TIDEPOOL Standard Operating Procedure		Title: Risk Management	
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1. Purpose

1.1. The purpose of this procedure is to define the risk management process used by Tidepool for identifying hazards associated with Tidepool's medical devices, estimating and evaluating the associated risks, controlling these risks, and monitoring the effectiveness of the controls. This procedure defines the risk management activities required, including criteria for risk acceptability.

2. Scope

2.1. This procedure applies to all products developed by Tidepool in all phases of the product lifecycle.

3. References

3.1. ISO 14971:2019 Medical devices — Application of risk management to medical devices

3.2. ISO/TR 24971:2020 Medical devices — Guidance on the application of ISO 14971

3.3. ISO 13485:2016 Medical Devices - Quality Management Systems

3.4. 21 CFR Part 820, US FDA Quality Management System Regulation

3.5. 21 CFR Part 820.7 Incorporation by reference

3.6. AAMI TIR 45 Guidance on the use of AGILE practices in the development of medical device software

3.7. SOP-0004 Corrective and Preventive Action

3.8. SOP-0005 Design, Development and Release

3.9. SOP-0007 Complaint Handling

3.10. SOP-0008 Reportable Events

3.11. SOP-0009 Cybersecurity Risk Management

3.12. SOP-0010 User Experience Assessment

3.13. SOP-0012 Field Actions

3.14. DOC-0015 Explanation of Tidepool's Severity Definitions

3.15. DOC-0018 Explanation of Tidepool's LBGI Metric

3.16. DOC-0019 Explanation of Tidepool's DKAI Metric
3.17. TWI-0020 Risk Assessment for Tidepool Data Platform Tickets
3.18. TWI-0025 Clinical and Senior Management Risk Review

4. Definitions

4.1. Benefit - Positive impact or desirable outcome of the use of a medical device on the health of an individual, or a positive impact on patient management or public health
4.2. Harm - Injury or damage to the health of people, or damage to property or the environment
4.3. Hazard - Potential source of harm
4.4. Hazardous Situation - Circumstance in which people, property, or the environment are exposed to one or more hazard(s)
4.5. Life-cycle – All phases in the life of a medical device, from the initial conception to final decommissioning and disposal
4.6. Mitigation - A control applied to reduce the severity, probability of occurrence, or probability of harm if the situation occurs; this may include user interface design, software controls, or other elements. "Mitigation", throughout Tidepool's Quality Management System, has the same definition as "Risk Control Measure" as defined in ISO 14971 and should be considered an interchangeable term.
4.7. Post-production – Part of the life-cycle of the product after the design has been completed and medical device or software version has been deemed ready for commercialization or commercial release
4.8. Residual Risk – Risk remaining after risk control measures have been taken
4.9. Risk – Combination of the probability of occurrence of harm and the severity of that harm
4.10. Risk Analysis – Systematic use of available information to identify hazards and to estimate the risk
4.11. Risk Assessment – Overall process comprising a risk analysis and a risk evaluation
4.12. Risk Control – Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels
4.13. Risk Estimation – Process used to assign values to the probability of occurrence of harm and the severity of that harm
4.14. Risk Evaluation – Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk
4.15. Risk Management – Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk
4.16. Risk Management File (RMF) – Set of records and other documents that are produced by risk management
4.17. Safety – Freedom from unacceptable risk

4.18. Senior Management – One or more of CEO, VP of Product, VP of Engineering, VP of Quality, VP of Regulatory, VP of Support or other executive deemed as qualified by the CEO

4.19. Severity – Measure of the possible consequences of a hazard

4.20. State of the Art - Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

4.21. Use error – Act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user

4.22. Verification – Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

5. Summary of Tidepool Risk Management Process

5.1. All software and medical devices have risks. Tidepool's risk management process reduces risk to a level judged acceptable by Senior Management. Tidepool's policy for establishing acceptability criteria is stated in the Risk Acceptability section of this SOP.

