



Audible Alert Signal Behavior

QR – Quiet Room

SR – Silent Room

SI – Silent ICU

Defns. From 60601-1-8

DAS - * DISTRIBUTED ALARM SYSTEM

ALARM SYSTEM that involves more than one item of equipment in a ME SYSTEM intended for delivery of ALARM CONDITIONS with technical confirmation

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

NOTE 2 A DISTRIBUTED ALARM SYSTEM is intended to notify OPERATORS of the existence of an ALARM CONDITION.

NOTE 3 For the purposes of this document, technical confirmation means that each element of a DISTRIBUTED ALARM SYSTEM confirms or guarantees the successful delivery of the ALARM CONDITION to the next element or appropriate

Examples could be:

Traditional Central Station w/o alarm acknowledge;

CDAS - DISTRIBUTED ALARM SYSTEM WITH OPERATOR CONFIRMATION

DISTRIBUTED ALARM SYSTEM that includes the capability to receive an OPERATOR response

Examples could be:

Traditional Central Station; Bed to Bed alarm feature supporting alarm acknowledge; Caregiver worn device supporting alarm acknowledge

Defns. From 60601-1-8

DIS - * DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS

system that involves more than one item of equipment in a ME SYSTEM intended to provide information about ALARM CONDITIONS but does not guarantee delivery of that information

NOTE 1 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended to notify OPERATORS of the

existence of an ALARM CONDITION as a RISK CONTROL measure. A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM

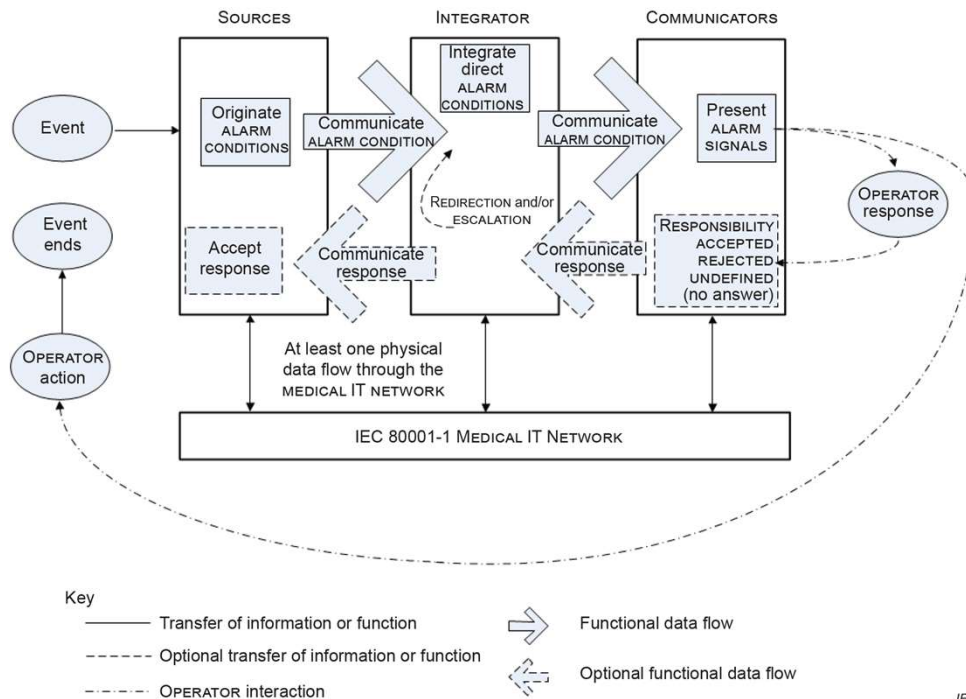
CONDITIONS is intended to provide information about an ALARM CONDITION while the OPERATOR is aware of the existence of the ALARM CONDITION by an ALARM SYSTEM.

NOTE 2 A DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS is not intended for confirmed delivery of ALARM CONDITIONS.

Examples could be:

Sometimes referred to as secondary alerting devices: Hallway display of active alarms; Hallway light over room door; Caregiver worn device;

Defns. From 60601-1-8



Thus, in a network of bedside PATIENT monitors, one bedside PATIENT monitor can act as a COMMUNICATOR for ALARM CONDITIONS from a different bedside PATIENT monitor. A central station can act as a COMMUNICATOR for ALARM CONDITIONS from multiple PATIENTS. A two-way wireless communication system can act as a COMMUNICATOR for ALARM CONDITIONS to a caregiver in an area far removed from the PATIENT. All these are examples of DISTRIBUTED ALARM SYSTEMS.

EXAMPLE 1 A central station.

EXAMPLE 2 An electronic record-keeping device.

EXAMPLE 3 Remote viewing from home or office.

EXAMPLE 4 Bed-to-bed viewing of ALARM CONDITIONS (e.g. one nurse for two beds).

EXAMPLE 5 Transmission of ALARM CONDITIONS to pagers, cell phones, hand-held computers, etc.

Alert System Variants

Description	Type	Guaranteed Delivery	Operator Confirmation	Example
Aggregates alert signals for devices for a patient's <u>room</u>	DISr	No	No	Room dashboard, Remote view
	DASr	Yes	No	
	cDASr	Yes	Yes	Room proxy/cockpit
Aggregates alert signals for multiple patients	DISm	No	No	Multi-Pt. hall Dashboard
	DASm	Yes	No	Multi-Pt. View Station
	cDASm	Yes	Yes	Multi-Pt. Central Station
Aggregates and directs alert signals to responsible caregivers' <u>personal</u> devices.	DISp	No	No	Alerts to pager, Mobile viewer
	DASp	Yes	No	Guaranteed alerts to smartphone
	cDASp	Yes	Yes	Smartphone with alert ack

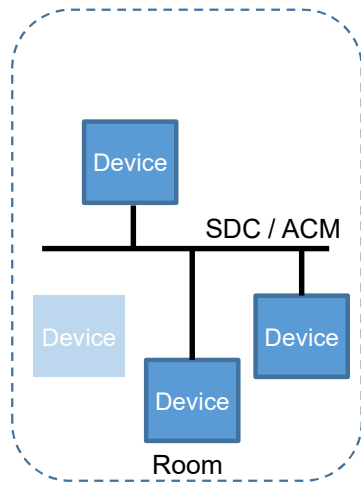
Guide to Table Columns

- Location: An example of where this type of use case may be applicable.
- Central DISm/DASm/cDASm: Centrally located system that aggregates and signals alerts for Multiple-Patients
 - Central DISm – Multi-pt. alert signaling for information only
 - Central DASm – Multi-pt. alert signaling (no alert acknowledgement) – primary alert source
 - Central cDASm – Multi-pt. alert signaling with alert acknowledgement – primary alert source
- Caregiver Location: It may be possible to change system behavior based on the location of the caregiver:
 - Unknown
 - Out of Room
 - In room: in patient room
 - At Central Station
 - In isolation area (w/o mobile)
 - Do not disturb

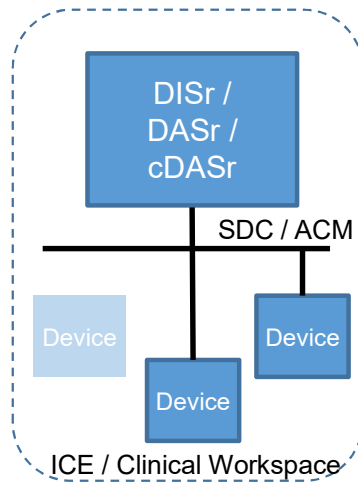
Guide to Table Columns

- Room DISr/DASr/cDASr: Room located system that aggregates and signals alerts from all networked devices associated with a patient.
 - Room DISr – Single-pt. alert signaling for information only
 - Room DASr – Single-pt. alert signaling (no alert acknowledgement) – primary alert source
 - Room cDASr – Single-pt. alert signaling with alert acknowledgement – primary alert source
- Stand-Alone (SA) / Networked (NW):
 - Stand-alone: Not connected to a network
 - ACM AR: Networked devices communicating alert information using IHE ACM
 - SDC NW: Networked devices using IEEE SDC for alert management
- Audible:
 - Paused: The alert audible signal is automatically temporarily muted in the presence of a ???
 - Device Audible: No – Under normal circumstances the individual devices do not generate audible signals
 - Room Proxy Audible: No – Under normal circumstances the room proxy does not generate audible signals
 - CS Audible: No – Under normal operation the Central Station(s) does not generate audible signals for room alerts
 - Mobile Audible: No – Under normal operation a caregiver mobile device generates audible or haptic signals for room alerts
- Quiet Room (QR) / Silent Room (SR) / Silent ICU (SI):

