Distributed Alarm System (DAS) & Smart Alert System (SAS) Use Case Scenarios

The following diagrams discuss various Distributed Alarm System (DAS) without/with Confirmation (CDAS) and Smart Alert System (SAS) use case scenarios.
On the Point-of-Care (PoC) device (PoCD) side, the IEEE 11073 Service-oriented Device Connectivity (SDC) standard is utilized for the communication with the corresponding alarm integrator (AI) and/or smart alert system (SAS) with the goal to prove if a particular use case scenario is supported by the standard, or if there are gaps in the standard which have to be addressed.
The communication between the alarm integrator (AI) and the alarm communicator (AC) is considered proprietary in diagrams and out of scope of this document which focuses on the PoCD SDC communication.

Note: in the diagrams, the nomenclature of the IEC 60601-1-8 alarm standard is widely used. Although conformance with the alarm standard is not mandatory, it is highly recommended to conform to the standard since this simplifies the regulatory approval of the DAS/CDAS and its components.

Legend:

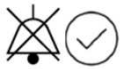
Established data connection between devices and/or systems exchanging alerts, status information, vital signs etc.

Interrupted data connection between devices and/or systems

Visual alert signal e.g. displayed on patient monitor. The color indicates the severity of the alert e.g. red for high

Audible alert signal is enabled e.g. sound at the ventilator

Audible alert signal is disabled e.g. no sound at the ventilator



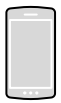
Alert acknowledged either locally at the PoCD or remotely by the caregiver. The audible alert signal is disabled.

Alert accepted by the caregiver at one of the relevant AC. The PoCD is not involved in the workflow. Usually, this stops the alert escalation to other ACs in the DAS.

Alert rejected by the caregiver at one of the relevant AC. The PoCD is not involved in the workflow. Usually, this escalates the alert to next AC in the DAS.

Caregiver that acknowledges, accepts, or rejects an alert at a relevant AC. At the PoCD, the caregiver can only acknowledge an alert.

A relevant alarm communicator is a term from the IEC 60601-1-8 alarm standard. Relevant alarm communicators are the primary remote alarming devices in a DAS.

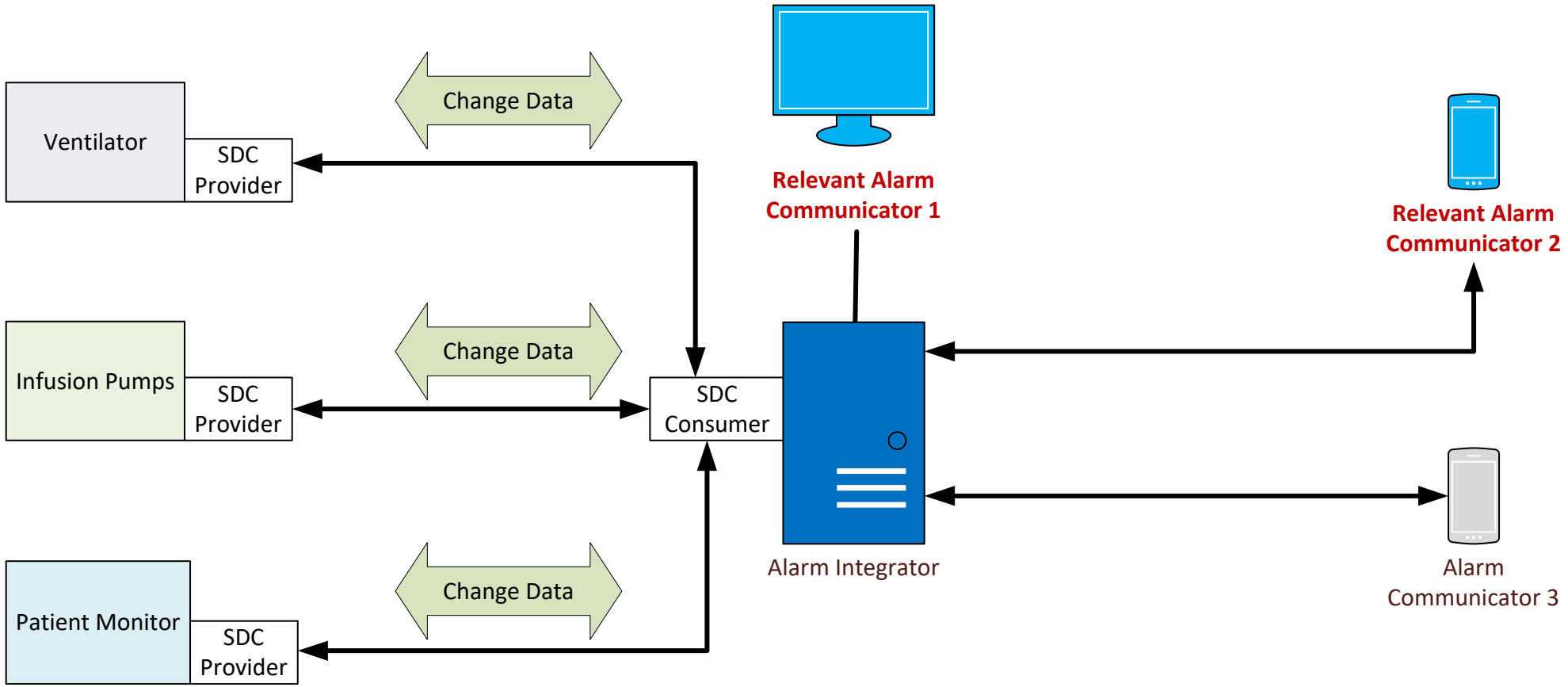


Other alarm communicators are either not relevant for certain alerts (e.g. alert type filter, PoC location, etc.), or considered as secondary remote alarming devices, and therefore, they are not part of the DAS.

DAS Scenario 1: DAS is fully operational and there are no device alerts

When the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
And the connection to the relevant alarm communicator devices is established to the alarm integrator by checking the connection state on a regular basis
Then no further indication that the DAS is fully operational shall be announced to the user

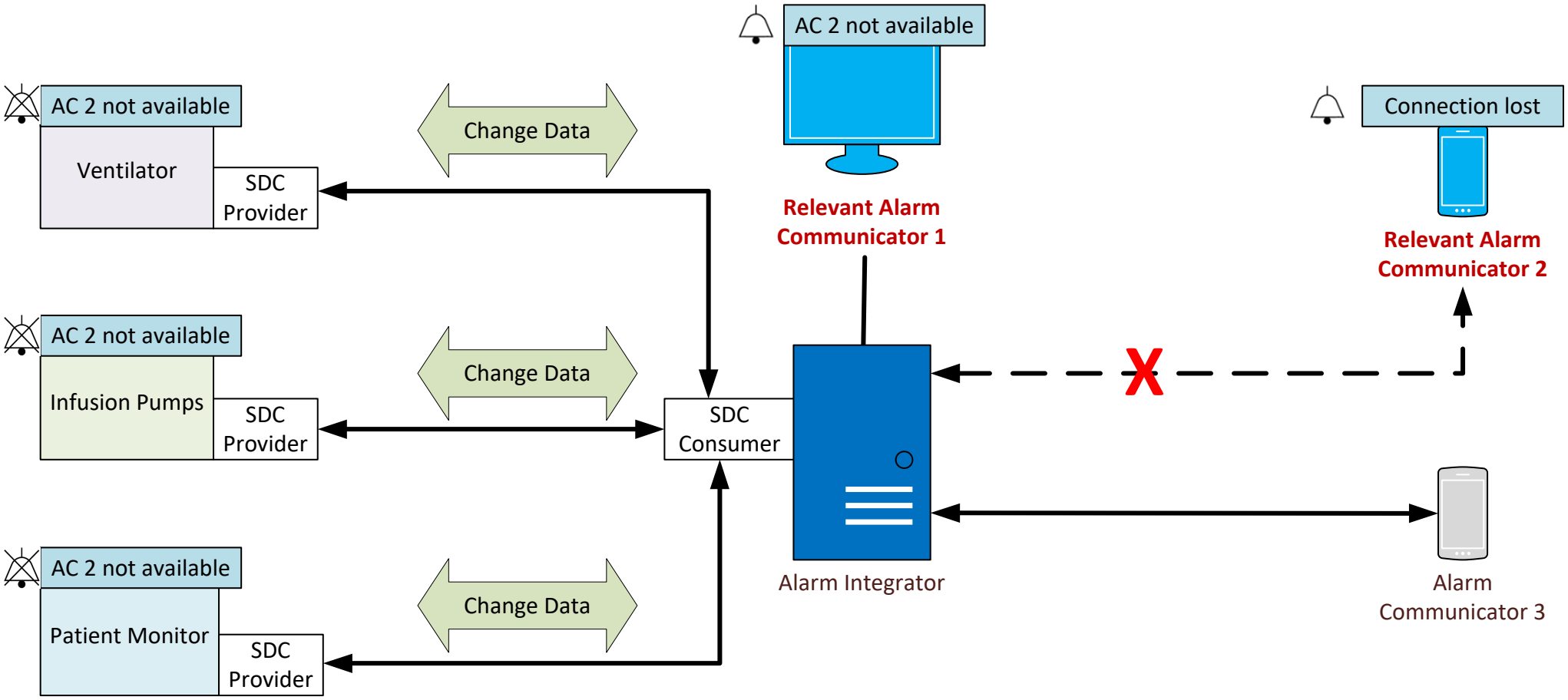
Note: customers may require to have an indicator that the DAS is fully operational. This might be configurable at the PoCD and/or AC (e.g. a notification shown at the display).



DAS Scenario 2: Connection to relevant alarm communicator lost, other ACs are available, and there are no device alerts

- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator device has been lost
  And other alarm communicators are available
- **Then** the user shall be notified on all connected, relevant alarm communicators that the connection to one or more ACs has been lost
  And the user may be notified on all PoC devices that the connection to one or more ACs has been lost
  And the audio alarm at all PoC devices shall be disabled
  And the audio alarm at all connected, relevant alarm communicators shall be enabled
  And the alarm communicator which is not connected to the alarm integrator shall notify the user visually and audibly about the lost connection

Note: this depicts a worst case scenario. The current AI products address those failure scenarios by redirection, escalation, etc. when an AC is not available any longer. How individual AI products handle those failure scenarios in detail is not subject of this document. It is the responsibility of the AI, if a corresponding status message is shown on the PoCD as well.



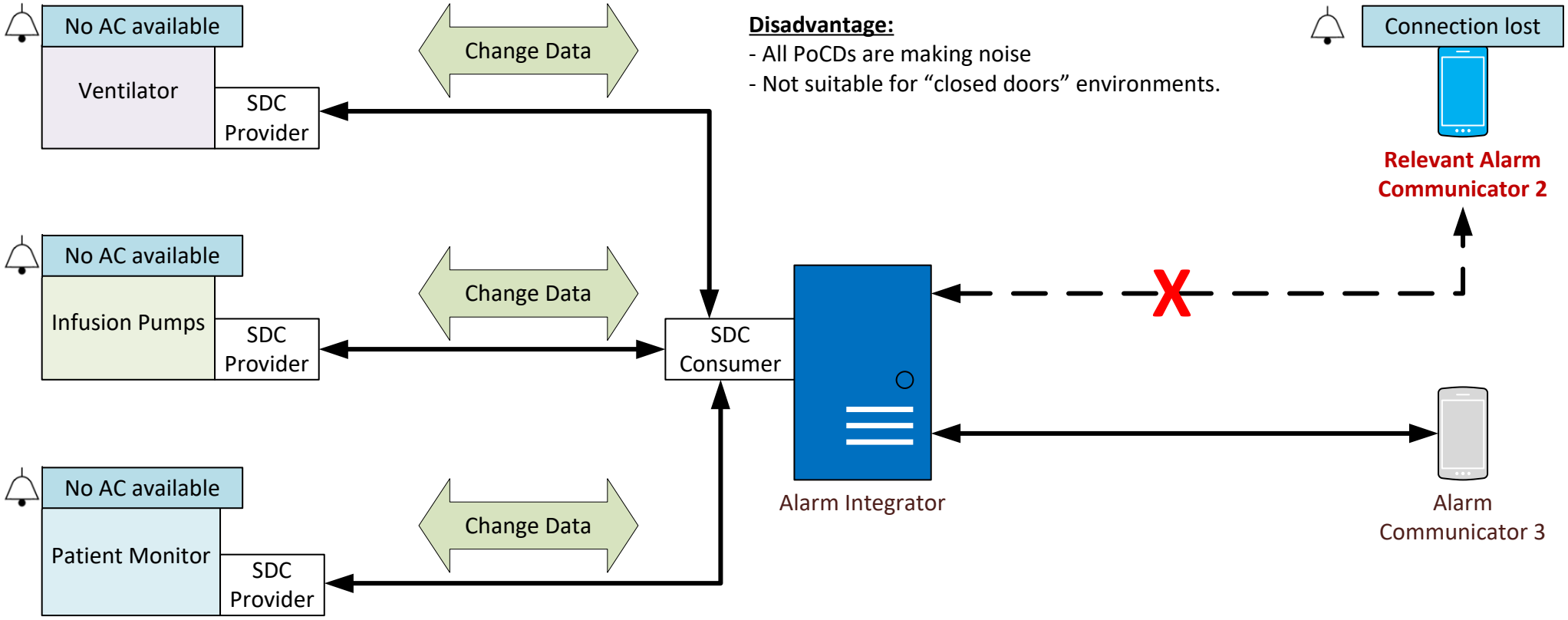
DAS Scenario 3: Connection to relevant alarm communicator lost, other ACs are unavailable, and there are no device alerts

- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator device has been lost
  And other alarm communicator are unavailable
- **Then** the user may be notified on all PoC devices that the connection to one or more ACs has been lost
  And the audio alarm at all PoC devices may be enabled
  And the alarm communicator which is not connected to the alarm integrator shall notify the user visually and audibly about the lost connection

Note: this depicts a worst case scenario. The current AI products address those failure scenarios by redirection, escalation, etc. when an AC is not available any longer. How individual AI products handle those failure scenarios in detail is not subject of this document. It is the responsibility of the AI, if a corresponding status message is shown on the PoCD as well.

