Market Requirements Document
***ActivFlow Sport:* Insulin Drug Delivery System**

1 Introduction

1.1 Overview

Diabetes refers to a group of chronic diseases that involve issues with the hormone insulin and result in high amounts of sugar in the blood (hyperglycemia). Though the disease can be managed, it is a lifelong health condition that affects the day-to-day activities of over 450 million people. Diabetes is a major contributor to heart, kidney, and vascular diseases in addition to strokes and vision loss. If left untended or improperly treated, the effects of diabetes have been known to result in death.

For people without diabetes, the body naturally processes consumed calories into energy through the following process. Carbohydrates, a macronutrient present in almost every meal, break down into glucose molecules during the digestion of food. These molecules are absorbed across the wall of the small intestine and into the bloodstream. Glucose cannot be directly absorbed into cells and thus remains in the bloodstream. The resulting rise in blood glucose (BG) signals cells in the pancreas to release the hormone insulin. Once secreted, insulin binds to specific insulin-receptors on the surface of cells. The binding process activates glucose transporter proteins, allowing the sugar molecules to enter the cell body. Organelles within the cell (mitochondria) then use the glucose in addition to oxygen in a chemical reaction that produces carbon dioxide, water, and energy.

Typically if an individual has Type I diabetes, the insulin-signaling cells in their pancreas have been destroyed by autoimmunity; the body fails to produce insulin altogether. In contrast, individuals with Type II diabetes do produce insulin, but have developed a resistance to the action of the hormone on its receptor, requiring additional insulin to overcome cells' weak response. In both cases, insulin injections are critical to the regulation of blood glucose levels.

Maintaining a healthy lifestyle by monitoring blood glucose and taking regular insulin injections necessitates near-continuous individual attention. Scheduled meals and snacks, precise dosage calculations, and planned exercise become a requisite part of any daily routine. Biomedical devices such as insulin pumps may serve to relieve this regulatory burden while performing their intended function.

Highly active individuals, such as athletes, are even more challenged to manage diabetes while performing activities of daily life. Strenuous physical activity consumes energy produced in the body and can lead to low blood sugar (hypoglycemia), which in turn may cause poor balance, heart palpitations, and loss of consciousness. Athletes are thus forced to repeatedly break in the middle of games and practices to check their blood glucose levels and either self-inject doses of insulin or consume additional calories and carbohydrates. Devices that can be worn during periods of physical activity to monitor BG and perform auto-injections do not satisfy user needs for agility, comfort, and safety. Thus, a competitive athlete may ignore diabetic treatment for the hours in which they are engaged in a game or match. This can be extremely dangerous for their health and wellbeing and can lead to a higher risk of hyperglycemia. For this reason, *ActivFlow Sport* will cater to the population of athletes with Type I diabetes by providing an accurate and safe dual-regulatory system to manage both high and low blood glucose

levels. A three-hour worry-free window will ensure any athlete's safety while they take break from monitoring diabetes to focus on their passion.

1.2 Document Scope

This is the Market Requirements Document (MRD) for *ActivFlow Sport*. It comprises requirements for the first release for commercial launch.

1.3 Naming conventions

The use of the term "shall", when underlined indicates a requirement that is a "Must Have" and the use of the term "should", when underlined is a "Nice to Have" requirement.

Blood Glucose (BG): A measure of glucose molecules in the bloodstream in milligrams per deciliter.

Bolus: A high concentration of insulin taken in a single dose before meal times to keep blood glucose levels under control following a meal.

Basal: Small concentrations of insulin given in continuous doses to keep blood glucose levels at consistent levels during periods of fasting.

User: The individual that will use *ActivFlow Sport* to administer an injection. The user of *ActivFlow Sport* may be a patient or, in some instances, a caregiver.

> Patient: the individual for which use of *ActivFlow Sport* and a specific medication dose has been prescribed.
>
> Caregiver: The individual that uses *ActivFlow Sport* to administer the medication to a patient.

Device: Medical insulin pump used to regulate BG levels, and administer insulin via injection as needed.

Band: A shock-absorbing material that contains the DEVICE and allows it to adhere and be worn comfortably around the upper arm.

