**Integrating the Healthcare Enterprise**

# IHE <Domain Name>
# Technical Framework Supplement

# <Profile Name
# (Profile Acronym) >

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HL7® FHIR® STU x

Using Resources at FMM Level n-n

# Revision x.x – Draft in Preparation for Public Comment (*or* Trial Implementation)

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*<Volumes 1, 2, and/or 3 are developed together for Public Comment and Trial Implementation submission. Volume 4, National Extensions, is typically developed at a later point in time, usually at Trial Implementation or later. Templates for all four volumes are included in this document for the sake of completeness. If you are beginning a new profile, you are strongly discouraged from using National Extensions and should instead focus on optional data sets or other alternatives. For more information, see http://wiki.ihe.net/index.php?title=National_Extensions_Process.>*

 

## Foreword

This is a supplement to the IHE <Domain Name> Technical Framework <VX.X>. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

*<For Public Comment:>* This supplement is published on <Month XX, 201x> for Public Comment. Comments are invited and can be submitted at http://www.ihe.net/Public_Comment/#domainname. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 201X>.

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This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

| *Amend section X.X by the following:* |
|---|

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text ~~**bold strikethrough**~~. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

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Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE <Domain name>Technical Framework can be found at http://ihe.net/Technical_Frameworks.

*<Comments may be submitted on IHE Technical Framework templates any time at http://ihe.net/Templates_Public_Comments. Please enter comments/issues as soon as they are found. Do not wait until a future review cycle is announced.>*

 

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## Introduction to this Supplement

 

# Volume 1 – Profiles

### X.4.2 Use Cases

For detailed information concerning the SDPi Use Cases, Narratives and Scenarios please refer to Volume 1 - Appendix C.

#### X.4.2.1 Use Case #1: SDPi-R Standalone OR Dashboard Use Case - SORD

Aggregated display of information relevant to a surgeon in an Operating Room from multiple data sources on a "Dashboard".

Additional information on this Use Case can be found in Volume 1 – Appendix C.2.

##### X.4.2.1.1 SDPi SORD Use Case Description

This Use Case describes a general purpose "Dashboard" information display which aggregates information from different sources. While the Dashboard may display visual alert information it does not signal alerts or have any remote-control capabilities.

##### X.4.2.1.2 SDPi SORD Process Flow

*<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are "external" to this profile (using appropriate notation.)*

*The set of process flows will typically be exemplary, not exhaustive (i.e., it will address all the use cases, but will not show all possible combinations of actors, or all possible sequencing of transactions).*

*If there are detailed behavioral rules that apply to a specific process flow or multiple process flows, an appendix may be added as needed.>*

*<The roles at the top of the swimlane diagram should correspond to actor names, include the profile acronym:actor name if referencing an actor from a different profile.>*

*<Modify the following "Swimlane Diagram".>*

 

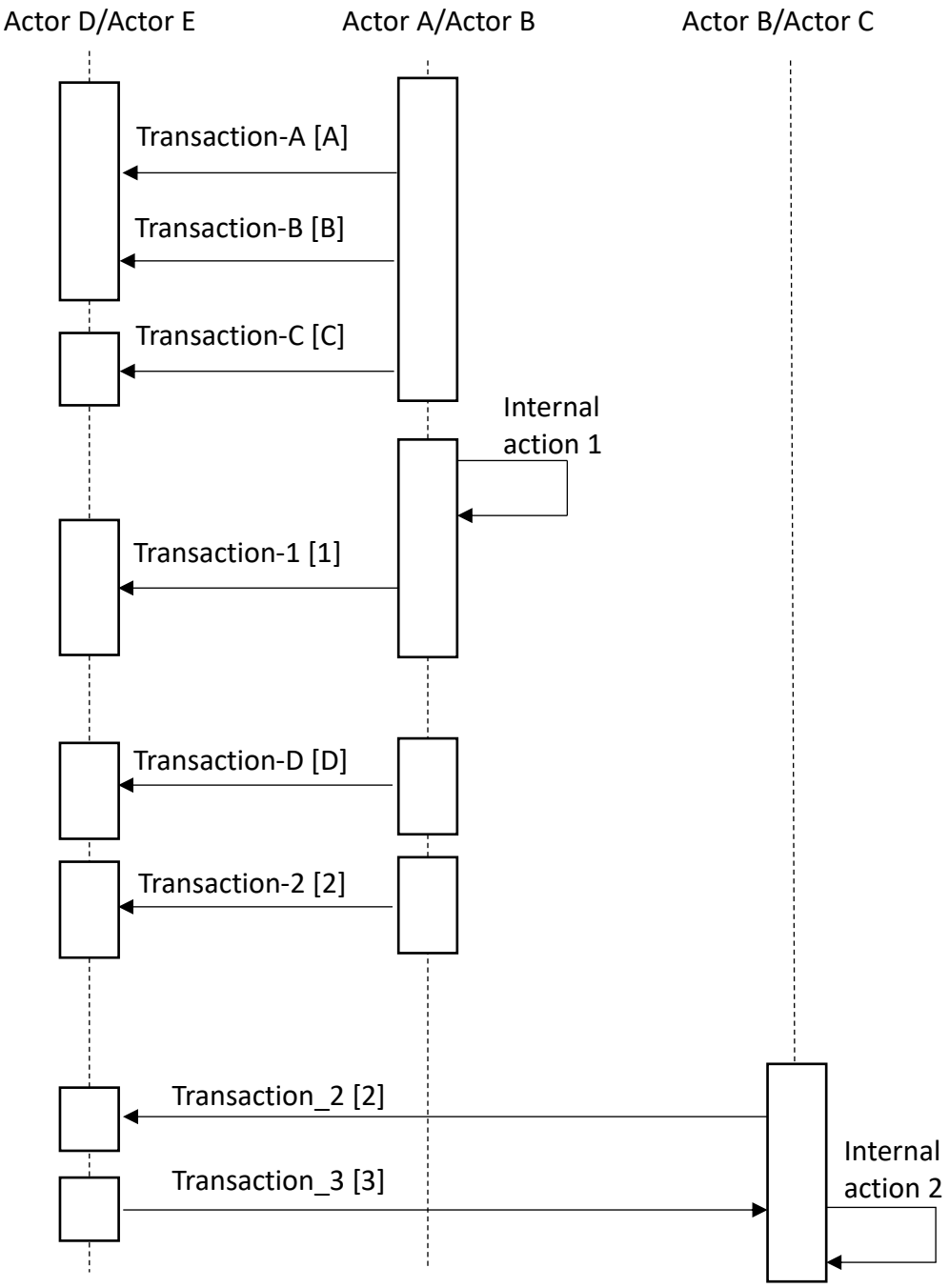


**Figure X.4.2.1-1: Basic Process Flow in SDPI Profile – SORD Use Case**

 

*<If process flow "swimlane" diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>*

*<Delete the material below if this is a workflow or transport profile. Delete the material above if this profile is a content module only profile.>*

**Pre-conditions**:

- Bedside devices are SDC compliant
- At least one OR Dashboard (DISsp) (see Annex C)

**Main Flow**:

- Devices are all turned on.
  - Devices advertise their presence
- User sets the Dashboard device into configuration mode.
  - Dashboard device builds list of available devices in the room.
  - User configures which devices he/she wants to view on the Dashboard.
- User sets the Dashboard device into operational mode.
  - Dashboard connects to each configured device and collects the data from each device and displays it on the Dashboard display.

**Post-conditions:**

The surgeon has an overview of all relevant data regarding the patient and device status.

### X.4.2.2 Use Case #2: SDPi-R Standalone OR Cockpit Use Case - SORC

Aggregated display of information relevant to a surgeon in an Operating Room from multiple data sources on a Surgical "Cockpit".

Additional information on this Use Case can be found in Volume 1 – Appendix C.3.