5.2. Tidepool's risk management process is based on the existing state of the art for software and medical devices.

5.3. Tidepool's approach to controlling and evaluating risk is also based on these tenets:

5.3.1. **Reduction of risk through software iteration over time.** Processes that inhibit iteration cycles add risk. Tidepool uses agile design and development methodology (SOP-0005 and DOC-0001), including verification and validation processes. The more quickly we can iterate on our software, the more quickly we can converge on high quality software that meets the user's needs while maintaining (or improving) software safety and effectiveness.

5.3.2. **Comparison of risks and mitigations, including comparison to baseline risk of living with diabetes**: All software and medical devices contain risks and flaws, both known and unknown. Diabetes is also an inherently risky disease. Existence of a residual risk in Tidepool's software must be weighed against the benefit of Tidepool software or other diabetes management software for a person living with diabetes.

5.3.3. Risk identification, analysis, evaluation, control, and acceptance activities are iterative and continuous and are documented in Jira. Specifically:

5.3.3.1. All requirements and anomalies are documented within Jira. Changes to requirements are tracked within Jira. Designs are documented in Figma and linked to the appropriate Jira issues..

5.3.3.2. Each Jira issue must include a documented risk analysis before being moved to testing.

5.3.3.3. Prior to any software release, the risk analysis is reviewed and updated as applicable.

5.3.4. Other risk management activities may be performed at a point in time as follows:

5.3.4.1. A Risk Management Report (RMR) will be generated for a new product launch. The RMR will apply to the release version of the product. See the Risk Management Report section later in this SOP.

5.3.4.2. A benefit/risk analysis will be generated for a product regulatory submission or for a required regulatory report. The benefit/risk analysis will apply to the version described in the submission/report.

5.4. Tidepool's senior management ensures that there are adequate resources for the risk management process and that these personnel are qualified for risk management with the knowledge and experience appropriate to the tasks assigned to them.

6. Risk Management Plan

1.1. A risk management plan is established for each new product developed by Tidepool. The risk management plan will contain details specific to that product, including risk management activities, and relevant risk analysis, evaluation, and acceptability criteria.

7. Risk Analysis

7.1. Risk Analysis, consisting of hazard identification and risk estimation, is conducted on all risks. Hazard and hazardous situation identification is accomplished by using methods that are appropriate for the product being analyzed. Risk Estimation is conducted by assigning Severity and Probability scores to each identified hazardous situation. Tidepool's definitions of Severity and Probability are below.

7.2. For each identified risk, these questions are asked and the results are documented:

7.2.1. What is the severity of the harm that may occur if this risk occurs?

7.2.2. What is the probability that the harm will occur?

7.3. Severity and Probability assignments are made using available information or data.

7.4. Risk analysis occurs regularly and continuously as a part of all design and development activities as described in SOP-0005 Design, Development and Release. If a task is determined to have risk(s), then those risk(s) are documented as described in SOP-0005.

8. Definitions of Severity Terms

8.1. Severity of a risk is determined by applying the appropriate Severity Score from Table 1.

8.1.1. For each severity score, there is a general description of what the score represents (e.g. “The hazard results in inconvenience or temporary discomfort” for a score of 1).

8.1.2. The employee conducting the risk estimation will apply the appropriate severity score indicated by the description for that score.

8.1.3. For certain risks, the employee may use the Tidepool Risk Severity Evaluation Tool (TRSET) to inform their determination of an appropriate severity score. The TRSET scores scenarios defined by the employee conducting the risk estimation based on the two metrics measured by the TRSET, Diabetic Ketoacidosis Index (DKAI) and Low Blood Glucose Index (LBGI).[1] The mapping of DKAI and LBGI to Severity Scores is shown in Table 1.

8.1.4. Tidepool defines the harm for noncompliance with Web Content Accessibility Guidelines (WCAG) 2.2, Guideline 2.3 Level A as Seizure or Physical Reaction and assigns a severity level of 3 (Serious), consistent with the description of that level in Table 1.

