NOVABAND

February 21, 2021

Dr. Craig Scratchley
Dr. Shervin Jannesar
Dr. Andrew Rawicz
School of Engineering Science, Simon Fraser University
British Columbia, V5A 1S6

RE: ENSC 405W/440 Requirements Specification for NovaBand

Dear Dr. Scratchley, Dr. Jannesar, and Dr. Rawicz,

Attached to this letter you will find the Requirements Specification document outlining NovaBand. NovaBand is a programmable resistance band that varies tension as it is pulled upon. This allows for the product to accurately match the muscle curve of a given muscle group, improving rehabilitation speed for the patients of physiotherapists.

This document details the requirements and features of the device, giving a high-level overview into the limitations and standards for various components of the system. Requirements for areas such as safety and sustainability are also included in this document.

NovaBand Solutions is comprised of a diverse team of senior engineering students: Jordan Lei, Nicolas Skinner, Arvin Amini, George Lertzman-Lepofsky, and Kevin Jerome. Through our team's various experiences from internships, clubs, and personal curiosity, we aim to combine the skills of each member to create a truly excellent product.

We appreciate consideration in reading the Requirements Specifications for NovaBand. Should any questions arise, please contact our Chief Communications Officer, George Lertzman-Lepofsky at gmlertzm@sfu.ca.

Sincerely,

Jordan Lei
Chief Executive Officer
NovaBand Solutions

SFU SIMON FRASER UNIVERSITY

ENSC 405W: Company 6

Requirements Specification: NovaBand

Jordan Lei (CEO)
Kevin Jerome (COO)
Arvin Amini (CTO)
Nicolas Skinner (CFO)
George Lertzman-Lepofsky (CCO)

Contact:
George Lertzman-Lepofsky
gmlertzm@sfu.ca

Abstract

Elastic resistance bands are commonly used by licensed physiotherapists to aid in muscle rehabilitation. Given a particular resistance band, it is observed that the force exerted by the band increases linearly as it is stretched and decreases linearly as the band is contracted. On the contrary, human muscles are only able to exert maximal force near the midpoint of extension; minimal force is exerted when the muscle is fully flexed or extended. This contrast between elastic band force and human muscle strength leads to suboptimal rehabilitation when traditional elastic bands are used.

NovaBand Solutions aims to address the disparity between the elastic band force and human muscle strength by better personalizing the rehabilitation process. The movement that occurs during one repetition of a rehabilitation exercise will be examined and improved upon to provide a custom-tailored solution for individuals undergoing muscular rehabilitation.

NovaBand Solutions proposes a programmatic resistance band which is precisely controlled by a physiotherapist and specialized software to best meet their individual client's rehabilitation needs on a case-by-case basis.

This document outlines the requirements for the proposed solution during the proof-of-concept, engineering prototype, and production phases of development. Broad safety and sustainability requirements are also included. Lastly, an acceptance test plan is defined to establish the criteria used to evaluate the product during the proof-of-concept phase.

Contents

Glossary

TABLE I
DOCUMENT TERMS AND DEFINITIONS

Term	Definition
Isokinetic	Exercises that keep the speed of muscle movement constant throughout the exercise.
Muscle strength curve	Shape of the graph of muscle strength with respect to amount of muscle extension.
Sarcomere	Basic contractile unit of muscle fiber. Responsible for muscular contraction.
Consumables	Parts which have a known limited lifespan and need to be replaced.
Normal use	30 minutes of daily use under the instructed guidelines included.
Rep	One repetition (from starting position back to starting position) of a given exercise.

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1 Introduction

The NovaBand programmatic resistance band is an adjustable system designed for use in muscular rehabilitation. The product outputs a resistive force which adheres to the muscle strength curve of specific human muscle groups with the goal of improving rehabilitation speed. NovaBand is a direct alternative to traditional elastic resistance bands and is customizable for rehabilitating injuries that are unique to each patient.

Standard elastic resistance bands are commonly used by patients performing muscular rehabilitation exercises. These bands exert a set amount of resistive force as they are stretched. Lower resistance bands are used during early stages of rehabilitation and higher resistance bands are used as the recovering patient's condition improves [1]. While the use of standard elastic resistance bands for both exercise and rehabilitation has been embraced by companies like TheraBand, there are some long standing issues with the efficiency and practicality of using a set of resistance bands for rehabilitation. Many of these exercises require mounting the resistance band and when performed at home the safest option is to purchase expensive wall mounts [2] or risk damage to home furnishings and the patient.