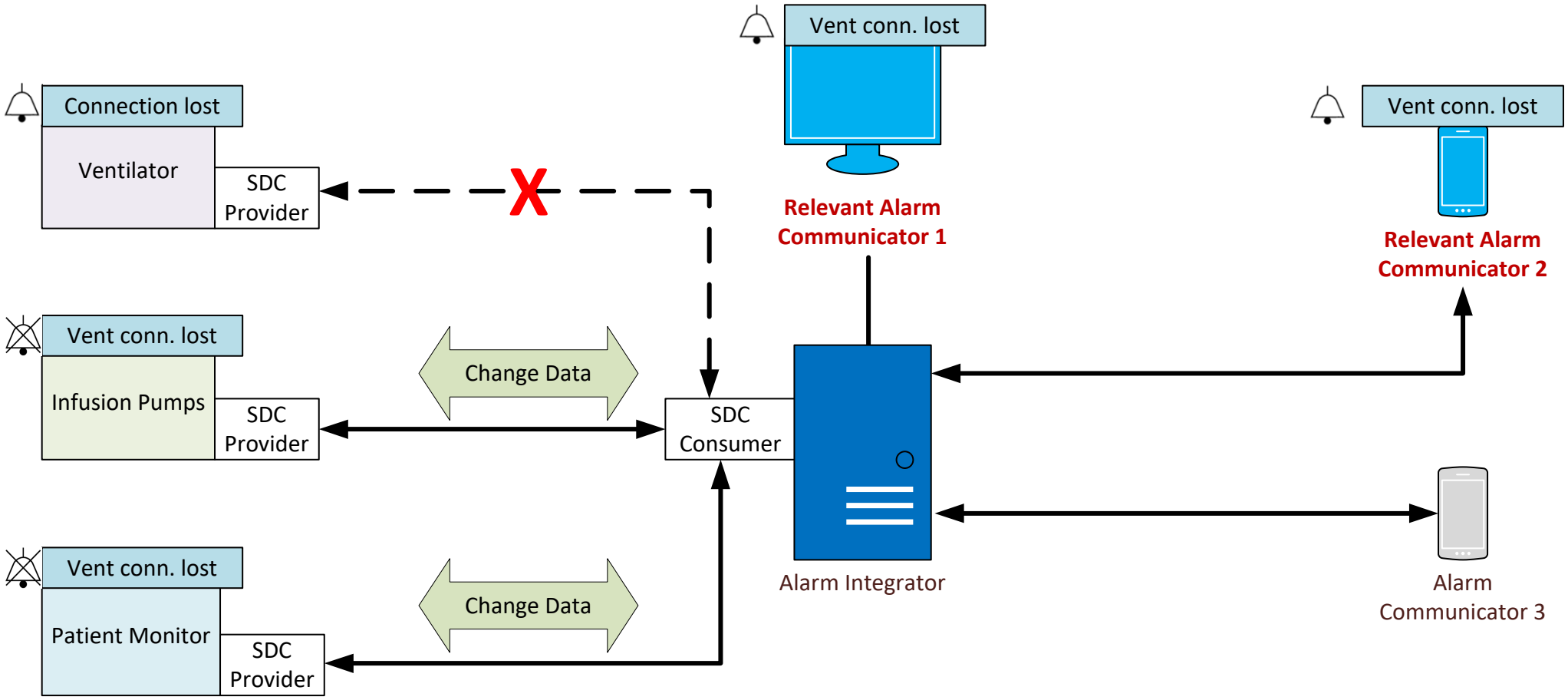
Advantage:
- Alarm Integrator does not need to prioritize PoCDs
- User may acknowledge alarm on any PoCD

Disadvantage:
- All PoCDs are making noise
- Not suitable for “closed doors” environments.



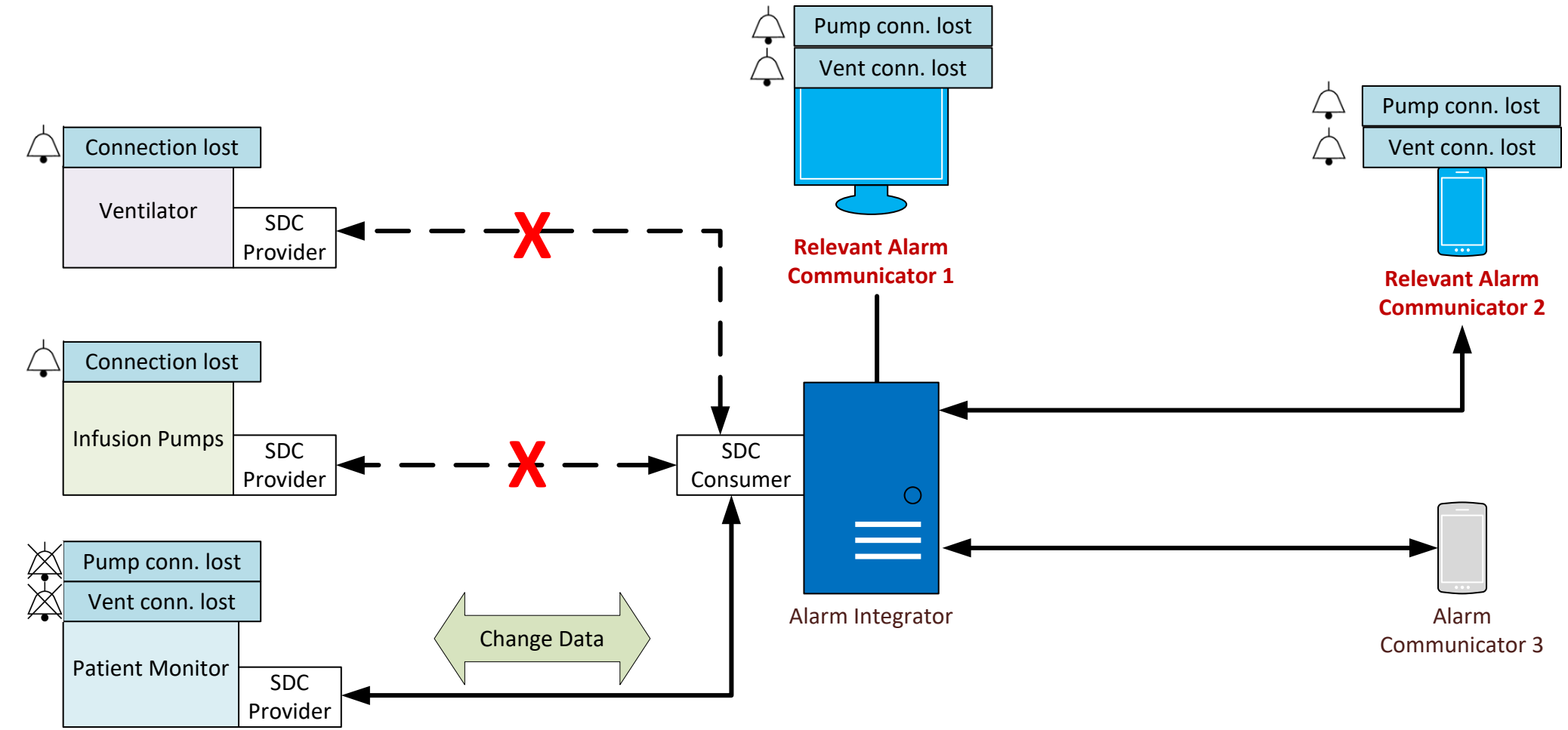
DAS Scenario 4: Connection to one PoC devices is lost, relevant alarm communicators are available, and there are no device alerts

- **When** the connection to one PoC device is lost
  And the connection to the relevant alarm communicator devices are available
- **Then** the user shall be notified on all connected, relevant alarm communicators that the connection to one or more PoC devices has been lost
  And the user may be notified on all PoC devices that the connection to one or more PoC devices has been lost
  And the audio alarm at all connected PoC devices shall be disabled
  And the audio alarm at all connected, relevant alarm communicators shall be enabled
  And the PoC device which is not connected to the alarm integrator shall notify the user visually and audibly about the lost connection



DAS Scenario 4.1: Connections to multiple PoC devices are lost, relevant alarm communicators are available, and there are no device alerts

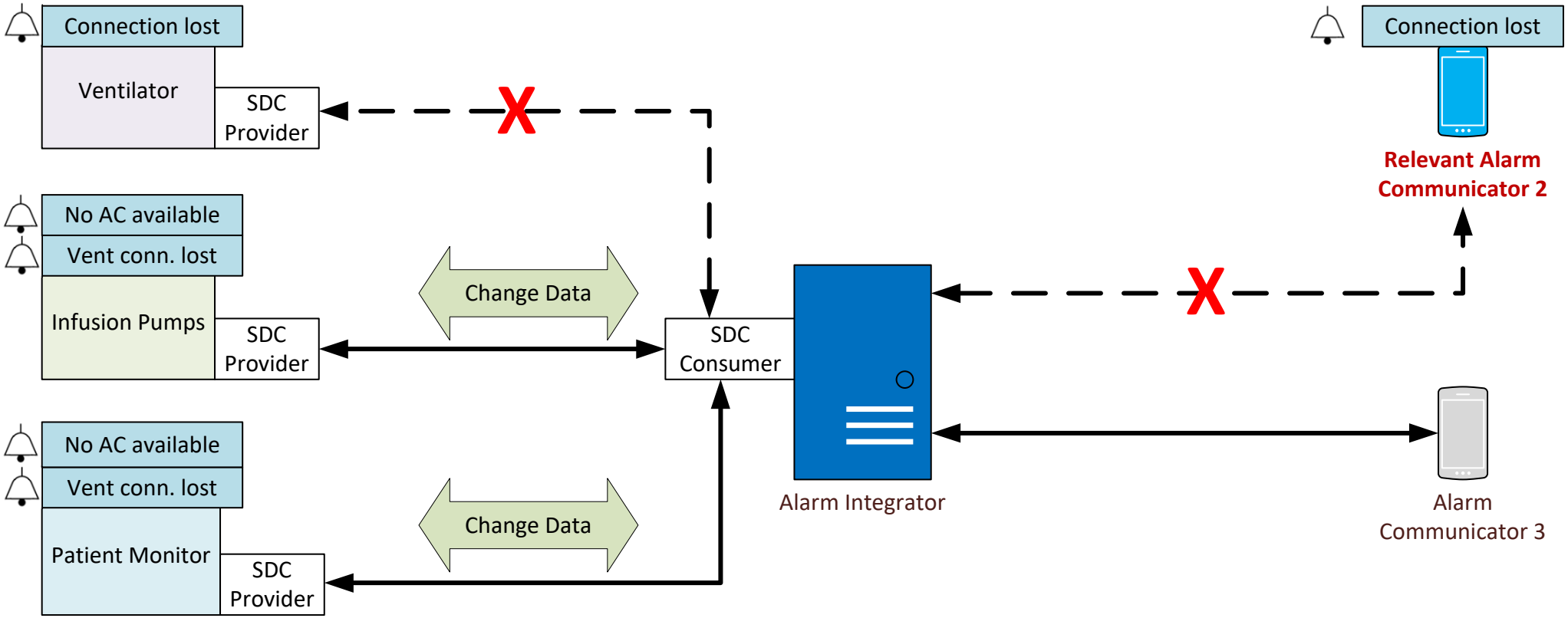
- **When** the connections to multiple PoC devices are lost
  And the connection to the relevant alarm communicator devices are available
- **Then** the user shall be notified on all connected, relevant alarm communicators that the connection to one or more PoC devices has been lost
  And the user may be notified on all PoC devices that the connection to one or more PoC devices has been lost
  And the audio alarm at all connected PoC devices shall be disabled
  And the audio alarm at all connected, relevant alarm communicators shall be enabled
  And the PoC device which is not connected to the alarm integrator shall notify the user visually and audibly about the lost connection



DAS Scenario 5: Connection to PoC devices are lost, relevant alarm communicators are unavailable, and there are no device alerts

- **When** the connection to individual PoC devices is lost
  And the connection to the relevant alarm communicator devices are unavailable
- **Then** the user may be notified on all PoC devices that the connection to one or more PoC devices and relevant ACs has been lost
  And the audio alarm at all connected PoC devices may be enabled
  And the PoC device which is not connected to the alarm integrator shall notify the user visually and audibly about the lost connection
  And the alarm communicator which is not connected to the alarm integrator shall notify the user visually and audibly about the lost connection

