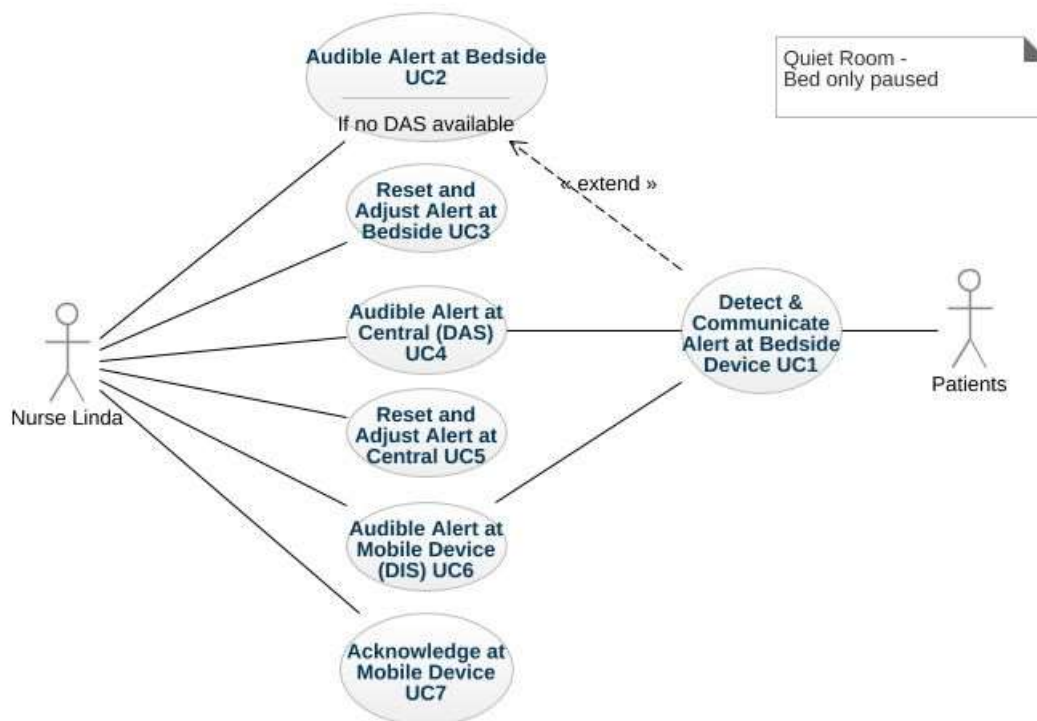


Feature / Use Case Narrative: Quiet Room (QR) Alert distribution

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 (UC1). This does not generate an audible tone in the patient room (UC2) though Linda could reset or otherwise handle the alert at the bedside (UC3). It does generate an alarm tone at the central station (DAS) (UC4) as well as a notification on her mobile device (DIS) (UC6). Since she is already at the central station, she can check the situation, **reset** the alert and otherwise adjust the alert parameters using the central station UI (UC5), 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 (UC1) once again generating alarm tones at the central station (UC4) and on her phone (UC6) but not in the patient room. Linda decides to **acknowledge** the alert on her phone (UC7) and take care of the other patient after she is done with the first patient.



Rule: Combination of primary and secondary remote alert systems

There is a combination of primary and secondary remote alert 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) as well as for Distributed Information System about Alarm Conditions (DIS).

QR Use Case 1: Detect & Communicate Alert at Bedside Device

Scenario 1.1: Medical device detects an alert situation and all remote alert systems are accessible (Happy Path)

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

When all remote alert systems 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 the audio alarm shall be **disabled** on the medical device

Scenario 1.2: 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 the audio alarm shall be **disabled** on the medical device

Scenario 1.3: 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 the audio alarm shall be **paused** on the medical device

Scenario 1.4: Medical device detects an alert situation and all remote alert systems are inaccessible

Given alert event was detected by a medical device attached to the patient
When all remote alert systems are inaccessible
Then the audio alarm shall be enabled on the medical device

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

Scenario 1.6: Alert situation has been resolved and at least one remote alert system is accessible

Given medical device detected that the alert situation has been resolved
When at least one remote alert system is accessible
Then the alert shall be shown as inactive/ended at the medical device
And the audio alarm shall be **disabled** on the medical device
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

QR Use Case 2: Audible Alert at Bedside

Scenario 2.1: Medical device detects an alert situation and no remote alert systems are accessible (same as 1.4)

