Use case #1: Domestic Medical Device

System definition

The Ankle Monitor Predictor of Stroke (AMPS)[1][3]

AMPS is a fictional home use medical device worn at night (or when resting) by patients considered at risk for a stroke. The AMPS system gathers medical readings that can be later analyzed by a medical professional. While the system can help predict a patient's risk of experiencing a stroke, it does not alert – and is not intended to alert – if a stroke is imminent or occurring

- *Period of expected use: One to three months*
- *Medical capability: Diagnostic only*
- *Device invasiveness: Low (easily removable, like a wristwatch)*

Scenario

Alice has been informed by her doctor, based on her family history and several other risk factors, that she is at increased risk of experiencing a stroke. To gain further insight and determine a treatment plan, her doctor has instructed her to take the **AMPS system** home and wear it when she sleeps to take readings. She is also directed to install a **companion app on her phone** that will connect to the AMPS system (via Bluetooth Low Energy) and upload the readings every day to **the AMPS cloud service**, where they will be analyzed by an automated algorithm. Alice's doctor will check the results after the first week to identify any immediate causes of concern, and they will schedule a follow-up consult in two months

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AMPS Device

AMPS is a health monitoring system worn on a patient's ankle when they are resting. It has the following specifications and capabilities:

- On/off switch
- Physical Bluetooth pairing button
- Proprietary stroke-predicting sensor.
- Heart rate monitor
- Body temperature sensor
- Bluetooth Low Energy (BLE) connectivity
- Onboard computer and flash storage that can store up to two weeks of patient data for later transmission

AMPS Cloud Service

The AMPSCS is a collection of virtual machines hosted in a cloud infrastructure. It consists of the following functionality:

- An application gateway server to inspect and limit traffic going into the AMPSCS systems
- A set of backend services that perform analysis of the patient data
- A collection of patient-facing services that communicate with the patient app, provide a web portal for patients to register their AMPS device, and authorize clinicians to view their data
- A collection of health delivery organization (HDO)-facing services that provide a web portal for clinicians to create an account and access a patient's data
    - Clinicians' access to the portal using a web browser.
    - Authentication is provided via username and password.
    - Clinician service identifiers that clinicians can provide to patients so the patients can authorize them through the app.
    - The clinicians can view a summary of the patient's raw data and the analysis performed by the AMPSCS backend algorithms.
    - The ability for clinicians to download a patient's data via an encrypted zip file.

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AMPS Patient App

There are two different versions of the patient app, one for Apple iOS, and another for Android devices. Both apps contain the following functionality:

- It can pair with the AMPS device via Bluetooth.
- It contains an interface for a patient to create an account with the AMPS cloud services, register an AMPS device, and authorize clinicians to view their data.
- If the patient gives permission to the app, it will automatically connect to the AMPS device once a day and upload readings to the AMPSCS. If the patient does not give it permission, the app will store the data retrieved from the AMPS device until a manual upload is initiated. The amount of data transferred per upload is typically less than 1 megabyte a day.
- The app will display status information to the patient, including the last time the app synced with the AMPSCS, a log of the days the app was able to pull data from the AMPS device, and a log listing if the AMPS device was successfully collecting data.
- There is a device management screen that primarily focuses on diagnosing Bluetooth connection problems, and common issues that may prevent the AMPS device from collecting data. In addition:
  - The app can wipe patient data from the AMPS device.
  - The app can check for and update the firmware of the AMPS device with new versions.
  - The app can revert the AMPS device to factory default settings.
- If the device does not successfully sync to the cloud services once every 24 hours, an in-app notice will appear directing the patient to sync their data. After 72 hours have elapsed since a successful sync, the patient will be emailed an automatic reminder. [13]

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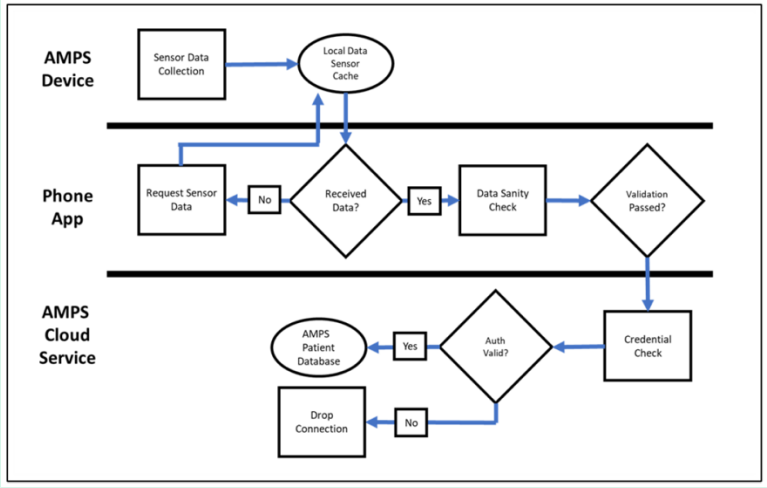
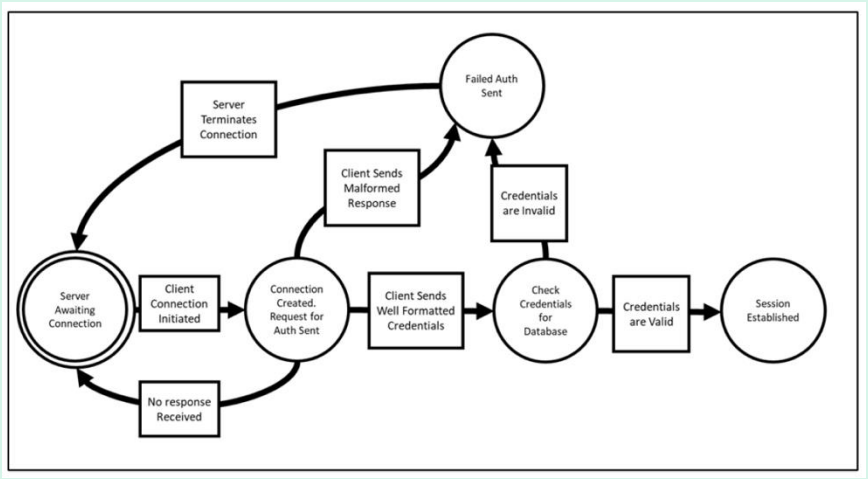
Supporting information



[13]



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Exercice 1 – Data Flow Diagram

Draw the data flow diagram from Domestic Medical Device defined on previous slides, incl. system parts, communication flows and trust boundaries