Finally, the most prevalent issue with elastic bands is their lack of adherence to the muscle strength curve. Elastic bands exert a near-linear resistive force as the band is extended, while muscles have more of a bell-shaped curve of strength [3] [4]. As a result, towards the end of each exercise the resistance band is at its strongest point while the muscle is nearing its weakest point. The solution to better match the muscle strength curve is to do exercises with an isokinetic exercise machine. Isokinetic exercises are defined as exercises that keep the speed of muscle movement constant throughout the exercise [5]. The discrepancy of strength and resistance curves leads to a less efficient exercise and injured patients can overload their muscles by attempting to do an exercise they are not strong enough for [6].

1.1 Background

1.1.1 Muscle Strength Curve

As depicted in Fig. 1, the human muscle strength curve has a near bell-shaped curve. The shape of this curve is a direct result of the composition of muscle fibers which are made up of many sarcomere units [3].

At point '1' in Fig. 1, the muscle is overly contracted; there is a large amount of sarcomere overlap which results in a lower overall strength. Once point '2' is reached, the sarcomere is more evenly stretched, resulting in the maximum strength possible for the muscle. At points '3' and '4', the sarcomeres are stretched significantly, which results in the lower muscle strength yet again [3].

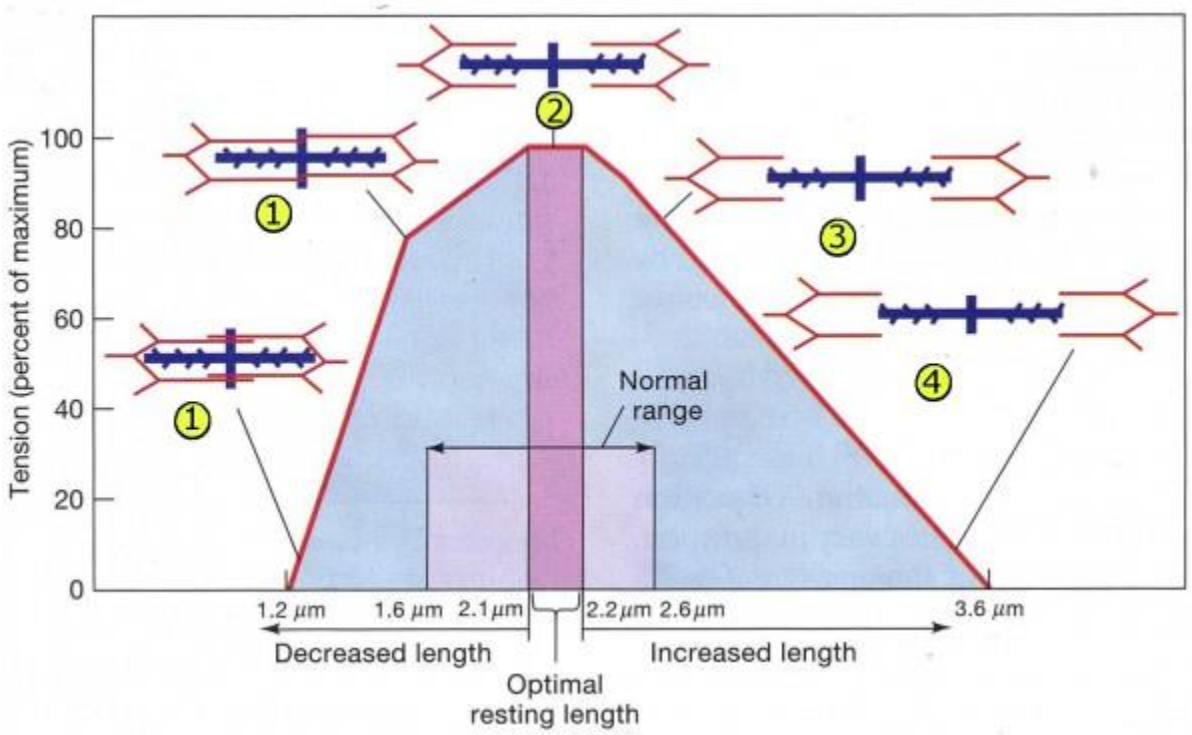

Fig. 1 Length-tension relationship of sarcomeres in graphical form [3].