#### X.4.2.2.1 SDPi SORC Use Case Description

This Use Case discusses a general purpose Surgical "Cockpit" information and control display which aggregates information from different SDC compliant devices. The Cockpit can signal audio alerts and may remotely control the SDC compliant devices.

 

#### X.4.2.2.2 SDPi SORC Process Flow

*<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are "external" to this profile (using appropriate notation.)*

*The set of process flows will typically be exemplary, not exhaustive (i.e., it will address all the use cases, but will not show all possible combinations of actors, or all possible sequencing of transactions).*

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*<The roles at the top of the swimlane diagram should correspond to actor names, include the profile acronym:actor name if referencing an actor from a different profile.>*

*<Modify the following "Swimlane Diagram".>*

 

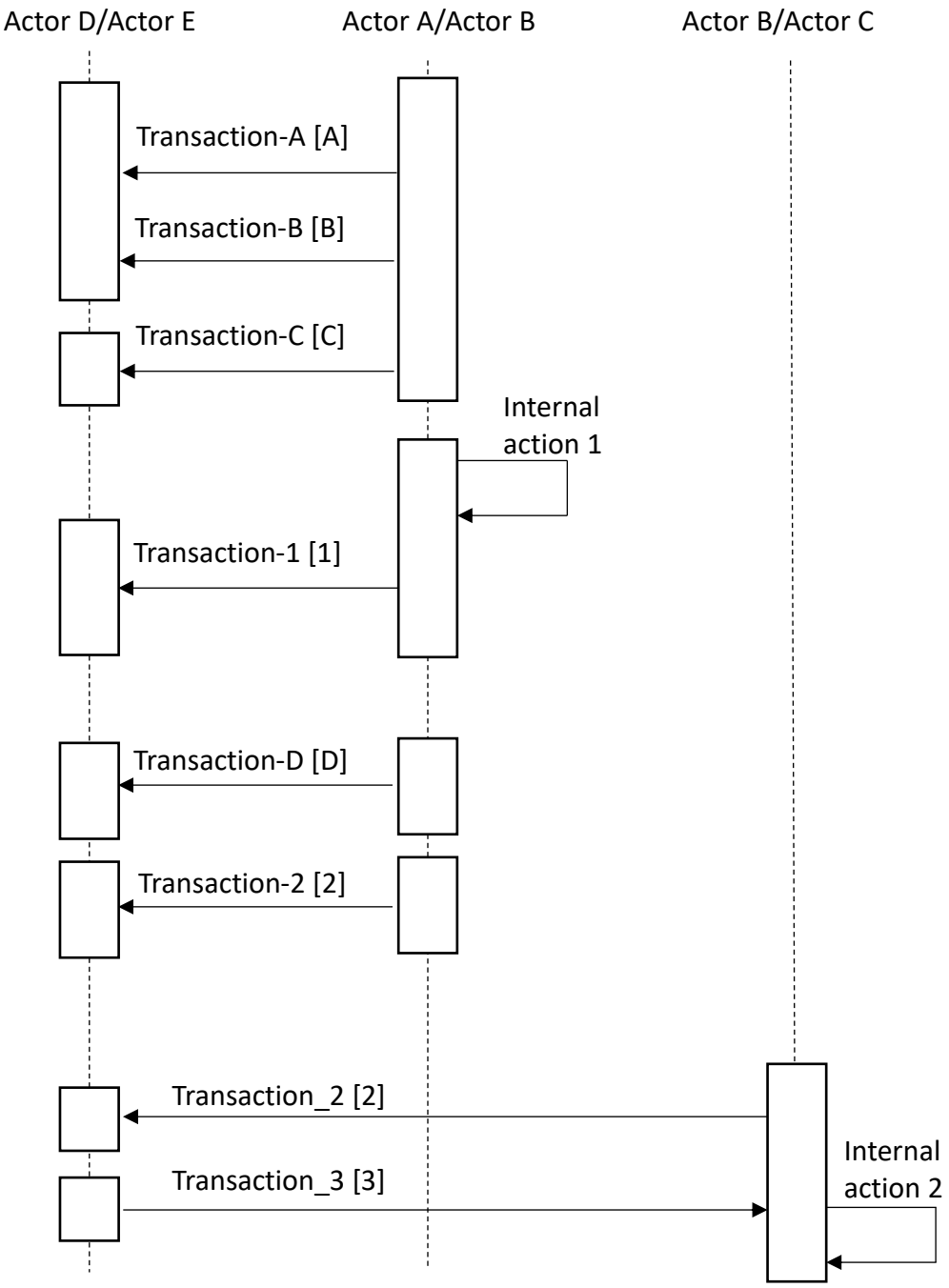


**Figure X.4.2.2-1: Basic Process Flow in SDPi Profile – SORC Use Case**

 

*<If process flow "swimlane" diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>*

*<Delete the material below if this is a workflow or transport profile. Delete the material above if this profile is a content module only profile.>*

**Pre-conditions**:

- Bedside devices are SDC compliant
- At least one Anesthesia and/or Surgical Cockpit (xDASsp) (see Annex C)

**Main Flow**:

- Devices are all turned on.
    - Devices advertise their presence
- User sets the Cockpit device into configuration mode.
    - Cockpit device builds list of available devices in the room.
    - User configures which devices he/she wants to view on the Cockpit.
    - Cockpit advises viewed devices that it will be alerting on their behalf.
- User sets the Cockpit device into operational mode.
    - Cockpit connects to each configured device and collects the data from each device and displays it on the Cockpit display.
- Device goes into alarm
    - If a device viewed by the Cockpit goes into alarm, the Cockpit will signal the alarm.
    - The Cockpit will acknowledge receipt and processing of the alarm back to the alarming device.
    - The alarming device may or may not signal the alert based on its configuration.
- User decides to Accept the alarm
    - If the user decides to accept the alarm, the Cockpit will send an Accept message to the alarming device and stop signaling the alarm locally.

**Post-conditions:**

The surgeon or anesthesiologist has a broad overview and a single point of control for devices in the room.

 

### X.4.2.3 Use Case #3: SDPi-R/xC ICU Isolation PoC Use Case - IIPoC

A remotely located display provides access to data from patient connected devices and remote control of those devices.

Additional information on this Use Case can be found in Volume 1 – Appendix C.4.

#### X.4.2.3.1 SDPi IIPoC Use Case Description

This Use Case covers the general case of a remote Cockpit which allows access to patient data and remote control of a patient's devices in an isolation situation.

#### X.4.2.3.2 SDPi IIPoC Process Flow

*<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are "external" to this profile (using appropriate notation.)*

*The set of process flows will typically be exemplary, not exhaustive (i.e., it will address all the use cases, but will not show all possible combinations of actors, or all possible sequencing of transactions).*

*If there are detailed behavioral rules that apply to a specific process flow or multiple process flows, an appendix may be added as needed.>*

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*<Modify the following "Swimlane Diagram".>*

 

