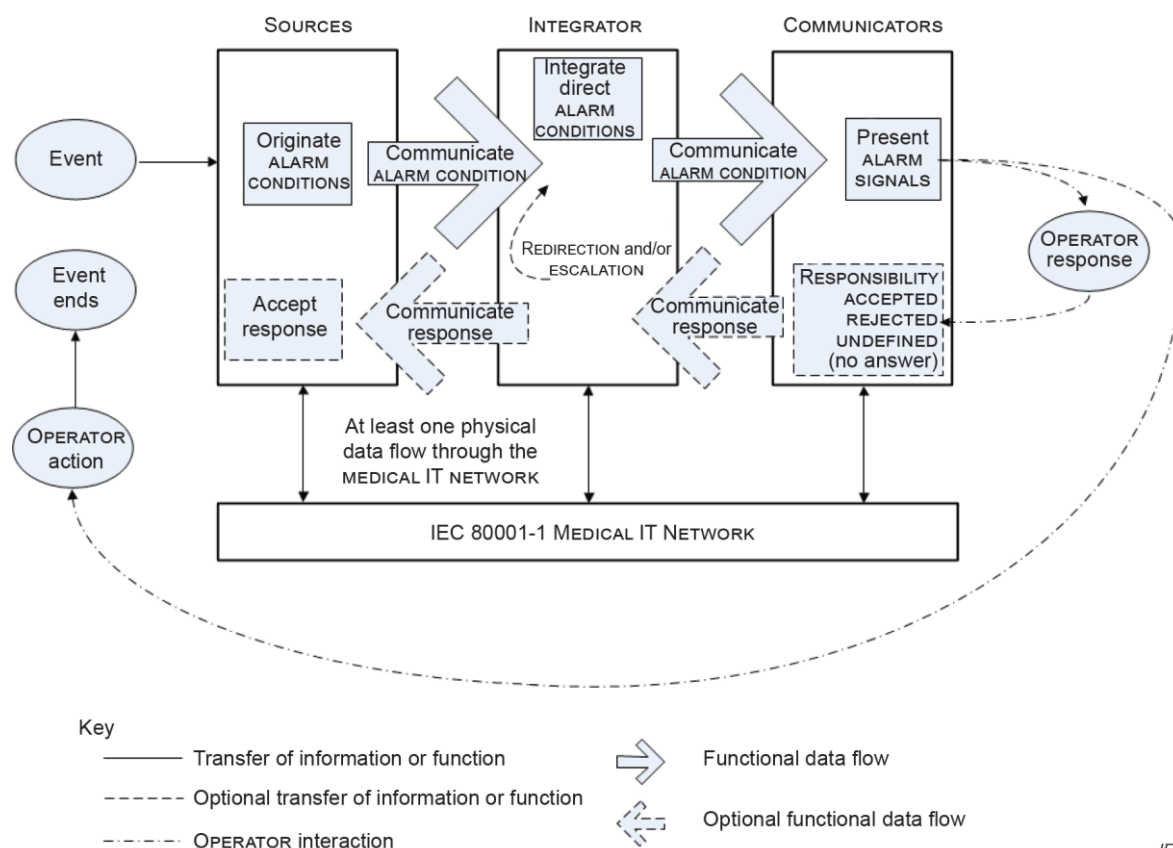
NOTE 1 The parts of a DISTRIBUTED ALARM SYSTEM can be widely separated in distance.

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.