1.1.2 Elastic Resistance Curve

Fig. 2 shows a standard resistance curve for an elastic band. Clearly, this curve does not match the shape of the curve shown in Fig. 1. In Fig. 2, the force continues to increase as a function of extension position, whereas the muscle strength in Fig. 1 peaked in force near the midpoint of extension. At the maximum point of extension for the band, there is a clear indication of when the band fails, and the force required drops dramatically. As a result, using a standard elastic resistance band contributes to a less efficient workout compared to a device that can adjust to unique muscle curves [7].

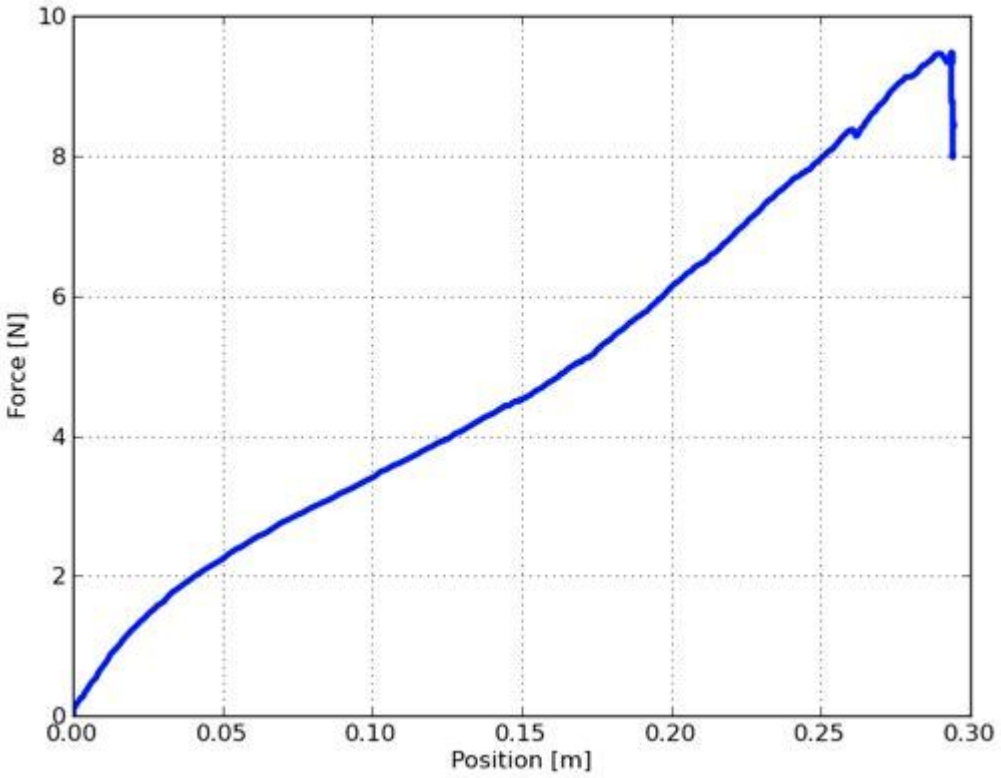

Fig. 2 Force from a rubber band as a function of the extension of the band [4].

1.1.3 An Engineered Solution

A major aspect of physiotherapy is targeted and deliberate strength training. Thus, improving the efficiency of strength training improves rehabilitation speed and efficacy [8]. The goal of NovaBand is to match the resistance curve of the exercise with the natural force curve produced by the targeted muscle through a rep. This matching will allow for more efficient exercises and should result in a safer and faster recovery [7]. In addition to matching a standard muscle curve, NovaBand will allow for a much more customizable experience for every unique patient and every unique injury.

1.2 Scope

1.2.1 Alpha

Once NovaBand reaches the alpha stage of production, the tension will be able to be modified programmatically using a set of predefined muscle curves and allowing the user to dynamically adjust the curve to better match the patient. NovaBand will have the beginnings of a modular mounting system and will have at least two systems of mounting to allow for a

greater variety of exercises to be completed. There will also be a rudimentary housing system for safety of both the users and the device itself.

1.2.2 Beta

The beta phase of NovaBand's production will begin to implement more features such as a feature to allow NovaBand to measure the muscle strength curve of the patient. More research and testing will have to be done to determine the utility and accuracy of this feature. In addition to this, the durability of the housing will be improved to ensure that the product is not damaged by small drops and scratches. The mounting options will also be expanded in the beta phase to allow for as many kinds of exercises as possible.