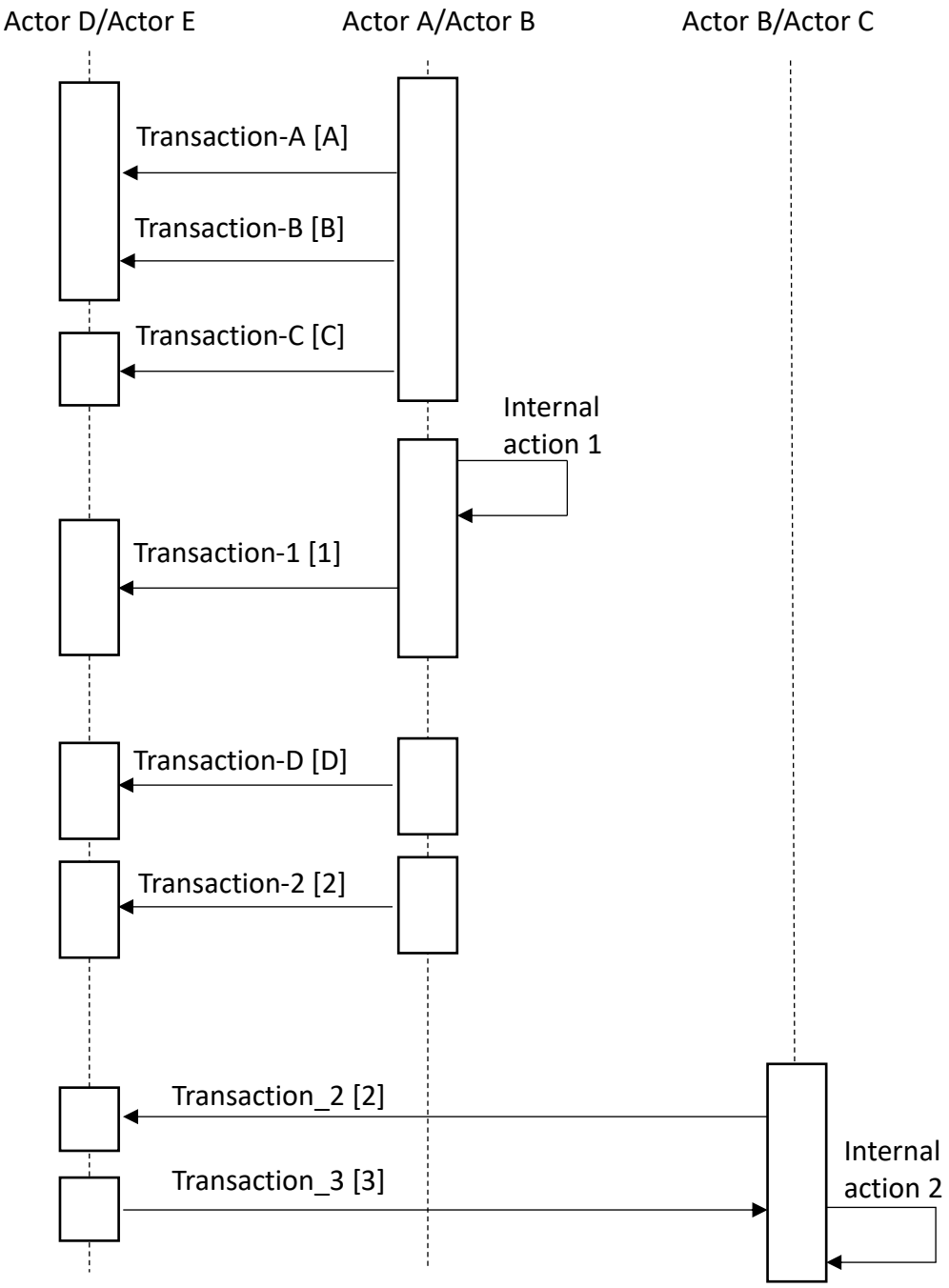


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**Figure X.4.2.3-1: Basic Process Flow in SDPi Profile – IIPoC Use Case**

 

*<If process flow "swimlane" diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>*

*<Delete the material below if this is a workflow or transport profile. Delete the material above if this profile is a content module only profile.>*

**Pre-conditions**:

- Bedside devices are SDC compliant
- At least one xDASsp (see Annex C) that is SDC compliant
- Devices in room allow remote-control from the sDASsp.

**Main Flow**:

- Devices are all turned on.
    - Devices advertise their presence
- User sets the Cockpit device into configuration mode.
    - Cockpit device builds list of available devices in the room.
    - User configures which devices he/she wants to view on the Cockpit.
    - Cockpit advises viewed devices that it will be alerting on their behalf.
- User sets the Cockpit device into operational mode.
    - Cockpit connects to each configured device and collects the data from each device and displays it on the Cockpit display.
- User decides to adjust settings on a (remote) bedside device.
    - The Cockpit will send an settings adjustment message to the (remote) bedside device.
    - The device will adjust the settings are requested; assuming the Cockpit is authorized to request the change.
    - The device will send a confirmation of the change to the Cockpit.

**Post-conditions:**

Reduced need for caregivers to put on and remove PPE and reduced likelihood of infection of caregivers.

 

### X.4.2.4 Use Case #4: SDPi-A Silent PoC Alert Distribution Use Case - SPoC

Alerts from bedside devices are delegated to and signaled at a Central Station.

Additional information on this Use Case can be found in Volume 1 – Appendix C.5.

#### X.4.2.4.1 SDPi SPoC Use Case Description

This Use Case covers the implementation of a "Silent" Point of Care. SDC based devices in the patient room delegate their alerts to a multi-patient Central Station.

#### X.4.2.4.2 SDPi SPoC Process Flow

*<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are "external" to this profile (using appropriate notation.)*

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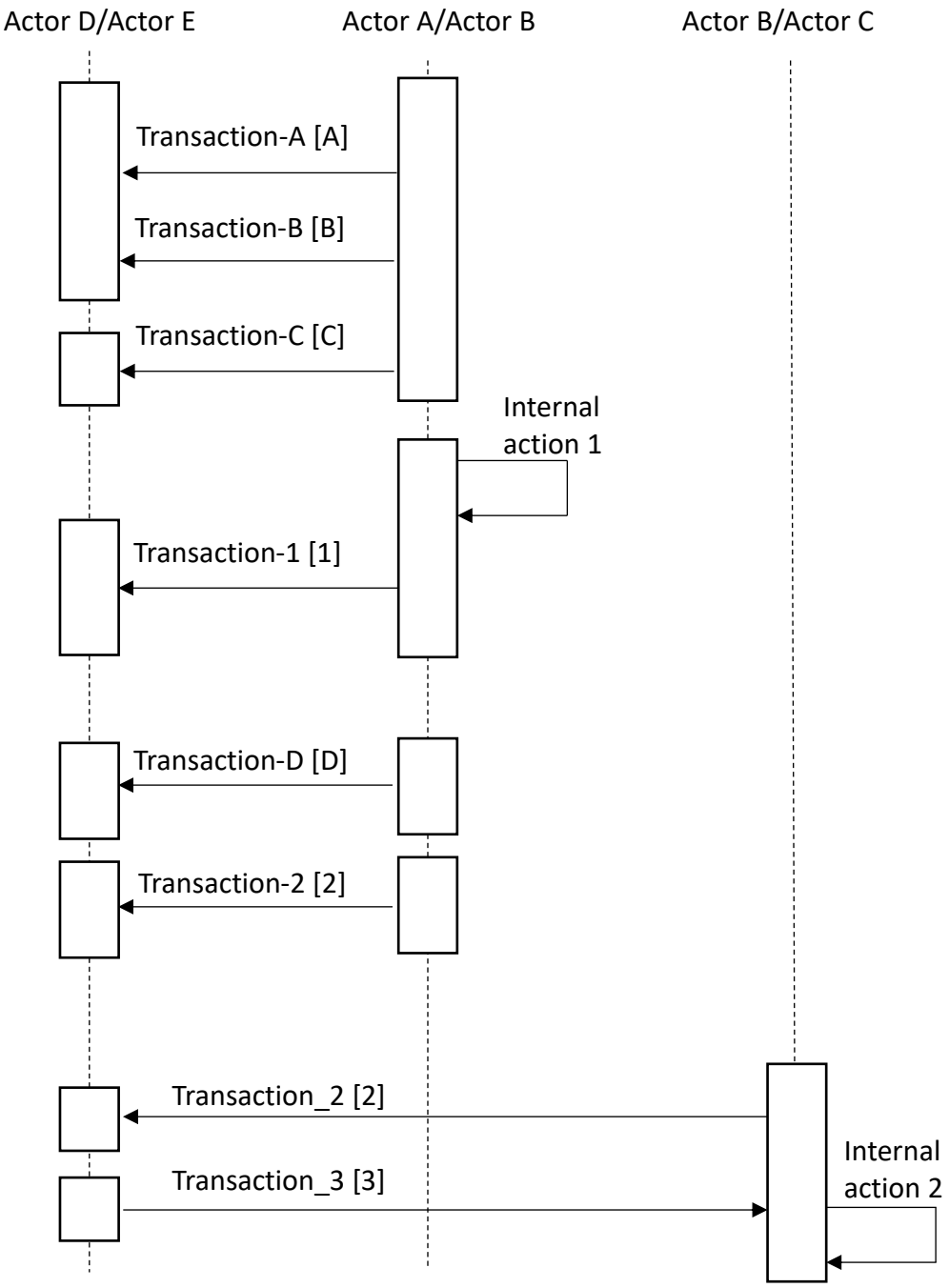