QR Use Case 3: Reset and Adjust Alert at Bedside

Scenario 3.1: Caregiver acknowledges the alert at the Bedside device – DAS and DIS accessible

Scenario 3.2: Caregiver acknowledges the alert at the Bedside device – DAS accessible, DIS not accessible

Scenario 3.3: Caregiver acknowledges the alert at the Bedside device – DIS accessible, DAS not accessible

QR Use Case 4: Audible Alert at Central Station (DAS)

Scenario 4.1: Medical device detects and alert condition and DAS (CS) announces the alert

QR Use Case 5: Reset and Adjust Alert at DAS

Scenario 5.1: Caregiver acknowledges the alert at the DAS

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

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

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

QR Use Case 6: Audible Alert at Nurse Device

Scenario 6.1: Medical device detects an alert condition and DIS announces the alert at Caregiver device

QR Use Case 7: Acknowledge Alert at Nurse Device

Scenario 7.1: 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

Scenario 7.2: 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

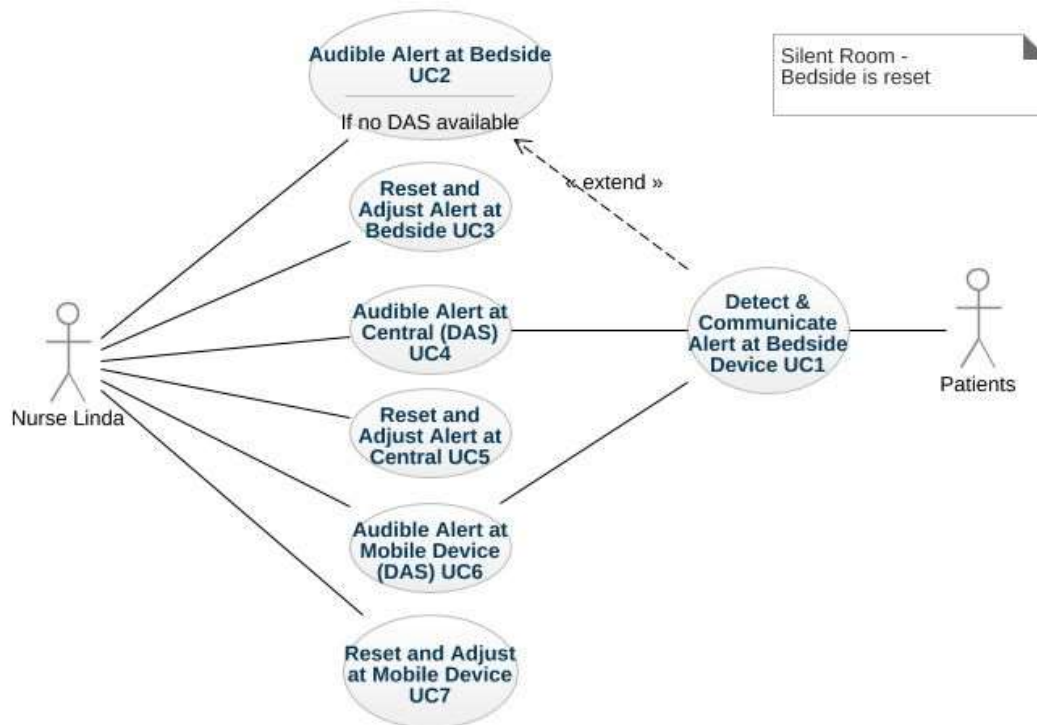
Then the alert shall only be shown as confirmed on all accessible DIS remote alerting devices

And the audio alarm shall be **paused** on the medical device

Feature / Use Case Narrative: Silent Room (SR) 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 (UC1). This does not generate an audible tone in the patient room (UC2) though Linda could reset or otherwise handle the alert at the bedside (UC3). It does generate an alarm tone at the central station (UC4) as well as a notification on her mobile device (UC6). Since she is already at the central station, she can check the situation, reset the alert and otherwise adjust the alert parameters using the central station UI (UC5), 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 (UC1) once again generating alarm tones at the central station (UC4) and on her phone (UC6) but not in the patient room. Linda decides to reset the alert on her phone (UC7), adjust the alarm limits (UC7) and take care of the other patient after she is done with the first patient.



Rule: Multiple primary remote alert systems

There are multiple primary remote alert 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).

