Hello MassMedic!

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Today's topics

Considerations when implementing a Home Medical Device

Being user-centered in your development approach

Achieving Human Factors Engineering success

System Architecture and Home Connectivity

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Bringing Medical Devices into the Home

There's a tension between business model, technology and user needs.

These need to be balanced to ensure successful adoption of a Home use device.

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Successful Project Development

Reduce development project risk

MVP

Balancing: Quality Cost Schedule.

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Product Roadmap: Design the system well for rapid time to market and still support growth

Market /User Requirements document

Include both MVP and future requirements

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Product Roadmap

Consider starting with the Minimum Viable Product

Be ruthless when minimizing

Resist the temptation to expand MVP features

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Product Roadmap

Architect the MVP for expandability and future features

Include the happy path

Included needed not so happy paths: errors, invalid inputs

Include hooks for the not so happy paths: nice to have features, service, manufacturability

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Stakeholder balance

Balance the different stakeholders needs & wants

The User wants:
- Value from their time using the device
- Easy to set up and use
- Private

The Physician wants
- Actionable information.
- Not a flood of data.
- Improved outcomes

Company wants
- Build a business infrastructure
- Data for Improved algorithms
- Control of payment mechanisms and usage
- Ability to service and diagnose

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Stakeholder balance

Stakeholder Desires, Ease of use, safety, privacy, perceived benefits can be at odds to each other

Examples:
- User may not want to share medical or personal use information
- Medical device company wants abundant information for:
- Billing, ML data, device tracking and service

- Patient want to control their own usage
- Clinicians desire patient compliance

- User might not want to bother
- Hospital system wants to reduce readmission costs

- An extra step may increase device effectiveness
- But introduce safety related usability errors

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Stakeholder balance

If stakeholder balance is off, it can negatively affect market acceptance of the product

It can also overreach on development:
- Less User acceptance
- Higher costs
- Longer schedules
- Unnecessary regulatory burden

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Adjust plan to meet business objectives

Balance your stakeholders needs

Requirements to reflect the right product

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We want to deliver healthcare at home, so now what?

We are starting your project today but are feeling pressure to deliver your technology to the market yesterday…

Instinctively, we get the problem, right?

Let's cut to the chase and start developing

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You don't know what you don't know

We may know the disease/health condition

We may understand the technology

We are changing the environment where healthcare is delivered

We are also working with less skilled users

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You aren't your user, and you don't think like they do

Users and patients aren't a single monolithic group

We all have blind spots about their experience

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To succeed, you need to meet users where they are

You've learned about your users.

You've learned about where they live.

So, how are you going to act on it?

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For patients: Behavior change drives adoption

How will your device support your patients or their caregivers?

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For clinicians:
How does your device support them?

Raw data is a burden, insights with backing data is valuable

Clinicians want to focus on relating to the patient and treating them. They didn't get into medicine to become a data scientist

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How are you integrating into the clinician's existing workflow

Integrating into their current tool set is critical.

Changing enterprise systems is not usually within an HCP's sphere of influence.

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Medical ≠ a lifestyle brand

What can we learn from consumer products?

What should we leave behind?

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Consumer products: Success = keeping the user's attention for longer lengths of time

Successful plays in the commercial space like gamification and stickiness aren't 1:1 translations for medical devices

Like consumer products, your device is going into a home or in a pocket…

How are you going to address the intimate position you will occupy in your user's life?

You have been invited into their home, is your device a polite guest or is it going to take over?

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"Bring it home" with a solid Human Factors validation strategy

Meeting the FDA's expectations for Human Factors Engineering can seem daunting or unpredictable.