**Figure X.4.2.4-1: Basic Process Flow in SDPi Profile – SpoC Use Case**

 

*<If process flow "swimlane" diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>*

*<Delete the material below if this is a workflow or transport profile. Delete the material above if this profile is a content module only profile.>*

**Pre-conditions**:

- Bedside devices are SDC compliant
- At least one xDASmp (see Annex C) that is SDC compliant
- All devices in room delegate their alerts to one or more xDASmp (see Annex C).

**Main Flow**:

- Devices are all turned on.
    - Devices advertise their presence
- User sets the multi-patient Central Station (xDASmp) device into configuration mode.
    - Central Station device builds list of available devices of each room it is responsible for.
    - User configures which devices he/she wants to view on the Central Station.
    - Central Station advises viewed devices that it will be alerting on their behalf.
- User sets the Central Station device into operational mode.
    - Central Station connects to each configured device and collects the data from each device and displays it on the Central Station display.
- Device goes into alarm
    - If a device viewed by the Central Station goes into alarm, the Central Station will signal the alarm.
    - The Central Station will acknowledge receipt and processing of the alarm back to the alarming device.
    - The alarming device may or may not signal the alert based on its configuration.
- User decides to Accept the alarm
    - If the user decides to accept the alarm, the Central Station will send an Accept message to the alarming device and stop signaling the alarm locally.

**Post-conditions:**

 

A patient room that has no audible alarms or alert sounds going off. This enables the patient to get more rest and less stressed.

### X.4.2.5 Use Case #5: SDPi-A Silent ICU Alert Distribution - SICU

Alerts from bedside devices and Central Stations are delegated to and signaled at the caregiver's mobile device.

Additional information on this Use Case can be found in Volume 1 – Appendix C.6.

#### X.4.2.5.1 SDPi SICU Use Case Description

This Use Case covers the implementation of a "Silent" ICU. SDC based devices in the patient room delegate their alerts to a multi-patient Central Station which in turn delegates its alerts to a caregiver's mobile device. This results in a Silent ICU.

#### X.4.2.5.2 SDPi SICU Process Flow

*<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are "external" to this profile (using appropriate notation.)*

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*If there are detailed behavioral rules that apply to a specific process flow or multiple process flows, an appendix may be added as needed.>*

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*<Modify the following "Swimlane Diagram".>*

 

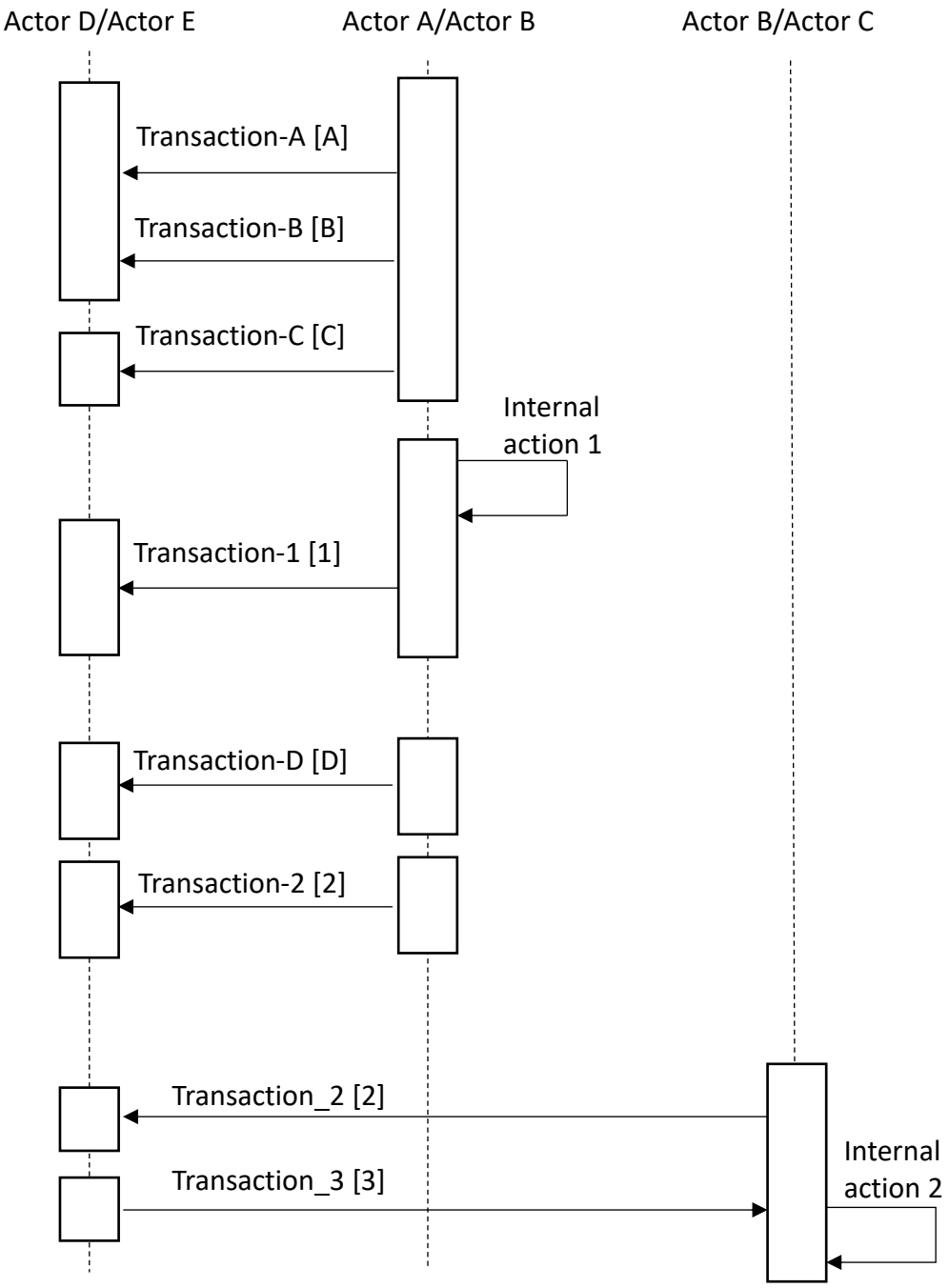


**Figure X.4.2.5-1: Basic Process Flow in SDPi Profile – SICU Use Case**

 

*<If process flow "swimlane" diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>*

*<Delete the material below if this is a workflow or transport profile. Delete the material above if this profile is a content module only profile.>*

**Pre-conditions**:

- Bedside devices are SDC compliant
- An Alert Distribution System xDAScg (see Annex C) that is SDC compliant
- All Devices in Room delegate their alerts to one or more DASxx or CDASxx (see Annex C).