Pad: A shock-absorbing material that contains the DEVICE and allows it to adhere and be worn comfortably on the abdomen, upper thigh, or buttocks.

ActivFlow Sport: A portable insulin pump designed for athletic use. Describes the set of the DEVICE and the BAND or PAD.

1.4 References

Reference material used in the creation of this document:

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- Medtronic. (2017, March). Minimed 670G System User Guide. Retrieved from https://www.medtronicdiabetes.com/download-library/minimed-670g-system
- FDA Introduction to Medical Device Labeling
- FDA Regulation 21 CFR Part 11 - Electronic Records and Electronic Signatures
- ISO 14971 Medical Devices - Application of risk management to medical devices
- Device Labeling: 21 CFR Part 801; 21 CFR Part 830

2 Market Overview

2.1 Market Outlook

The target market for *ActivFlow Sport* is active individuals with Type I or Type II diabetes who are seeking a lightweight, low-profile, and reliable pump to use during periods of strenuous activity.

Commercial medical devices for insulin injections can be broadly grouped into the following categories:

- Disposable single-use syringes
- Auto-injector pens (reusable and disposable)
- Programmable pumps

Many products in the first two categories are not durable, fail to conceal the device's needle for patients with trypanophobia (fear of needles or injections), require frequent needle insertion and rigorous scheduling of meals, drinks, and exercise. The user must convert the amount of carbohydrates the patient has eaten into the proper insulin dose, most of which is trial and error. In addition, much of the treatment with this method is reactive; the users feel or observe symptoms of high or low blood sugar, and react. For these reasons, many countries with access to modern medical technology have made a shift in the marketplace away from auto-injectors and towards insulin pumps, which are more preventative and autonomous treatment.

Insulin pumps are relatively new to the market, but interest is rapidly growing. Pumps allow for unplanned exercise and meals and do not require daily use of needles. An injection site needs to be set up once or twice a week; this process involves the user removing the existing cannula and inserting a new one in a different place to prevent fatty build-ups. The injection site is defined as the cannula and the tubing that connects it

to the insulin pump. Once the pump is connected to the site, the user programs in a basal (long-lasting, slow flow) rate of insulin depending on their body type and general activity level. Over the course of the day, the user notes how many carbohydrates they have eaten so that bolus insulin (a short-term, fast-acting dose) can be injected as needed, with minimal math on the user's behalf.

Primary concerns about existing insulin pumps include accuracy, bulkiness, inability to be removed for long periods of time, and discomfort. Certain characteristics of the pump, including bulkiness and discomfort, make it difficult and dangerous to move around for any period of time. Athletes generally need be active for a longer period of time than would be safe to remove the pump. *ActivFlow Sport* seeks to remedy these concerns for the group of users that cannot endure periods of strenuous activity while wearing a pump. This group includes, but is not limited to: professional athletes, runners, active professionals (nurses, teachers, coaches, etc).

2.2 Diabetes Patient Population

There are over 450 million people with diagnosed diabetes worldwide, 30.3 million of which are Americans. Approximately ten percent of this number are individuals with Type I diabetes. As an autoimmune disease, Type I diabetes exists from birth and is often diagnosed between the ages of three and eighteen.

Rates of insulin pump usage vary widely by age. Roughly seventy percent of those under age six received insulin pump therapy, while only thirty-five to forty percent of older subjects used a pump.

2.3 Positioning and Competitive Differentiation

Insulin pumps are a quickly growing solution for reliably delivering insulin to people with Type I diabetes within the past decade. Their designs have greatly improved in both accuracy and in form. Medical advances in the last few years have allowed for this increased accuracy, and where pumps were once, without exception, bulky devices, many have become smaller and easier to handle. Few—if any—insulin pumps, however, have been designed with the needs of a competitive athlete in mind. The *ActivFlow Sport* aims to be the first insulin pump that can be worn safely during intense physical activities like competitive sports. Few insulin pumps can be worn in an athletic band on the arm, leg, or abdomen and provide the shock absorbance necessary for physical activity. *ActivFlow Sport* will likely be the first pump of its kind on the market.

