Clotime
Impedance-based point of care blood coagulation monitoring device

Requirement specifications

FILE: BMEG556-2022 P04D02b “Clotime” Requirement Specifications V02draft1

Change history

Revision	Change	Change Date	Author
R1	Created	29/11/22	Walid
R2	Finalized for initial submission	05/11/22	Walid, Alireza, Dawn, Sadan
R3	Addition of RS21 and onwards following risk assessment	21/11/22	Walid, Alireza, Dawn, Sadan

Approvals

Title/Function	Signature	Scope of Approval	Date
Sadan Wani		Reviewer	07/12/22
Dawn Lo		Reviewer	07/12/22
Alireza Bahari		Reviewer	07/12/22
Walid AlChamaa		Primary Author	07/12/22

Table of Contents

List of tables

List of abbreviations

IR - initial requirements
RS - requirement specifications

1. General Information

1.1. Device name

The device and its components are named as follows:

- The Device: Referred to as “Clotime”, derived from the combination and truncation of the words Clot and time, or “the device”.
- The Strips: Referred to as “Clotime strips”, “test strips”, and “strips”

1.2 Scope

This document is intended to list and describe the requirement specifications and their relation with the initially set requirements. The document also includes the verification method for every requirement and the category under which the requirement falls. The requirements outlined in this document are intended to be accessible and comprehensive of the entire design. They will serve as a guide for the development of the device.

Add something about how this was updated (RS21 and onwards) after performing hazard analysis

Add soemthing about how this document is one in a series

1.3 Indications for use

The Clotime device is indicated for measuring blood coagulation time in patients with health conditions such as liver disease, hemophilia and thrombophilia [4]. These individuals are often at high risk of internal clotting or excessive blood loss.

1.4 Intended use

The device is intended for use in monitoring of coagulation time in patients. The user is any adult including medical professionals, patients, or patient’s caregivers. The system is intended for home use.

2. Initial Requirements

The following table lists initial requirements with their IR identifier. The requirements are assigned into one of the following categories: Functionality, Performance, Physical characteristics, Compatibility, Safety, and Labeling.

Table 1. List of initial requirements.

IR#	**Requirement**	**Category**
IR01	The device shall comply with the ergonomics of human-system interaction standards (ISO 9241-11) [5].	Physical characteristics
IR02	The device shall be easy to use (IEC 62366-1) [6].	Functionality
IR04	The device shall be capable of measuring blood coagulation time accurately and in a timely manner.	Performance
IR05	The device shall comply with portability requirements of the (IEC 62366-1) [6].	Safety
IR06	The device shall comply with medical data transfer standards of the (IEC 62304) [7].	Compatibility
IR07	Labelling of the device should be in English and French (SOR/98-282) [8].	Labeling
IR08	The device can be used independently without the support of other devices.	Functionality
IR09	The device shall comply with Electrical safety standards (IEC 60601-1) [9].	Safety
IR10	The device shall not cause harm to the user.	Safety

3. Requirement Specifications

The following table lists requirements with their RS identifier, and the rationale for the requirement. The requirements are assigned into one of the following categories: Functionality, Performance, Physical characteristics, Compatibility, Safety, and Labeling. The source links back to one of the Initial Requirements in **Table 1**. The verification methods are also listed.

Table 2. List of requirement specifications.

RS#	Category	Requirement	Rationale	Verification	Source
RS01	Physical characteristics	Easily accessible back-button on the display at all times.	The user should be able to easily rectify any input mistakes	Functional	IR01
RS02	Physical characteristics	Easily accessible menu button on the display at all times.	The user should be able to easily navigate the device's software.	Functional	IR01
RS03	Physical characteristics	Unidirectional strip-device interface.	To make it easy for users to know how to insert the strip into the device	Functional	IR01
RS04	Physical characteristics	The device is battery-powered.	To enable portability, the device shall be capable of working even when not connected to an external power source.	Functional	IR08
RS05	Physical characteristics	The device shall have rounded features with minimum radii of 20 mm.	The device should be easy to hold for users and robust in case of falls.	Measurement	IR01
RS06	Physical characteristics	The device shall weigh less than 250 g.	The device should be easy to hold.	Measurement	IR02
RS07	Functionality	The device shall measure blood accurately with a margin of error of 0.01 seconds, 99.9% of the time when compared to a prothrombin time test.	The device should provide the user with an accurate measurement for further action.	Measurement	IR04