Table 1. Tidepool Severity Scores

Severity Score	Criteria for TRSET outputs (where applicable)	Category	Description
5		Catastrophic	The hazard results in death.
	DKAI ≥ 21 hrs		Same BHB as Critical Risk. DKA that results in death.
	LBGI > 10 AND glucose of ≤ 40 mg/dL for 4 or more hours, OR glucose level that falls to 0 mg/dL.		Hypoglycemia that results in death.
4		Critical	The hazard results in permanent impairment or life-threatening injury.
	DKAI ≥ 21 hrs		The person with diabetes likely has Beta-Hydroxybutyrate (BHB) present in their blood at a level (>4.4 mmol/L) that indicates that they are in Diabetic Ketoacidosis (DKA), though the severity

[1] For details about DKAI and LBGI, DOC-0015 Explanation of Tidepool's Severity Definitions

			of the DKA could vary between mild, moderate, and severe. DKA that does not result in death.
	LBGI > 10		The person with diabetes experiences a hypoglycemic event resulting in permanent impairment, or life-threatening injury.
3		Serious	The hazard results in injury or impairment requiring medical intervention, including administration of IV fluids
	14 ≤ DKAI < 21 hrs		The person with diabetes likely has BHB present in their blood at a level (>3.0 mmol/L) that indicates they are likely, though not certainly in DKA.
	5 < LBGI ≤ 10		The person with diabetes experiences a hypoglycemic event that results in injury or impairment requiring medical intervention, including administration of IV fluids.
2		Minor	The hazard results in temporary injury or impairment not requiring medical intervention.
	8 ≤ DKAI < 14 hrs		The person with diabetes likely has BHB present in their blood at a level (BHB > 1.8 mmol/L) that requires monitoring, but is only a minor risk of DKA.
	2.5 < LBGI ≤ 5		The person with diabetes experiences a hypoglycemic event that results in temporary injury or impairment not requiring medical intervention.
1		Negligible	The hazard results in inconvenience or temporary discomfort.
	2 ≤ DKAI < 8 hrs		The person with diabetes likely has BHB present in their blood at a level (<1.8 mmol/L) that is not likely to be DKA.
	LBGI ≤ 2.5		The person with diabetes experiences a hypoglycemic event that results in inconvenience or temporary discomfort.

9. Definition of “Probability of Harm” Terms

9.1. Probability of a risk is determined by estimating the likelihood that the risk will manifest as a harm during the period of time indicated in the applicable Risk Management Plan and applying the appropriate Probability Score from Table 2.

9.2. In calculating probability, Tidepool uses the following method:

P_1 = Probability of a hazardous situation occurring (exposure)
P_2 = Probability of the hazardous situation leading to harm
$P_1 \times P_2$ = probability of harm

Table 2. Tidepool Probability Scores

Rating	Term	Probability (P) of occurrence of the harm	Description for clarity
5	Frequent	$P \geq 0.1$	Likely to occur 1 in 10 times or more often.
4	Probable	$0.01 \leq P < 0.1$	Likely to occur between (1 in 10) and (1 in 100) times.
3	Occasional	$0.0001 \leq P < 0.01$	Likely to occur between (1 in 100) and (1 in 10,000) times.
2	Remote	$0.000001 \leq P < 0.0001$	Likely to occur between (1 in 10,000) and (1 in 1,000,000) times.
1	Improbable	$P < 0.000001$	Likely to occur less frequently than 1 in a million times.

10. Risk Acceptability

10.1. Tidepool’s policy for establishing risk acceptability criteria for its products is to look to the state of the art for equivalent products and real world evidence, where available, to determine an appropriate boundary between acceptable and unacceptable risks. Where appropriate, details regarding the determination of acceptability for a particular product will be recorded in the appropriate Risk Management Plan.

10.2. Decisions about risk acceptability are based on the following table (Figure 1):

Figure 1. Risk Acceptability Matrix

(The value in each cell may be referred to as "Risk Acceptability Score" or "Risk Priority Number")

		Severity				
		Negligible (1)	Minor (2)	Serious (3)	Critical (4)	Catastrophic (5)
Probability	Frequent (5)	5	10	15	20	25
	Probable (4)	4	8	12	16	20
	Occasional (3)	3	6	9	12	15
	Remote (2)	2	4	6	8	10
	Improbable (1)	1	2	3	4	5

10.3. **GREEN Risks:** Risks are acceptable and do not prevent product release. Additional risk reduction measures shall be applied, where technically feasible, to reduce the risk as far as possible. Where no additional technically feasible risk control measures are identified, or where further reduction would not meaningfully improve safety, the product may be shipped as-is.