Many of the pumps on the market alert users through beeps or other notifications when they need to eat something. Few—if any—give a prescribed amount of sugar or carbs. As such, the pump must retroactively react to what was eaten. *ActivFlow Sport* is meant to be paired with standard glucose pills. During activity, if blood sugar dips too low, *ActivFlow Sport* will alert the patient of their dropping BG and give the patient a timeframe for the ingestion of these pills before hypoglycemia reaches a critical level.

3 Use Scenario

3.1 Clinical Setting

Upon prescription, a medical professional may program the *ActivFlow Sport* pump for the patient's basal insulin dosage as well as recommendations for glucose intake. Aside

from this, no medical experience is required to operate *ActivFlow Sport*. This process is similar to other pumps on the market.

3.2 Home Setting

ActivFlow Sport is intended to be used on a daily basis during exercise or other activities with an increased need for mobility.

The user will be prescribed *ActivFlow Sport* by a medical professional for treatment of Type I diabetes. The medical professional will help the user determine a standard basal rate and glucose recommendations. No medical experience is needed beyond this point.

The pump is designed to be worn for a period of strenuous activity, with time before and after for the user to program the pump, prepare for the activity, and recover. These activities may be hikes, sports games, or a stressful shift at a job requiring movement. When the user goes to enter this period of activity, they will either switch their standard pump with *ActivFlow Sport* or refill the insulin reservoir on *ActivFlow Sport. ActivFlow Sport* can be worn for longer periods of time as long as the insulin reservoir is refilled twice daily.

ActivFlow Sport requires an input of consumed carbohydrates in order to calculate bolus insulin rates if the user eats while wearing the device. During activity, if blood sugar dips below the patient's healthy range, *ActivFlow Sport* will provide haptic warnings that set a timeframe for the user to ingest their standard glucose pills.

3.3 Intended Use

ActivFlow Sport is intended to deliver insulin in approved doses. It is also intended to remind the user to ingest prescribed glucose pills of a calculated concentration to prevent hypoglycemia.

4 Summary of Key Attributes

People with diabetes are often limited in the activities they can pursue, needing to balance medical safety and the time they spend preparing and recovering from strenuous activity. Diabetes can feel like it is controlling the life of patients, and prevent them from following their dreams. Diabetes does not mean inactive. Type I diabetes is an autoimmune disease that should not preclude people from exercising, although no products are specifically focused to meet this need. The insulin pumps currently on the market are not designed for frequent and powerful movement. They are bulky rectangular prisms that extend a fair distance along the body and have an external housing of hard, inflexible plastic. They are often attached using thin velcro bands or are situated in the patient's pocket; neither arrangement could withstand the forces present in intense athletic activity.

The current treatment option for athletic individuals with diabetes is insulin injections with either standard needles or autoinjectors. This mandates planned exercise activity time and stress. *ActivFlow Sport* will allow for more spontaneous and active movement while worn.

The primary attribute of *ActivFlow Sport* is to deliver insulin to the user in appropriate quantities. *ActivFlow Sport* constantly monitors the patient's blood glucose levels and uses haptic feedback to alert the patient of a downward trend in blood glucose levels. This warning will come with a recommended dosage of glucose tabs based on the instruction of a medical professional. The precision of the *ActivFlow Sport* combined with its glucose recommendations create a three-hour worry-free window in which the patient does not need to provide any additional programming or add additional insulin to the pump. This is an ideal feature for the target market of active individuals with Type I diabetes.

The secondary attribute of *ActivFlow Sport* pertains to its intention to be used in an athletic setting. *ActivFlow Sport* must be sturdy enough to not be damaged by impact in contact sports like football and basketball. It must also be flexible enough to allow for a full range of motion so as not to inhibit athletic performance. *ActivFlow Sport* should also have a discreet and athletic appearance to prevent unwanted attention.