SR Use Case 1: Detect and Communicate Alert at Bedside Device

Scenario 1.1: Medical device detects an alert situation and at least one remote alert system 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 the audio alarm shall be disabled on the medical device

Scenario 1.2: Medical device detects an alert situation and all remote alert systems are inaccessible

Given alert event was detected by a medical device attached to the patient
When all remote alert systems are inaccessible
Then the audio alarm shall be enabled on the medical device

Scenario 1.3: Alert situation has been resolved and at least one remote alert system is accessible

Given medical device detected that the alert situation has been resolved
When at least one remote alert system is accessible
Then the alert shall be shown as inactive/ended at the medical device
And the audio alarm shall be disabled on the medical device
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

SR Use Case 2: Audible Alert at Bedside Device

Scenario 2.1: Medical device detects and alert condition and DAS announces the alert

SR Use Case 3

Scenario 3.1: Caregiver acknowledges the alert at the Bedside device – all remote alert systems are accessible

Scenario 3.2: Caregiver acknowledges the alert at the Bedside device – one remote alert system is accessible

Scenario 3.3: Caregiver acknowledges the alert at the Bedside device – no remote alert systems are accessible

SR Use Case 4: Audible Alert at Central Station (DAS)

Scenario 4.1: Medical device detects and alert condition and DAS announces the alert

SR Use Case 5

Scenario 5.1: Caregiver acknowledges the alert at one of the remote alert 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 remote alert system connected to this remote alerting device 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
And the audio alarm shall be disabled on all accessible remote alerting devices for this alert event

SR Use Case 6: Audible Alert at DAS Nurse Device

Scenario 6.1: Medical device detects and alert condition and DIS announces the alert at Caregiver device

SR Use Case 7: Acknowledge Alert at DAS Nurse Device

Scenario 7.1: Caregiver confirms the alert at their DAS Mobile Device

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

And remote alerting device is part of the DAS

When caregiver confirms the alert at a remote alerting device

And DAS 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

Scenario 7.2: Caregiver confirms the alert at their DAS mobile device but the respective DAS 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

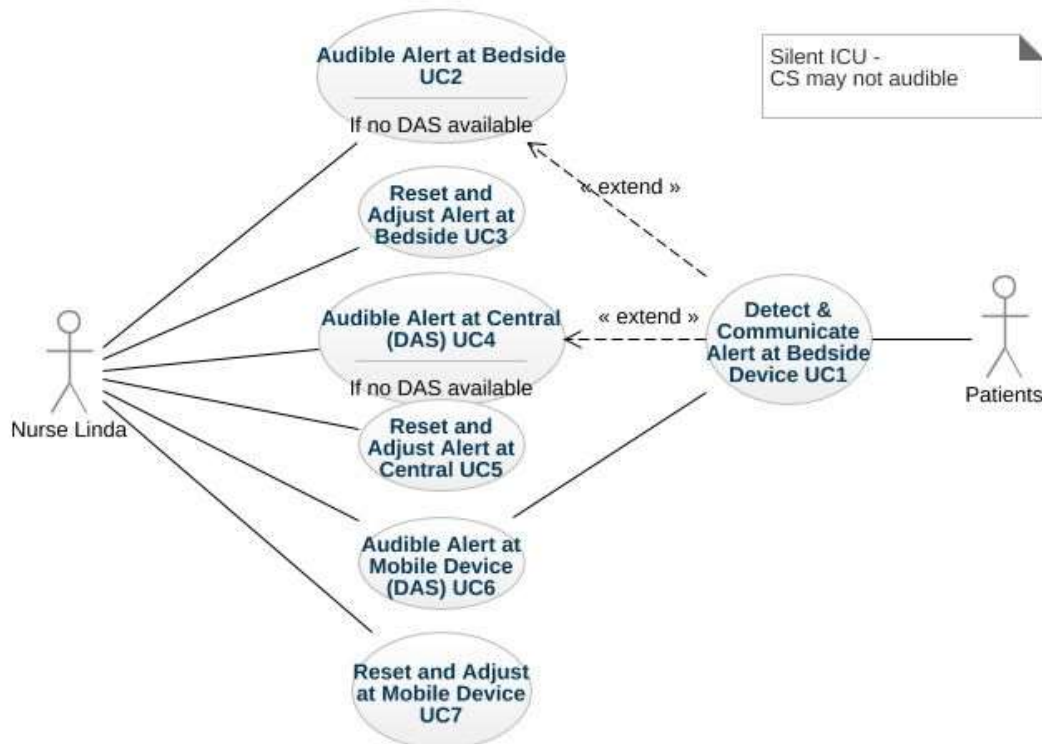
But DAS is inaccessible

Then ???