RS#	Category	Requirement	Rationale	Verification	Source
RS08	Functionality	The device must be able to monitor battery health.	The user should be able to see in advance when to charge the device.	Functional	IR02
RS09	Compatibility	The device must be able to transmit data to Android, iOS, and Windows systems via a USB port using I2C communication protocol.	The user should be able to export data from the device.	Functional	IR06
RS10	Performance	The device shall be able to measure, calculate, and display a measurement within a maximum of 30 seconds.	The device should be able to output a measurement in a reasonably short amount of time for further action.	Measurement	IR04
RS11	Safety	The device shall operate at voltage $\leq$12V and $\leq$1.2 A.	To prevent electric shock to the user	Measurement	IR05
RS12	Labelling; safety	The device shall have warning labels instructing proper use of charging ports in both English and French.	The device shall provide instruction and warning to prevent electric shock to the user	Observational	IR05
RS13	Performance	The electrodes or other electrical connections must not be exposed.	To prevent damage to electrodes which could impair performance.	Functional	IR05
RS14	Labeling	The device shall be labelled with instructions for the user to consult with a clinician before taking further action based on the device's output in both English and French.	Untrained users should not be encouraged to make decisions on their care without input from a clinician.	Observational	IR05
RS15	Labelling	The power button shall be labelled in both English and French.	The user must be able to identify buttons easily.	Observational	IR01
RS16	Labelling	The ports shall be labelled in both English and French.	The user must be able to identify relevant ports easily.	Observational	IR01
RS17	Functionality	The size of the display text on the display shall be	The user shall be able to select a font	Measurement	IR01

RS#	Category	Requirement	Rationale	Verification	Source
		adjustable via the Settings option, with at least one option for font size 24px.	size suitable for their sight.		
RS18	Functionality	The LCD backlight shall be adjustable, with at least one option above TBD lumens.	The user shall be able to adjust the light settings to accommodate their sight.	Measurement	IR01
RS19	Functionality	The text featured on the surface of the device must be at least font size 15px.	The device labels shall be readable to the general population.	Measurement	IR01
RS20	Functionality	The device shall have an easily accessible page where users can read labels featured on the device (ex: RS14, RS12) in their preferred font size.	The user shall be able to access a digital version of the device's labels, should they be unable to read the warning labels.	Inspection	IR01, IR05
RS21	Safety	The device shall not be easily opened except by manufacturer or authorized persons.	Untrained personnel shall not be permitted open the device to prevent harm from befalling them as well as preventing damage to internal components of the device	Functional	IR09, IR01
RS22	Labeling	The device shall be labelled with clear instructions to not touch lithium battery under any circumstances.	The user shall not touch the lithium battery to prevent harm from befalling the user	Observational	IR09
RS23	Safety	The device shall have protection circuit connected to the battery	To avoid overcharging, over discharging, and short circuiting.	Functional	IR09
RS24	Safety	The device shall have thermal probes at the battery to maintain a suitable battery temperature.	When a critical thermal cutoff temperature is reached, the device	Measurement	IR10

RS#	Category	Requirement	Rationale	Verification	Source
			shall shut down to prevent burning hazard to the user.		
RS25	Physical characteristics	The device shall have a wrist strap.	The user shall use the wrist strap to prevent the device from falling in case of an accident	Observational	IR01
RS26	Labeling	The device shall provide instructions and warnings to store it out of reach of small children and in a secure location where it will not fall.	To prevent a falling hazard and harm to small children	Observational	IR10
RS27	Labeling	The device shall come with instructions that users use the device while seated at a table or desk.	To prevent a falling hazard	Observational	IR10
RS28	Physical characteristics	The device shall have an acrylic plastic screen	In case the device fell, to reduce the risk of the screen breaking.	Observational	IR01
RS29	Physical characteristics	The test strip container shall have a child safety lock.	To prevent chocking hazard from happening to small children	Observational	IR01
RS30	Physical characteristics	The non-functional parts of test strips shall be coated with bitrex.	To prevent cheldren from ingesting the test stips	Observational	IR01
RS31	Labeling	The test strips shall have instructions and warnings to store the test strips out of the reach of small children.	To prevent chocking hazard from happening to small children	Observational	IR01
RS32	Safety	The device shall have suitable and accessible disposal methods based on the region the device is sold in.	The user shall not be able to cause harm to the environment by improperly disposing of the device	Observational	
RS33	Safety	Sale of the device shall	The user shall safe	Observational	IR10