**Main Flow**:

- Devices are all turned on.
    - Devices advertise their presence
- User sets the caregiver Alert Distribution System (xDAScg) device into configuration mode.
    - The ADS device builds list of available devices of each room it is responsible for.
    - User configures which devices he/she wants to monitor on the ADS.
    - The ADS advises monitored devices that it will be alerting on their behalf.
    - The user also assigns specific rooms to specific caregivers.
- User sets the ADS device into operational mode.
    - The ADS connects to each configured device and monitors the alerts from each device.
- Device goes into alarm
    - If a device monitored by the ADS goes into alarm, the ADS will signal the alarm at the configured mobile device.
    - The ADS and mobile device will acknowledge receipt and processing of the alarm back to the alarming device.
    - The alarming device will not signal the alert. (It has delegated its alerts).

**Post-conditions:**

An ICU (or other Care Unit) that has no audible alarms or alert sounds going off. This enables the patients to get more rest and makes the overall Care Unit less stressful.

 

### X.4.2.6 Use Case #6: SDPi-A/xC Remote Alert Management - RAM

Remote management of device alert setting using a personal device.

#### X.4.2.6.1 SDPi RAM Use Case Description

This Use Case covers the use of a personal device worn by an authorized caregiver to adjust alert related settings on a bedside device.

Additional information on this Use Case can be found in Volume 1 – Appendix C.7.

#### X.4.2.6.2 SDPi RAM Process Flow

*<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are "external" to this profile (using appropriate notation.)*

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*<Modify the following "Swimlane Diagram".>*

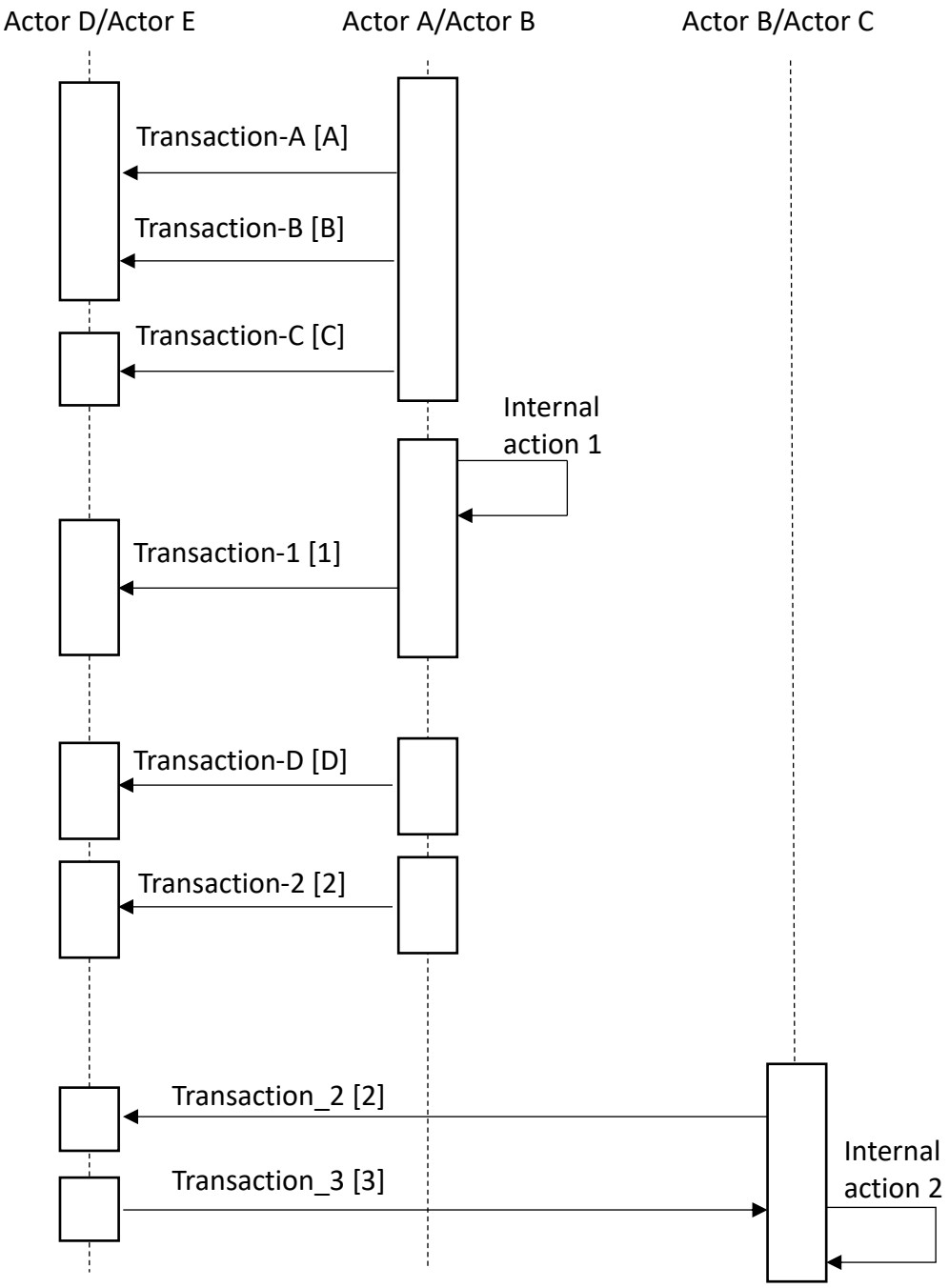



**Figure X.4.2.6-1: Basic Process Flow in SDPi Profile - RAM**

*<If process flow "swimlane" diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>*

*<Delete the material below if this is a workflow or transport profile. Delete the material above if this profile is a content module only profile.>*

**Pre-conditions**:

- Bedside devices are SDC compliant
- A CDAScg (see Annex C) that is SDC compliant
- Devices in Room allow remote setting adjustment

**Main Flow**:

- User decides to adjust bedside setting from mobile device
    - The mobile device will send a settings adjustment message (via the ADS?) to the (remote) bedside device.
    - The device will adjust the settings are requested; assuming the mobile device is authorized to request the change.
    - The device will send a confirmation of the change to the mobile device.

**Post-conditions:**

Device settings are adjusted according to the caregiver's input from a mobile device.

### X.4.2.7 Use Case #7: SDPi-A Smart Alerting System - SAS

Integration of a Smart Alerting System into an ICU.

Additional information on this Use Case can be found in Volume 1 – Appendix C.8.

#### X.4.2.7.1 SDPi SAS Use Case Description

This Use Case covers the scenarios involved with the deployment of a separate Smart Alerting System in an ICU.

#### X.4.2.7.2 SDPi SAS Process Flow

*<Diagram and describe the process flow(s) covered by this profile in order to satisfy the use cases. Demonstrate how the profile transactions are combined/sequenced. To provide context*

*and demonstrate how the profile interacts with other profiles, feel free to include transactions and events that are "external" to this profile (using appropriate notation.)*

*The set of process flows will typically be exemplary, not exhaustive (i.e., it will address all the use cases, but will not show all possible combinations of actors, or all possible sequencing of transactions).*

*If there are detailed behavioral rules that apply to a specific process flow or multiple process flows, an appendix may be added as needed.>*

*<The roles at the top of the swimlane diagram should correspond to actor names, include the profile acronym:actor name if referencing an actor from a different profile.>*