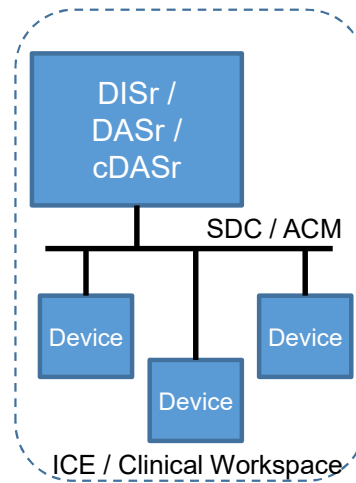
No Multi-Pt. Central Alert Aggregator



No Alert Aggregator



Some devices NW'd

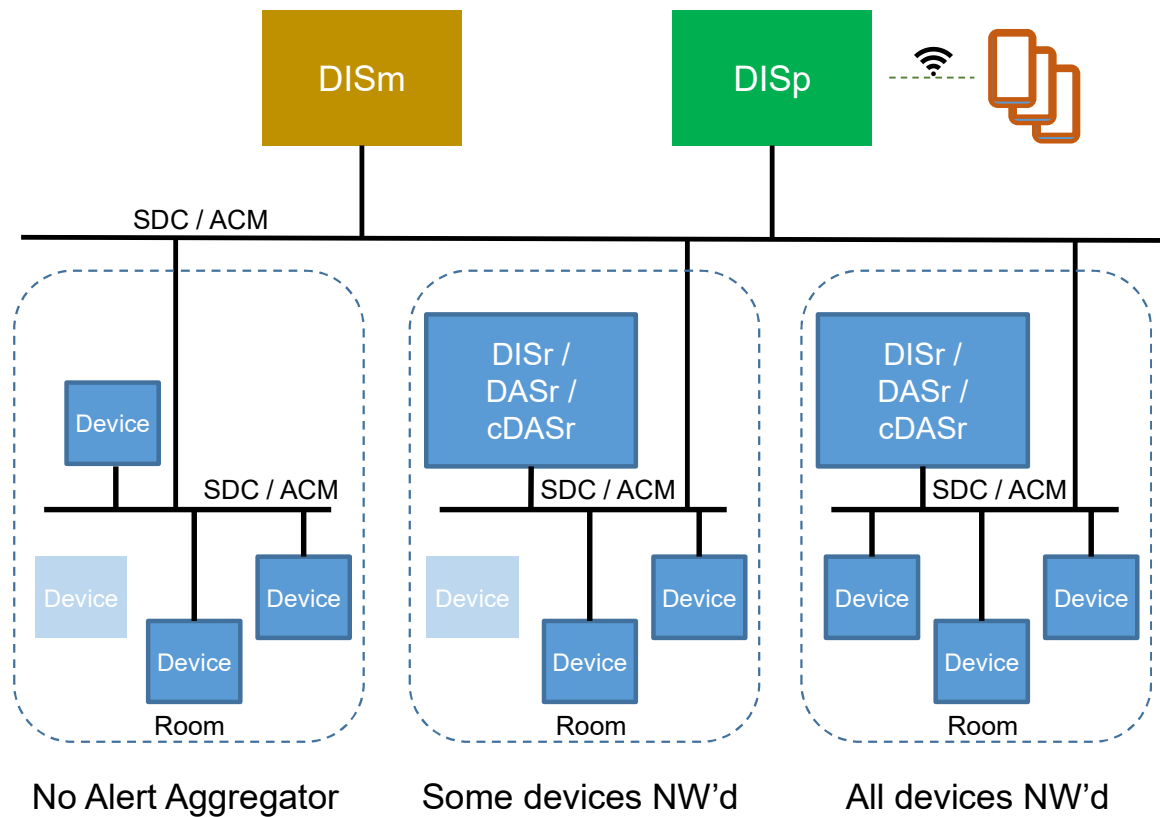


All devices NW'd

No Multi-Pt. Central Alert Aggregator

Location	Central	Caregiver Location	Room	Stand-alone / Networked	Audible				QR /SR /SI
					@Device	@Room Proxy	@CS	@Mobile	
OR	None	In room	No / DISr	SA & NW	Yes	N/A	N/A	N/A	--
				ACM AR	Yes	N/A	N/A	N/A	--
				SDC NW	Yes	N/A	N/A	N/A	--
			DASr / cDASr	SA & NW	SA -Yes NW - No	NW - Yes	N/A	N/A	--
				ACM AR	No	Yes	N/A	N/A	--
				SDC NW	No	Yes	N/A	N/A	--

Central Multi-Patient Alert Aggregator DISm and/or DISp



Central Multi-Patient Alert Aggregator

DISm

Location	Central DAS / DIS	Caregiver Location	Room DAS Proxy	Stand-alone / Networked	Audible				QR /SR /SI
					@Device	@Room Proxy	@CS	@Mobile	
MedSurg	DISm	Unknown / Out of Rm	No / DISr	SA & NW	Yes	N/A	NW - Yes	N/A	--
				ACM AR	Paused	N/A	Yes	N/A	QR
				SDC NW	Paused	N/A	Yes	N/A	QR
			DASr / cDASr	SA & NW	SA -Yes NW – No	Paused	Yes	N/A	--
				ACM AR	Paused	Paused	Yes	N/A	QR
				SDC NW	No	Paused	Yes	N/A	QR
		In room	No / DISr	SA & NW	Yes	N/A	No	N/A	--
				ACM AR	Yes	N/A	No	N/A	--
				SDC NW	Yes	N/A	No	N/A	--
			DASr / cDASr	SA & NW	SA -Yes NW – No	NW – Yes	No	N/A	--
				ACM AR	Paused	Yes	No	N/A	--
				SDC NW	No	Yes	No	N/A	--

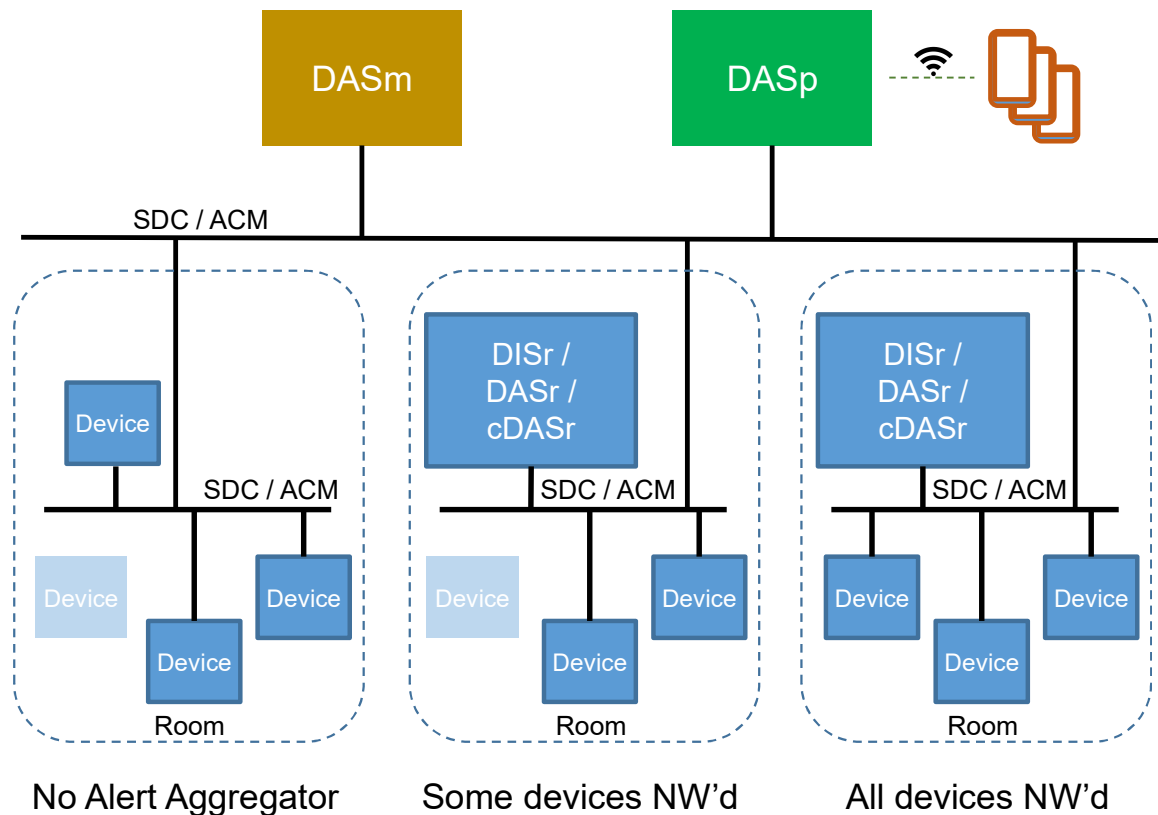
Central Multi-Patient Alert Aggregator

DISp

Location	Central DAS / DIS	Caregiver Location	Room DAS Proxy	Stand-alone / Networked	Audible				QR /SR /SI
					@Device	@Room Proxy	@CS	@Mobile	
MedSurg	DISp	Unknown / Out of Rm	No / DISr	SA & NW	Yes	N/A	N/A	NW - Yes	--
				ACM AR	Paused	N/A	N/A	Yes	QR
				SDC NW	Paused	N/A	N/A	Yes	QR
			DASr / cDASr	SA & NW	SA -Yes NW – No	Paused	N/A	Yes	--
				ACM AR	Paused	Paused	N/A	Yes	QR
				SDC NW	No	Paused	N/A	Yes	QR
		In room	No / DISr	SA & NW	Yes	N/A	N/A	No	--
				ACM AR	Yes	N/A	N/A	No	
				SDC NW	Yes	N/A	N/A	No	QR
			DASr / cDASr	SA & NW	SA -Yes NW – No	NW – Yes	N/A	No	--
				ACM AR	Paused	Yes	N/A	No	
				SDC NW	No	Yes	N/A	No	QR