ActivFlow Sport will be marketed with a companion smartphone application that allows for the intuitive control of the pump's features. The patient will seek the consultation of a medical professional who will aid in inputting the patient's medical requirements, such as their height, weight, hormone levels, the resulting recommended dosage of insulin, and further specifications as needed. This medical information will remain confidential and protected within the app and will be updated regularly by the medical professional. The patient will be able to monitor their blood glucose levels from the app and observe the trends and statistics of their levels. The patient will also use the app to program doses of insulin for delivery by the pump by simply inputting the numbers of carbohydrates they consumed. The application will also allow the user to easily contact a medical professional in case of emergency or if further instruction is needed.

5 General Requirements

REC5.1 *ActivFlow Sport* should be capable of storing up to four past program settings. Program settings include information such as expected activity, heart rate, and other information used in calculating the correct time to ingest a glucose pill. Accurate program settings provide higher accuracy. If the user is participating in a daily or weekly activity, the ability to store these settings will cut down significantly on the preparation and programming time.

REC5.2 *ActivFlow Sport* shall alert the patient of decreasing blood glucose levels if the device has calculated that the blood glucose levels are on trend to drop below a preset threshold. This alert shall be in the form of a haptic alert that increases in frequency as the patient's blood glucose levels continue to drop.

REC5.3 *ActivFlow Sport* shall recommend a dosage of glucose pills in conjunction with its haptic low blood glucose alerts via the companion smartphone application described below. This dosage shall be programmed at the recommendation of a medical professional. It is the responsibility of the user to keep a supply of these pills. *ActivFlow Sport* shall have enough storage for exactly two of these pills in the band.

REC5.4 *ActivFlow Sport* shall have a companion smartphone application compatible with all major smartphone brands. This application shall contain the medical information of the patient as programmed by the patient's medical professional, including the patient's height, weight, BMI, insulin requirements, recommended glucose pill dosages, and other factors provided at the discretion of the medical professional. This data shall be kept entirely confidential within the smartphone app. The app shall regularly recommend that the patient's medical information be kept up to date.

REC5.5 The *ActivFlow Sport*'s companion application shall allow the patient to connect wirelessly to the *ActivFlow Sport* device in order for the pump to accurately deliver the proper insulin doses.

REC5.6 The patient shall be able to program a bolus dosage of insulin from the app by inputting the number of carbohydrates they consumed. *ActivFlow Sport* is designed to be worn for 6-8 hours, three of which require no additional programming. It is expected that athletes may eat directly before or after a game and leave sufficient time to switch or refill the device. *ActivFlow Sport* can be worn for longer than this period, but the insulin reservoir must be refilled.

6 Injection

REC6.1 *ActivFlow Sport* shall allow the user to visually inspect the medication for particulates and discoloration prior to injection or wearing.

REC6.2 *ActivFlow Sport*'s insulin reservoir shall have a capacity of 100 units, or approximately 1 mL in order to maintain the low-profile form of the device.

A healthy human within the range of 50-100 kg requires between 50 and 200 units of insulin per day; thus, a 100-unit insulin reservoir surpasses the the quantity of insulin needed to sustain the three-hour worry-free window. A typical daily basal dose of insulin accounts for approximately 40% of total daily insulin consumption. This equates to approximately 2.5 units of insulin per hour.

REC6.3 The reservoir shall be able to be removed easily in under 5 seconds from its storage position in either the band or the pad.

REC6.4 The reservoir shall be refilled by the patient each day with medical human insulin.

REC6.5 *ActivFlow Sport* shall send an alert to the user when the insulin reservoir is empty via the companion smartphone app.

REC6.6 *ActivFlow Sport* shall be able to deliver a basal dose within the range of 0.5-7 units per hour of insulin with 95% accuracy.

REC6.7 The basal rate shall be a programmable value within the *ActivFlow Sport* smartphone app and must be calculated by a medical professional.

REC6.8 *ActiveFlow Sport* should have the capability of an adjustable bolus speed controlled by the patient from the *ActivFlow Sport* smartphone application between 0.5 and 18 units of insulin per minute with 97% accuracy. The standard bolus rate is 1.5 units per minute.