There are a couple of key approaches that help

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The Human Factors Engineering Validation in a successful FDA submission is easier when its collaborative

Integrate Human Factors Engineering early in your project

Have a well articulated Human Factors Engineering strategy for your product so your team can focus on the areas that matter

Pre-subs with the FDA are a powerful tool and aren't always used well

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Home Connected Device

Architecture Choices

UI Platforms

Connection mechanisms

Servers

Enterprise System

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Living in a dynamic connectivity environment

Managing change :

Cybersecurity management

Cell phone, tablets and PC compatibility
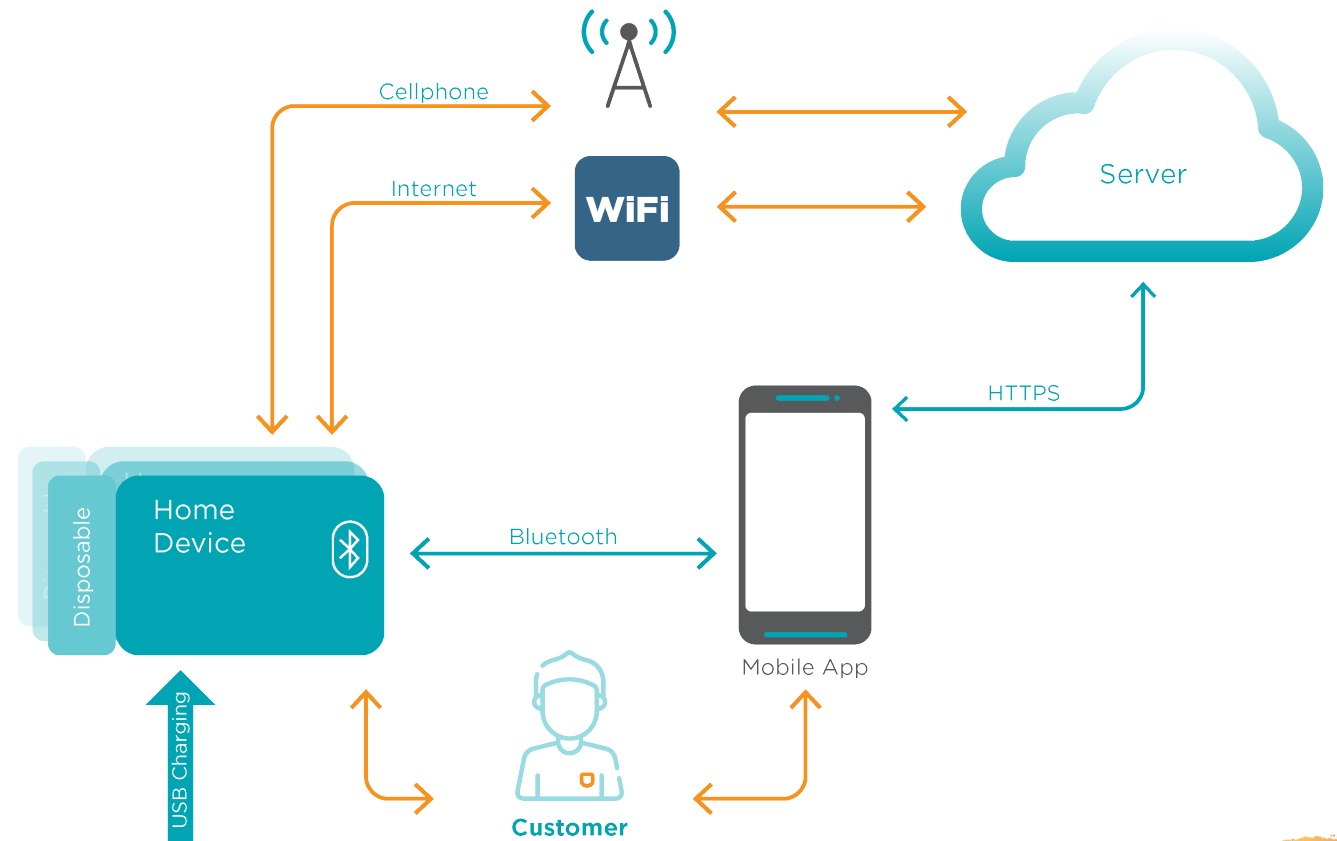
Wireless infrastructure