Central Multi-Patient Alert Aggregator

DASm and/or DAsp



Central Multi-Patient Alert Aggregator

DASm

Location	Central DAS / DIS	Caregiver Location	Room DAS Proxy	Stand-alone / Networked	Audible				QR /SR /SI
					@Device	@Room Proxy	@CS	@Mobile	
ICU	DASm	Unknown / Out of Rm	No / DISr	SA & NW	SA -Yes NW – No	N/A	SA – No NW - Yes	N/A	--
				ACM AR	Paused	N/A	Yes	N/A	
				SDC NW	No	N/A	Yes	N/A	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	No	SA - No NW - Yes	N/A	--
				ACM AR	Paused	Paused	Yes	N/A	
				SDC NW	No - Ack	Paused?	Yes	N/A	SR
		In room	No / DISr	SA & NW	Yes	N/A	SA – No NW - Paused	N/A	--
				ACM AR	Yes	N/A	Paused	N/A	
				SDC NW	Yes	N/A	No	N/A	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	Yes	SA - No NW - Paused	N/A	--
				ACM AR	Paused	Yes	Paused	N/A	
				SDC NW	No - Ack	Yes	No	N/A	SR

Central Multi-Patient Alert Aggregator

DASp

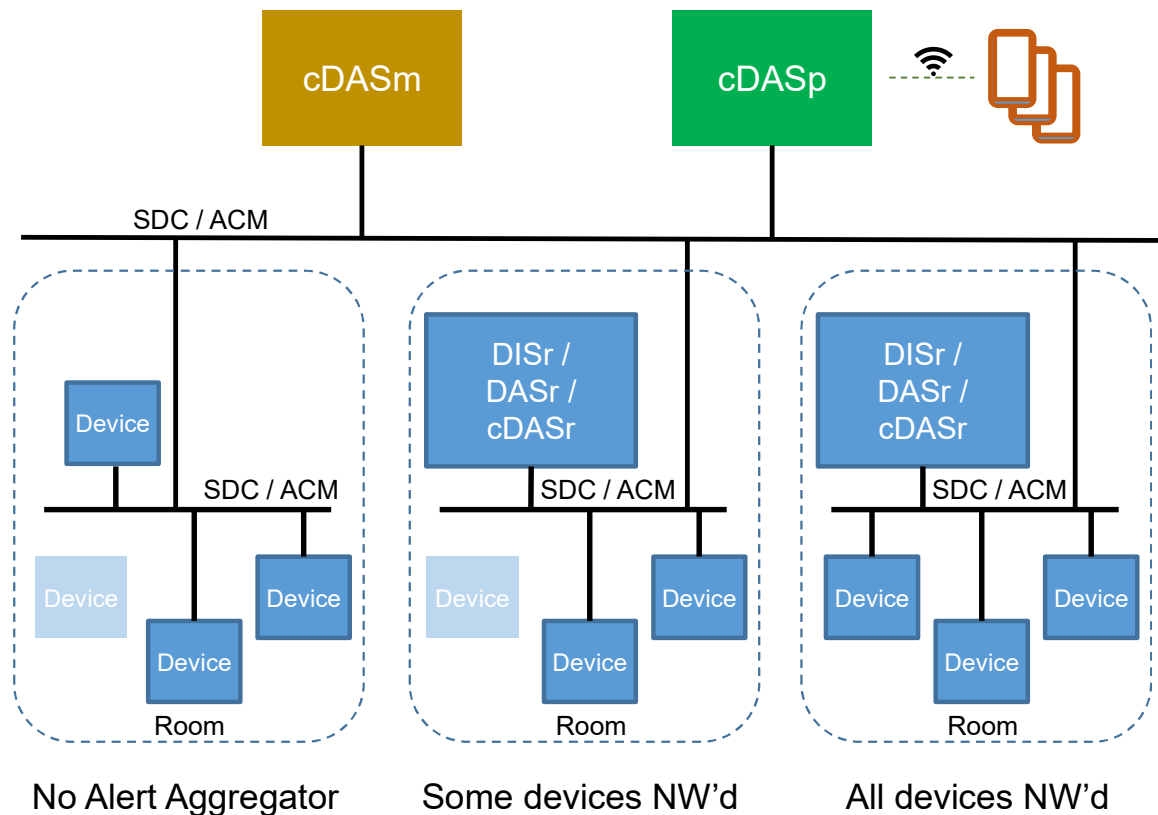
Location	Central DAS / DIS	Caregiver Location	Room DAS Proxy	Stand-alone / Networked	Audible				QR /SR /SI
					@Device	@Room Proxy	@CS	@Mobile	
ICU	DASp	Unknown / Out of Rm	No / DISr	SA & NW	SA -Yes NW – No	N/A	N/A	SA – No NW - Yes	--
				ACM AR	Paused	N/A	N/A	Yes	
				SDC NW	No	N/A	N/A	Yes	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	No	N/A	SA - No NW - Yes	--
				ACM AR	Paused	Paused	N/A	Yes	
				SDC NW	No - Ack	Paused?	N/A	Yes	SR
		In room	No / DISr	SA & NW	Yes	N/A	N/A	SA – No NW - Paused	--
				ACM AR	Yes	N/A	N/A	Paused	
				SDC NW	Yes	N/A	N/A	No	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	Yes	N/A	SA - No NW - Paused	--
				ACM AR	Paused	Yes	N/A	Paused	
				SDC NW	No - Ack	Yes	N/A	No	SR

Central Multi-Patient Alert Aggregator

DASm & DASp

Location	Central DAS / DIS	Caregiver Location	Room DAS Proxy	Stand-alone / Networked	Audible				QR /SR /SI
					@Device	@Room Proxy	@CS	@Mobile	
ICU	DASm & DASp	Unknown / Out of Rm	No / DISr	SA & NW	SA -Yes NW – No	N/A	SA – No NW - Yes	SA – No NW - Yes	--
				ACM AR	Paused	N/A	Yes	Yes	
				SDC NW	No	N/A	Yes	Yes	SR
				SA & NW	SA -Yes NW – No	No	SA - No NW - Yes	SA - No NW - Yes	--
		In room	DASr / cDASr	ACM AR	Paused	Paused	Yes	Yes	
				SDC NW	Paused?	Paused?	Yes	Yes	SR
			No / DISr	SA & NW	Yes	N/A	SA – No NW - Paused	SA – No NW - Paused	--
				ACM AR	Yes	N/A	Paused	Paused	
			DASr / cDASr	SDC NW	Yes	N/A	No	No	SR
				SA & NW	SA -Yes NW – No	Yes	SA - No NW - Paused	SA - No NW - Paused	--
				ACM AR	Paused	Yes	Paused	Paused	
				SDC NW	No - Ack	Paused?	No	No	SR

Central Multi-Patient Alert Aggregator cDASm and/or cDASp



Central Multi-Patient Alert Aggregator

cDASm

Location	Central DAS / DIS	Caregiver Location	Room DAS Proxy	Stand-alone / Networked	Audible				QR /SR /SI
					@Device	@Room Proxy	@CS	@Mobile	
ICU	cDASm	Unknown / Out of Rm	No / DISr	SA & NW	SA -Yes NW – No	N/A	SA – No NW - Yes	N/A	--
				ACM AR	Paused	N/A	Yes	N/A	
				SDC NW	No	N/A	Yes	N/A	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	N/A	SA - No NW - Yes	N/A	--
				ACM AR	Paused	Paused	Yes	N/A	
				SDC NW	No - Ack	No - Ack	Yes	N/A	SR
		In room	No / DISr	SA & NW	Yes	N/A	SA – No NW - Paused	N/A	--
				ACM AR	Yes	N/A	Paused	N/A	
				SDC NW	Yes	N/A	No	N/A	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	Yes	SA - No NW - Paused	N/A	--
				ACM AR	Paused	Yes	Paused	N/A	
				SDC NW	No - Ack	Yes	No	N/A	SR

