



# DataLogger

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# Data Logger in MDIRA-Compliant System

- Stores all system and patient data during a care encounter for later download to an information system
- Record in real time the information sent and received between MDIRA-compliant components and the Supervisor subsystem
- Record user actions on the system and its components as made available by the Supervisor and the system components through their network interface
- The data log will allow a user to review prior system and clinical events associated with the care of a patient and support the post-care, root-cause analysis of system, treatment protocol, or patient safety issues.



## ■ 3.1.7 Forensics Data Logging

- Provide a data log for capturing a detailed record of system and patient events, data collected, and data generated during use of the platform. The data log should support root-cause analysis of component and system failures, patient safety incidents, care quality and best practice improvements, and advanced medical research.
- A MDIRA-compliant system should monitor network communications between components (e.g., devices or applications). Components are responsible for determining whether the fidelity and integrity levels of data received from the rest of the system are suitable for them to operate according to their specifications. The system supervisory subsystem and components all have a particular role:
  - The Supervisor subsystem monitors the networking communications availability, fidelity, and integrity and resolves fidelity and integrity conflicts between components.
  - Components provide signal integrity of sensor and actuator communication, monitor the fidelity and integrity of consumed data, and report sensor and actuator data integrity and fidelity issues.

# Data Logger in MDIRA-Compliant System

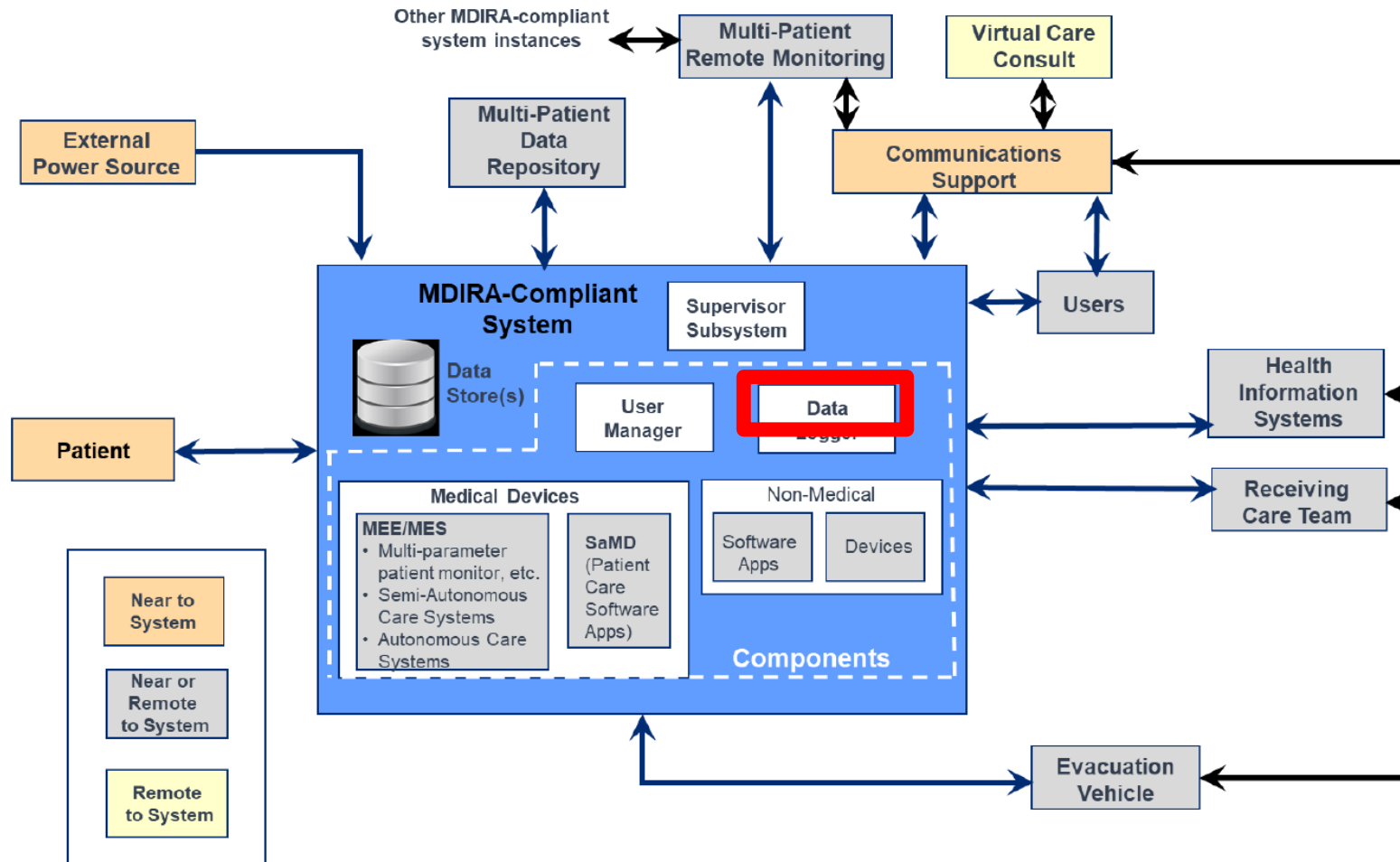


Figure 4-2 Functional Elements of a MDIRA-Compliant System

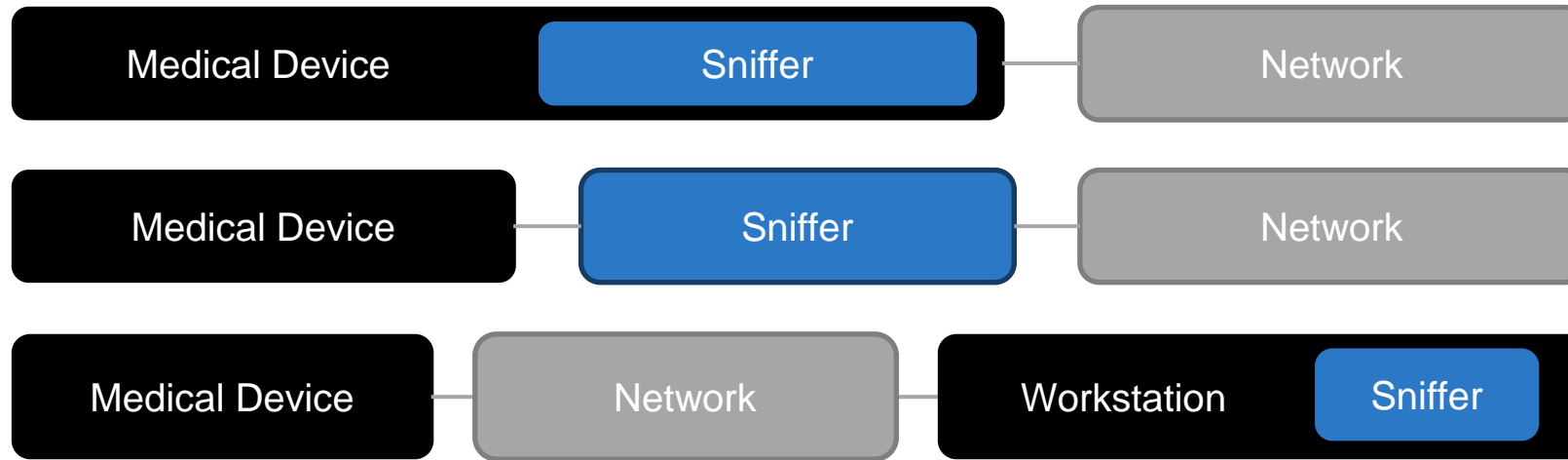
# Logging Requirements: Supervisor

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- **Supervisor** Requirements: System Monitoring and Fault Recovery
  - Record System Status and Fault Recovery Information
- **(MR-046)** The Supervisor **SHALL** record time-correlated system health and operating status data, as well as data regarding fault protocols executed, for generating system health and operating status reports.
- Such reports could be in the form of dashboards showing the system's health and operating status trends during a patient care episode. The specifics of the reports would depend on the operational requirements of the MDIRA-compliant system. The Data Logger (see Section 5.5) will log similar data for detailed forensics reconstruction of system health and operating status changes after a patient care episode is completed.
- A Supervisor receives health/operating/patient/device data from the system components

# Discussion mediTEC

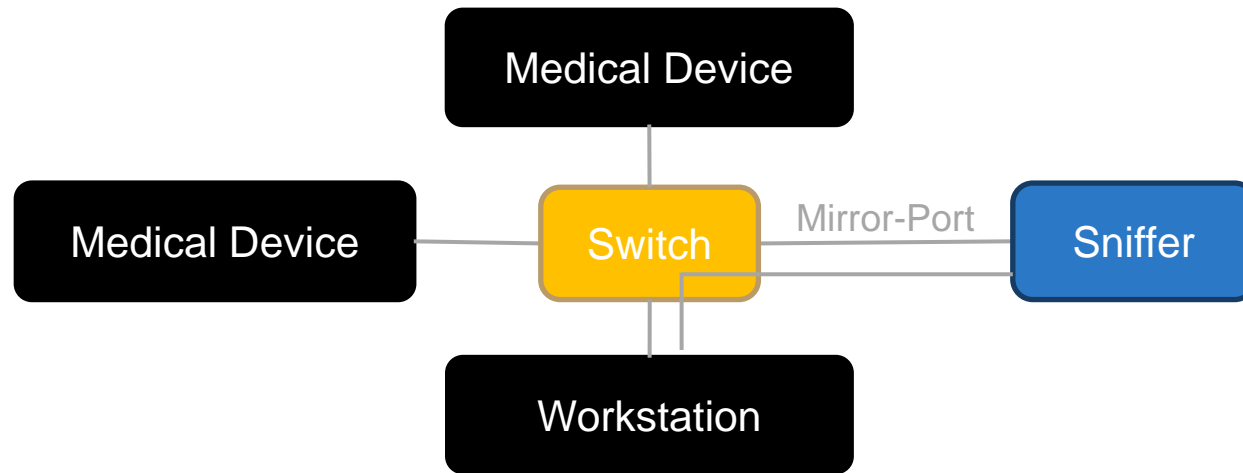
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# Result

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