Feature: Alert distribution

Linda is an ICU nurse responsible for 4 patients. While she is updating documentation at the nursing station one of her patients goes into an alarm state. This does not generate an audible tone in the patient room though Linda could acknowledge or otherwise handle the alert at the bedside. It does generate an alarm tone at the central station as well as a notification on her mobile device. Since she is already at the central station, she can check the situation, acknowledge the alert and otherwise adjust the alert parameters using the central station UI, and rush to the patient's room in order to resolve the critical situation.

While she is still taking care of the first patient, another patient goes into an alarm state once again generating alarm tones at the central station and on her phone but not in the patient room. Linda decides to acknowledge the alert on her phone and take care of the other patient after she is done with the first patient.

Note that the local audio alarm may still be enabled per configuration for certain alert events and/or the role of the device in the distributed alarm system. This is out of scope for the following scenarios.

Scenario: Medical device detects an alert situation and all distributed alarm systems (DAS/DIS) 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: Caregiver acknowledges the alert at the medical device and at least one distributed alarm system (DAS/DIS) is accessible

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

When caregiver acknowledges the alert at the medical device

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

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

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

Scenario: Alert situation has been resolved and at least one distributed alarm system (DAS/DIS) 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

Rule: One DAS/DIS

There is one distributed alarm system (e.g. mobile alerting device system, central monitoring station, etc.) compliant with the IEC 60601-1-8 alarm standard for Distributed Alarm Systems (DAS) or Distributed Information System about Alarm Conditions (DIS).

Scenario Outline: Medical device detects an alert situation and distributed alarm system (DAS/DIS) is accessible

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

When <system> is accessible

Then the alert shall be shown on the caregiver's remote alerting device

And the audio alarm shall be enabled on the caregiver's remote alerting device for this alert event

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:

| system | action | |
|--------|----------|-----|
| DAS | disabled | |
| DIS | paused | - 1 |

Scenario Outline: Caregiver acknowledges the alert at the DAS/DIS remote alerting device

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

When caregiver acknowledges the alert at the DAS/DIS remote alerting device

And <system> is accessible

Then the alert shall be shown as <visualL> at the medical device locally

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

And the alert shall be shown as <visualR> on the caregiver's remote alerting device

And the audio alarm shall be disabled on the caregiver's remote alerting device for this alert event

| system | visualL | visualR | action | |
|--------|--------------|--------------|----------|--|
| DAS | acknowledged | acknowledged | disabled | |
| DIS | paused | confirmed | paused | |

Rule: Multiple DAS

There are multiple distributed alarm systems (e.g. mobile alerting device system, central monitoring station, etc.) compliant with the IEC 60601-1-8 alarm standard for Distributed Alarm Systems (DAS).

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

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

When at least distributed alarm 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: Caregiver acknowledges the alert at a remote alerting device connected to one of the distributed alarm systems

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

When caregiver acknowledges the alert at a remote alerting device

And distributed alarm system connected to this remote alerting device is accessible

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

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

Scenario: Caregiver acknowledges the alert at the medical device

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

When caregiver acknowledges the alert at the medical device

And at least distributed alarm system is accessible

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

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

Rule: Combination of DAS and DIS

There is a combination of DAS and DIS (e.g. mobile alerting device system, central monitoring station, etc.) compliant with the IEC 60601-1-8 alarm standard for Distributed Alarm Systems (DAS) as well as for Distributed Information System about Alarm Conditions (DIS).

Scenario: Medical device detects an alert situation and DAS & DIS are accessible

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

When DAS & DIS are 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 the medical devices in the patient room

Scenario: Medical device detects an alert situation and DAS is accessible, but DIS is inaccessible

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

When DAS is accessible

But DIS is inaccessible

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 the medical devices in the patient room

Scenario: Medical device detects an alert situation and DIS is accessible, but DAS is inaccessible

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

When DIS is accessible

But DAS is inaccessible

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 paused on the medical devices in the patient room

Scenario: Caregiver acknowledges the alert at the DAS, and DIS may or may not be accessible

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

And remote alerting device is part of the DAS

When caregiver acknowledges the alert at a remote alerting device

And DAS is accessible

Then the alert shall be shown as acknowledged 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 acknowledged on all accessible remote alerting devices (DAS & DIS)

And the audio alarm shall be disabled on all accessible remote alerting devices (DAS & DIS) for this alert event

Scenario: Caregiver confirms the alert at the DIS and DAS is 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

And DIS is accessible

And DAS is accessible

Then the alert shall only be shown as confirmed on all accessible DIS remote alerting devices