RS#	Category	Requirement	Rationale	Verification	Source
		include a secure container for storing used test strips before final disposal.	from harm caused by used strips before diposing of them		
RS34	Labeling	The device manual shall direct users to an instructional video.	To make sure that the user is well-educated on how to operate the device	Observational	IR02
RS35	Labeling	The device manual shall contain thorough instructions for use, reagents to be used, and more, with illustrations wherever suitable.	To make sure that the user is well-educated on how to operate the device	Observational	IR06
RS36	Safety	Sale or transfer of the device shall come with contact information of specialists or help services.	The user shall not be able to allow anautherized use of the drive	Observational	IR10
RS37	Functionality	The device software shall have reminders for calibration.	The results of the measurement shall remain within acceptable range of error	Functional	IR04
RS38	Labeling	The user manual shall instruct users to bring device to specialists for calibration at regular intervals (TBD).	The results of the measurement shall remain within acceptable range of error	Observational	IR04
RS47	Physical characteristics	The test strip docks shall be proprietary and compatible only with approved test strips.	The user shall not be able to damage the strip dock with unapproved test strips	Functional	IR01
RS40	Labeling	Users shall be instructed to not clean test dock.	To prevent unintentional damage to the test dack	Observational	IR07
RS41	Labeling	Instructions for cleaning the exterior of the device shall be included in the device manual	To make sure the user is well informed on how to clean the device to prevent	Observational	IR07

RS#	Category	Requirement	Rationale	Verification	Source
			unintentional damage		
RS42	Labeling	The device manual shall instruct users to bring device to specialists for cleaning and inspection of test dock at suitable intervals (TBD).	To prevent unintentional damage to the test dock	Observational	IR07
RS43	Labeling	The device shall be labeled with warnings against the dangers of electric shock.	The user shall never be harmed by using the device	Observational	IR10
RS44	Functionality	The device shall have reminders for users to bring device to specialists for software updates at regular intervals (TBD) should they be unable to do so themselves.	To make sure the device delivers the most accurate results at all times	Functional	IR04
RS45	Labeling	The device manual should provide clear instructions for indications of the device to both clinicians and users.	The user shall be well informed on how to operate the device	Observational	IR07
RS46	Safety	Over-the-counter sale of the device without the supervision or approval of clinicians shall be limited.	The user shall not be able to buy and distribute the device without the approval of a clinician	Observational	IR07

References

[1] S. Wani *et al.*, *P04D01 "Clotime" Product Concept*, CarePoint, 2022.

[2] A. Bahari *et al.*, *P04D02a "Clotime" Architectural Design*, CarePoint, 2022.

[3] W. AlChamaa *et al.*, *P04D02b "Clotime" Requirements Specifications*, CarePoint, 2022.

[4] A. Pietrangelo, *Coagulation tests: Types, procedure, and results*, Healthline, 2018. Accessed: Oct. 14, 2022. [Online]. Available: https://www.healthline.com/health/coagulation-tests

[5] ISO 9241-11, *Ergonomics of human-system interaction; Usability and human interaction*, 2018.

[6] IEC 62366-1, *Medical devices; Application of usability engineering to medical devices*, 2015.

[7] IEC 62304, *Medical device software; Software life cycle processes*, 2006.

[8] SOR/98-282 § 23(3), *Medical Devices Regulations*, "Labelling Requirements", Government of Canada. Accessed: Oct. 29, 2022. [Online]. Available: https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/

[9] IEC 60601-1, *Medical electrical equipment; General requirements for basic safety and essential performance*, 2015.