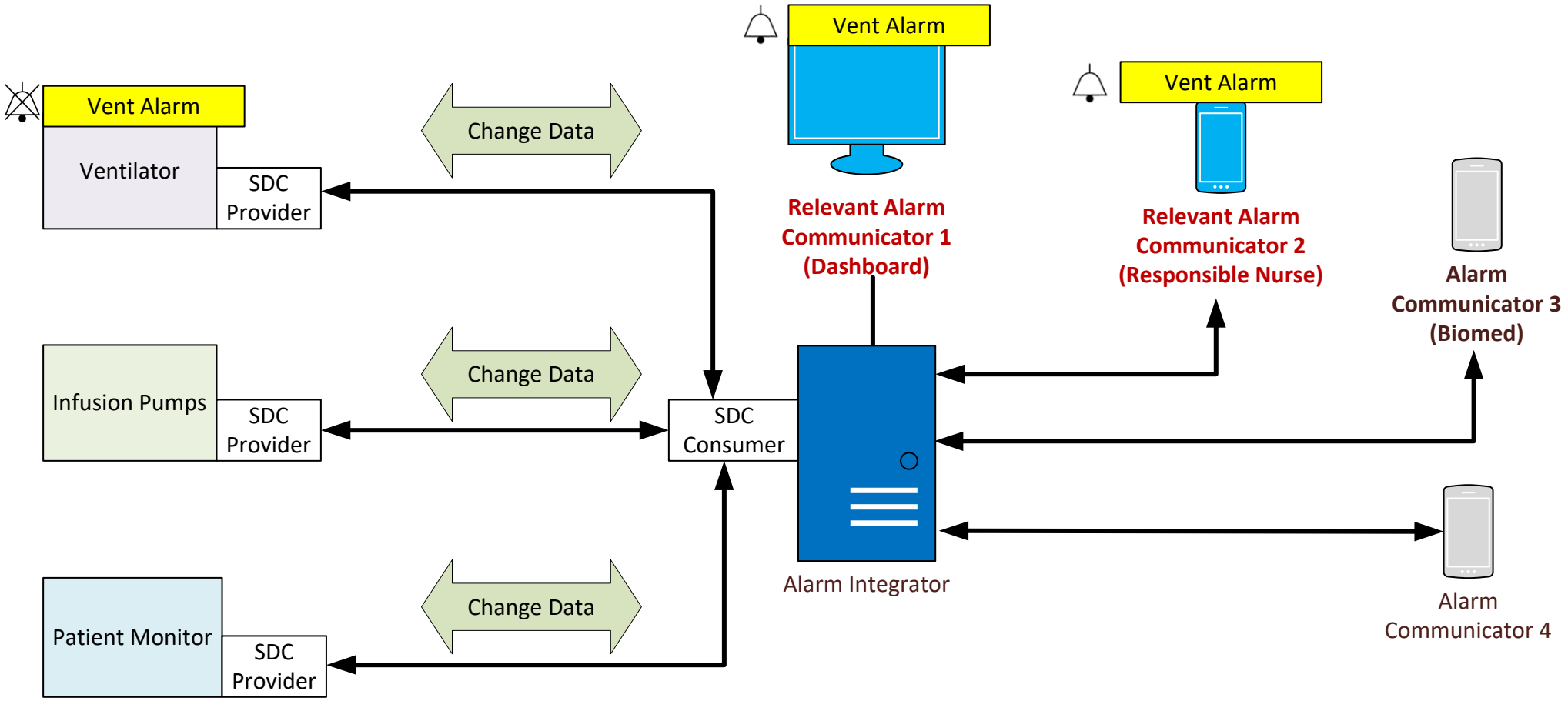
Note: this depicts a worst case scenario. The current AI products address those failure scenarios by redirection, escalation, etc. when an AC is not available any longer. How individual AI products handle those failure scenarios in detail is not subject of this document. It is the responsibility of the AI, if a corresponding status message is shown on the PoCD as well.



DAS Alarm Scenario 1: Alarm is active at PoC

- **When** there is an active physiological alarm at a PoC device
- **Then** the alarm shall visually shown at the PoC device
  And the audio alarm shall be disabled at the PoC device
  And the alarm shall visually and audibly shown on all relevant remote alerting devices that have physiological alarms assigned

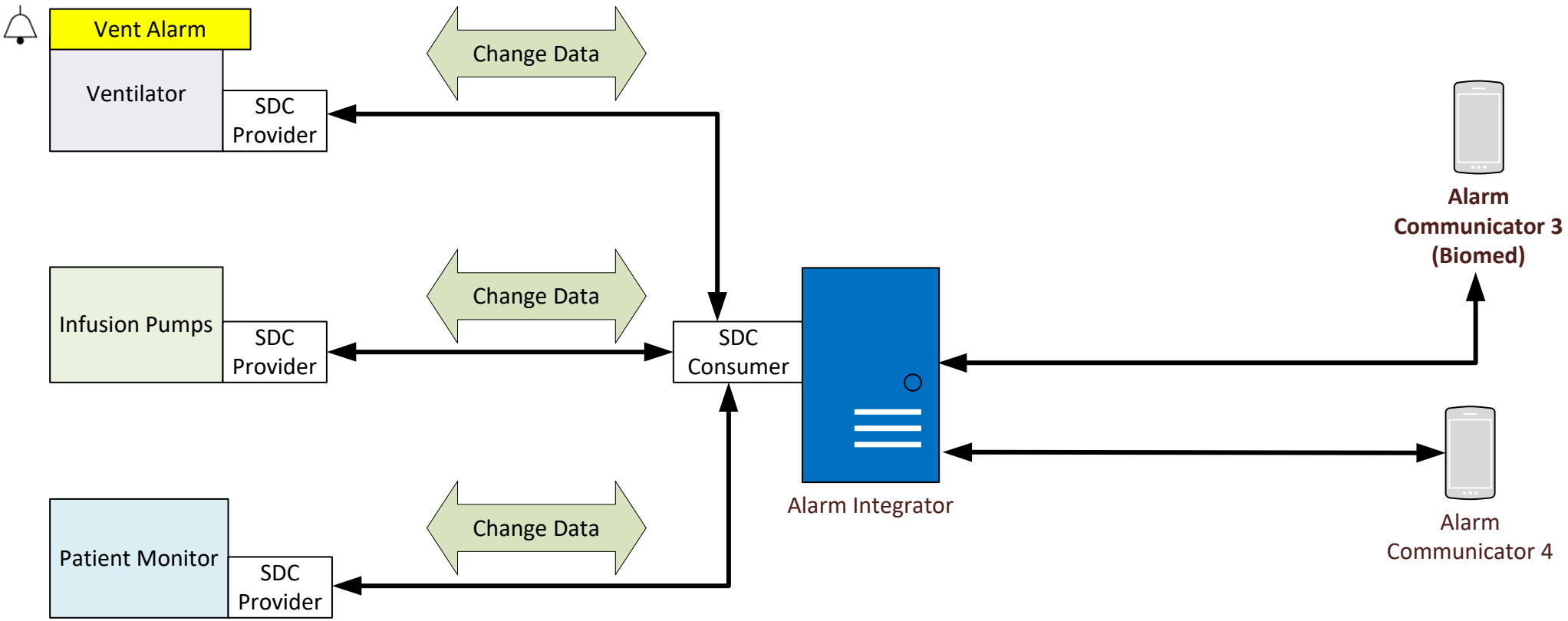
Note: in this scenario, alarm communicator 3 is assigned to technical alarms. Therefore, this alarm communicator is not a relevant alarm communicator for physiological alarms from these PoCDs according to the IEC 60601-1-8 alarm standard.



DAS Alarm Scenario 1.1: Alarm is active at PoC but there is no relevant alarm communicator available for this alarm

- **When** there is an active physiological alarm at a PoC device
  And there is no relevant alarm communicator available for this alarm
- **Then** the alarm shall visually shown at the PoC device
  And the audio alarm shall be enabled at the PoC device

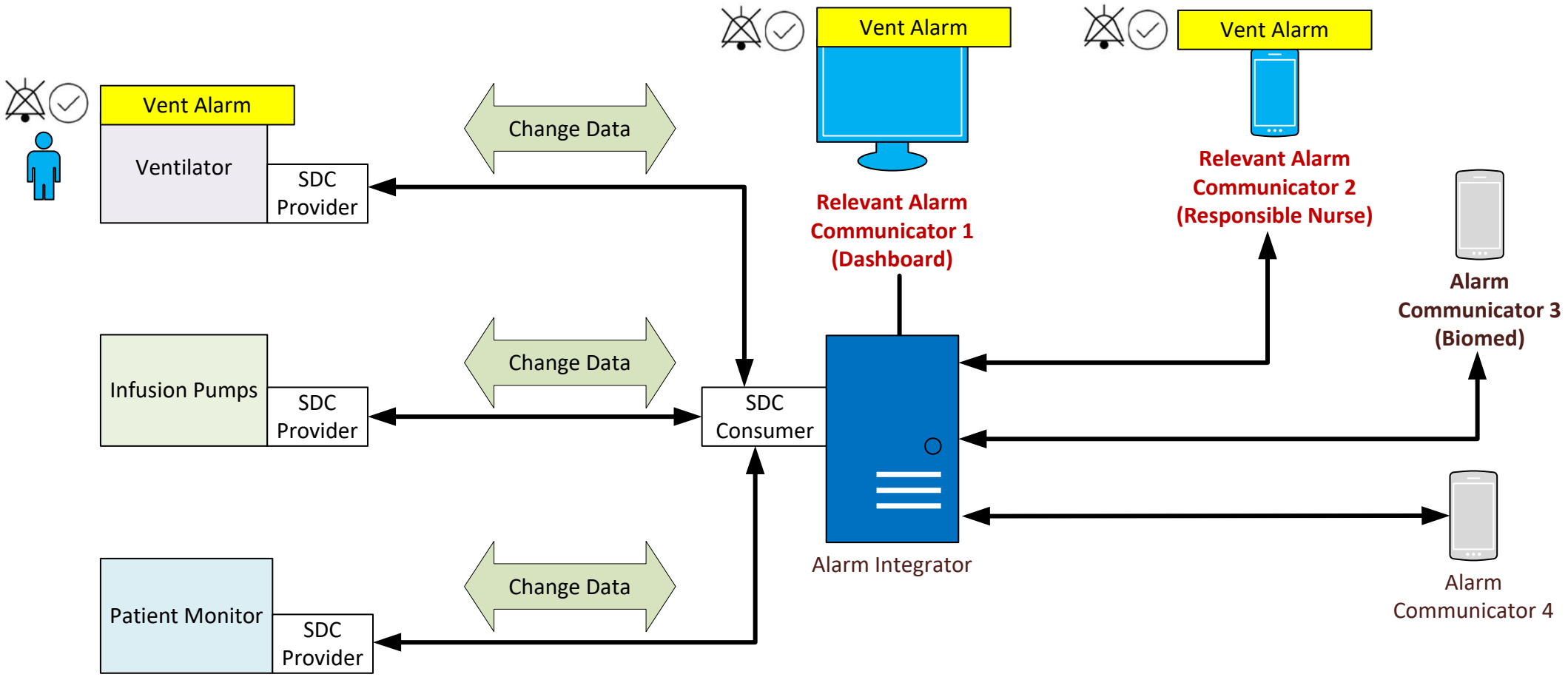
Note: in this scenario, alarm communicator 3 is assigned to technical alarms. Therefore, this alarm communicator is not a relevant alarm communicator for physiological alarms from these PoCDs according to the IEC 60601-1-8 alarm standard.