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

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

And the alert shall be shown on the medical device locally

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

Scenario: Caregiver confirms the alert at the DIS and DAS is inaccessible

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

And DIS is accessible

But DAS is inaccessible

Then the alert shall only be shown as confirmed on all accessible DIS remote alerting devices

And the alert shall be shown on the medical device locally

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

Feature: Audio alarm behavior dependent on the presence of caregiver

Claire is an ICU nurse and responsible for patients which have severe infectious disease and therefore, these patients are housed in isolation rooms in order to prevent the spread of diseases in the hospital. According to hospital's protocol for isolation rooms, she has to wear protective clothing and is not allowed to use her mobile device in the isolation room. Therefore, before she enters the isolation room, Claire suspends the audio alarm delegation for all the bedside device in the isolation room through her mobile device, so that she will directly acoustically be notified by the devices in the isolation room detecting an alarm event. The audio alarm at her smart phone is disabled at the same time

At another care unit, the caregivers are automatically located, and when the system detects the presence of a caregiver in the isolation room, the system automatically enables the audio alarm at the medical devices and disables the audio alarm at the smart phone.

Later in the day, Claire is back in the nurse station. At the nurse station, they have a central patient monitoring station showing the patient data from all the patients Claire's care team is responsible for. While she is in the nurse station, the audio alarm at her smart phone is disabled since the central patient monitoring station will activate an audio alarm if one of the monitored patients has an alert event.

Extended scenario:

Staff resources and skill level varies within a team. At the same time, workload can change during a shift. The clinical team needs to be able to readily adapt and re-allocate their resources. A differentiated alarm logistics system must support this workflow by enabling allow dynamic patient allocation (alarm notifications) from one caregiver to another caregiver.

Scenario Outline: Caregiver is not present in the patient room and a distributed alarm system (DAS/DIS) is accessible

Given caregiver indicated his/her absence or the absence of a caregiver was automatically detected **When** there is an alert event on one or more medical devices in the patient room **And** <system> is accessible

Then the alerts on the medical devices shall be shown on the remote alerting devices **And** the audio alarm shall be enabled on the remote alerting devices

And the alert shall be shown on the medical device locally

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

| system | action | |
|--------|----------|-----|
| DAS | disabled | |
| DIS | paused | - 1 |

Scenario Outline: Caregiver is present in the patient room and a distributed alarm system (DAS/DIS) is accessible

Given caregiver indicated his/her presence or the presence of a caregiver was automatically detected **When** there is an alert event on one or more medical devices in the patient room **And** <system> is accessible

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 <action> on the remote alerting devices for these alert events **And** the alert shall be shown on the medical device locally

Examples:

| system | action | |
|--------|---------------------------------------|-----|
| DAS | disabled | |
| l DIS | enabled/disabled as per configuration | - 1 |

Scenario: Caregiver is not present in the patient room and a distributed alarm system (DAS/DIS) is inaccessible

Given caregiver indicated his/her absence or the absence of a caregiver was automatically detected **When** there is an alert event on one or more medical devices in the patient room

And distributed alarm system (DAS/DIS) is inaccessible

Then the alert shall be shown on the medical device locally

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

Scenario Outline: Caregiver is at the nurse station equipped with a central monitoring station. A mobile device distributed alarm system (DAS/DIS) and the central station are accessible.

Given caregiver indicated his/her presence or the presence of a caregiver was automatically detected **And** audio alarm for the caregiver's mobile alerting device is configured as <configuration> when caregiver is at the nurse station

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

And distributed alarm system (DAS/DIS) is accessible

And the central monitoring station is accessible

Then the alert shall be shown on the medical device locally

And the alert shall be shown on the central monitoring station

And the audio alarm shall be enabled at the central monitoring station

And the alert shall be shown on the caregiver's mobile alerting device

And the audio alarm shall be <action> at the caregiver's mobile alerting device

| configuration | action | |
|---------------|----------|---|
| disabled | disabled | |
| enabled | enabled | l |

Scenario: Caregiver is at the nurse station equipped with a central monitoring station. A mobile device distributed alarm system (DAS/DIS) is accessible but the central station is inaccessible or become inaccessible.

Given caregiver indicated his/her presence or the presence of a caregiver was automatically detected

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

And distributed alarm system (DAS/DIS) is accessible

And the central monitoring station is inaccessible

Then the alert shall be shown on the medical device locally

And the alert shall be shown on the caregiver's mobile alerting device

And the audio alarm shall be enabled at the caregiver's mobile alerting device

Scenario: Caregiver is at the nurse station equipped with a central monitoring station. The central station is accessible, but the mobile device distributed alarm system (DAS/DIS) is inaccessible.