Software updates

Open source software - licensing and management
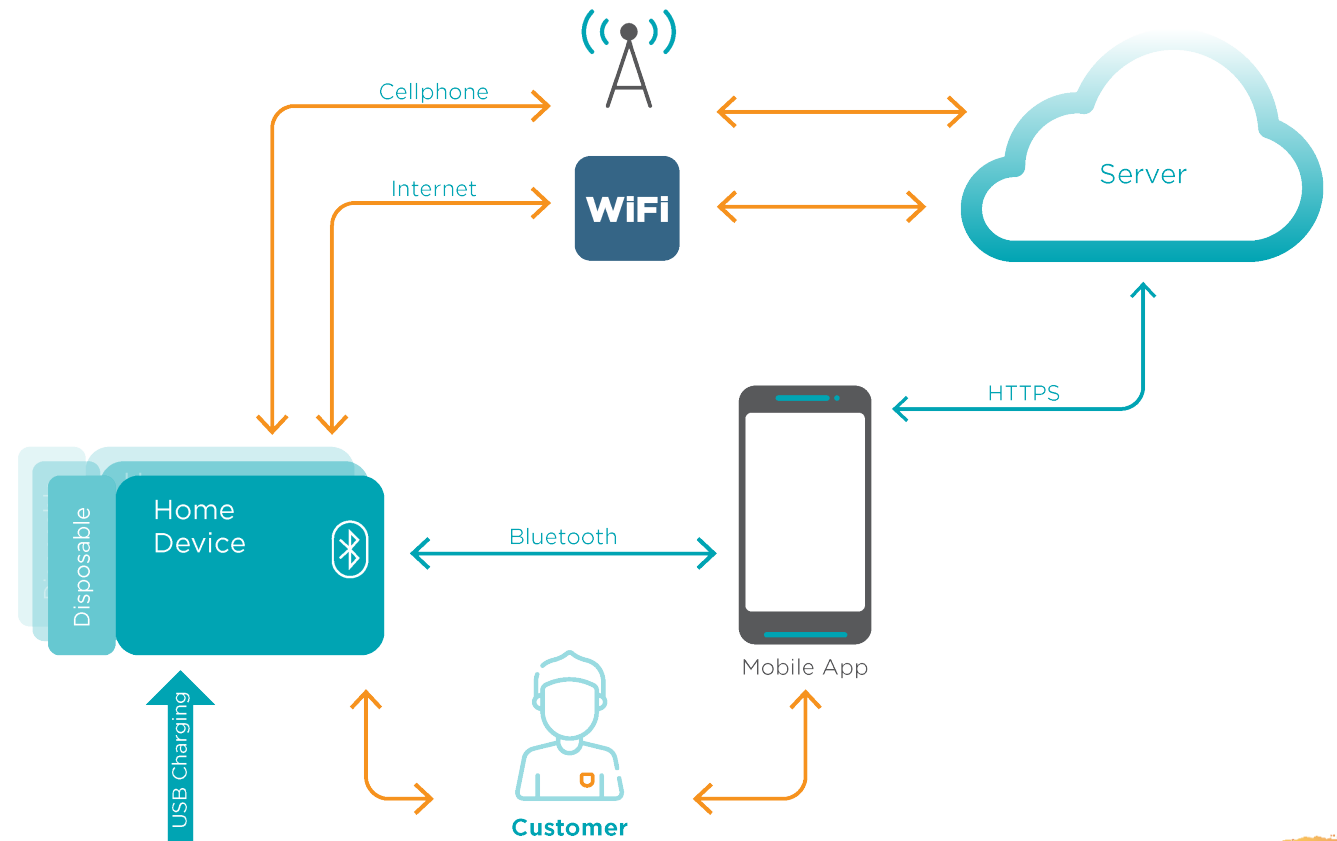