DAS Alarm Scenario 2: Acknowledge at PoC device

- **When** there is an active physiological alarm at a PoC device
  And the alarm is shown visually and audibly on all relevant remote alerting devices that have physiological alarms assigned
  And the caregiver acknowledges the alarm at the POC device
- **Then** the alarm shall be shown as acknowledged at the PoC device
  And the alarm shall be shown as acknowledged on all relevant alerting devices
  And the audio signal for this alarm shall be disabled at the Poc device and all relevant alerting devices

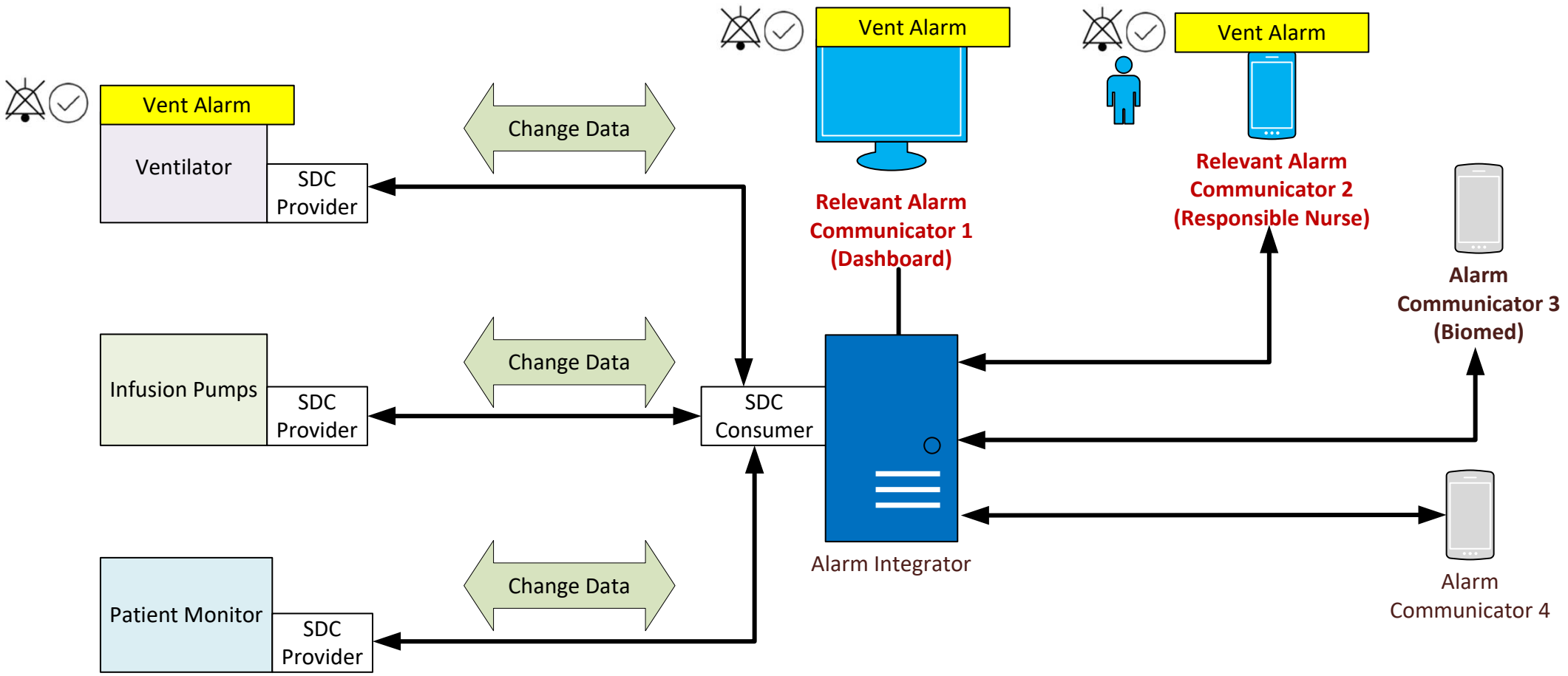
Note: in this scenario, alarm communicator 3 is assigned to technical alarms. Therefore, this alarm communicator is not a relevant alarm communicator for physiological alarms from these PoCDs according to the IEC 60601-1-8 alarm standard.



DAS Alarm Scenario 3: Acknowledge at remote device

- **When** there is an active physiological alarm at a PoC device
  And the alarm is shown visually and audibly on all relevant remote alerting devices that have physiological alarms assigned
  And the caregiver acknowledges the alarm on any remote alerting device
- **Then** the alarm shall be shown as acknowledged at the PoC device
  And the alarm shall be shown as acknowledged on all relevant alerting devices
  And the audio signal for this alarm shall be disabled at the Poc device and all relevant alerting devices

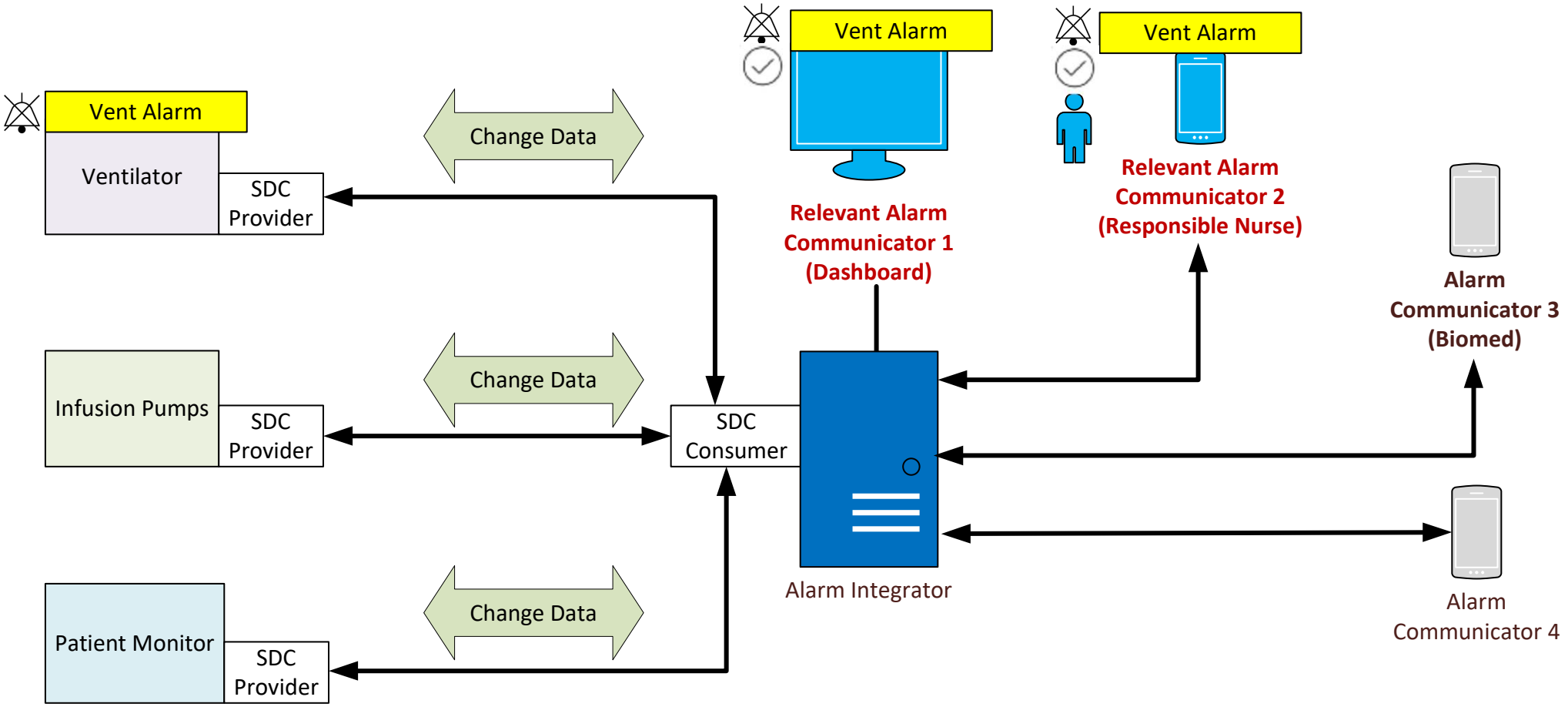
Note: in this scenario, alarm communicator 3 is assigned to technical alarms. Therefore, this alarm communicator is not a relevant alarm communicator for physiological alarms from these PoCDs according to the IEC 60601-1-8 alarm standard.



DAS Alarm Scenario 4: Responsibility Accepted at any of the relevant alarm communicators

- **When** there is an active physiological alarm at a PoC device
  And the alarm is shown visually and audibly on all relevant remote alerting devices that have physiological alarms assigned
  And the caregiver accepts the alarm on any remote alerting device
- **Then** the alarm shall visually be shown as accepted on all remote alerting device
  And the alarm audio shall be disabled on all other relevant remote alerting devices
  And the alarm shall be shown at the PoC device
  And the audio signal for this alarm shall be disabled at the Poc device

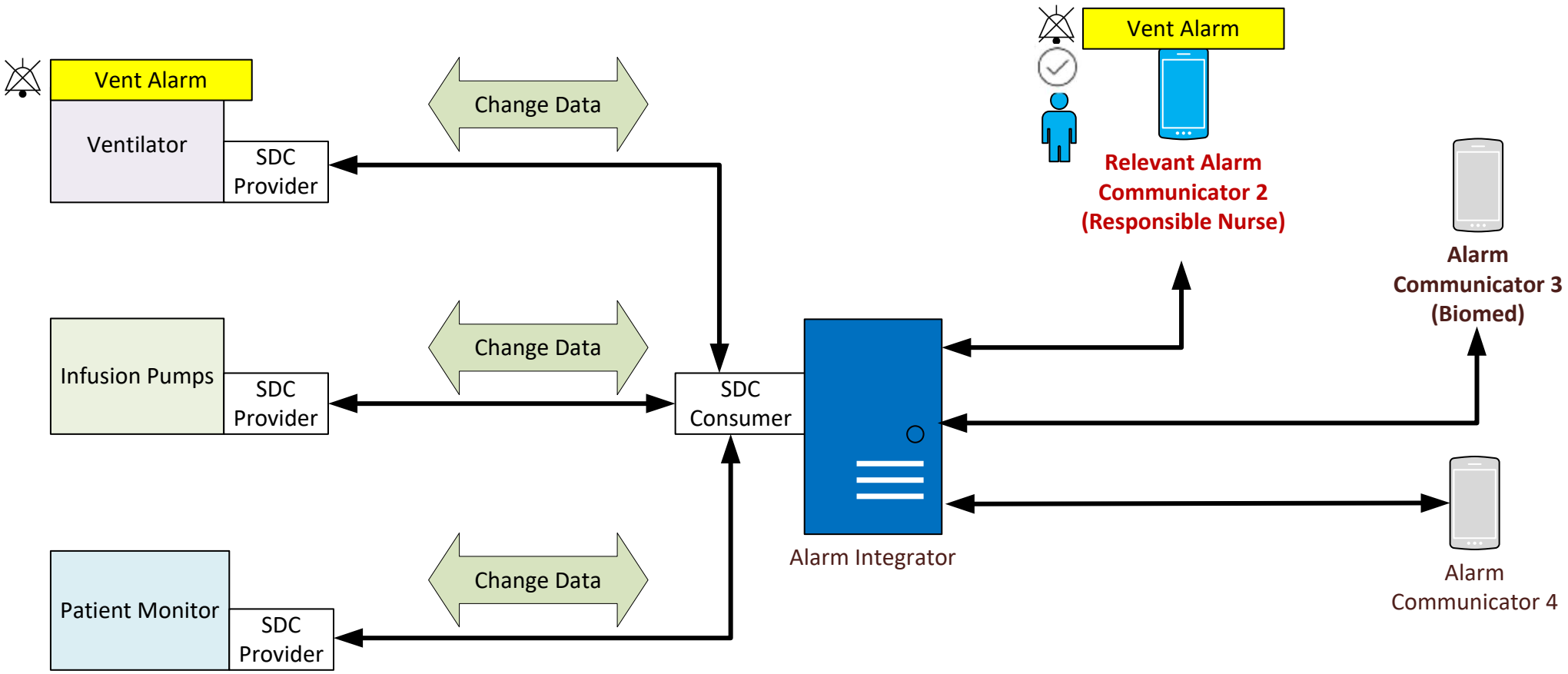
Note: in this scenario, alarm communicator 3 is assigned to technical alarms. Therefore, this alarm communicator is not a relevant alarm communicator for physiological alarms from these PoCDs according to the IEC 60601-1-8 alarm standard.



DAS Alarm Scenario 4.1: Responsibility Accepted at the relevant alarm communicator device

- **When** there is an active physiological alarm at a PoC device
  And the alarm is shown visually and audibly on the relevant remote alerting device that have physiological alarms assigned
  And the caregiver accepts the alarm on the remote alerting device
- **Then** the alarm shall visually be shown as accepted on the remote alerting device
  And the alarm shall be shown at the PoC device
  And the audio signal for this alarm shall be disabled at the PoC device