*<Modify the following "Swimlane Diagram".>*

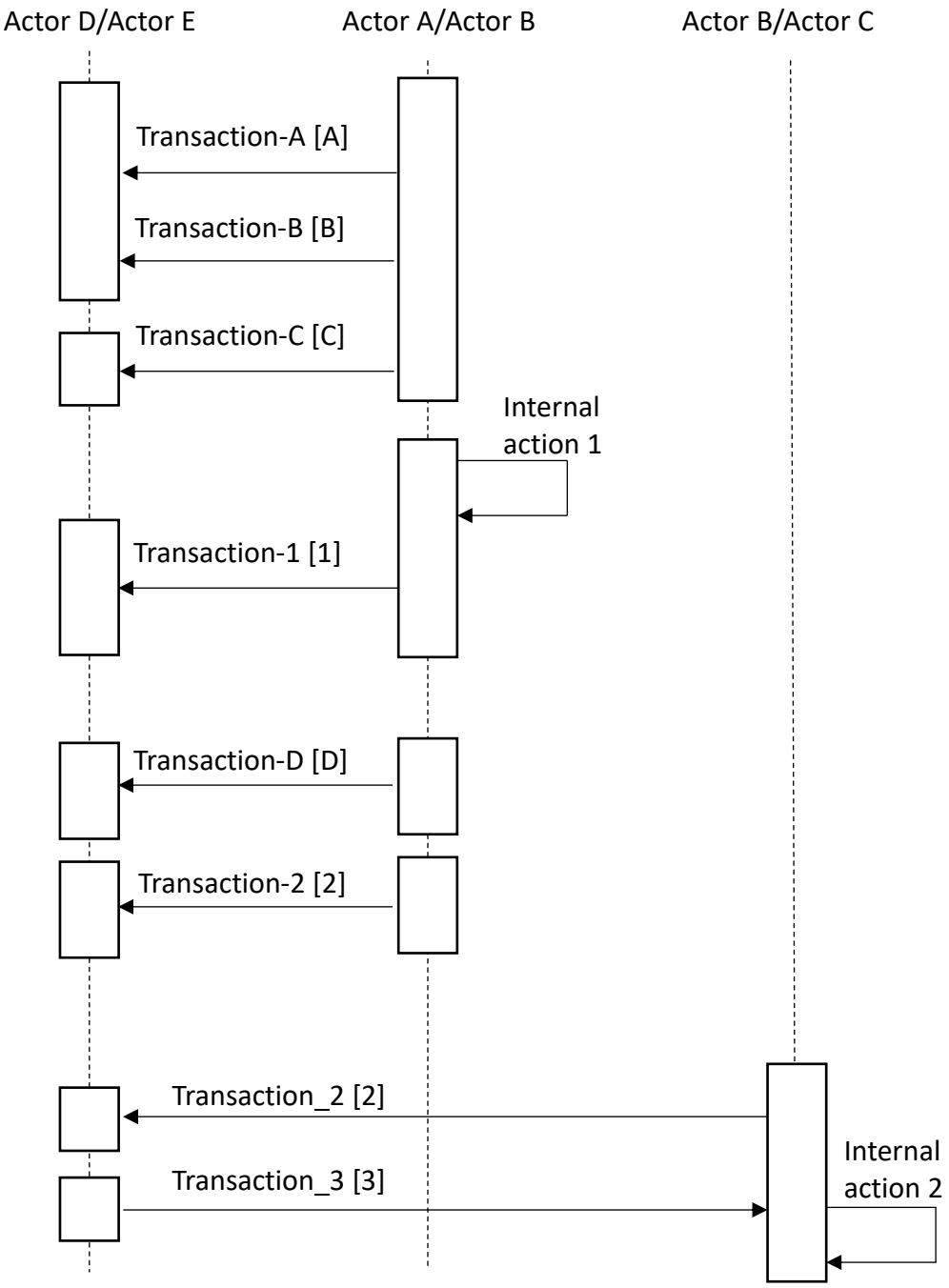



**Figure X.4.2.7-1: Basic Process Flow in <Profile Acronym> Profile**

*<If process flow "swimlane" diagrams require additional explanation to clarify conditional flows, or flow variations need to be described where alternate systems may be playing different actor roles, document those conditional flows here.>*

*<Delete the material below if this is a workflow or transport profile. Delete the material above if this profile is a content module only profile.>*

**Pre-conditions**:

- Bedside devices are SDC compliant
- A single smart alert system that is SDC compliant
- The SAS is a component with no visual or audible alert outputs
- There is an xDASmp and/or xDAScg that is SDC compliant (see Annex C for explanation of these terms.)

**Main Flow**:

- Devices are all turned on.
    - Devices advertise their presence
- User sets the Smart Alert System (SAS) device into configuration mode.
    - The SAS builds a list of available devices in the rooms it is responsible for.
    - User configures which devices he/she wants to be monitored by the SAS.
    - The SAS advises viewed devices that it will be alerting on their behalf.
    - The SAS also is configured to connect to one or more Central Stations.
- User sets the SAS device into operational mode.
    - The SAS connects to each configured device and collects the data and alerts from each device.
    - If no alert is communicated from any of the configured devices, the SAS may still generate alert messages based on data trends or other factors it is monitoring. It communicates these Smart Alert to the Central Station(s).
- Device goes into alarm
    - If an alert is communicated from any of the configured devices, the SAS will decide whether to forward the alert to the Central Station or create a Smart Alarm based on other data and alerts it has received.
    - The SAS will acknowledge receipt and processing of the alarm back to the alarming device.

- The alarming device may or may not signal the alert locally based on its configuration.

*If the user decides to accept the alarm, the Cockpit will send an Accept message to the alarming device and stop signaling the alarm locally*

**Post-conditions:**

Smart Alerts are communicated properly with fallback modes in case of failures.

# Appendices to Volume 1

*<Add appendices to Volume 1 for this profile here. Examples of an appendix include HITSP mapping to IHE Use Cases or long use case definitions.>*

*<If there are no Volume 1 appendices, enter "Not applicable" and delete the Appendix A and Appendix B placeholder sections.>*

*<Volume 1 appendices are informational only. No "SHALL" language is allowed in a Volume 1 Appendix.>*

# Appendix C – Use Cases - Detail

This Appendix provides further details concerning the Use Cases that illustrate the use of the IHE SDPi actors and transactions.

## C.1 Overview of the Concepts for DIS and DAS

While IEC 60601-1-8 is focused on alarm and alert functionality, it also provides some very useful system concepts such as the Distributed Information System (DIS) and Distributed Alarm System (DAS). We use these concepts in many of our use cases, so we have included the following is a quick guide to the functionality of DIS, CDIS, DAS and CDAS systems.

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
  - Examples:
    - "Dashboard" - display which integrates the data from one patient. Dashboards do not support audible alerts or remote control.
    - "View Station" - display which integrates the data from multiple patients. View Stations do not support audible alerts or remote control.

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)

xDIS – Connotes a system that can be either a DIS or CDIS

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
  - Supports local alert confirmation
  - A communications failure or failure in any remote component of the DAS must initiate a technical alarm.
  - Examples:
    - "Cockpit"- display which integrates the data from one patient and support audible alerts. The DAS Cockpit only supports local operations while the

CDAS cockpit supports operator confirmation and optional remote control.

- "Central Station" - display which integrates the data from one patient and support audible alerts. The DAS Central Station only supports local operations while the CDAS Central Station supports operator confirmation and optional remote control.

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.
  - Examples:
    - Cockpit and/or Central Station with remote confirmation and optional alarm management.
    - System that sends alarm to caregiver mobile device with accept / reject. Integrator may redirect

xDAS – Connotes a system that can be either a DAS or CDAS

In addition to the various types of xDIS and xDAS, we have also distinguished between various types of xDIS and xDAS as follows:

- xDxSsp – forms of DxS that are for single patients.
- xDxSmp – forms of DxS that are for multiple patients
- xDxScg – forms of DxS that communicated directly to the caregiver.