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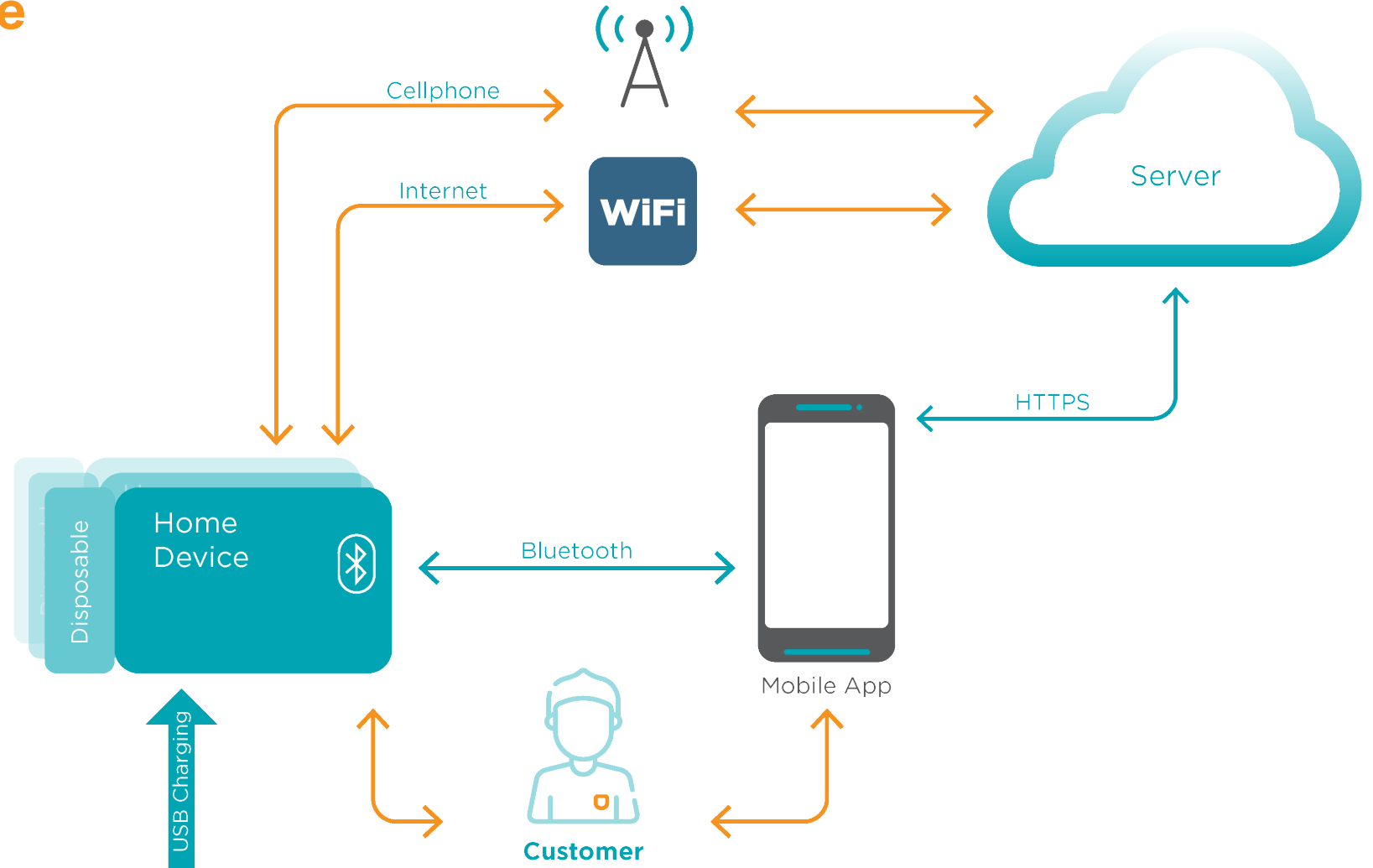
Home connectivity environment