Given caregiver indicated his/her presence or the presence of a caregiver was automatically detected

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

And distributed alarm system (DAS/DIS) is inaccessible

And the central monitoring station is accessible

Then the alert shall be shown on the medical device locally

And the alert shall be shown on the central monitoring station

And the audio alarm shall be enabled at the central monitoring station

Scenario Outline: Caregiver has left the nurse station equipped with a central monitoring station. A mobile device distributed alarm system (DAS/DIS) and the central station are accessible.

Given caregiver indicated his/her absence or the absence of a caregiver was automatically detected **And** audio alarm at the central monitoring station is configured as <configuration> when caregiver has left the nurse station

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

And distributed alarm system (DAS/DIS) is accessible

And the central monitoring station is accessible

Then the alert shall be shown on the medical device locally

And the alert shall be shown on the central monitoring station

And the audio alarm shall be <action> at the central monitoring station

And the alert shall be shown on the caregiver's mobile alerting device

And the audio alarm shall be enabled at the caregiver's mobile alerting device

| configuration | action | |
|---------------|----------|-----|
| disabled | disabled | |
| enabled | enabled | - 1 |

Scenario: Caregiver has left the nurse station equipped with a central monitoring station. The central station is accessible, but the mobile device distributed alarm system (DAS/DIS) is inaccessible.

Given caregiver indicated his/her absence or the absence of a caregiver was automatically detected When there is an alert event on one or more medical devices in the patient room And distributed alarm system (DAS/DIS) is inaccessible
And the central monitoring station is accessible
Then the alert shall be shown on the medical device locally
And the alert shall be shown on the central monitoring station
And the audio alarm shall be enabled at the central monitoring station

Rule: Individual audio alarming on all medical devices is configured

Per configuration, the audio alarm delegation is suspended on all medical devices in the patient room when a caregiver is present in the patient room.

Scenario: Caregiver is present in the patient room

Given caregiver indicated his/her presence or the presence of a caregiver was automatically detected **When** there is an alert event on one or more medical devices in the patient room **Then** the audio alarm shall be enabled on all medical devices which have an alert event

Rule: Only audio alarming for alert events with highest priority is configured

Per configuration, the audio alarm is enabled only for the devices which have alert events with the highest priority.

Scenario: Caregiver is present in the patient room

Given caregiver indicated his/her presence or the presence of a caregiver was automatically detected **When** there is an alert event on one or more medical devices in the patient room

Then the audio alarm shall only be enabled on the medical devices which have alert events with the highest priority

But the audio alarm shall still be disabled on medical devices which have alert events with a lower priority

Rule: Dedicated alert notifier device is configured

Per configuration, the audio alarm is disabled on all medical devices except for dedicated alert notifier device which has its audio alarm enabled and all other devices delegate their audio alarm to this device.

Scenario: Caregiver is present in the patient room and the alert notifier device is accessible

Given caregiver indicated his/her presence or the presence of a caregiver was automatically detected **When** there is an alert event on one or more medical devices in the patient room

And the dedicated alert notifier device is accessible

Then alert events from all medical devices in the patient rooms shall be shown at the dedicated alert notifier device

And the audio alarm shall only be enabled on the dedicated alert notifier device

And the audio alarm shall be disabled on all other medical devices

Scenario: Caregiver is present in the patient room and the alert notifier device is inaccessible

Given caregiver indicated his/her presence or the presence of a caregiver was automatically detected **When** there is an alert event on one or more medical devices in the patient room

And the dedicated alert notifier device is inaccessible

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

Feature: Smart alerting

Ben is an ICU nurse. Suddenly, he got a "Check ventilation hose!" smart alert for one of his patients he is responsible for. The alert was generated by a smart alerting system that collects all the data from the PoC devices such as vital signs, alerts, settings, waves, etc., and combines them to a more actionable information for the care giver to guide care, intervention and treatment.

In the example above, an algorithm combines "Low SPO2" alarm from the patient monitor and a "Peak Pressure" alarm and "Minute Volume low" alarm from the ventilator and suggests possible root causes to the caregiver (i.e. obstruction (sputum/kinked hose). This leads to quicker, more adequate intervention.

The original alerts at 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 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 supported and some of the scenarios may not apply in this case.

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 | - 1 |
|-----------|-----------|-----|
| disabled | disabled | - 1 |
| l enabled | l enabled | - 1 |

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 | |
| l enabled | l enabled | - 1 |

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

| 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

| state | action | |
|----------|----------|-----|
| disabled | disabled | |
| enabled | enabled | - 1 |