The following table provides examples and 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. 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 | Alert Distribution System (ADS) to caregiver pager, Mobile viewer |
| | CDIScg | No | Yes[3] | Remote[3] | ADS to caregiver pager, w/ accept/reject |
| | DAScg | Yes | No | Local | ADS to caregiver w/ audible/haptic alarms |
| | CDAScg | Yes | Yes | Remote | ADS 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

## C.2 Feature: Use Case 1 - SDPi-R Standalone OR Dashboard - SORD

### C.2.1 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 xDISsp.)

### C.2.2 Background: Technical Pre-Conditions

**Given** all devices communicate using SDC

**And** at least one OR Dashboard display

### C.2.3 Scenario: SORD 1.1 - OR Devices are Accessible to the Dashboard

**Given** dashboard detected at least one accessible OR device

**When** one or more OR Devices are operational

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

### C.2.4 Scenario: SORD 1.2 - OR Devices are inaccessible to the Dashboard

**Given** dashboard did not detect any accessible OR devices

**Then** the Dashboard shall display an error message

### C.2.5 Scenario: SORD 1.3 - One or more OR Devices are inaccessible to the Dashboard

**Given** dashboard did not detect configured OR devices (based on configuration)

**Then** the Dashboard shall display an error message

## C.3 Feature: Use Case 2 - SDPi-R/A/xC Standalone OR Cockpit - SORC

### C.3.1 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 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.

### C.3.2 Background: Technical Pre-Condition

**Given** all devices communicate using SDC

**And** at least one Anesthesia Cockpit and/or Surgical Cockpit

### C.3.3 Scenario: SORC 2.1 - OR Devices are accessible to the Cockpit

**Given** Cockpit detected at least one accessible OR device

**When** the one or more OR Devices are operational

**And** audio alarms are enabled on the Cockpit

**And** remote control is enabled on the Cockpit

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

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

**And** the user shall be able to control device settings at the source device or at the Cockpit

### C.3.4 Scenario: SORC 2.2 - OR Devices are inaccessible to the Cockpit

**Given** Cockpit did not detect any accessible OR devices

**When** any OR Device detects an alert condition

**Then** the Cockpit will display an error message

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

### C.3.5 Scenario: SORC 2.3 - Some OR Devices are inaccessible to the Cockpit

**Given** Cockpit did not detect some configured OR devices (based on configuration)

**When** the OR Device detects an alert condition

**Then** the Cockpit will display an error message

**And** the audio alarm shall be signaled at that source device in the OR for the devices not detected by the cockpit

## C.4 Feature: Use Case 3 - SDPi-R/xC ICU Isolation PoC Use Case - IIPoC

**Narrative:**

**Background: Technical Pre-Condition**

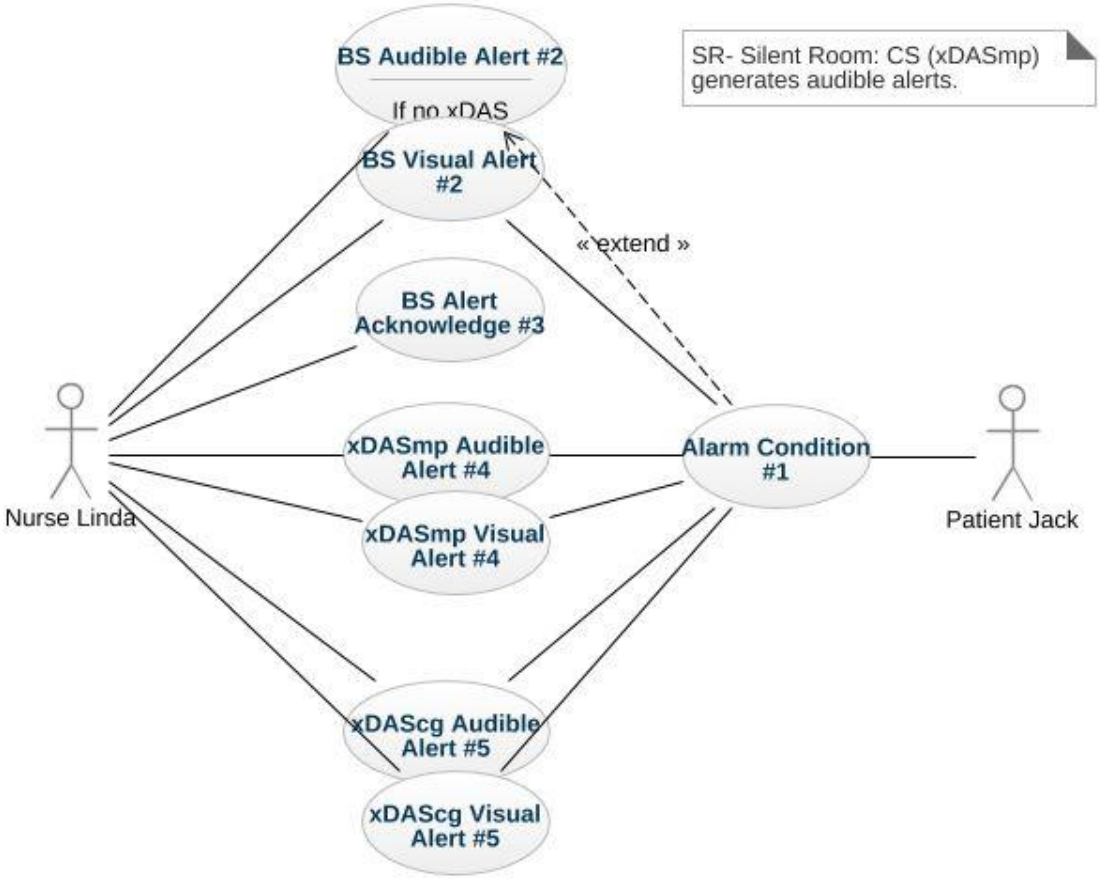
Coming soon…

## C.5 - Feature: Use Case 4 - SDPI-A - Silent PoC Alert distribution - SPoC

### C.5.1 Narrative

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).




### C.5.2 Background: Technical Pre-Condition

**Given** all devices communicate using SDC

**And** at least one xDASmp

**And** all devices in room delegate their alerts to one or more xDASmp.

### C.5.3 Scenario: SPoC 4.1 - Medical device detects an alert situation and at least one distributed alarm system (xDASxx) 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

