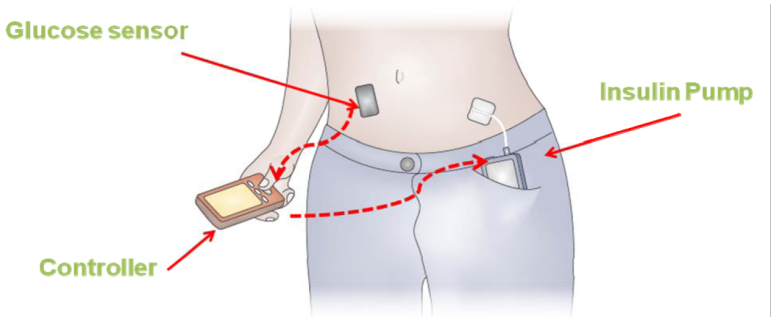
Challenge: Omitting the need for carbohydrate counting for people with type 1 diabetes

What is the problem?

Type 1 diabetes is a disease that impacts approximately 300,000 Canadians. It is a lifelong condition in which the pancreas produces no insulin. Insulin, which allows glucose to enter into the body's cells to provide energy, regulates an individual's blood glucose levels. Blood glucose levels that are too high or too low may cause serious, even deadly, complications. Thus, it is important to regulate blood glucose levels, often using up-to-date technology.

One technology to control blood sugar levels is with a closed-loop insulin delivery system, also known as the artificial pancreas or automated insulin delivery system. The closed-loop system is composed of three components: a pump containing insulin, a glucose sensor that detects blood glucose levels, and a dosing algorithm to control how much insulin the pump delivers based on the sensor readings (picture attached below). This is a promising choice for people with type 1 diabetes.

However, those with type 1 diabetes still need to count carbohydrates, which increase blood glucose levels, and enter the information into the closed-loop system in order for insulin dosing to be accurate. This can cause problems as it is not only burdensome on the individual with type 1 diabetes, but inaccurate counting leads inaccurate insulin dosing, which may lead to poor control of blood glucose levels.



Artificial Pancreas System. A sensor measures glucose levels and transmits them to a mobile-phone-sized controller, which runs a control algorithm. An insulin pump delivers insulin subcutaneously. The communication is wireless. Reprinted from Hovorka, Nature Reviews Endocrinology, 2016.

What outcome does the industry require?

The industry requires new, innovative, and efficient ways to ensure accurate insulin dosing while removing the need for carbohydrate counting in a closed-loop system. This can be achieved with automatic meal detection technologies and perhaps automatically estimating the amount of carbohydrate.

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Parameters and Guidelines

Innovators should consider the following parameters when developing their solution, as well as provide information (if applicable) following guidelines:

a) The material of the meal detection technology should be safe for use in/on the human body;
b) The technology should be practical and effective in accurately detecting meals;
c) Provide the medical device classification (from regulatory point of view);
d) Discuss, if applicable, your plan to continue with the non-clinical testing of the technology;
e) Discuss, if applicable, your plan to conduct clinical studies;
f) Discuss what a regulatory package to Health Canada to obtain approval would include.
g) Consider the following concepts:
    i. Risk Assessment
    ii. Standards and Declaration of Conformity (DoC)
    iii. Verification and Validation: device design (e.g. mechanical, electrical); performance; shelf life; sterilization; bioburden; pyrogenicity; software; packaging stability; and biocompatibility