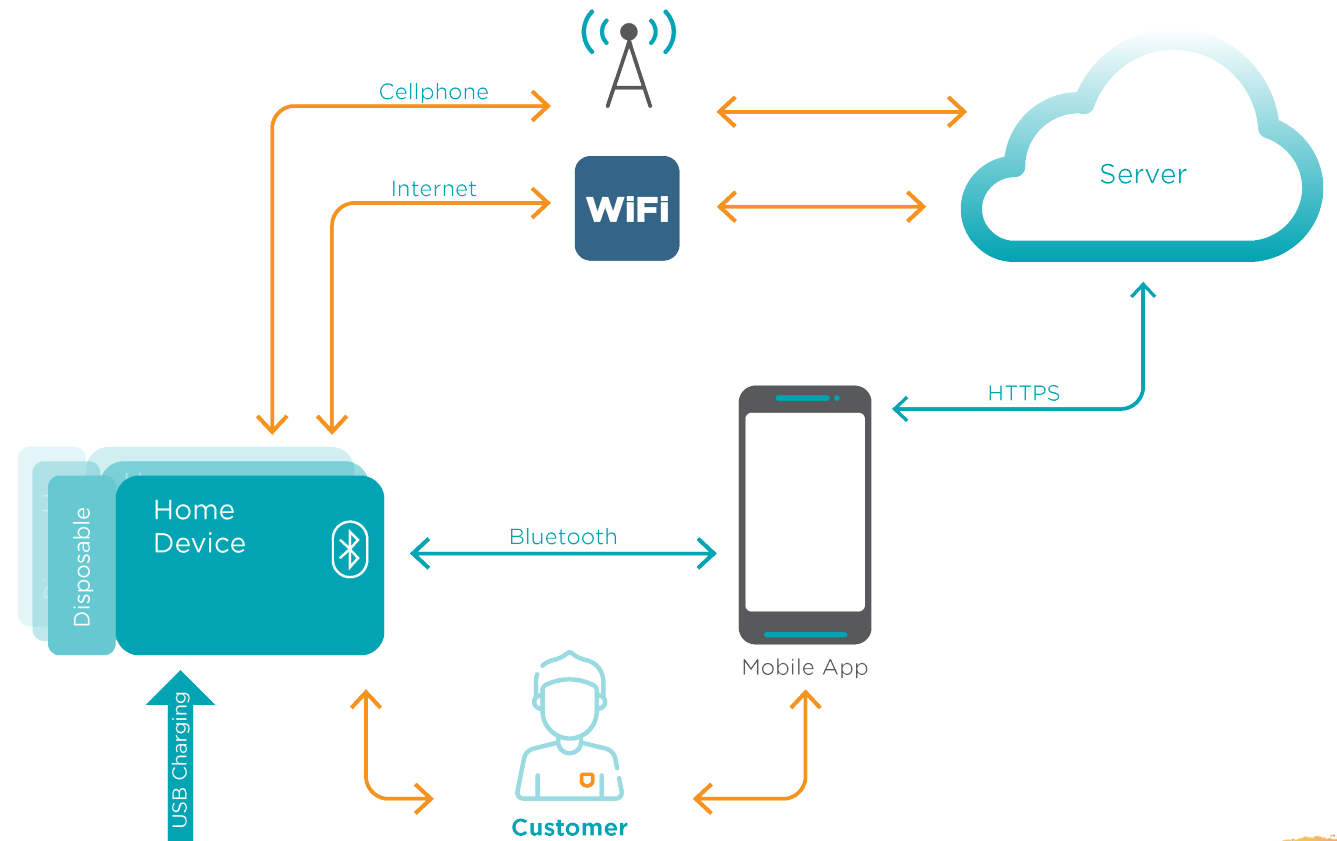
Connectivity mechanisms from the home
Pros and Cons