### C.5.4 Scenario: SPoC 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

### C.5.5 Scenario: SPoC 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

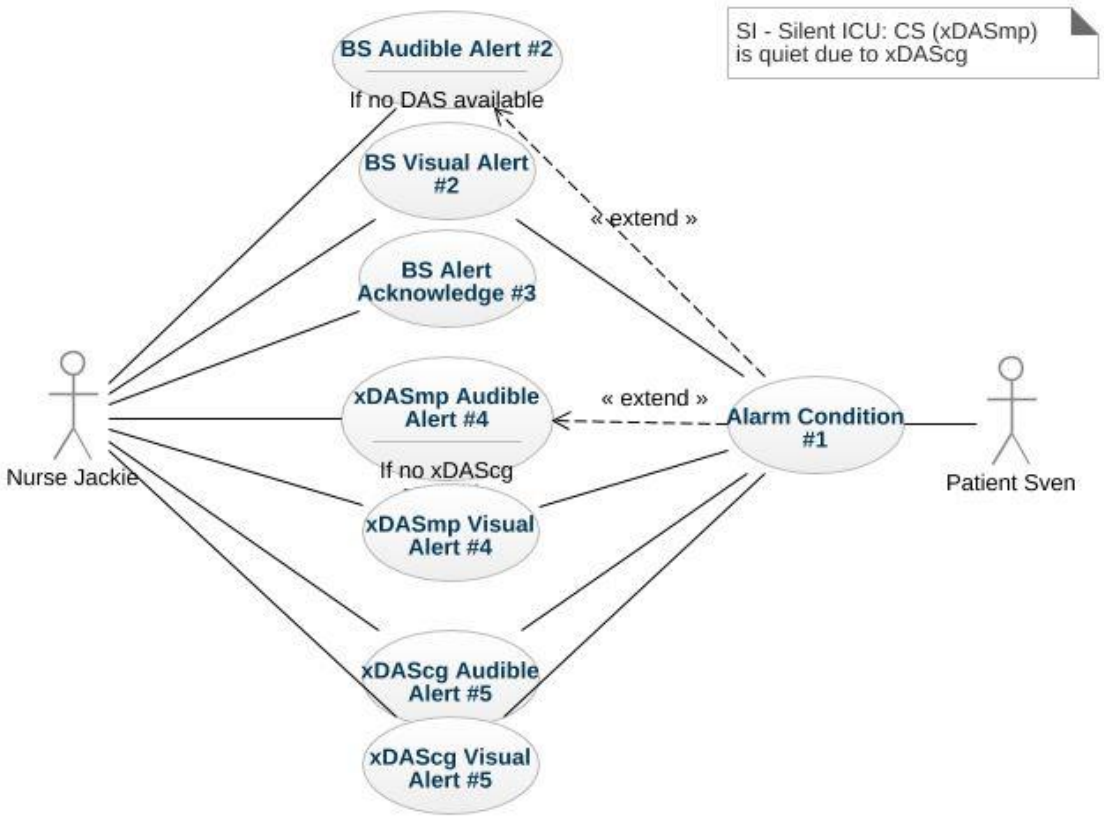
 

### C.5.6 Scenario: SPoC 4.4 - Medical device detects an alert situation, initially xDASxx is accessible but fails

## C.6 Feature: Use Case 5 - SDPi-A: Silent ICU Alert Distribution - SICU

### C.6.1 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).



### C.6.2 Background: Technical Pre-Condition

**Given** all devices communicate using SDC

**And** at least one xDAScg

And all devices in room delegate their alerts to one or more xDASxx

### C.6.3 Scenario: SICU 5.1 - Medical device detects an alert situation and the distributed alarm system CDAScg 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 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

### C.6.4 Scenario: SICU 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

### C.6.5 Scenario: SICU 5.3 - Medical device detects an alert situation and all distributed alarm systems (xDASxx) are 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

### C.6.6 Scenario: SICU 5.4 - 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

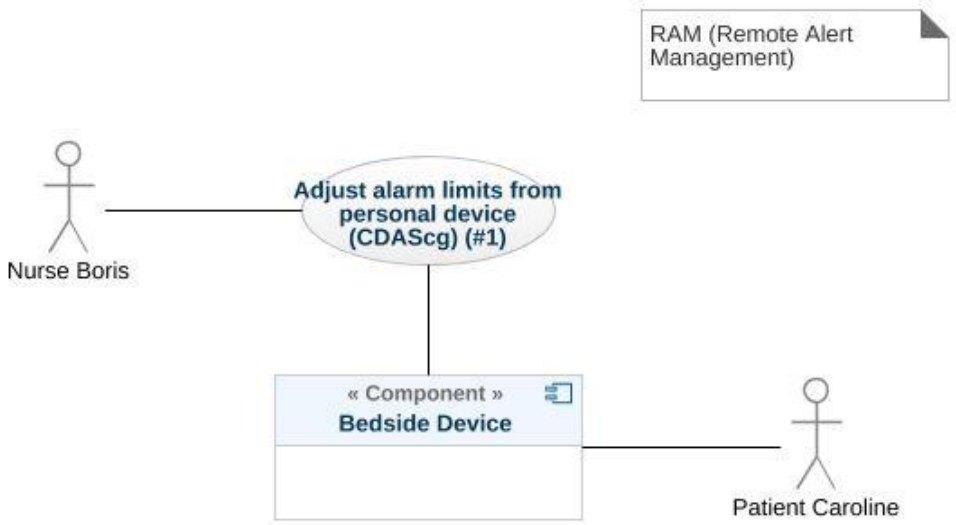
### C.6.7 Scenario: SICU 5.5 - Medical device detects an alert situation, initially DAS is accessible but fails

## C.7 Feature: Use Case 6 - SDPi-A/xC: Remote Alert Management - RAM

### C.7.1 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).




870

### C.7.2 Background: Technical Pre-Condition

**Given** all devices communicate using SDC

875 **And** at least one CDAScg

**And** all devices in room enable remote control

### C.7.3 Scenario: RAM 6.1 - Caregiver adjusts alarm limit at their Mobile Device

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

880 **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

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

### C.7.4 Scenario: RAM 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** ???

## C.8 Feature: Use Case 7 - SDPi-A Smart Alerting System - SAS

### C.8.1 Narrative:

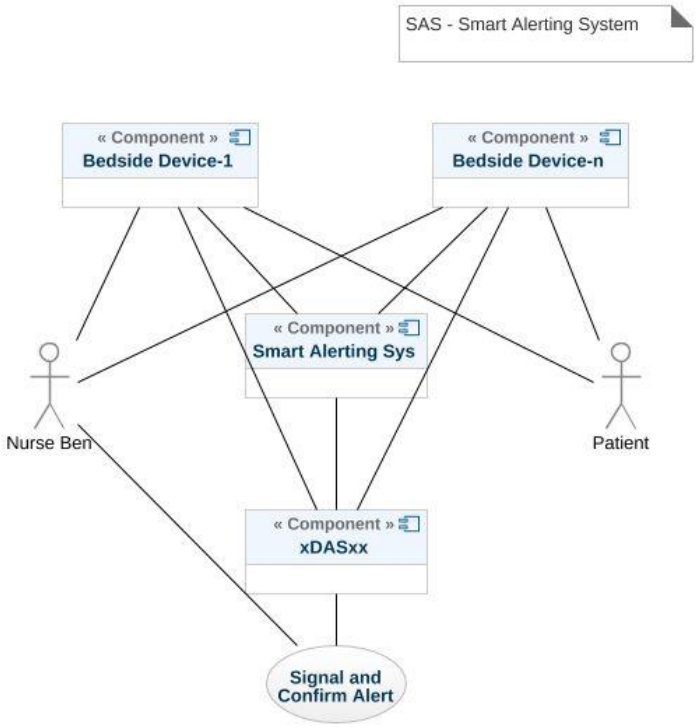
Ben is an ICU nurse. Suddenly, he gets a "Check Ventilation Hose!" alert for one of the patients he is responsible for. In addition, the alert suggests possible root causes to the caregiver (i.e. obstruction (sputum/kinked hose)). This leads to a quicker, more adequate intervention.

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.




920

### C.8.2 Background: Technical Pre-Conditions

**Given** bedside devices are SDC compliant

**And** a single smart alert system (SAS) that is SDC compliant

**And** the SAS is a component with no visual or audible alert output

925 **And** an xDASmp and/or xDAScg that is SDC compliant

### C.8.3 Scenario Outline: SAS 7.1 - Local device generates alerts, Smart Alerting System is accessible, and xDASmp and/or xDAScg is accessible

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

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

**And** smart alerting system is accessible

**And** xDASmp and/or xDAScg 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

**And** smart alerts from the SAS shall be delegated to the xDASmp and/or xDAScg

Examples:

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

### C.8.3 Scenario Outline: SAS 7.2 - Local device generates alerts, Smart Alerting System is inaccessible, and xDASmp and/or xDAScg 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 inaccessible

**And** xDASmp and/or xDAScg is accessible

**Then** the alerts on the medical devices in the patient room shall be delegated to the xDASmp and/or xDAScg

**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 |

### C.8.4 Scenario: SAS 7.3 - Local device generates alerts, and xDASmp and/or xDAScg is inaccessible

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

**And** xDASmp and/or xDAScg is 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

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### C.8.5 Scenario: SAS 7.4 -Smart Alerting generates an alert and an xDASxx is accessible

**When** SAS is accessible
**And** there is an alert event detected by the SAS (e.g. derived from vital signs data)
**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~~

### C.8.6 Scenario: SAS 7.5 - Smart Alerting generates an alert and an xDASxx is inaccessible

**When** SAS is accessible
**And** there is an alert event detected by the SAS
**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

### C.8.6 Scenario: SAS 7.6 - 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

### C.8.7 Scenario: SAS 7.7 - 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

 

### C.8.8 SAS Scenario 7.8: 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

 