Feature / Use Case Narrative: Silent ICU (SI) 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 (UC1). This does not generate an audible tone in the patient room (UC2) though Linda could reset or otherwise handle the alert at the bedside (UC3). In addition, it does **not generate an alarm tone at the central station (UC4)** however it does generate a notification on her mobile device (UC6). Since she is already at the central station, she can check the situation, **reset** the alert and otherwise adjust the alert parameters using the central station UI (UC5), 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 (UC1) once again generating alarm tones and on her phone (UC6) **but not at the central station (UC4)** or in the patient room. Linda decides to **reset** the alert on her phone (UC7), **adjust the alarm limits** (UC7) and take care of the other patient after she is done with the first patient.



Rule: Multiple primary remote alert systems

There are multiple primary remote alert 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). **The central station DAS does not create audible alerts as long as the other DAS is accessible. It will always alert the at the nurse mobile device.**

SR Use Case 1: Detect and Communicate Alert at Bedside Device

Scenario 1.1: Medical device detects an alert situation and at least one remote alert system 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 only on the nurse alerting device**

And the audio alarm shall be disabled on the medical device

Scenario 1.2: Medical device detects an alert situation and all remote alert systems are inaccessible

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

When all remote alert systems are inaccessible

Then the audio alarm shall be enabled on the medical device

Scenario 1.3: Alert situation has been resolved and at least one remote alert system is accessible

Given medical device detected that the alert situation has been resolved

When at least one remote alert system is accessible

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

And the audio alarm shall be disabled on the medical device

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

SR Use Case 2: Audible Alert at Bedside Device

Scenario 2.1: Medical device detects and alert condition and DAS announces the alert

SR Use Case 3

Scenario 3.1: Caregiver acknowledges the alert at the Bedside device – all remote alert systems are accessible

Scenario 3.2: Caregiver acknowledges the alert at the Bedside device – one remote alert system is accessible

Scenario 3.3: Caregiver acknowledges the alert at the Bedside device – no remote alert systems are accessible

SR Use Case 4: Audible Alert at Central Station (DAS)

Scenario 4.1: Medical device detects and alert condition and DAS announces the alert

SR Use Case 5

Scenario 5.1: Caregiver acknowledges the alert at one of the remote alert 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 remote alert system connected to this remote alerting device 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
And the audio alarm shall be disabled on all accessible remote alerting devices for this alert event

SR Use Case 6: Audible Alert at DAS Nurse Device

Scenario 6.1: Medical device detects and alert condition and DIS announces the alert at Caregiver device

SR Use Case 7: Acknowledge Alert at DAS Nurse Device

Scenario 7.1: Caregiver confirms the alert at their DAS Mobile Device

Given alert event was detected by a medical device attached to the patient
And remote alerting device is part of the DAS
When caregiver confirms the alert at a remote alerting device
And DAS 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

Scenario 7.2: Caregiver confirms the alert at their DAS mobile device but the respective DAS 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 ???

Rule / Pre-Condition: One primary remote alert system

There is one primary remote alert 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).

Scenario: Caregiver acknowledges the alert at the remote alerting device

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

When caregiver acknowledges the alert at the remote alerting device

And remote alert system 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 the caregiver's remote alerting device

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

Scenario: Alert situation has been resolved and remote alert system is accessible

Given medical device detected that the alert situation has been resolved by the caregiver

When remote alert system is accessible

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

And the audio alarm shall be disabled on the medical device

And the alert shall be shown as inactive/ended 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

Scenario: Medical device detects an alert situation and remote alert system is inaccessible

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

When remote alert system is inaccessible

Then the audio alarm shall be enabled on the medical device

Feature: Audio alarm behavior dependent on the presence of caregiver in patient room

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.

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 suspends the audio alarm delegation.

Scenario Outline: Caregiver is not present in the patient room and a remote alerting system according 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 remote <system> alerting 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 audio alarm shall be <action> on the medical devices in the patient room

Examples:

system	action	
DAS	disabled	
DIS	paused	

Scenario Outline: Caregiver is present in the patient room and a remote alerting system 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 remote <system> alerting 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

Examples:

system	action	
DAS	disabled	
DIS	enabled	

Scenario: Caregiver is not present in the patient room and a remote alerting system 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 remote alerting system is inaccessible

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

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