Central Multi-Patient Alert Aggregator

cDASp

Location	Central DAS / DIS	Caregiver Location	Room DAS Proxy	Stand-alone / Networked	Audible				QR /SR /SI
					@Device	@Room Proxy	@CS	@Mobile	
ICU	cDASp	Unknown / Out of Rm	No / DISr	SA & NW	SA -Yes NW – No	N/A	N/A	SA – No NW – Yes	--
				ACM AR	Paused	N/A	N/A	Yes	
				SDC NW	No	N/A	N/A	Yes	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	N/A	N/A	SA - No NW - Yes	--
				ACM AR	Paused	Paused	N/A	Yes	
				SDC NW	No - Ack	No - Ack	N/A	Yes	SR
		In room	No / DISr	SA & NW	Yes	N/A	N/A	SA – No NW - Paused	--
				ACM AR	Yes	N/A	N/A	Paused	
				SDC NW	Yes	N/A	N/A	No	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	Yes	N/A	SA - No NW - Paused	--
				ACM AR	Paused	Yes	N/A	Paused	
				SDC NW	No - Ack	Yes	N/A	No	SR

Central Multi-Patient Alert Aggregator

cDASm & cDASp

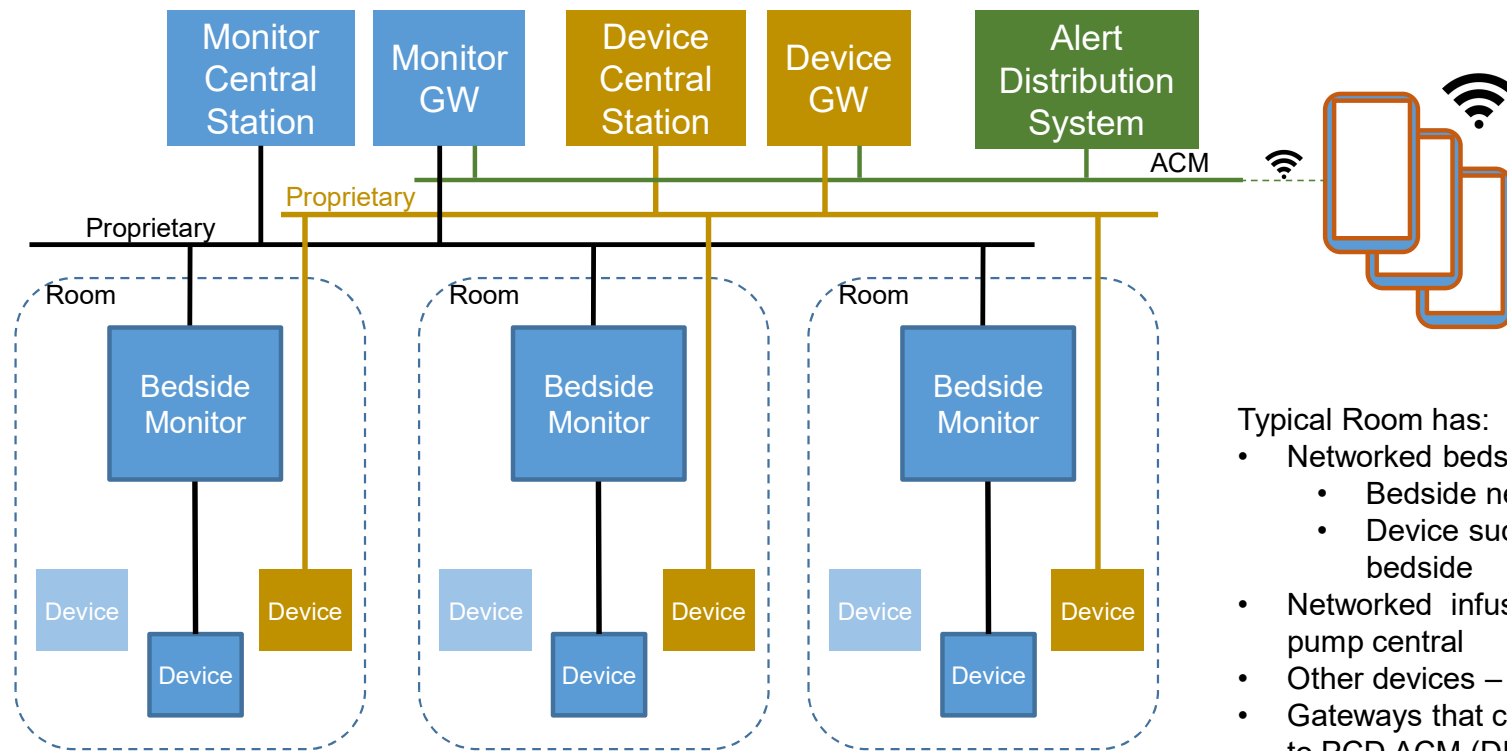
Location	Central DAS / DIS	Caregiver Location	Room DAS Proxy	Stand-alone / Networked	Audible				QR /SR /SI
					@Device	@Room Proxy	@CS	@Mobile	
ICU	cDASm & cDASp	Unknown / Out of Rm	No / DISr	SA & NW	SA -Yes NW – No	N/A	SA – No NW – Yes	SA – No NW – Yes	--
				ACM AR	Paused	N/A	Yes	Yes	
				SDC NW	No	N/A	Yes	Yes	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	N/A	SA - No NW - Yes	SA - No NW - Yes	--
				ACM AR	Paused	Paused	Yes	Yes	
				SDC NW	No - Ack	No - Ack	Yes	Yes	SR
		In room	No / DISr	SA & NW	Yes	N/A	SA – No NW - Paused	SA – No NW - Paused	--
				ACM AR	Yes	N/A	Paused	Paused	
				SDC NW	Yes	N/A	No	No	SR
			DASr / cDASr	SA & NW	SA -Yes NW – No	Yes	SA - No NW - Paused	SA - No NW - Paused	--
				ACM AR	Paused	Yes	Paused	Paused	
				SDC NW	No - Ack	Yes	No	No	SR





Typical Alert Distribution System network topology today

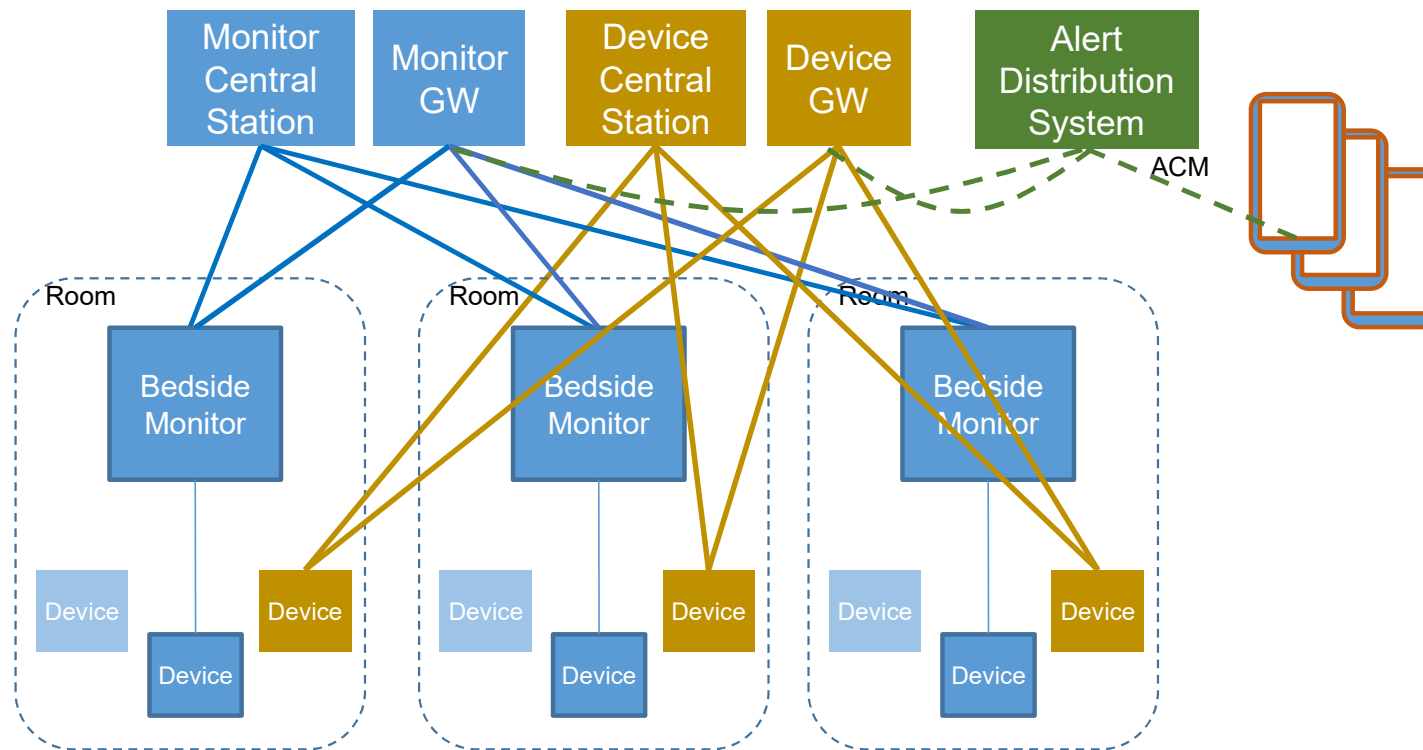
Current 2020 - Typical Network Architecture



Typical Room has:

- Networked bedside
 - Bedside networked to Central Cockpit
 - Device such as vent connected to bedside
- Networked infusion pumps connected to pump central
- Other devices – standalone (not networked)
- Gateways that convert proprietary protocols to PCD ACM (DEC, etc.)