1.2.3 Production (Beyond Scope of ENSC 405W/440W)

Finally, once NovaBand moves into the final production stage of development, the finishing touches will be put onto the device. The components of NovaBand will be optimized for both weight and cost to keep the device as lightweight and affordable as possible. The housing for NovaBand will also be further optimized for durability in addition to weight at this stage. The diagnostic feature that will be implemented in NovaBand will have further research and testing to improve the functionality and accuracy of the feature.

1.3 Intended Audience

The intended audience for this product centers heavily around physiotherapists and rehabilitation specialists. NovaBand is best used by medical professionals who have the required background knowledge of the muscle curve, as well as an understanding of how to modify that curve based on specific injuries. In addition to general physiotherapists, another target for this product is medical staff attached to high performance sports teams. NovaBand's higher efficiency exercises should appeal to high performance athletes as any increase in speed of rehabilitation is very important [8].

1.4 Requirement Classification

The following notation will be used in this document for each requirement label:

[Req X.Y.Z S]

X – Denotes the requirement document section.
Y – Denotes the requirement document subsection.
Z – Denotes the requirement number.
S – Denotes the stage of production that the requirement applies to.

The stages of production are labeled as “A”, “B”, and “P” for alpha, beta, and production stages, respectively. The alpha stage focuses on a proof-of-concept prototype which only has some of the basic product features completed. The beta stage refers to the engineering prototype which has all the important functions of the product completed. Lastly, the production stage focuses on optimization for other aspects of the product such as weight, look, and durability.

2 System Overview

2.1 Required Components

2.1.1 Resistance/Tension System

The tension system is the component to which the user applies tension. This should act similarly to how an elastic resistance band works. The resistance system is the component which will be handling the variable tension in the device. This system will vary the tension in real time while in use. After a single repetition of an exercise is performed, the tension system should retract back to its original state. While a user is using the device, as they pull on the tension mechanism, the resistance system should be engaged and vary the tension as they use it, mapped to a muscle curve which was determined before the action has started.

2.1.2 Housing & Mounting Mechanisms

All the previous components will need to be put inside housing to protect the user and the device from any harm or damage. A computer will be required to be inside the device to control components such as the resistance system.

Both the tension system and the device housing will need mounting mechanisms. On the housing, this allows it to stay in a single location as tension is applied to the product. On the tension system, the user will need a way to hold it or have it mounted to a body part.

2.1.3 User Interface (UI)

To adjust the tension in the product, the user will need some form of interface to interact with the device. The UI will allow the user to configure both the tension curve, as well as the amount of tension the device will apply when in use. The data from the configuration will be

sent to the onboard computer in the device via a pre-determined communication method. This can be done either by the user using the device or by a third party, such as a physio/physical therapist, for rehabilitation sessions with clients.

3 Requirements

3.1 High-Level Requirements

TABLE II
HIGH-LEVEL REQUIREMENTS

Requirement ID	Requirement Description
Req 3.1.1 A	The product must be able to programmatically vary resistance based on the user defined settings.
Req 3.1.2 B	The product must be able to be easily and safely mounted in multiple ways to allow for multiple types of exercises.
Req 3.1.3 B	The product must support at least 140 N (about 30 lb) of resistance to compete with existing lightweight elastic bands [9].
Req 3.1.4 P	The product must not require any additional tools to setup.
Req 3.1.5 P	The product must be able to be used after reading instructions.

3.2 Physical Requirements

TABLE III
REQUIREMENTS FOR THE PRODUCT DURABILITY

Requirement ID	Requirement Description
Req 3.2.1 A	The product exterior must be resistant to the chemicals found in common cleaning and sanitation solutions.
Req 3.2.2 A	The product must be able to indefinitely operate in a 31 °C (87.8 °F) environment to match working temperature exposure limits [10].
Req 3.2.3 A	The product should be able to operate after brief exposure to water at a temperature of 49 °C (120 °F) [11].
Req 3.2.4 B	The product must be able to operate after being dropped 1.75 m (5.73 ft), the average measured height of Canadian men (95% confidence interval) [12].
Req 3.2.5 B	The product should be resistant to scratching and puncturing encountered during mounting, transport, and use.
Req 3.2.6 P	The product should be able to operate after exposure to sweat.

Req 3.2.7 P	Under normal use, the product should last a minimum of two years to remain competitive to similar or competing products [13].