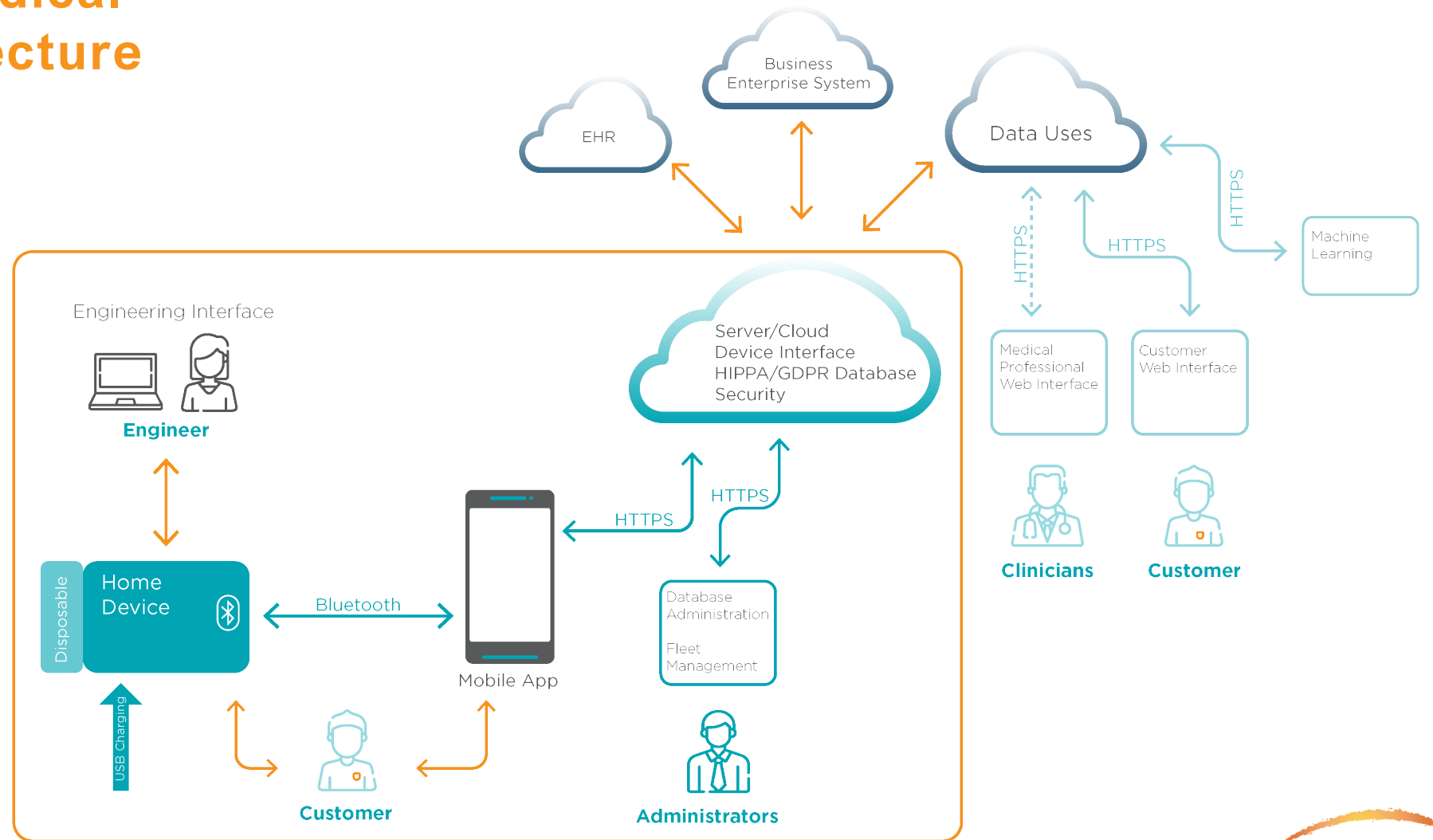# Home connectivity environment

User Interface Platform

- Cellphone
- Internet
- WiFi
- Server
- HTTPS
- Disposable
- Home Device
- Bluetooth
- Mobile App
- USB Charging
- Customer

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Home connectivity environment

Multiple Home Devices

Cellphone

Internet

WiFi

Server

HTTPS

Disposable

Home Device

Bluetooth

Mobile App

USB Charging

Customer

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Architecture and infrastructure

