Continua Health Alliance

Insulin Pump Command and Control

Project Description

Title	<goal of the use case as a short active phrase>
Theme(s)	☐ Health and Fitness ☒ Chronic Disease management ☐ Aging Independently ☐ Other – specify:
Relation with implemented V1 use case(s)	This use case is an extension of the original *Insulin Pump Monitor Device* Use Case (UC 24, 2008). The original use case focused on monitoring the insulin pump device – this use case considers the requirements relating to controlling the device settings and actions.
Description	An insulin pump provides a means for continual delivery of insulin in the treatment of diabetes mellitus, also known as continuous subcutaneous insulin infusion (CSII). By adjusting the insulin level during the day to match the individual's biological rhythms and to compensate for food intake, insulin pumps can help to stabilize blood glucose levels. This stability in glucose levels – glycemic control – reduces the frequency of diabetic complications. Given the need to maintain stable glucose levels over time, there is great value in the review and analysis of insulin delivery and other associated events recorded by the insulin pump. Work is already underway to create interoperable standards for the **monitoring** of the insulin pump (the aforementioned Use Case, and its associated Work Items). This Use Case extends the need for interoperability to the insulin pump **controls**, notably: - programming a *24-hour insulin basal profile setting* - setting the active profile and activating the profile. - setting a specific basal rate for a temporary period of time and activating the temporary rate (as controlled by the user under certain circumstances). - stopping or cancelling a temporary basal rate - setting a *bolus* delivery and activating the bolus (commonly used to match the intake of a meal) - stopping or cancelling a bolus delivery - programming *insulin-to-carbohydrate ratio profiles* and/or the insulin sensitivity/*correction factor* Interoperable control over the insulin pump should enhance the development of novel disease management software (predominantly developed for mobile devices). Interoperability would be of particular value for the ongoing development of artificial pancreas technology. This technology would allow for ongoing control over insulin delivery based on measured glucose changes from a continuous glucose monitor (thereby in essence, substituting for the endocrine functionality of the pancreas). Interoperability among insulin pumps would enable accelerated innovation in the domain of artificial pancreas technology.
Scope	The scope of this use case includes the control of the insulin pump through connected compute engines, notably mobile devices, and laptops.
Problem statement, and/ or Benefit(s)	Insulin pump devices are predominantly controlled manually or via proprietary communication protocols. This limits the tools made available to insulin pump users. Interoperability would enable effective development of diabetes management software. It would also accelerate innovation of artificial pancreas

Insulin Pump Command and Control

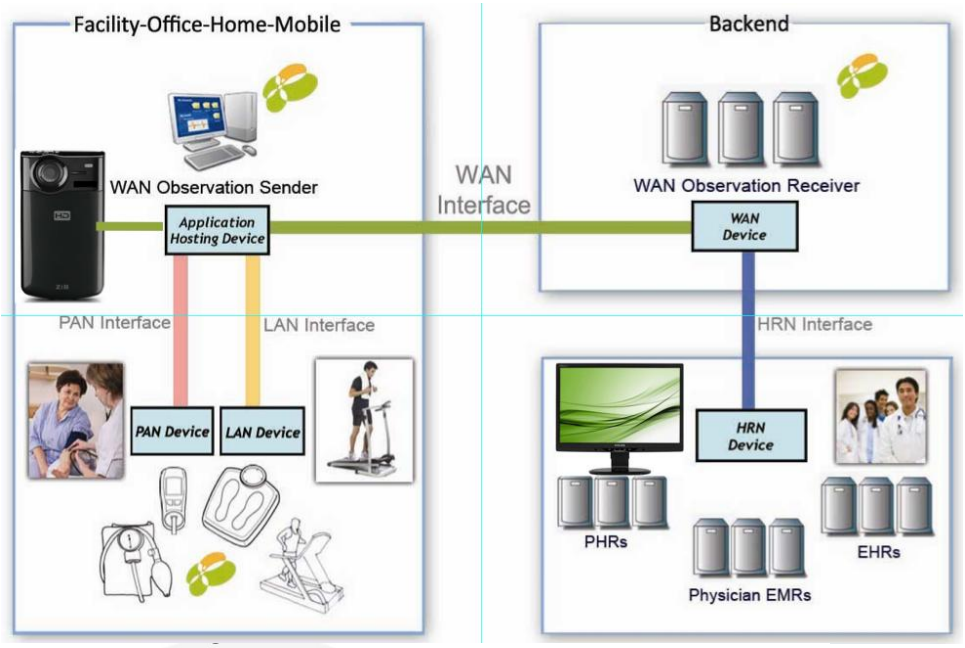
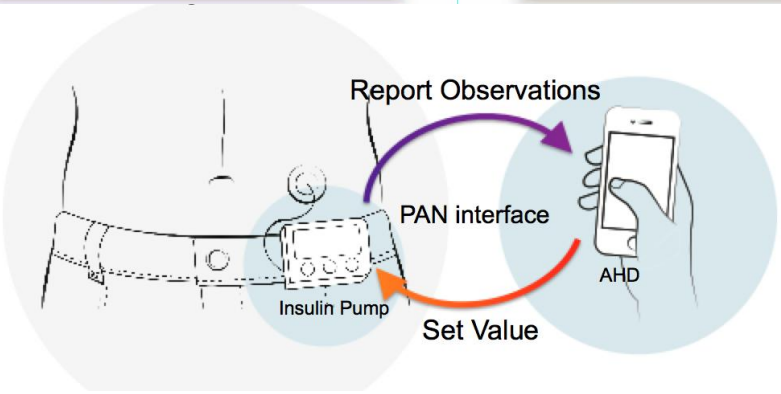
provided to end user	technology, which is seen as the future of effective diabetes therapy as indicated by the recent publication and release of the Final Guidance for Industry and the Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems [1] and through initiatives funded by JDRF and the American Diabetes Association.
Actors	**Clinician** – a clinician – or perhaps a designated technician supporting the clinician – would likely be involved in initiating the connections between the insulin pump and an AHD that is used to control the pump. **Insulin Pump User** – the insulin pump users may run the programs on an AHD that would allow them to control the insulin pump (deliver boluses, temporary basal rates, or adjust the 24-hour profile or carbohydrate profile). **Family Caregiver** – in certain situations, a family caregiver may take the place of the insulin pump user in controlling the device (e.g. a parent caring for a child, or a family member providing support for an elderly relative).
Minimal Guarantees	If the use case fails, all changes in settings on the device must be controlled manually by the patient (or in some scenarios, the clinician, or family caregiver). Manual control over settings, as well as bolus and temporary rate delivery, is currently a standard operational mode for insulin pump devices. The minimal guarantee operationally is that the insulin pump must persist with the programmed insulin delivery as the therapy should not be halted if there is a broken communication connection or similar issue. Upon re-establishing connection, an AHD could resume control of the device.
Success Guarantees	An effective interoperable standard will result in either a patient, family caregiver, or clinician being able to connect to establish connectivity with the pump and relay all the necessary commands and configuration settings. These would include: • The upload of new 24-hour insulin profiles (either new profiles that could be used by the patient, or overwriting a profile already stored on the device). • Activation of a profile (essentially switching from one profile to another). After activation, the selected profile would now dictate the hour-by-hour changes of insulin delivery rates. • Setting of a temporary bolus rate (certain situations allow the user to set a temporary rate different from the bolus rate – such temporary rates would usually be set for a few minutes up to a few hours) • Commanding the delivery of a bolus insulin dose. • Setting other device parameters including the carbohydrate-to-insulin ratio profiles as well as the correction factor (also known as 'insulin sensitivity).