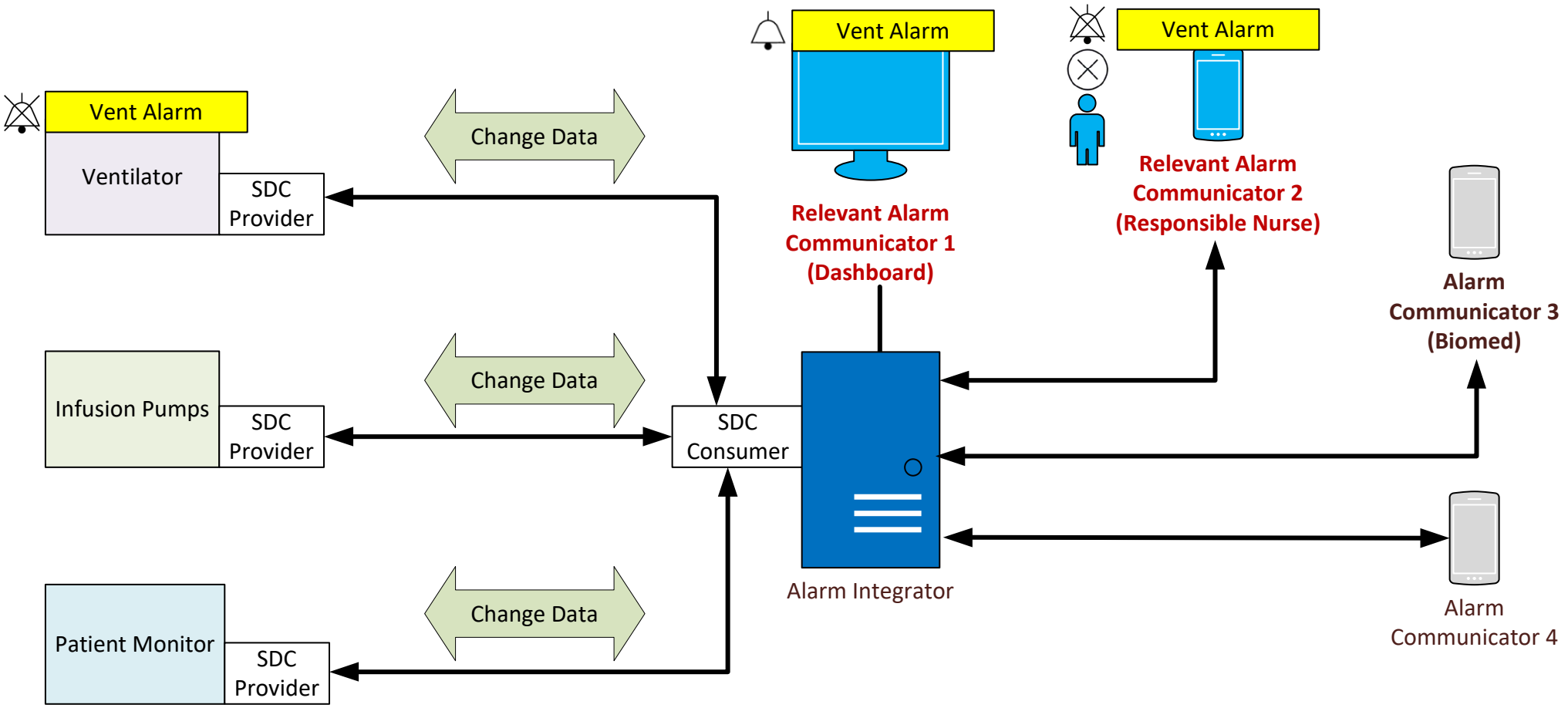
Note: in this scenario, alarm communicator 3 is assigned to technical alarms. Therefore, this alarm communicator is not a relevant alarm communicator for physiological alarms from these PoCDs according to the IEC 60601-1-8 alarm standard.



DAS Alarm Scenario 5: Responsibility Rejected at any of the relevant alarm communicators

- **When** there is an active physiological alarm at a PoC device
  And the alarm is shown visually and audibly on all relevant remote alerting devices that have physiological alarms assigned
  And the caregiver rejects the alarm on any remote alerting device
- **Then** the alarm shall visually be shown as rejected on this remote alerting device
  And the audio signal for this alarm shall be disabled on this remote alerting device
  And the alarm shall be shown at the PoC device
  And the audio signal for this alarm shall be disabled at the Poc device
  And the alarm shall visually and audibly be shown on all other relevant remote alerting devices

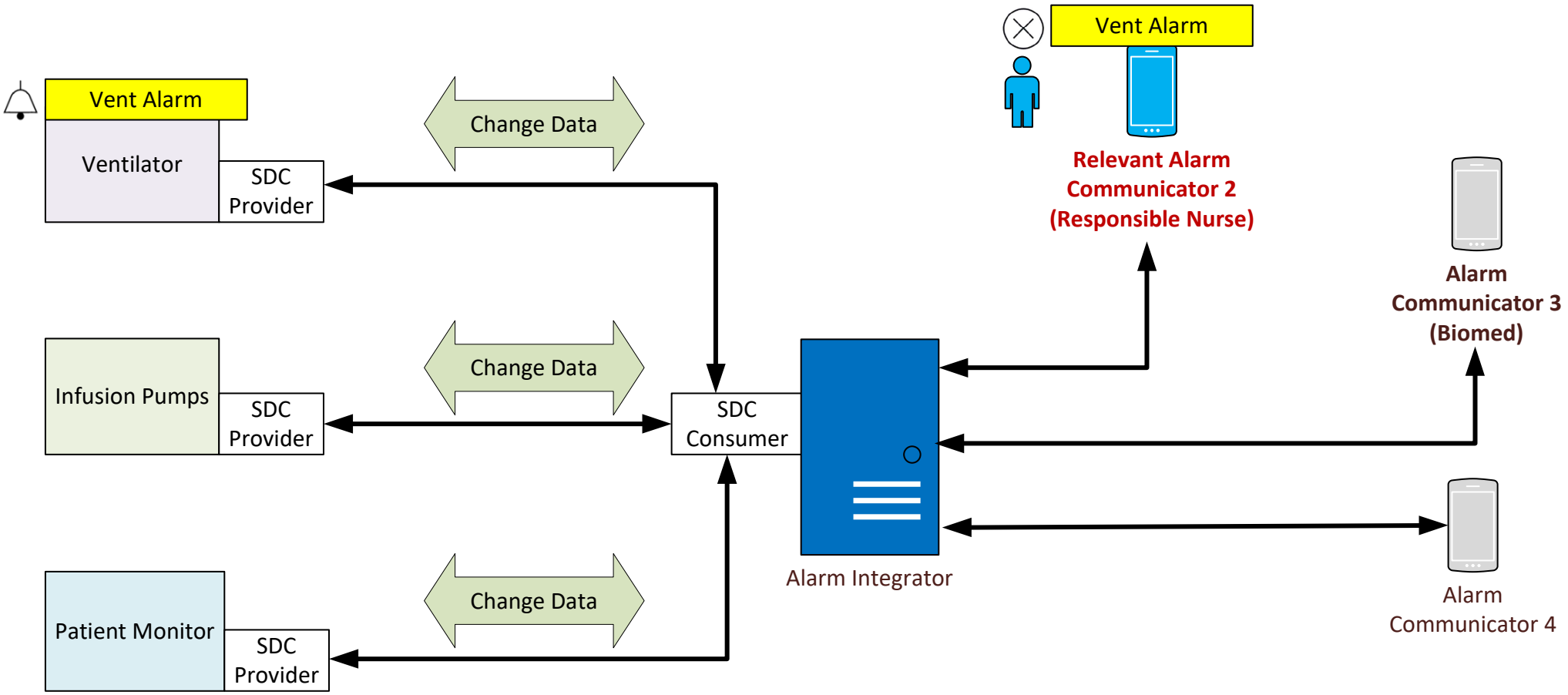
Note: in this scenario, alarm communicator 3 is assigned to technical alarms. Therefore, this alarm communicator is not a relevant alarm communicator for physiological alarms from these PoCDs according to the IEC 60601-1-8 alarm standard.



DAS Alarm Scenario 5.1: Responsibility Rejected at the relevant alarm communicator

- **When** there is an active physiological alarm at a PoC device
  And the alarm is shown visually and audibly at the relevant remote alerting device that have physiological alarms assigned
  And the caregiver rejects the alarm at the remote alerting device
- **Then** the alarm shall visually be shown as rejected on this remote alerting device
  And the audio signal for this alarm shall be disabled on this remote alerting device
  And the alarm shall be shown at the PoC device
  And the audio signal for this alarm shall be enabled at the Poc device

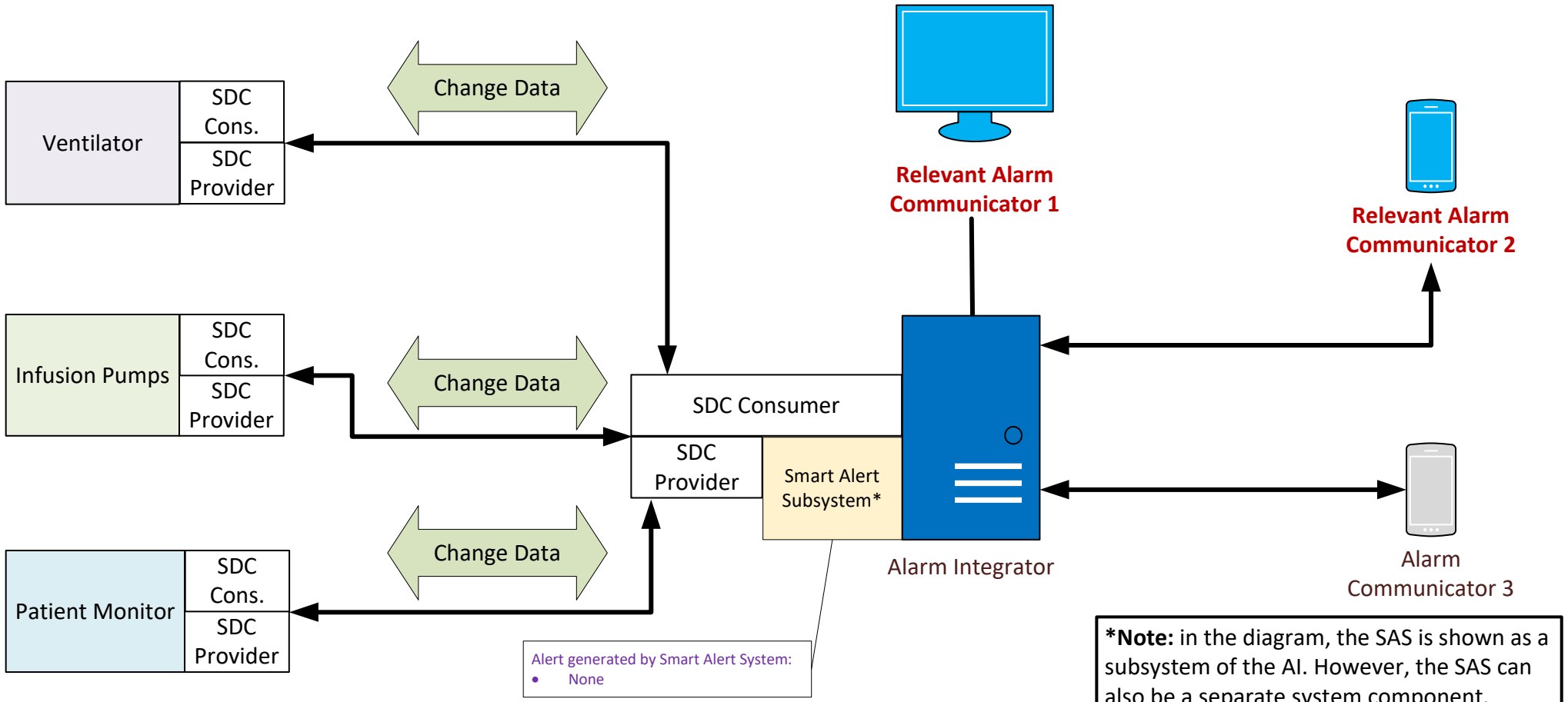
Note: in this scenario, alarm communicator 3 is assigned to technical alarms. Therefore, this alarm communicator is not a relevant alarm communicator for physiological alarms from these PoCDs according to the IEC 60601-1-8 alarm standard.



SmartSys Scenario 1: Smart Alert System is fully operational and there are no alerts

- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator devices is established to the alarm integrator by checking the connection state on a regular basis
- **Then** no further indication that the Smart Alert System is fully operational shall be announced to the user

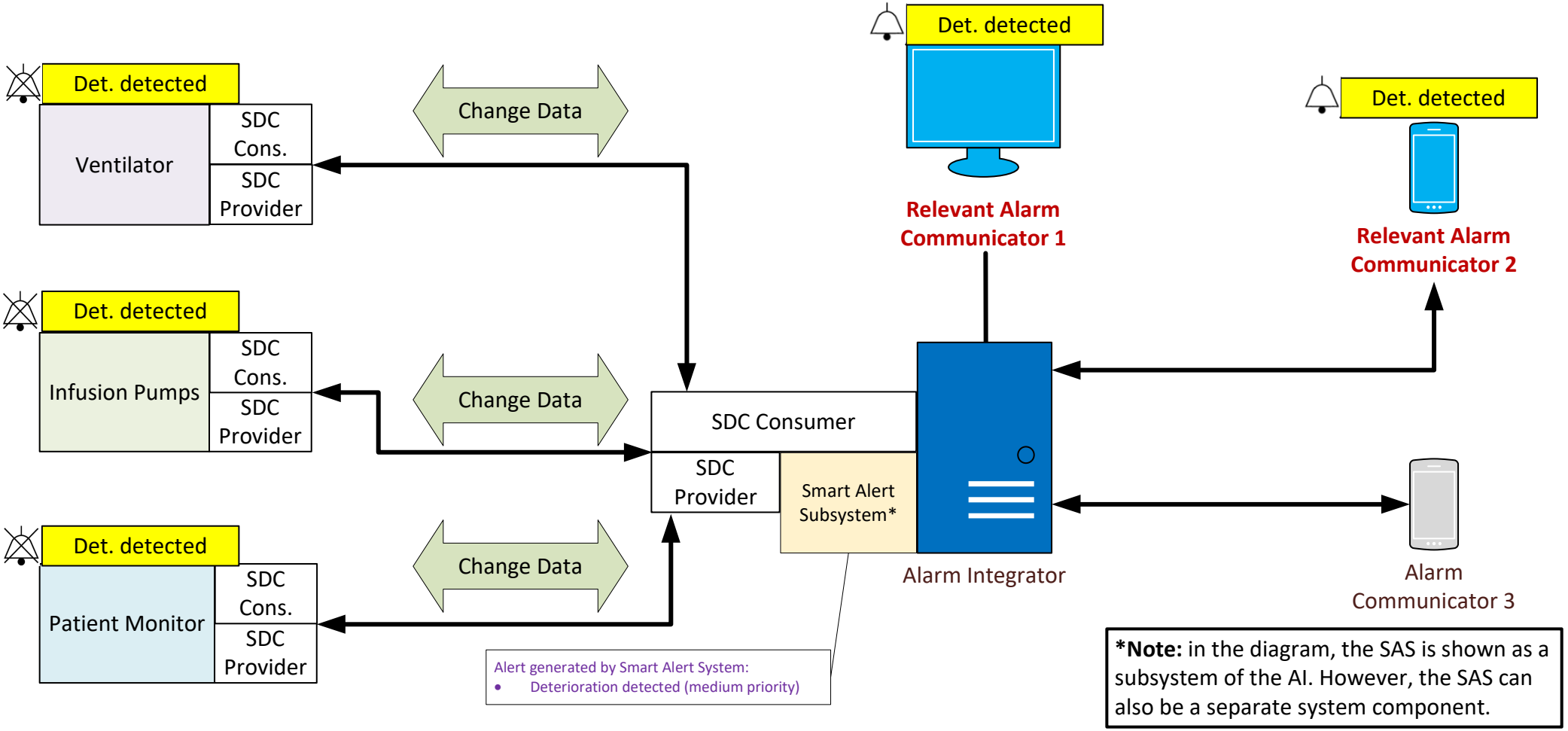
Note: customers may require to have an indicator that the DAS and the SAS is fully operational. This might be configurable at the PoCD and/or AC (e.g. a notification shown at the display).