TABLE IV
REQUIREMENTS FOR THE PRODUCT SIZE AND WEIGHT

Requirement ID	Requirement Description
Req 3.2.8 A	When mounted, the product weight must be totally supported by the mounting mechanism such that the user is not required to lift the product during use.
Req 3.2.9 B	The product weight must be less than or equal to 4.54 kg (10 lb).
Req 3.2.10 P	The product should be of size and shape to be held comfortably in one hand, i.e., approximately equal to 17.2 cm (6.8") by 7.8 cm (3.1") (50^{th} percentile) [14].

TABLE V
REQUIREMENTS FOR THE PRODUCT WIRING

Requirement ID	Requirement Description
Req 3.2.11 B	The product wiring must be physical located in the product interior.
Req 3.2.12 P	The product wiring should be hidden from the user when the user is performing maintenance on the resistance system.

3.3 Hardware Requirements

TABLE VI
REQUIREMENTS FOR THE TENSION SYSTEM

Requirement ID	Requirement Description
Req 3.3.1 A	The tension system must be strong enough to safely sustain the maximum tension defined by Req 3.1.3.
Req 3.3.2 A	The tension system must not stretch more than 5% of its length during normal use to prevent undesired tension variability [15].
Req 3.3.3 B	Handle must be of size and shape to be held comfortably by an average hand, i.e., diameter equal to 3.39 cm (1.33 ft) [14] [16] while applying the maximum tension defined by Req 3.1.3.
Req 3.3.4 P	The tension system must be durable enough to resist frictional wear applied by the internal mechanism and tensile force applied over the product's lifetime.

TABLE VII
REQUIREMENTS FOR THE RESISTANCE SYSTEM

Requirement ID	Requirement Description
Req 3.3.5 A	The resistance system must be able to apply enough resistive force to match the maximum tension specified by Req 3.1.3.
Req 3.3.6 A	Regardless of force applied by the user, the resistance system must slow and stop unspooling of tension system near the maximum extension to prevent damage to the mechanism.
Req 3.3.7 B	The resistance system must not be damaged by heat produced by frictional braking.
Req 3.3.8 B	The resistance system should not produce over 60 dB of noise to avoid drowning out a normal conversation [17].

TABLE VIII
REQUIREMENTS FOR THE RETRACTION SYSTEM

Requirement ID	Requirement Description
Req 3.3.9 A	The retraction system must stop retracting system within 0.10 seconds of the user reapplying tension to the tension system.
Reg 3.3.10 A	The retraction system must not exceed 1.0 m/s (3.28 ft/s) at any time during retraction.
Req 3.3.11 B	The retraction system should begin to retract tension system within 0.25 seconds of the user releasing tension.
Req 3.3.12 B	The retraction system should fully retract tension system from maximum extension within 3.0 seconds from starting to retract.

TABLE IX
REQUIREMENTS FOR THE ENCLOSURE

Requirement ID	Requirement Description
Req 3.3.13 A	The enclosure must be thermally or electrically isolated from any sensitive or hot internal components.
Req 3.3.14 B	The enclosure must not have corners or edges that are sharp enough to injure or abrade skin through contact during normal use.
Req 3.3.15 B	The enclosure must have a mechanical wipe or brush to prevent the accidental insertion of clothes, fingers, or alien objects into the moving components of the device.
Req 3.3.16 P	The enclosure should be an aesthetically pleasing colour that matches NovaBand marketing material and branding.

TABLE X
REQUIREMENTS FOR THE MOUNTING MECHANISMS

Requirement ID	Requirement Description
Req 3.3.17 A	The mounting system must be strong enough to support the weight of the device plus the maximum tensioned specified by Req 3.1.3.
Req 3.3.18 B	The mounting system should be able to be quickly and easily attached and detached from the attachment point at will.
Req 3.3.19 P	The modular mounting systems should be able to be quickly and easily attached and detached from the device at will.

TABLE XI
REQUIREMENTS FOR THE POWER SOURCE

Requirement ID	Requirement Description
Req 3.3.20 B	The power source must provide enough power to sustain continuous use of the device over a normal workday (8 hours).
Req 3.3.21 B	The power source must not damage batteries or power system if left charging over night or over a weekend.

3.4 Firmware Requirements

TABLE XII
REQUIREMENTS FOR THE PRODUCT FIRMWARE

Requirement ID	Requirement Description
Req 3.4.1 A	The product must respond to, and implement changes from, user input within 1 second.
Req 3.4.2 B	The firmware must communicate between all hardware components.
Req 3.4.3 B	The product must have a hard reset for the firmware to reset to default settings.