Current 2020 - Typical Communication Paths





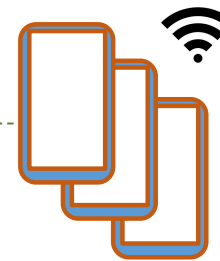
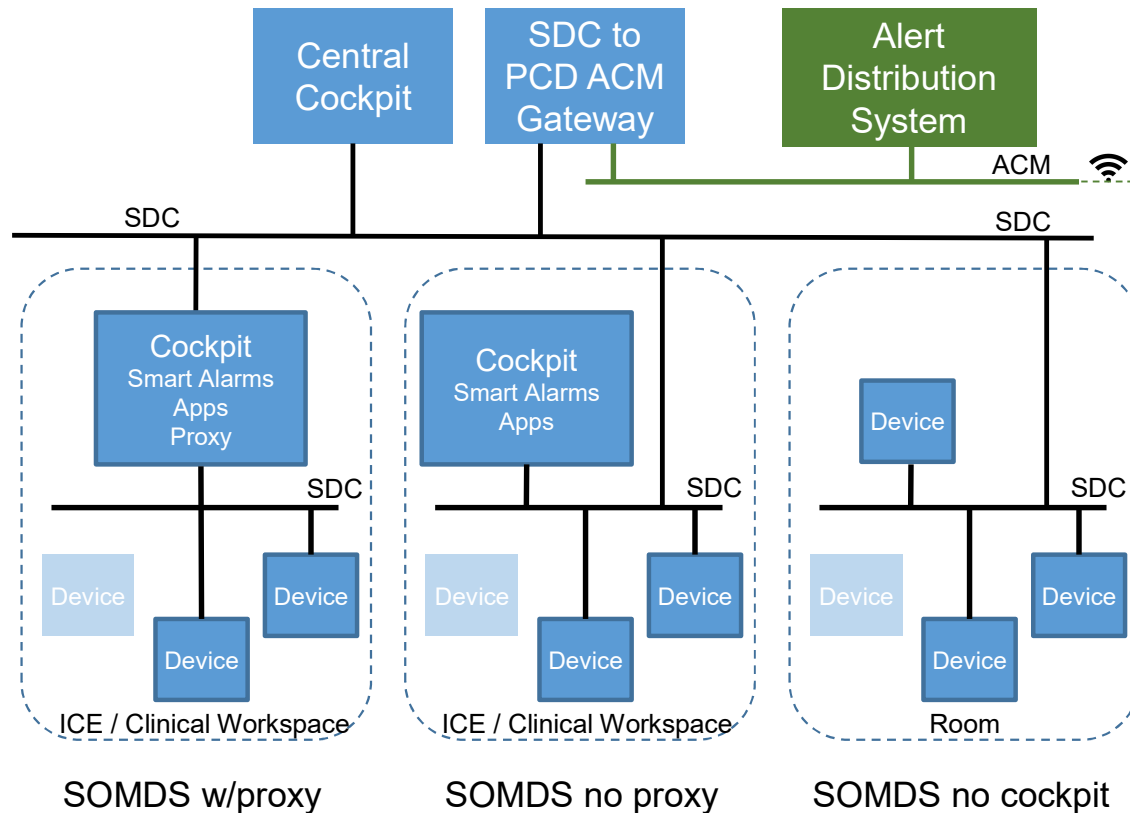
Step a:

SDPi implementation for Quiet Hospital

Mix of stand-alone and SDC devices – Partial QH

Target 202a?

- SDPi **Quiet** Hospital Network Architecture



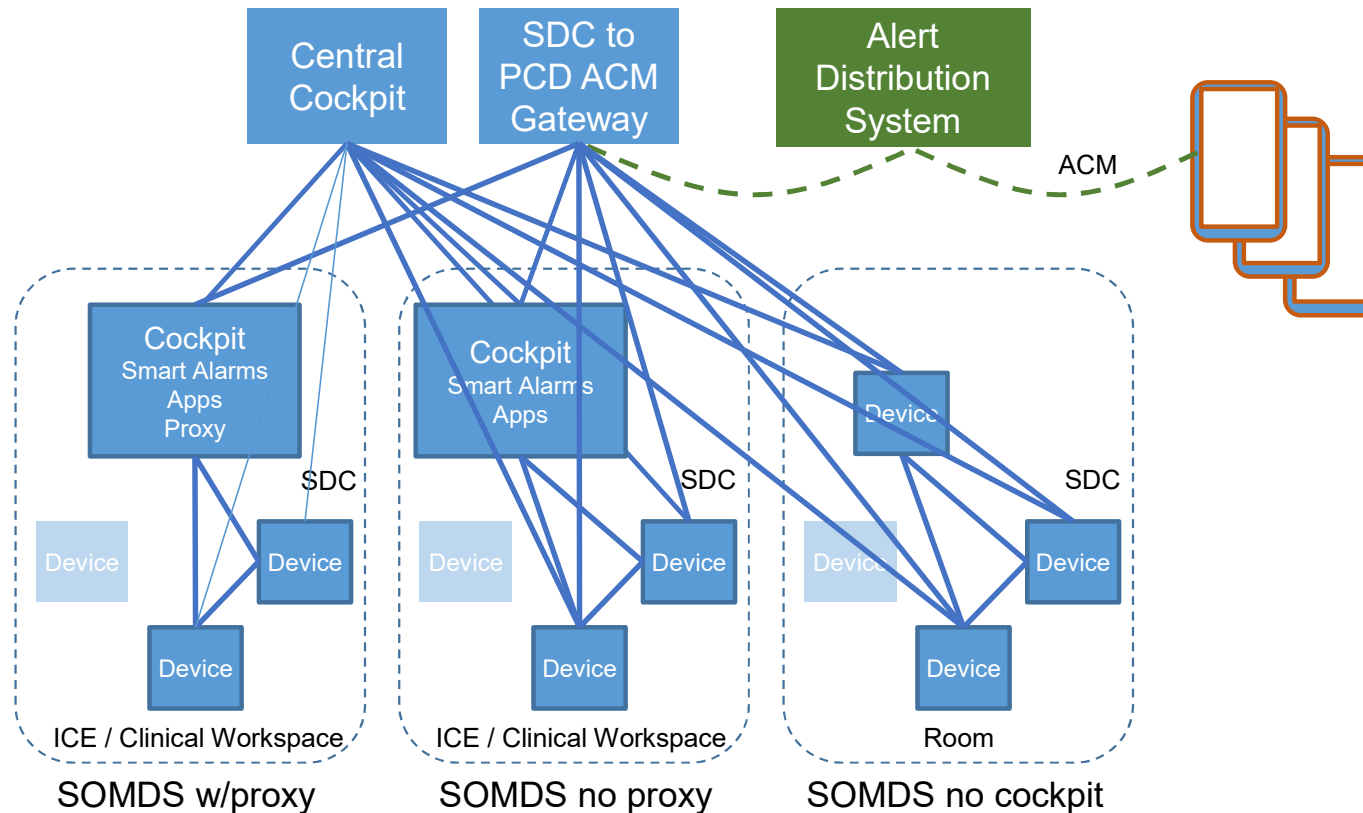
Assumes devices in room are connected via SDC or are standalone

- Quiet Hospital concept achieved with connected devices.

Nurse devices can receive and acknowledge alerts via the Alert Distribution System

Target 202a?