Medical Device Management
- User Authentication and Management
- Fleet Management and Monitoring
- Data Management
- Service and Diagnostics
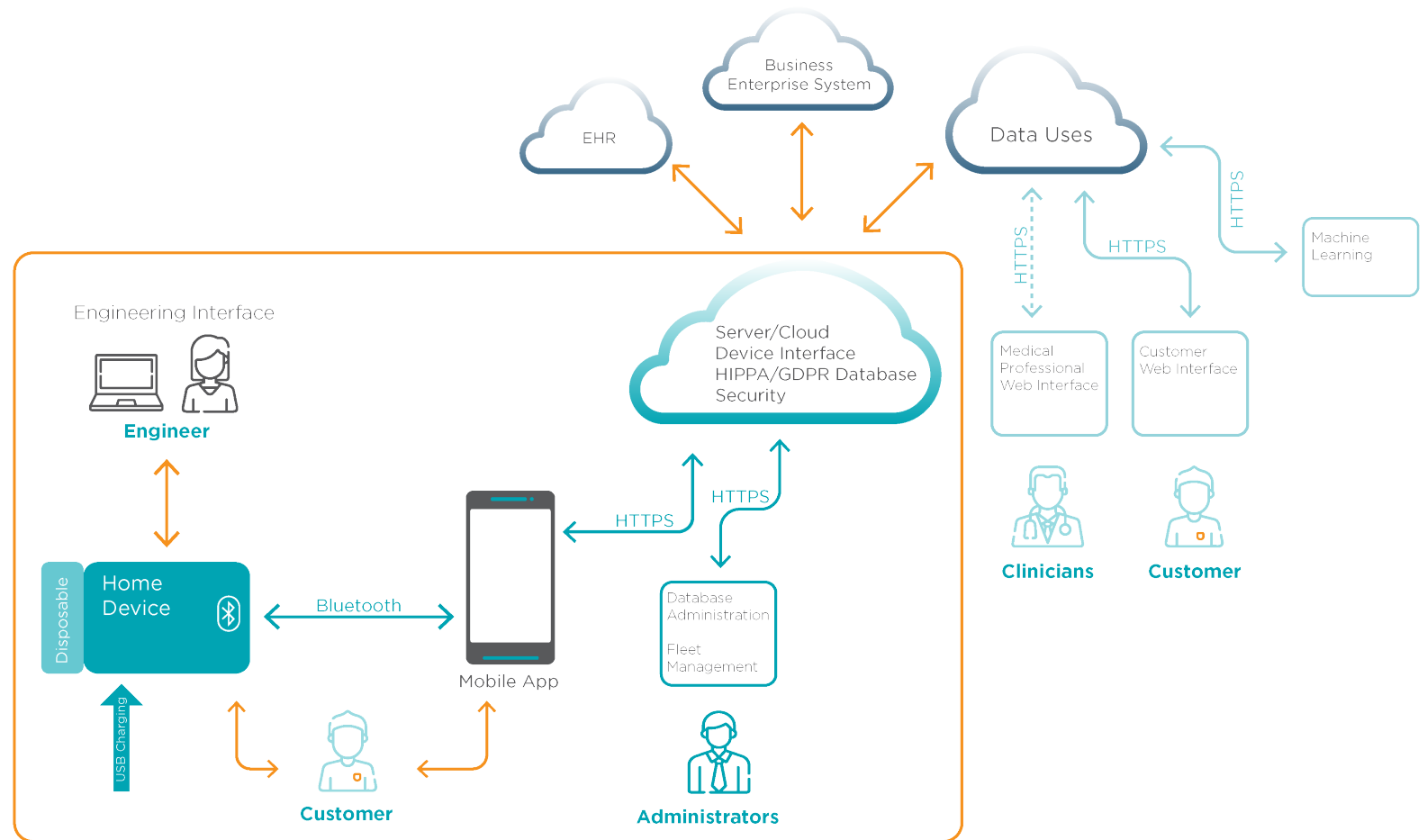- SW Upgrades
- Report Generation
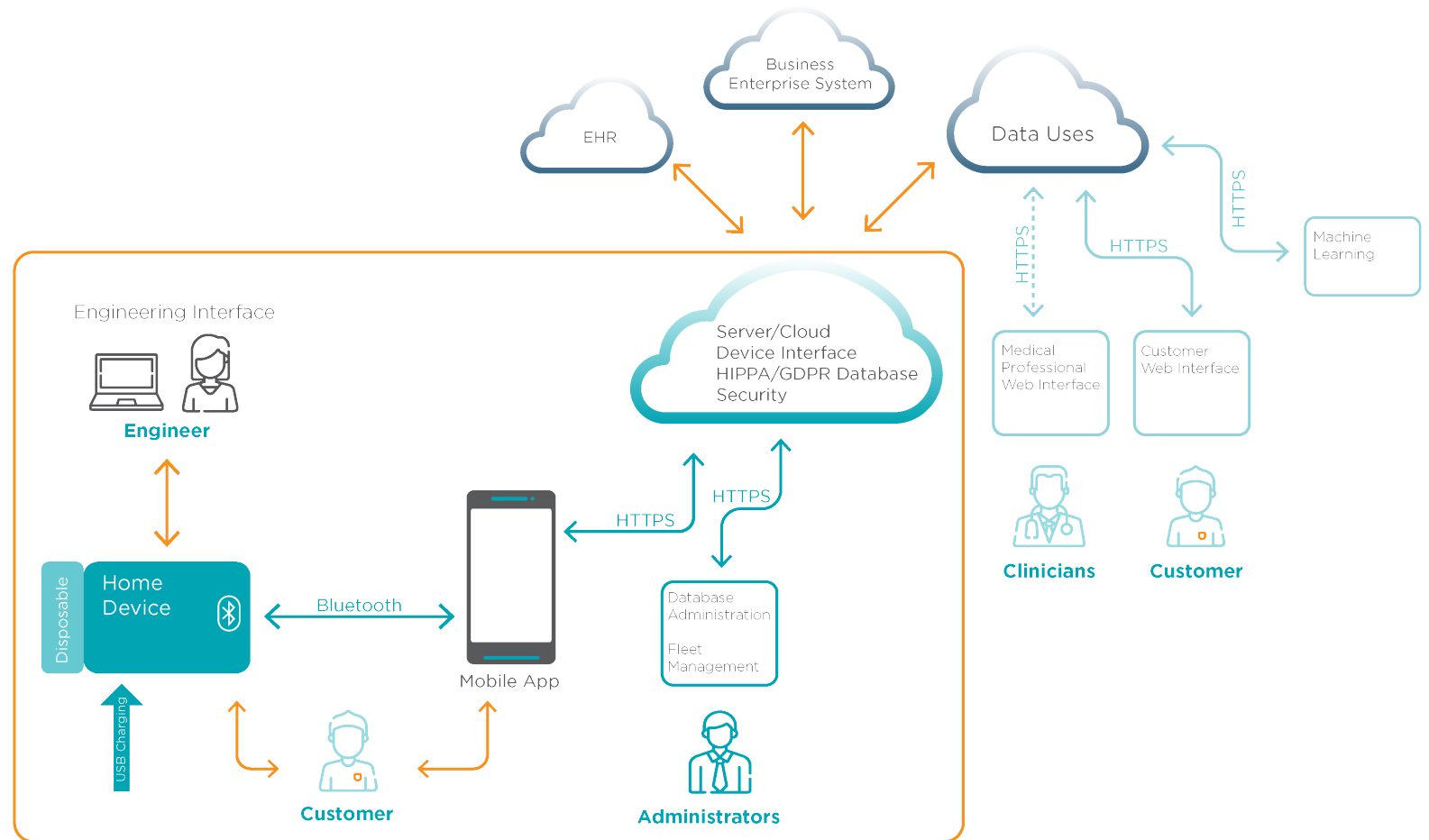
Architecture and infrastructure

Server Data manager
- HIPPA/GDPR
- What is the data used for?
- Does it need HIPPA compliance?
- Encryption needed inside and outside server

Thank You!

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