3.5 Economic Requirements

TABLE XIII
REQUIREMENTS FOR THE PRODUCT ECONOMICS

Requirement ID	Requirement Description
Req 3.5.1 P	The product must cost no more than $300 CAD ($250 USD) to ensure competitive pricing.

Req 3.5.2 P	The product manufacturing cost should be no more than 70% of the recommended retail price.
Req 3.5.3 P	Parts intended to be replaced should cost no more than 40% of the cost of the retail price.
Req 3.5.4 P	Most of the parts should be easily sourced and replaceable for service or replacements.

3.6 Documentation Requirements

TABLE XIV
REQUIREMENTS FOR PRODUCT DOCUMENTATION

Requirement ID	Requirement Description
Req 3.6.1 P	The product must include a manual with instructions for setup and intended use.
Req 3.6.2 P	The product documentation must contain instructions on how to replace any consumable parts.
Req 3.6.3 P	The product documentation must outline the physical restrictions and limitations on the device.
Req 3.6.4 P	The product should provide online access to the manual.

4 Safety

TABLE XV
REQUIREMENTS FOR PRODUCT SAFETY

Requirement ID	Requirement Description
Req 4.0.1 A	The product mounting system must always remain secured to the mounting surface when the mounting system is used.
Req 4.0.2 A	The product exterior must remain below 52 °C (127 °F) as to not burn the user when the product is held continuously for up to one minute [18].
Req 4.0.3 A	The product exterior should not produce a static shock when touched by the user.
Req 4.0.4 B	The product wiring must be electrically shielded.
Req 4.0.5 B	The product exterior must not expose any sharp edges.
Req 4.0.6 P	The product noise level must not exceed 85 dBA to comply with occupational exposure limits [19].

Req 4.0.7 P	The product should prevent hair, clothing, and any other loose materials to be caught inside any moving components.

5 Sustainability

Unfortunately, there is an inherent and unavoidable carbon cost to the design and manufacture of modern products, especially ones with electronic components. It is then the job of the designers to minimize the size of their product's footprint where possible.

The use of biologically sourced polymers, i.e., Polylactic acid (PLA) will be prioritized. This material is sourced from a renewable resource: the fermented starch of corn, sugar cane, and wheat. PLA can also be fully recycled back into pellets with no loss of purity or quality [20]. As such, any PLA in our product represents a net carbon sink before end-of-life of the material itself. Alternatively, PLA is suitable for decomposition in a hydrolysis/bacterial process in industrial composts – though it is not truly biodegradable [21].

Unfortunately, PLA is not suitable for all applications. In areas of the device where structural integrity is paramount, rigid, and light metals like aluminum (which has a cost-effective recycling stream [22]) will be used instead. Likewise, metal or ceramic components will be used in the resistance system in lieu of rubber—with regard to the low viability of rubber recycling and the wear applied during normal use (necessitating replacement). While minimally recyclable, natural rubbers will be used in components that the user is likely to grip under tension. As well, while printed circuit boards contain highly recyclable (and valuable) metals, they are held together by a glass-reinforced epoxy, which is non-recyclable [23].

TABLE XVI
REQUIREMENTS FOR PRODUCT SUSTAINABILITY

Requirement ID	Requirement Description
Req 5.0.1 A	The product's enclosure should be constructed out of PLA or another cradle-to-cradle-viable organic polyester.
Req 5.0.2 B	Highly recyclable metals like aluminum should be used for structurally important components.
Req 5.0.3 B	PCBs should be designed to minimize area.
Req 5.0.4 P	Resistance system should be made with durable components that need infrequent replacement.