- SDPi **Quiet** Hospital Network Architecture

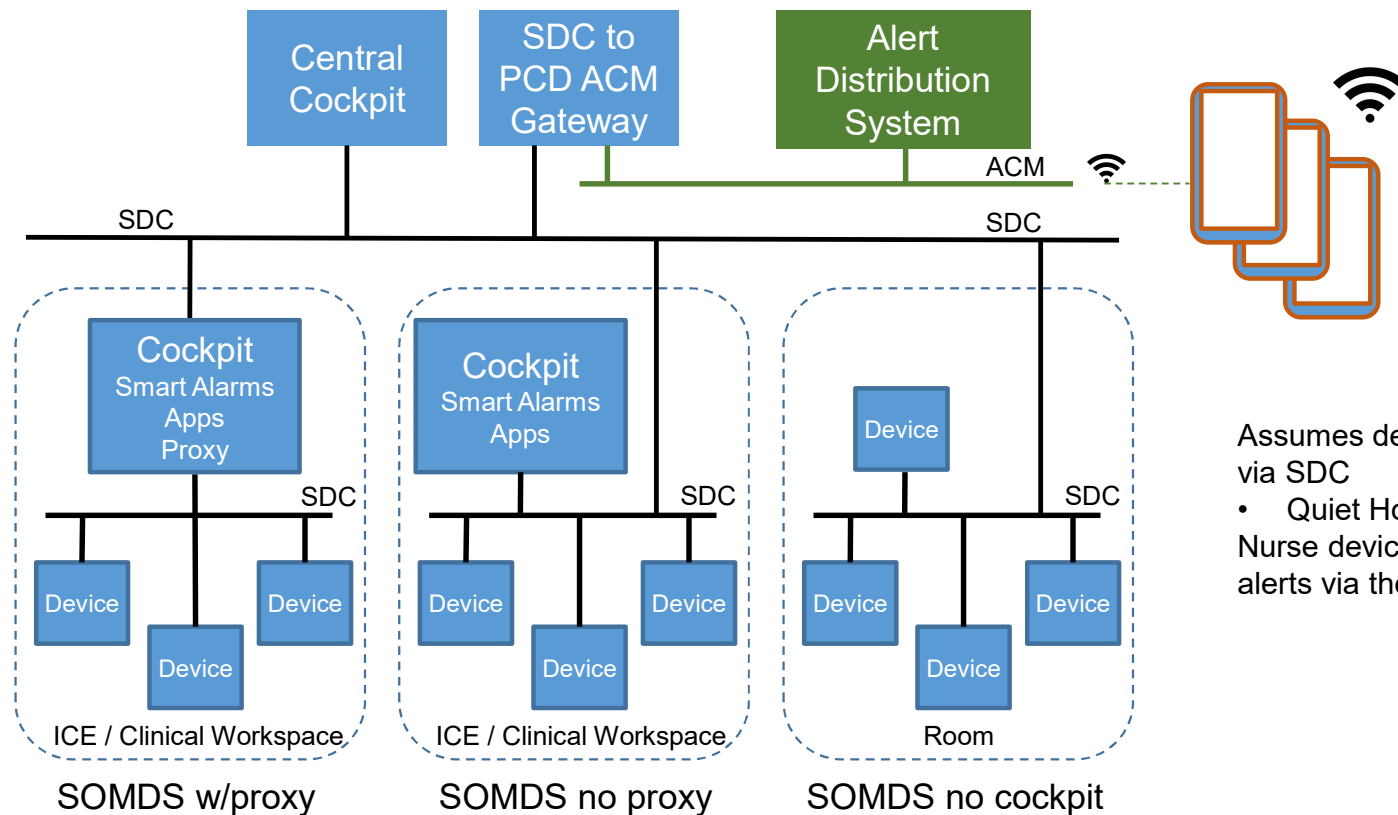




Step b:
SDPi implementation for Quiet Hospital
Only SDC devices – full QH

Target 202b?

- SDPi **Quiet** Hospital Network Architecture

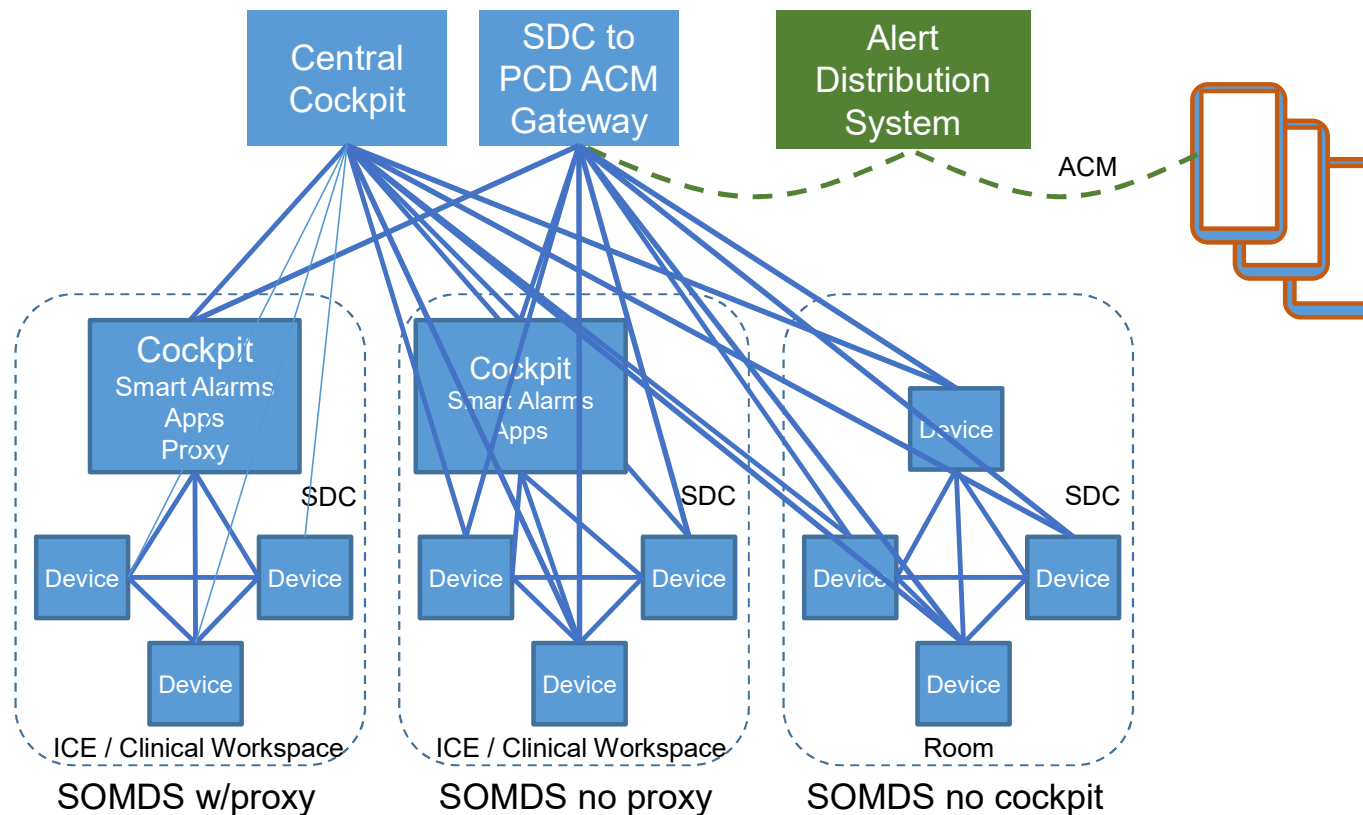


Assumes devices in room are all connected via SDC

- Quiet Hospital concept achieved
- Nurse devices can receive and acknowledge alerts via the Alert Distribution System

Target 202b?