[1] Food and Drug Administration Staff: The Content of Investigational Device Exemption (IDE) and Premarket Approval (PMA) Applications for Artificial Pancreas Device Systems http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM259305.pdf

Insulin Pump Command and Control

Trigger	The trigger would be initiated by the user of the insulin pump through the operation of the AHD. As has been noted, the program could also be operated by a clinician or family caregiver. In the case of artificial pancreas technology, the application itself may send these commands directly, as its mode of operation is to make automated adjustments of insulin delivery based on control algorithms.
Steps of Basic Flow (Include flow descriptions from multiple actor perspectives, if applicable)	***User control*** Precondition: John, an insulin pump user begins use with a Continua-enabled insulin pump that works with a diabetes management application run on a smartphone. Step 1: With the smartphone application, John programs a new 24-hour insulin profile, and uploads it to the insulin pump. Expected result: The insulin pump's basal rate profile is updated. Step 2: With another command, he activates this profile, and the insulin pump now begins to use it as the hour-by-hour basal insulin levels for delivery. Expected result: A new active profile is set. Step 3: At 2pm, John programs a temporary basal rate into his device to compensate for the exercise he will have during an afternoon soccer game. Expected result: The temporary basal rate command is received by the insulin pump, and insulin delivery is adjusted. Step 4: At 6pm, John programs a bolus to account for the carbohydrates he is consuming for his dinner. Expected result: The bolus command is received by the insulin pump, and the appropriate bolus is delivered. ***Clinician control*** During a follow-up visit, John takes his insulin pump to the clinic and connects it to an AHD to download historical information. John's physician reviews the recorded data from John's insulin pump and continuous glucose monitor. She decides that John's basal insulin profile and carbohydrate profile should be adjusted. She educates John on the modifications to his profiles and uses an application to set his new insulin pump profiles. ***Artificial Pancreas*** An artificial pancreas application on John's smartphone receives data from his continuous glucose monitor. This data provides the application with information to compute an amount of insulin to be delivered to maintain glucose control. Every 3 minutes, the application commands a "micro-bolus" to stabilize John's blood glucose level. The micro-bolus command is sent to the insulin pump and in response the insulin amount is properly delivered.
Failure Modes	If there is a wireless connection failure between the AHD and the insulin pump, commands would not be able to be sent to the insulin pump to control delivery. In such a case, the application on the AHD should clearly indicate that commands are not being received. To ensure such incidents are identified, the application should clearly indicate whether a command has been received and acted upon. In case of a continual interruption in the wireless connectivity, the user can be alerted to take manual control of the insulin pump to ensure the proper insulin amounts are still being delivered. As well, as an insulin pump would be programmed with a 24-hour profile, this basal insulin would continue to be

Insulin Pump Command and Control

	delivered to the patient in the absence of the AHD control.
Diagram (mandatory)	As with the prior use case for the insulin pump, this command and control use case still resides in the Continua E2E architecture as a PAN Device.  
Request to Expedite	Yes, we hope this can be expedited. As the work on the initial insulin pump use case is close to completion, this expansion of the use case will follow directly thereafter.

Insulin Pump Command and Control

Key Requirements

No	Keyword	Requirement Description	Acceptance criteria	Comments
	Basal profile setting	Programming a *24-hour basal profile setting*		
	Active basal profile	Setting an active basal profile		
	Active basal profile	Activating a basal profile		
	Basal rate set	Setting a temporary basal rate		
	Basal rate set	Stopping or cancelling a temporary basal rate		
	Bolus delivery	Setting a bolus delivery		
	Bolus delivery	Stop or cancel a bolus delivery		
	Insulin to carbohydrate ratios	Programming the insulin to carbohydrate ratios		
	Insulin sensitivity / correction factor	Programming the insulin sensitivity / correction factor		