6 Engineering Standards

6.1 Electrical Standards

TABLE XVII
ELECTRICAL STANDARDS

Standard	Description
ISO 31.200	Integrated Circuits and Microelectronics – Including electronic chips, logical and analogue microstructures [24]
ISO 31.240	Mechanical Structures for Electronic Equipment [25]
IEC 60194-1:2021	Printed Boards Design, Manufacture, and Assembly Vocabulary – Part 1: Common usage in printed board and electronic assembly technologies [26]
IEC 61508-2:2010	Functional safety of electrical/electronic/programmable electronic safety related systems – Part 2: Requirements for electrical/electronic/programmable electronic safety related systems [27]
CAN/CSA-C22.2 NO. 0-10	General Requirements – Canadian Electrical Code, part II [28]
CAN/CSAC22.2 NO. 60601-1:14	Medical Electrical Equipment – Part 1: General safety for basic safety and essential performance [29]

6.2 Medical Standards

TABLE XVIII
MEDICAL STANDARDS

Standard	Description
ISO 13485:2016	Medical Devices – Quality management systems – Requirements for regulatory purposes [30]
ISO 14971:2019	Medical Devices – Application of risk management to medical devices [31]
SOR 98/282	Medical Devices Regulations [32]

6.3 Software Standards

TABLE XIX
SOFTWARE STANDARDS

Standard	Description
ISO/IEC/IEEE 12207:2020	Software and Systems Engineering – Software Life Cycle Process [33]
ISO/IEC/IEEE 29119-1:2020	Software and Systems Engineering – Software Testing – Part 1: Concepts and definitions [34]
IEC 62304:2006	Medical Device Software – Software Life Cycle Process [35]
IEC 80002-1:2009	Medical Device Software – Part 1: Guidance on the application of ISO 14971 to medical device software [36]
IEC 82304-1:2016	Health Software – Part 1: General requirements for product safety [37]
IEEE 829:2008	IEEE Standard for Software and System Test Documentation [13]

6.4 Wireless Standards

TABLE XX
WIRELESS STANDARDS

Standard	Description
IEEE 802.15.1	Wireless Personal Area Network standards [38]

6.5 Hardware Standards

TABLE XXI
HARDWARE STANDARDS

Standard	Description
ASME Y14.5:2008	Dimensioning and tolerancing [39]
ASME Y14.100:2017	Engineering Drawing practices [40]

6.6 Environmental Standards

TABLE XXII
ENVIRONMENTAL STANDARDS

Standard	Description
ISO 13.030.10	Wastes – Solid Wastes [41]
ISO 13.030.50	Wastes – Recycling – Including relevant equipment [42]
ISO 14040:2006	Environmental Management – Life cycle assessment – Principal and framework [43]
ISO 14044:2006	Environmental Management – Life cycle assessment – Requirements and Guidelines [44]
ISO 15270:2008	Plastics – Guideline for the recovery and recycling of plastics waste [45]

7 Conclusion

In the modern physiotherapy industry, resistance bands are commonly used for rehabilitation and strength training post injury. Traditional resistance bands have a fixed tension curve and does not adjust to the exercise or patient. It has been shown that isokinetic exercises [5] are beneficial to the speed and effectiveness of rehabilitation [7]. However, existing isokinetic machines are hard to use, expensive, and use a lot of space—they are rarely used by practicing physiotherapists. Instead, NovaBand provides a cost-effective and compact system to perform many of these exercises.

This document outlined the requirement specifications for the NovaBand product for physical, hardware, and firmware specifications of the device. The safety and sustainability aspects of the product were considered in order to keep the users safe and ensure a holistic cradle-to-cradle cycle. The engineering, medical, and hardware standards to which this product is subject have all been listed to ensure that NovaBand is viable on the world market. Finally, the expectations and goals are laid out for each different stage of development: alpha, beta, and production. The requirements for the alpha stage will be complete by April 2021 and the requirements for the beta stage will be complete by August 2021. The test plan for the alpha stage prototype is included below in Appendix A. to ensure that the NovaBand prototype functions as expected.

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Appendix A. Proof-of-concept Acceptance Test Plan

TABLE XXIII
GENERAL TEST PLAN

Requirement	Test Procedure	Validation Criteria	Pass/Fail
Thermal performance and safety	Use product for 30 minutes of moderate use. Measure temperature of heat-sensitive components.	The component does not produce noxious heat, temperature measured should not exceed 52˚ C [18].	
Programmatic resistance performance and software latency	Set the product to a specific resistance curve. Use a force meter and graph the force required.	The curve of force required should roughly match the resistance curve set by the user. The product should be ready within a period of one second.	
Cleaning and corrosivity durability	Wipe down the product with a standard amount of cleaner.	The product should not have any signs of degradation after a period of eight hours.	
Tension and Mounting performance	Mount the product and use at maximum resistance level (30 pounds) five times over one week for five minutes.	The product must not exhibit any wear and the maximum resistance level should not decrease. The mounting system must be stable and the product should not move at all when disturbed by shaking.	