- SDPi **Quiet** Hospital Network Architecture





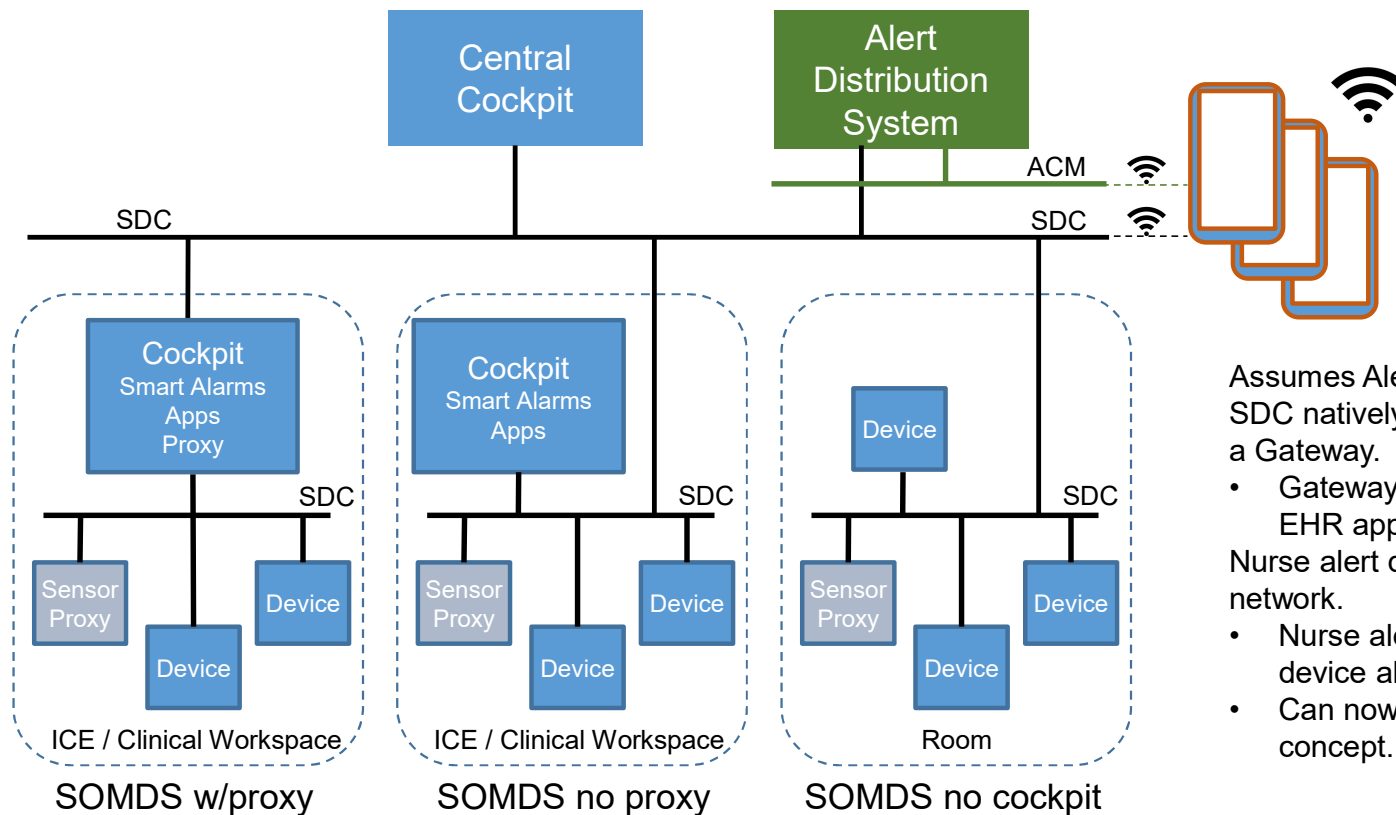
Step c:

SDPi implementation for Silent Hospital

Nurse devices can control bedside SDC devices

Target 202c?

- SDPi **Silent** Hospital Network Architecture



Assumes Alert Distribution System can talk SDC natively, thereby eliminating the need to a Gateway.

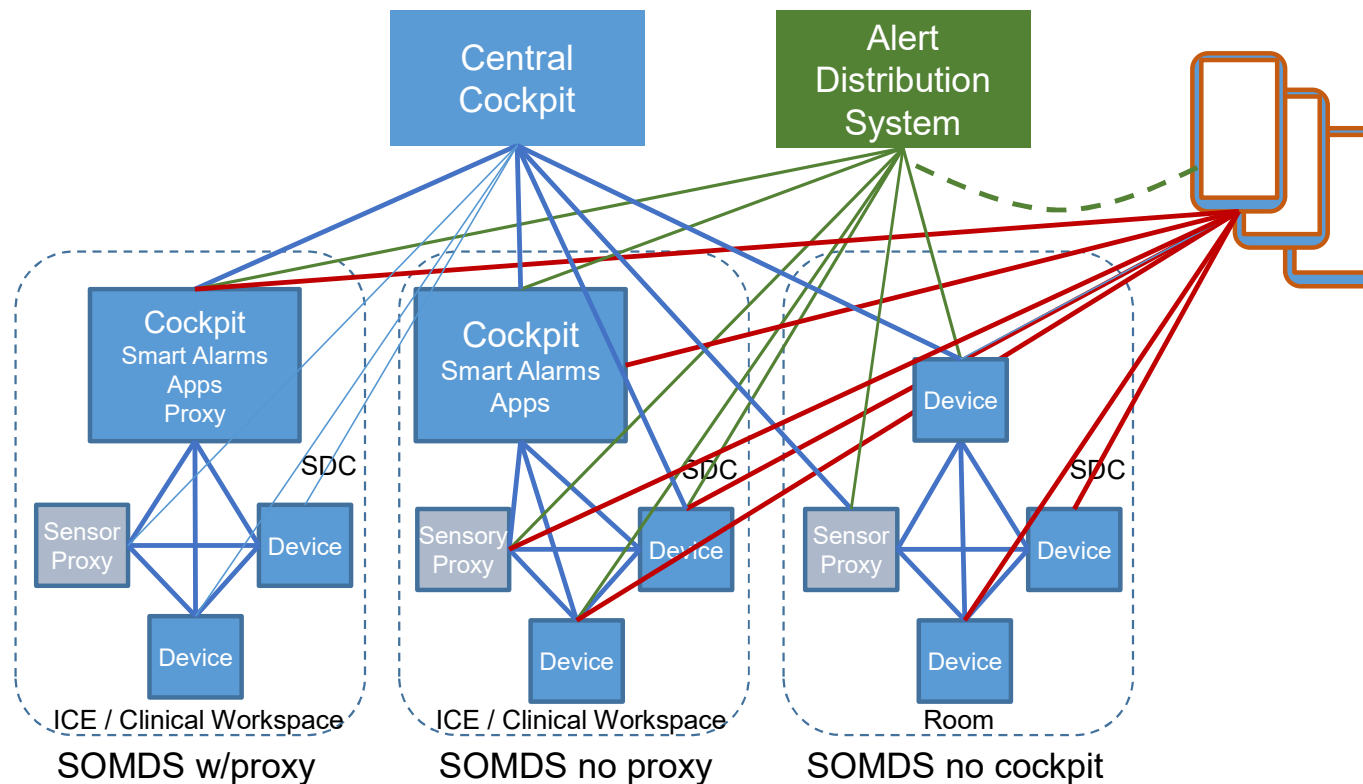
- Gateway may still be required for Device to EHR applications.

Nurse alert devices connect directly to SDC network.

- Nurse alert devices can fully manage device alerts and exposed settings.
- Can now fully support Silent Hospital concept.

Target 202c?