***Note:** in the diagram, the SAS is shown as a subsystem of the AI. However, the SAS can also be a separate system component.

SmartSys Scenario 2: Smart Alert System is fully operational, there are smart alerts derived from patient data, and smart alerts are shown on all PoC devices

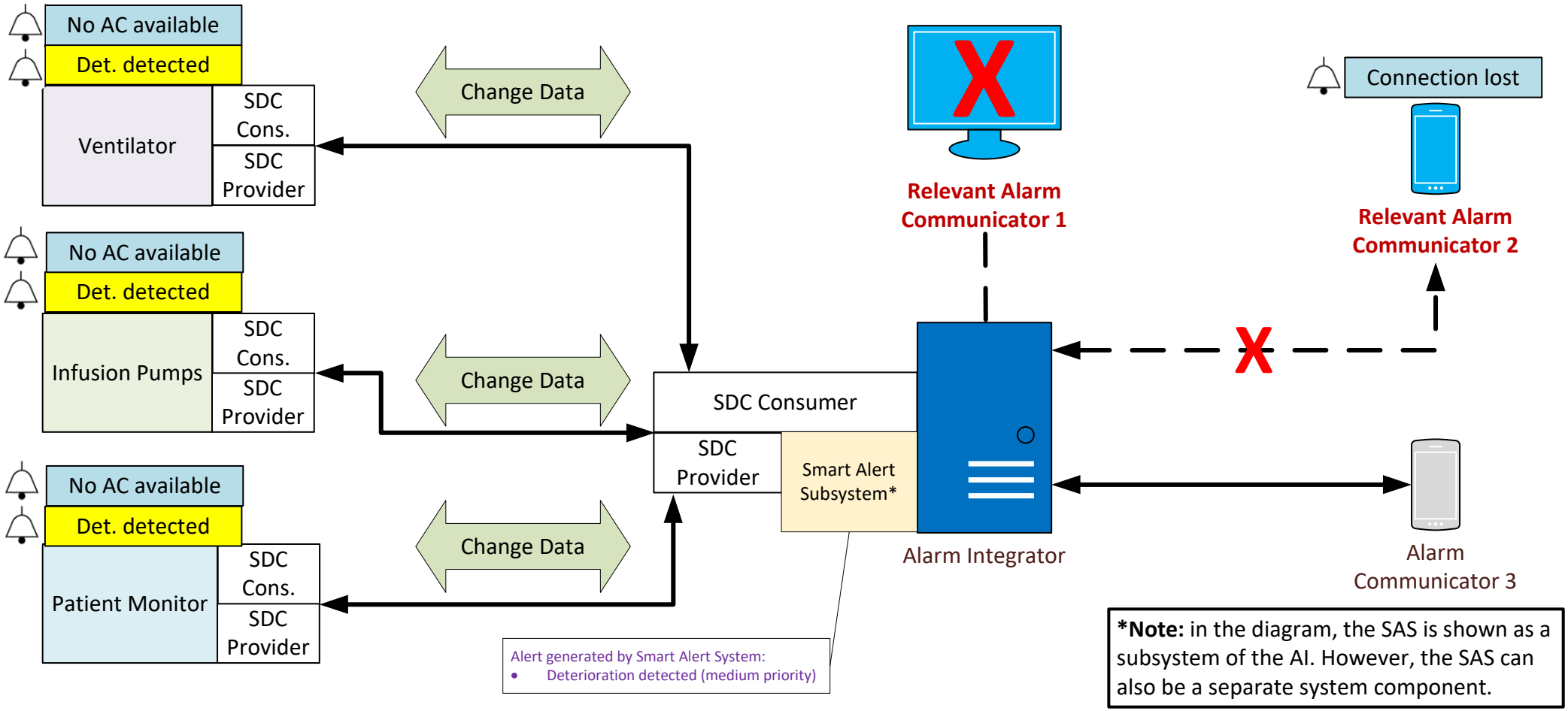
- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator devices is established to the alarm integrator by checking the connection state on a regular basis
  And there is an alert generated by the smart alert system based on patient data
- **Then** the user shall be notified on all connected, relevant alarm communicators that there is an alert event generated by the smart alert system
  And the user may be notified on all PoC devices that there is an alert event generated by the smart alert system
  And the audio alarm at all connected PoC devices shall be disabled
  And the audio alarm at all connected, relevant alarm communicators shall be enabled



***Note:** in the diagram, the SAS is shown as a subsystem of the AI. However, the SAS can also be a separate system component.

SmartSys Scenario 2.1: Smart Alert System is fully operational, connections to relevant ACs are lost, there are smart alerts derived from patient data, and and smart alerts are shown on all PoC devices

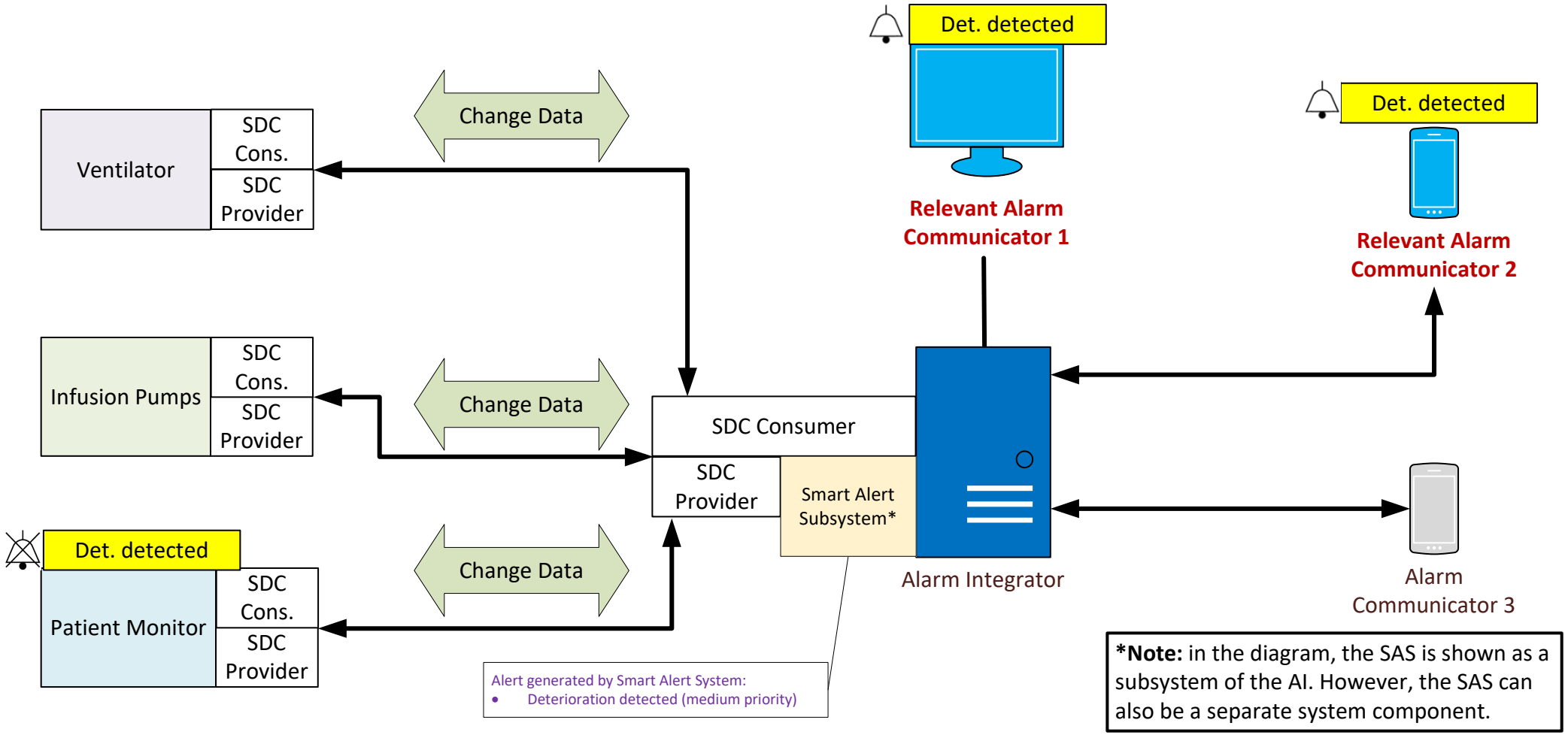
- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator devices is lost
  And there is an alert generated by the smart alert system based on patient data
- **Then** the user may be notified at all PoC devices that there is an alert event generated by the smart alert system
  And the user may be notified at all PoC devices that the connections to all alert communicators are lost
  And the audio alarm at all connected PoC devices shall be enabled
  And the alarm communicator which is not connected to the alarm integrator shall notify the user visually and audibly about the lost connection



***Note:** in the diagram, the SAS is shown as a subsystem of the AI. However, the SAS can also be a separate system component.

SmartSys Scenario 2.2: Smart Alert System is fully operational, there are smart alerts derived from patient data, and smart alert is only shown on one PoC device

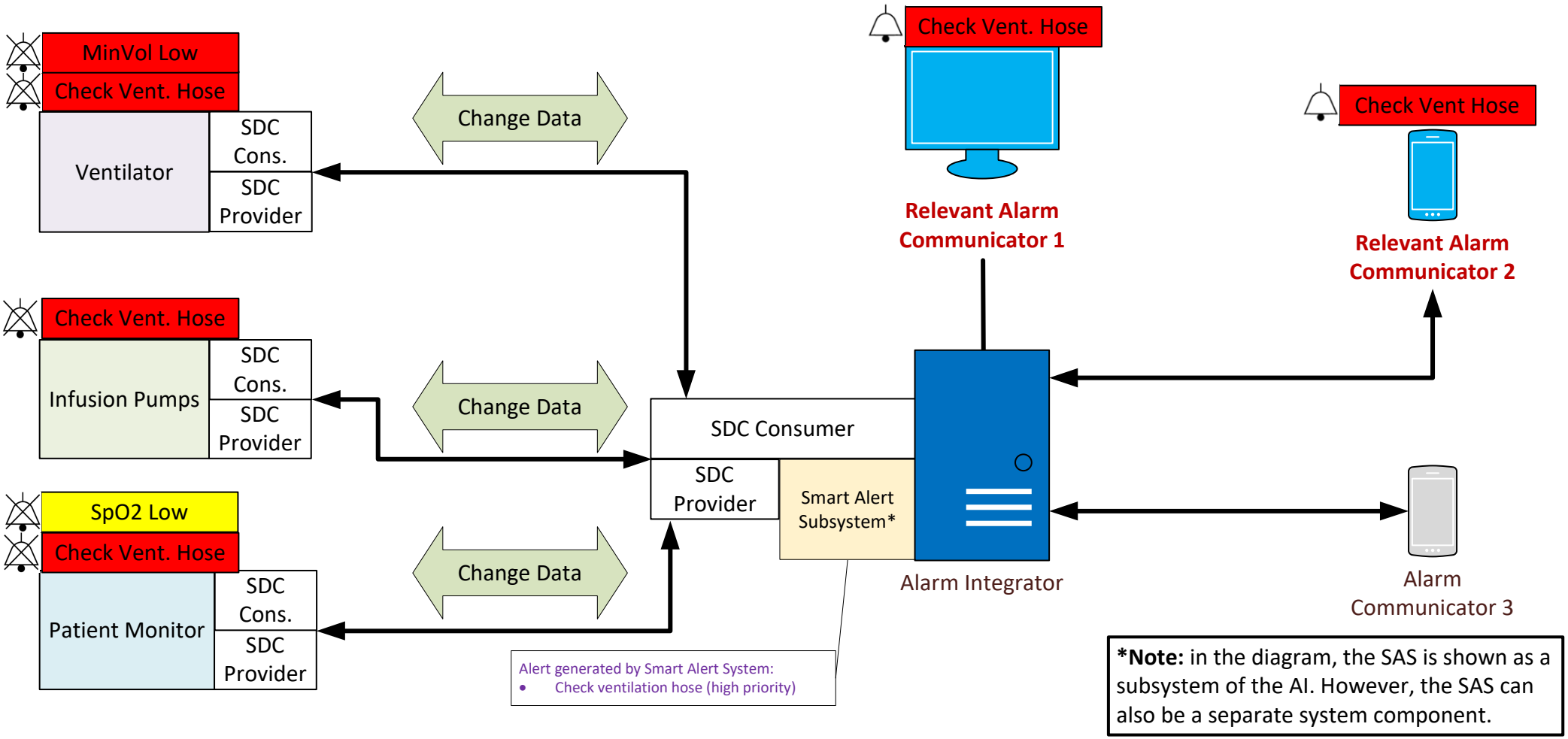
- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator devices is established to the alarm integrator by checking the connection state on a regular basis
  And there is an alert generated by the smart alert system based on patient data
  And there is a prioritization on which PoC devices the alert shall be signaled
- **Then** the user shall be notified on all connected, relevant alarm communicators that there is an alert event generated by the smart alert system
  And the user shall only be notified on the PoC device with the highest priority that there is an alert event generated by the smart alert system
  And the audio alarm at all connected PoC devices shall be disabled
  And the audio alarm at all connected, relevant alarm communicators shall be enabled



***Note:** in the diagram, the SAS is shown as a subsystem of the AI. However, the SAS can also be a separate system component.