REC6.9 *ActivFlow Sport* shall be compatible with existing injection sets manufactured by leading companies as so not to necessitate a new injection each time the device is applied or removed. This mandates that *ActivFlow Sport* shall be adjustable to fit the standard cannula lengths (6mm, 8mm, 10mm, 13mm). The length of the tubing on the injection set is determined by the user but should be as short as possible to minimize

distance between *ActivFlow Sport* and the injection site. This allows the overall size of the device to be minimized. Companies often sell these infusion sets with varying lengths of tubing which can be cut manually to the appropriate size.

REC6.10 The removal and application of of the *ActivFlow Sport* from an injection set shall not necessitate the removal of the injection set, thereby allowing other compatible pumps to be swapped easily with no new injection sites. This requires that the tubing of the injection set shall not be permanently set into *ActivFlow Sport*.

7 Shelf Life

REC7.1 *ActivFlow Sport* electronic pump shall have a Claimed Lifetime of 10 years.

REC7.2 *ActivFlow Sport* bands shall have a Claimed Lifetime of 1 year.

REC7.3 Insulin reservoirs shall have a shelf life equivalent to or greater than the shelf life of the approved medication (expected 30 days unrefrigerated or 3 months refrigerated).

8 Environment

REC8.1 *ActivFlow Sport* shall be water-resistant to withstand perspiration and rain for its entire lifetime without lasting damage.

REC8.2 *ActivFlow Sport* shall conform to IP65, designiating a device that is entirely dust-tight and resistant to water jets (one level above resistant to splashing) without any harmful or noticeable effect.

9 Mechanical

REC9.1 *ActivFlow Sport* and its accessories shall have adequate mechanical strength to withstand stress caused by normal home use.

REC9.2 *ActivFlow Sport* and its accessories shall have adequate mechanical strength withstand 2000 Newtons of direct force caused by participation in contact sports (e.g., football tackle).

REC9.3 The *ActivFlow Sport* band shall be sufficiently secure to withstand 10 Newtons of shear force.

REC9.4 *ActivFlow Sport* and its band shall have adequate flexibility to form to the shape of the upper arm and thigh.

REC9.5 *ActivFlow Sport* and its pad shall have adequate flexibility to form and adhere to the shape of the lower abdomen and buttocks.

10 Electrical

REC10.1 *ActivFlow Sport* shall run for 3 weeks without a need to change batteries.

REC10.2 *ActivFlow Sport* shall use three (3) 1.5V cell batteries.

11 Size and Weight

REC11.1 The BAND shall be 7 cm wide.

REC11.2 The BAND sizes shall cover the range of 20 cm to 80 cm to fit most bicep and thigh circumferences.

REC11.3 The BAND shall be designed to be worn securely around the bicep.

REC11.4 The PAD shall come in a standard 7 centimeter by 7 centimeter package.

REC11.5 *ActivFlow Sport* shall weigh less than 1 kg, with the DEVICE held by either the BAND or PAD.

12 Ergonomic / Human Factors

REC12.1 *ActivFlow Sport* shall comply with FDA and ISO requirements for human factors design in medical devices. [2], [3]

REC12.2 The *ActivFlow Sport* shall be marketed alongside bands of varying length that allow the patient to adjust the device's fit to his or her liking.

REC12.3 The adhesive on the bands shall be strong enough to withstand the shear strength of tightly applying the band such that the cannula does not shear against or through the patient's skin.

REC12.4 The bands shall be able to be removed from the application site by applying a pulling force no greater than 10 Newtons.

13 Packaging

REC13.1 *ActivFlow Sport* shall come with a carrying or travel case.

REC13.2 *ActivFlow Sport* packaging shall be capable of protecting the DEVICE during shipping.

REC13.3 *ActivFlow Sport* packaging shall be easy to open with simple hand manipulation.

REC13.4 The *ActivFlow Sport* DEVICE and its accessories shall meet all applicable US and EU shipping regulations.

14 Labeling

Note: *The FDA defines "Labeling" as all labels and other written, printed, or graphic matter (i) upon any article or any of its containers or wrappers, or (ii) accompanying such article at any time while a device is held for sale after shipment or delivery for shipment in interstate commerce. Material which is considered labelling may also be on a website, or other electronic media.*[1]

REC14.1 *ActivFlow Sport* shall comply with FDA and EU requirements for medical device labeling[2] and employ the use of symbols as appropriate.