- SDPi **Silent** Hospital Communication Paths



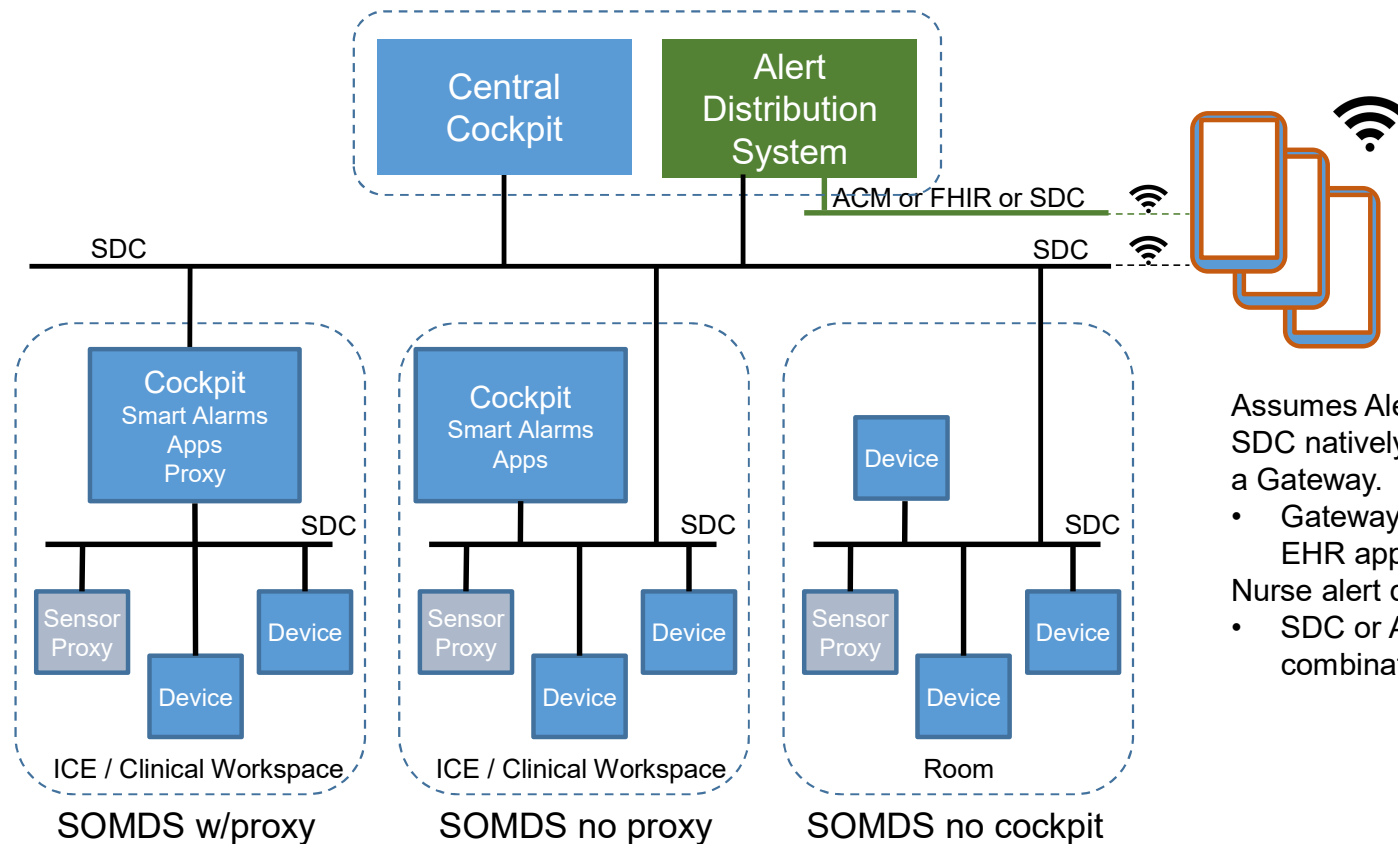
Not all communication paths drawn



Step d:
SDPi implementation for Silent Hospital
SDC replaces ACM

Target 202d?

- SDPi **Silent** Hospital Network Architecture



Assumes Alert Distribution System can talk SDC natively, thereby eliminating the need to a Gateway.

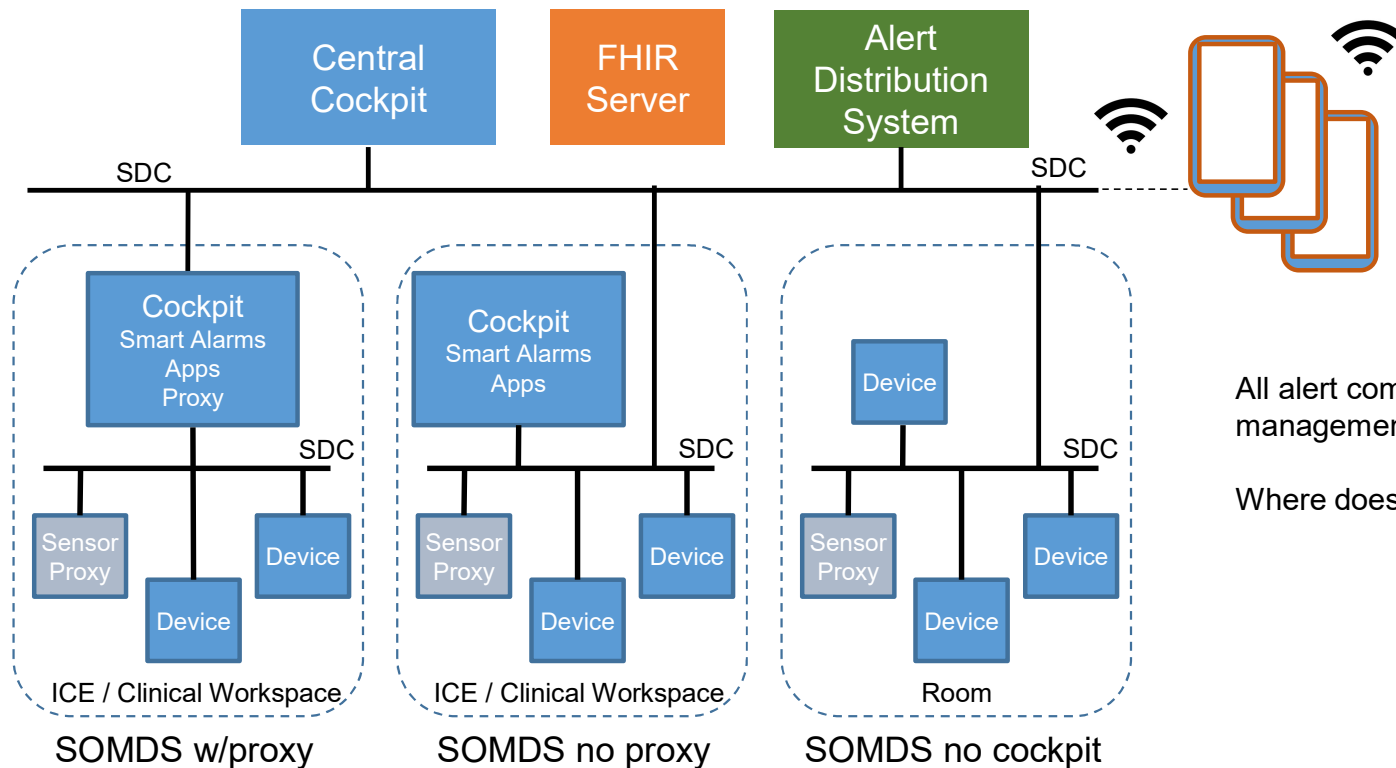
- Gateway may still be required for Device to EHR applications.

Nurse alert devices connect via:

- SDC or ACM (v2) or FHIR or some combination thereof...

Target 202e?

- SDPi **Silent** Hospital Network Architecture

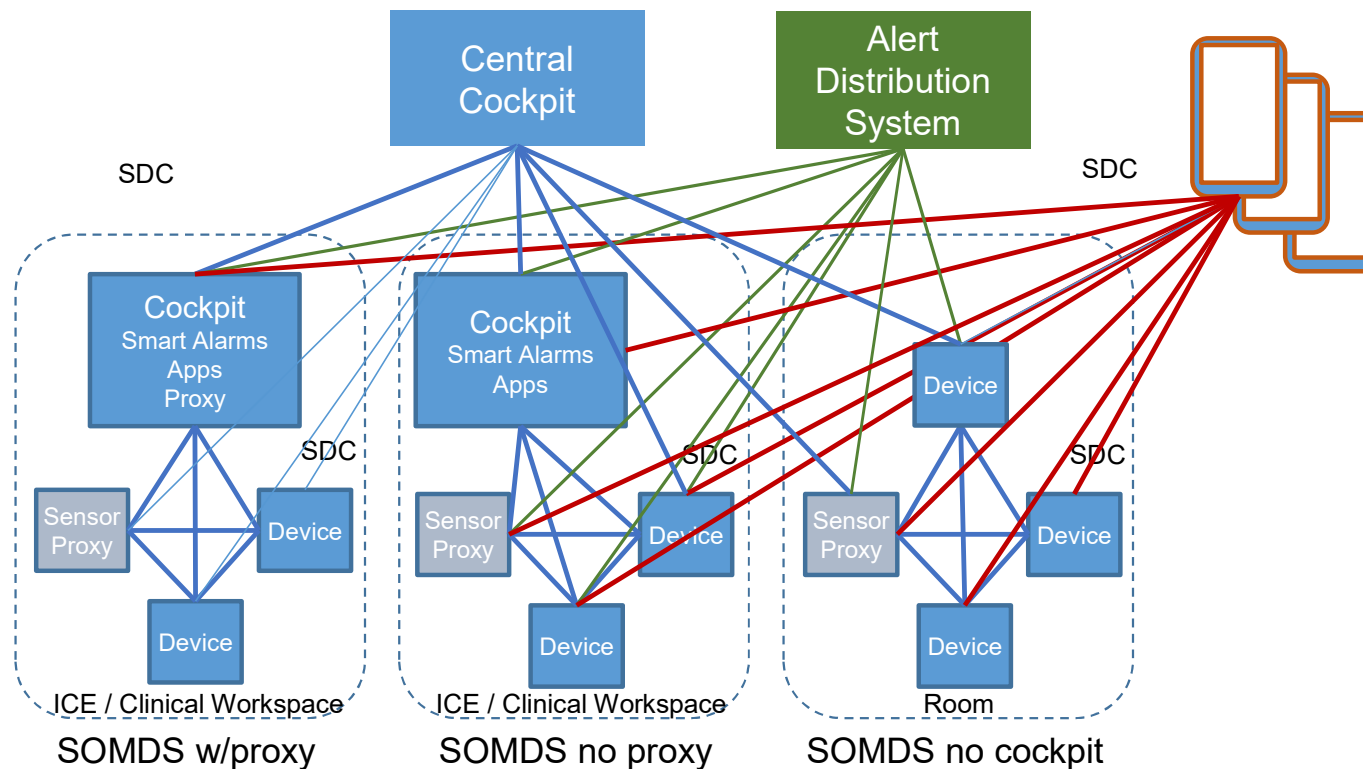


All alert communication and related management is via SDC.

Where does FHIR fit in?

Target 202d?

- SDPi **Silent** Hospital Communication Paths



Not all communication paths drawn