SmartSys Scenario 3: Smart Alert System is fully operational, there are smart alerts derived from PoC device alerts, and smart alerts are shown on all PoC devices

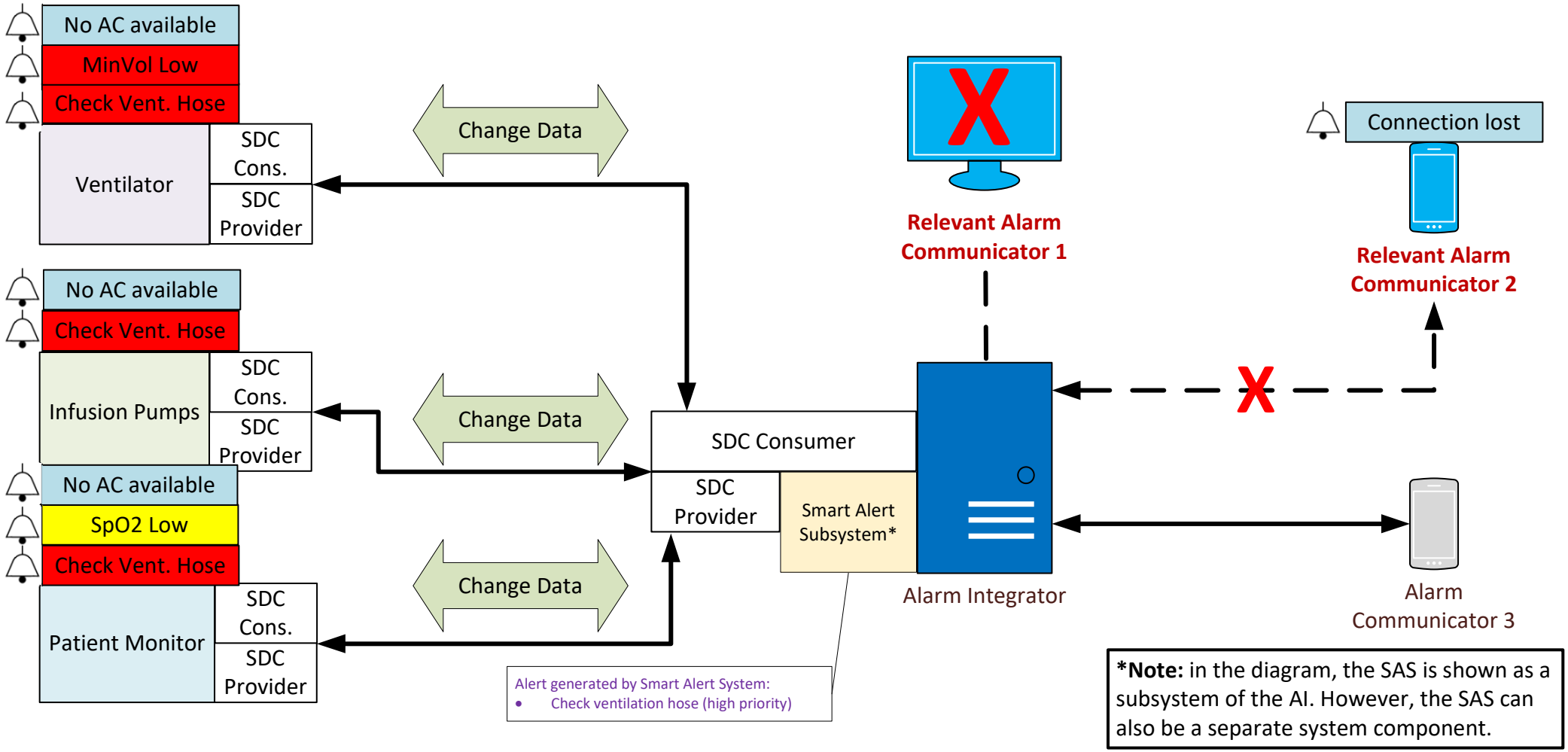
- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator devices is established to the alarm integrator by checking the connection state on a regular basis
  And one or more PoC device alerts are active
  And there is an alert generated by the smart alert system based on PoC device alerts
- **Then** the user shall be notified at all PoC devices and all connected, relevant alarm communicators that there is an alert event generated by the smart alert system
  And the device alerts are only shown at the corresponding PoC devices
  And the audio alarm at all connected PoC devices shall be disabled
  And the audio alarm at all connected, relevant alarm communicators shall be enabled



***Note:** in the diagram, the SAS is shown as a subsystem of the AI. However, the SAS can also be a separate system component.

SmartSys Scenario 3.1: Smart Alert System is fully operational, connections to relevant ACs are lost, there are smart alerts derived from PoC device alerts, and smart alerts are shown on all PoC devices

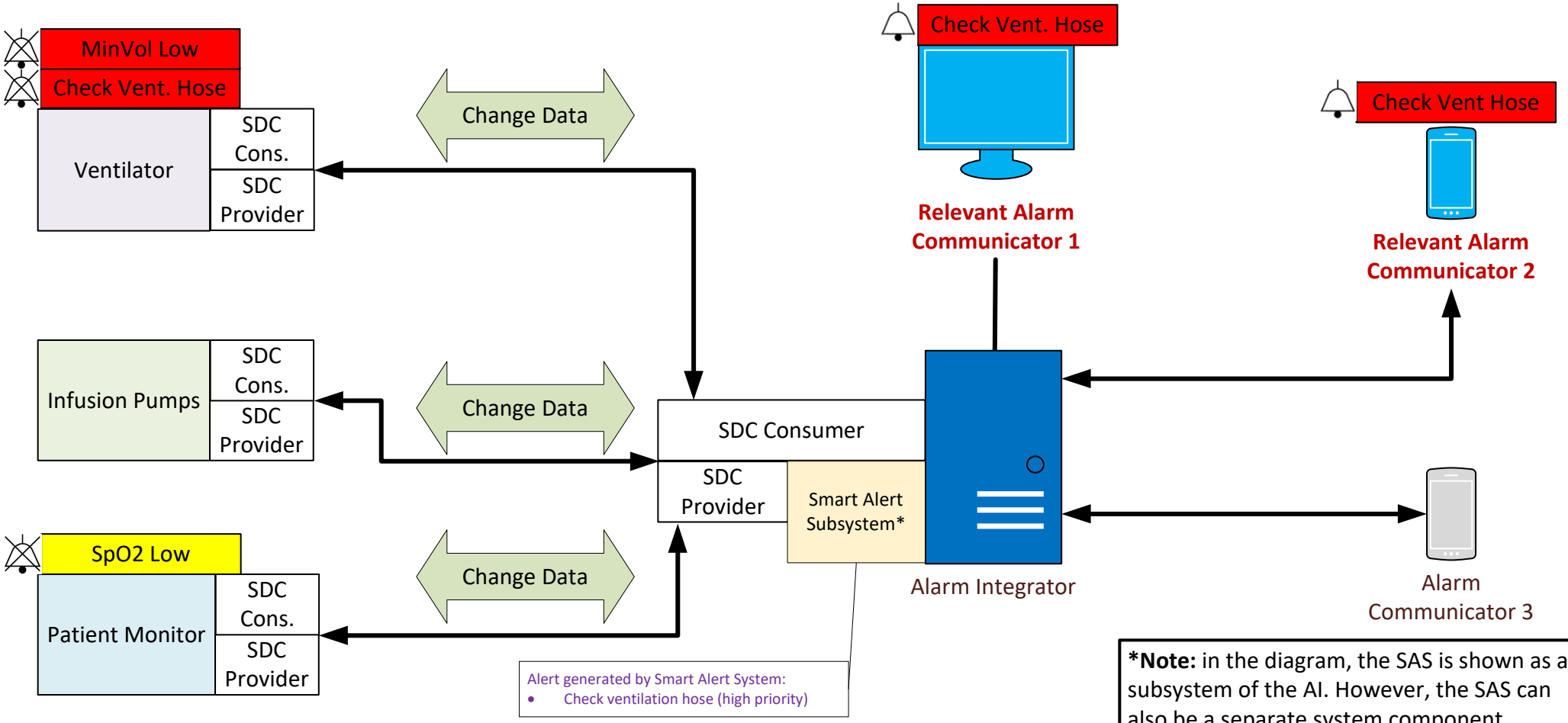
- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator devices is lost
  And one or more PoC device alerts are active
  And there is an alert generated by the smart alert system based on PoC device alerts
- **Then** the user shall be notified at all PoC devices that there is an alert event generated by the smart alert system
  And the device alerts are only shown at the corresponding PoC devices
  And the user shall be notified at all PoC devices that the connections to all alert communicators are lost
  And the alarm communicator which is not connected to the alarm integrator shall notify the user visually and audibly about the lost connection
  And the audio alarm at all connected PoC devices shall be enabled



***Note:** in the diagram, the SAS is shown as a subsystem of the AI. However, the SAS can also be a separate system component.

SmartSys Scenario 3.2: Smart Alert System is fully operational, there are smart alerts derived from PoC device alerts, and smart alerts are only shown on the relevant PoC devices

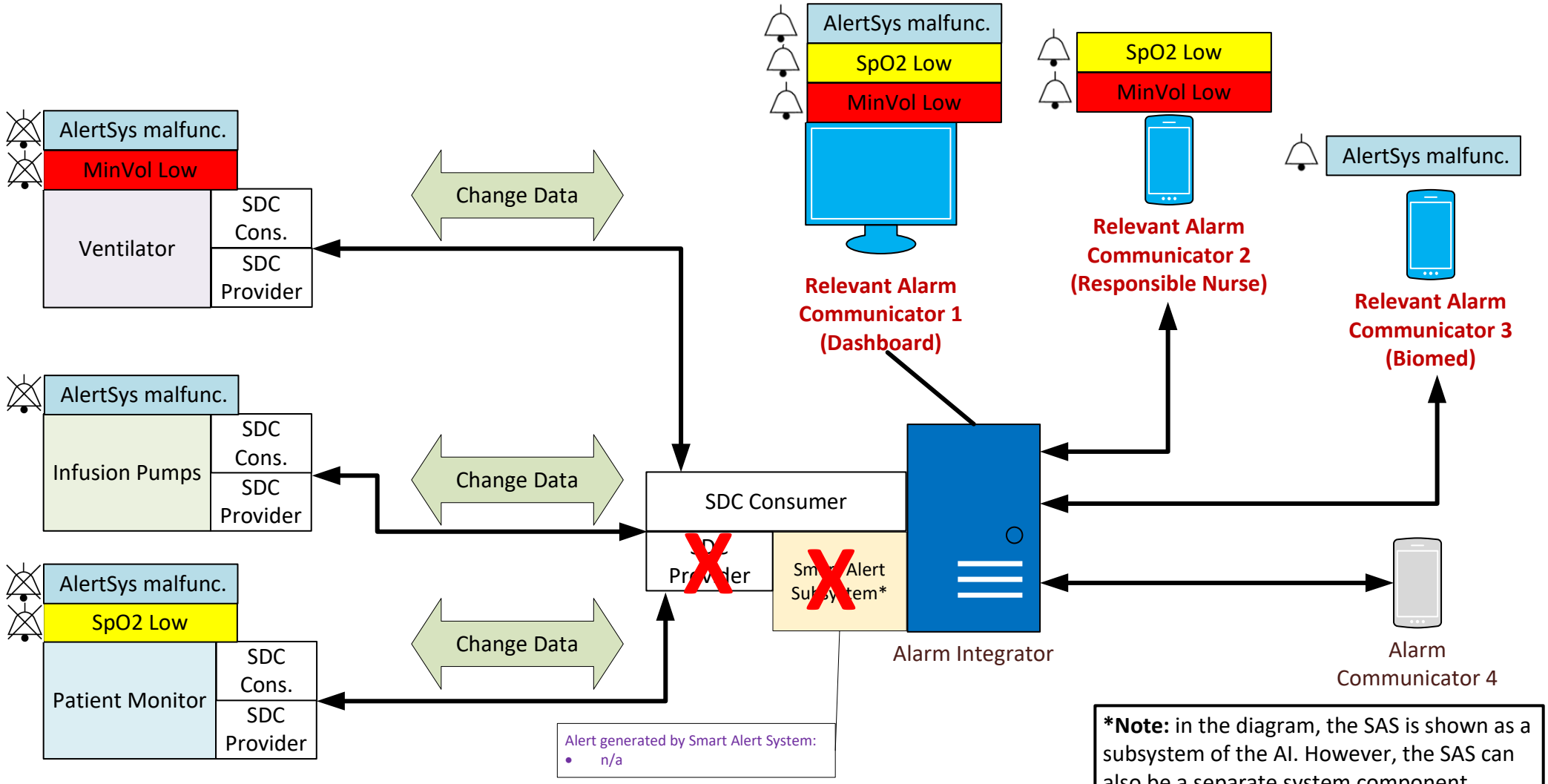
- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator devices is established to the alarm integrator by checking the connection state on a regular basis
  And one or more PoC device alerts are active
  And there is an alert generated by the smart alert system based on PoC device alerts
  And the smart alert relates to a specific PoC device
- **Then** the user shall be notified on all connected, relevant alarm communicators that there is an alert event generated by the smart alert system
  And the user shall be notified on the PoC device that relates to the alert event generated by the smart alert system
  And the original device alerts are only shown at the corresponding PoC devices
  And the audio alarm at all connected PoC devices shall be disabled
  And the audio alarm at all connected, relevant alarm communicators shall be enabled