REC14.2 *ActivFlow Sport* labeling shall clearly incorporate adequate information for use (IFU) as required by the FDA and EU regulations.

REC14.3 *ActivFlow Sport* labeling shall include instructions for proper storage of *ActivFlow Sport* and its accessories. For example, this could include but is not limited to exposure to sunlight, proper temperature, and humidity.

REC14.4 *ActivFlow Sport* labeling shall include information on how users can report complaints if they experience issues with the device.

REC14.5 *ActivFlow Sport* labeling shall be simple, visible, clear and easily understood by the user.

REC14.6 *ActivFlow Sport* labeling shall be able to withstand defacement or wear and tear over the claimed lifetime, including recommended cleaning.

REC14.7 *ActivFlow Sport* reservoir labeling shall be compliant with the FDA, EU and pharmaceutical required labeling of the medication primary package container.

REC14.8 *ActivFlow Sport* labeling shall include contraindications that clearly explain why any individual should not use the device, if any.

REC14.9 *ActivFlow Sport* labeling shall include clear warnings and precautions.

REC14.10 *ActivFlow Sport* labeling shall use consistent terminology throughout the

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[1] FDA: Introduction to Medical Device Labeling. Available at: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/ucm2005422.htm

[2] 21 CFR Part 801: Title 21 - Food and Drugs Chapter I; Food and Drug Administration; Department of Health and Human Services; Subchapter H - Medical Devices; Part 801 - Labeling

labeling.

REC14.11 *ActivFlow Sport* labeling shall use pictures, symbols and other graphics to aid understanding of instructional steps and other labeling materials, as appropriate.

REC14.12 *ActivFlow Sport* labeling shall include information concerning the proper return and disposal of the device and its accessories.

REC14.13 *ActivFlow Sport* labeling shall include a list of troubleshooting instructions.

15 Installation / Service / Maintenance

REC15.1 *ActivFlow Sport* shall be prescribed by a doctor with both written and online instructions available.

REC15.2 *ActivFlow Sport* shall have an online help page and a 24-hour active help hotline.

16 Biocompatibility, Toxicity and Sterility

REC16.1 The *ActivFlow Sport* shall be fully compatible with any type of human insulin.

REC16.2 Any cannulas accompanying the *ActivFlow Sport* shall arrive fully sterilized in an airtight package such that they are immediately ready for use by the patient.

REC16.3 All outward-facing or potentially exposable materials used on the *ActivFlow Sport*, including the cannula, the band fabric, the shock-absorbing material, and any plastics, shall be fully biocompatible with a human being.

REC16.4 Fluid path and user contact materials shall be compatible with the requirements of ISO 10993.

REC16.5 Insulin fluid path shall be sterile.

REC16.6 The *ActivFlow* DEVICE shall be compatible with the medication that is stored in it. The medication to be stored will be defined in conjunction with the pharmaceutical partner.

17 Regulatory Pathway

REC17.1 The *ActivFlow* DEVICE shall meet FDA, EU, ISO standards for medical devices and mobile connectivity.

REC17.2 *ActivFlow* regulatory pathways shall be 510(k) in the US under 21 CFR Section 880.5430 Non- electrically powered fluid injector.

REC17.3 *ActivFlow Sport* shall have a CE Mark for marketing in the EU. The handheld will be approved as a medical device under Medical Device Directive 2.4/1 Rev 9 June 2010 Rule 12 - Active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body.

18 Cost of Goods Sold (COGS)

REC18.1 *ActivFlow Sport* should be manufactured at volume (>5000 units per year) for < USD XXX per unit.

MRD REVISION HISTORY

Revision	Effective Date	Nature of Change	Originator(s)
A	16Sep2018	Initial Release	Zachary Davenport, Ava Lakmazaheri, Emma Westerhoff
B	17Sep2018	Minor Changes and Updates	Zachary Davenport, Ava Lakmazaheri, Emma Westerhoff
C	18Sep2018	Minor Changes and Updates	Zachary Davenport, Ava Lakmazaheri, Emma Westerhoff