***Note:** in the diagram, the SAS is shown as a subsystem of the AI. However, the SAS can also be a separate system component.

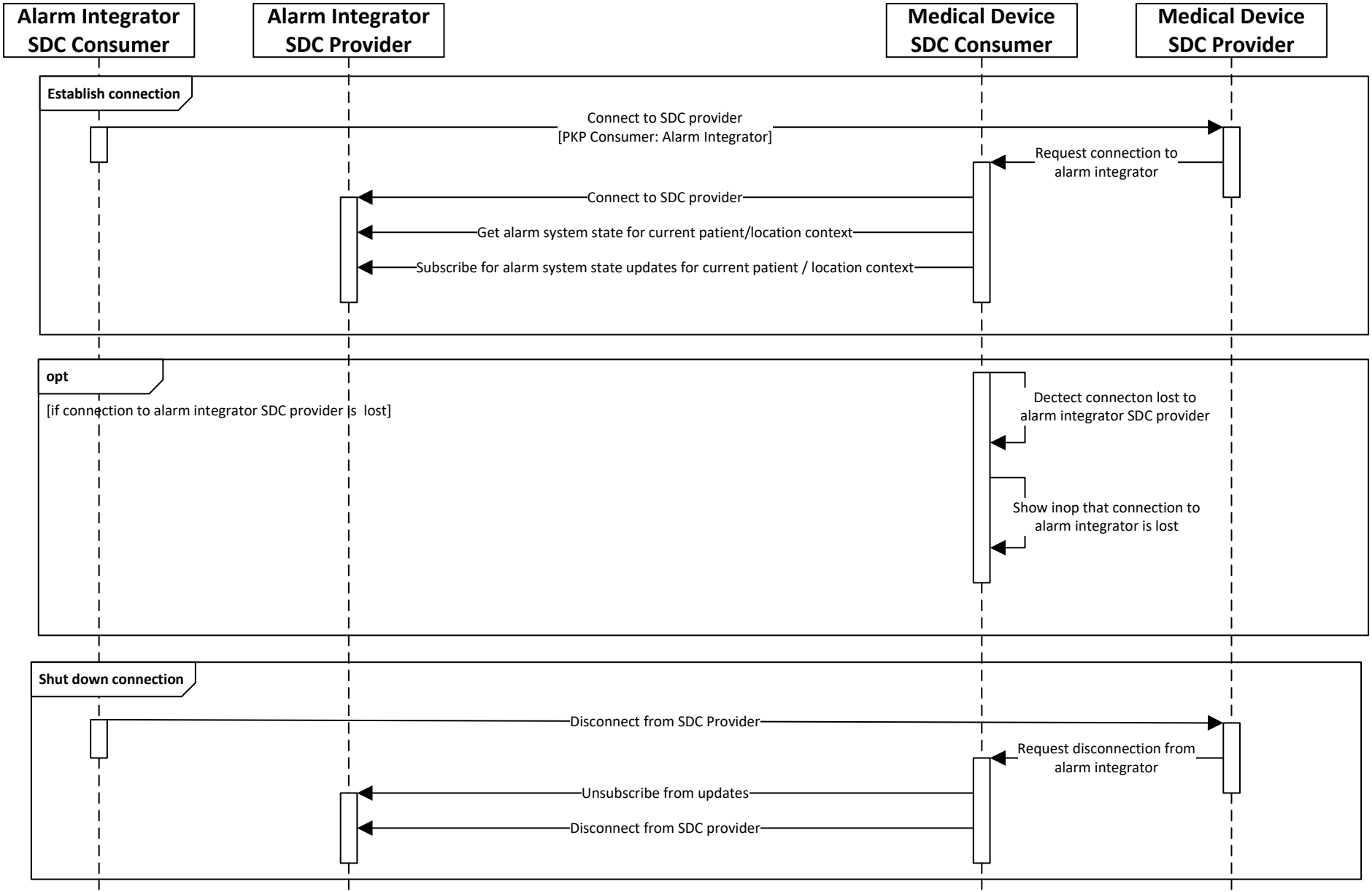
SmartSys Scenario 4: Smart Alert System is not operational and there are PoC device alerts

- **When** the connection to individual PoC devices is established to the alarm integrator by checking the connection state on a regular basis
  And the connection to the relevant alarm communicator devices is established to the alarm integrator by checking the connection state on a regular basis
  And one or more PoC device alerts are active
  But the smart alert system is not operational
- **Then** the user shall be notified at all PoC devices and all relevant alarm communicators that have physiological alerts assigned about PoCD alerts
  And the user shall be notified at all PoC devices and all relevant alarm communicators that have technical alerts assigned about SAS inops
  And the device alerts are shown at the corresponding PoC devices
  And the audio alarm at all connected PoC devices shall be disabled
  And the audio alarm at all connected, relevant alarm communicators shall be enabled

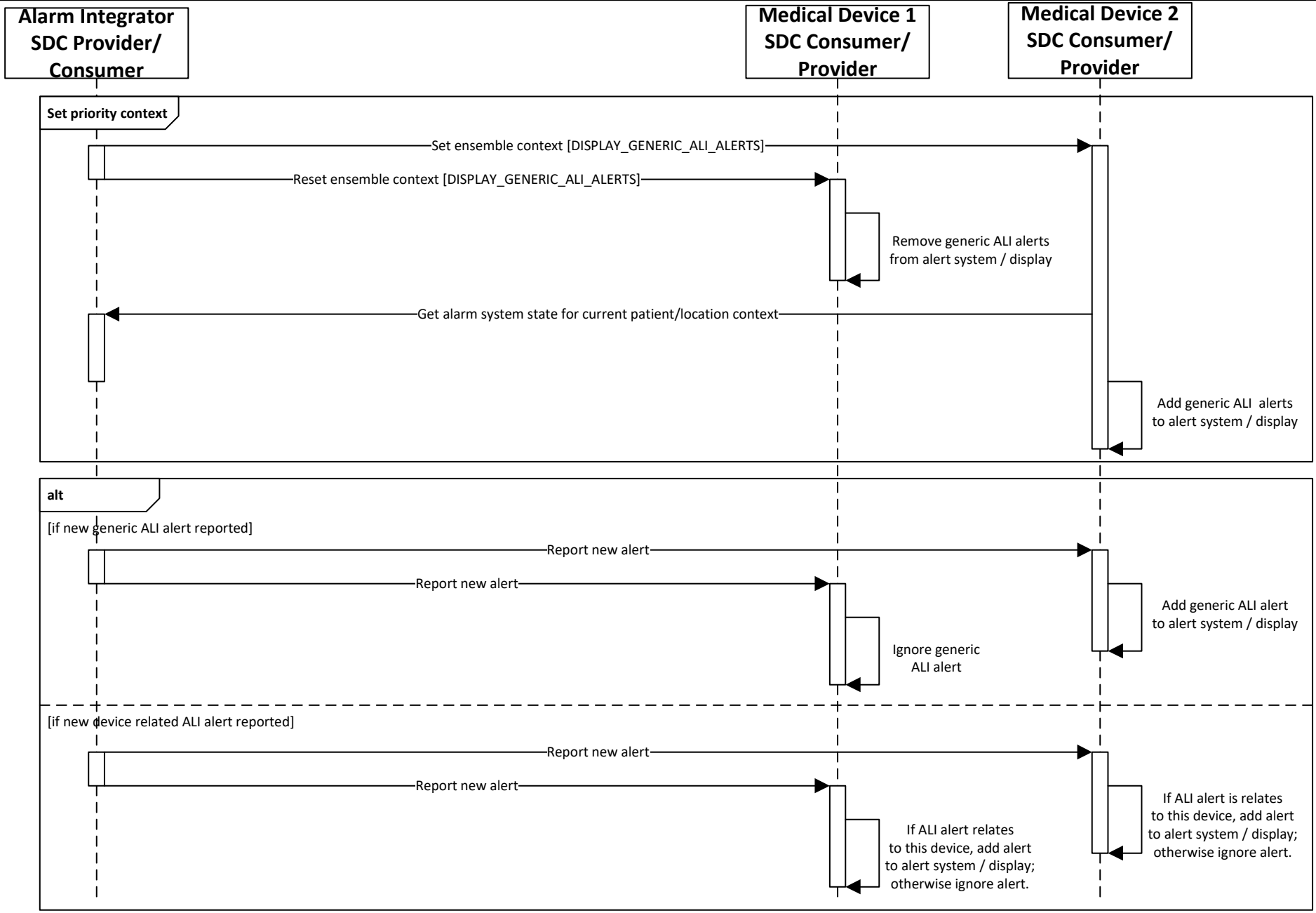


***Note:** in the diagram, the SAS is shown as a subsystem of the AI. However, the SAS can also be a separate system component.

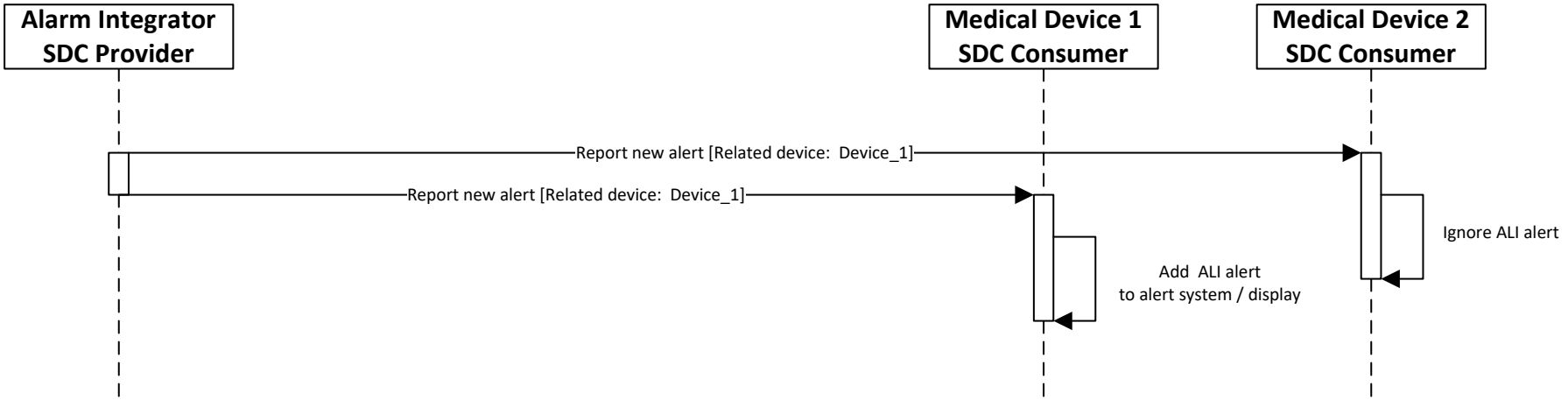
Alarm System Sequence Diagram 1: Connect / Disconnect to / from Alarm Integrator (ALI)



Alarm System Sequence Diagram 2: Display alarm integrator (ALI) alerts based on priority



Alarm System Sequence Diagram 3: Display smart alert related to specific device(s)



Alarm System Sequence Diagram 4: Alarm integrator (ALI) alert delegation handling