10.4. **YELLOW Risks:** Risks are conditionally acceptable, that is they are acceptable if they have been reduced as far as possible prior to product release.

10.5. **RED Risks**: Risks are unacceptable and must be reduced as far as possible prior to product release. If the risk remains RED after all possible risk controls are applied, a benefit-risk analysis must be performed, and a determination must be made and recorded by Senior Management that the benefits of the product justify accepting the residual risk prior to product release.

11. Risk Evaluation

11.1. For each identified risk, Tidepool will decide whether the risk can be further reduced. Any requirement for risk reduction, or if no further reduction is technically feasible or would not meaningfully improve safety, is recorded in the risk analysis.

11.2. All risks shall be reduced to a level judged acceptable by Senior Management and in accordance with this SOP.

11.3. Residual risks will generally be categorized as Acceptable, Conditionally Acceptable, or Unacceptable.

11.3.1. Risks determined to be Acceptable (GREEN) do not require further analysis or approval prior to product marketing or distribution.

11.3.2. Risks determined to be Conditionally Acceptable (YELLOW) may be determined to be acceptable if they have been reduced as far as possible and are approved by Senior Management.

11.3.3. Risks determined to be Unacceptable (RED) require reduction to Acceptable (or Conditionally Acceptable) levels, otherwise a risk-benefit analysis must be conducted and approved by Senior Management prior to product release.

12. Risk Control

12.1. When risk reduction is required, risk control activities as described below will be performed.

12.2. Risk control measures will be identified and documented. Risk control measures are applied in the following priority:

- Safety by design (inherent) - eliminates hazard or hazardous situation via design feature
- Protective measures - prevent or reduce likelihood of occurrence of hazard or hazardous situation, or reduce severity of harm
- Information for safety and, where appropriate, training to users - warnings, precautions, and/or information provided regarding hazard or hazardous situation

12.3. The risk control measures that are implemented are verified and the effectiveness of the risk control measures, which may include validation activities, are documented accordingly.

12.4. Upon implementing the risk control measures, the residual risks are then evaluated according to the criteria established above.

12.5. If residual risks are still determined to be unacceptable, additional risk controls will be identified and implemented.

12.6. For residual risks that have been reduced as far as possible, senior management will decide which residual risks to disclose and what information for safety is necessary to include in the Instructions for Use in order to disclose those residual risks.

12.7. Following the residual risk evaluation, an assessment is made as to whether the medical benefits of the device outweigh the residual risks. Benefits can be described in terms of positive impact on clinical outcome, and the patient’s quality of life. In comparing residual risks to benefits, the following should be considered:

- Characterization of the disease or condition of the intended patients;
- Uncertainty of data about risks and benefits of products that have not been released.
- Production and post-production information for similar products that are already available on the market;
- The generally acknowledged state of the art;

- Comparison of the residual risks and benefits of the product under development with the residual risks and benefits of similar products available on the market;

If the evaluation demonstrates that the benefits of the device do not outweigh the residual risks, the device is not released to production. Additional criteria for benefit-risk comparison may be provided in the Risk Management Plan.

12.8. The risk control measures that have been implemented are also evaluated to determine if they have introduced any new hazards or hazardous situations and whether the estimated risks for previously identified hazardous situations are affected.

12.9. Once all risk control measures have been implemented, a review is performed to determine whether the risks from all identified hazardous situations have been considered.

12.10. Tidepool will continuously and iteratively identify and consider risk control measures as new risk control measures may be identified or previously identified impracticable risk control measures may become practicable with the advance of technology.

13. Evaluation of Overall Residual Risk Acceptability

13.1. Prior to commercial availability of a new product, after all the risk control measures have been implemented and verified, it will be determined whether the overall residual risk posed by the medical device has been reduced to a level judged acceptable by Senior Management using the criteria defined in the Risk Management Plan for that product.

13.2. If the overall residual risk is not judged to be reduced to a level judged acceptable by Senior Management using the criteria established in the Risk Management Plan, then further data and literature may be gathered and reviewed to determine if the medical benefits of the intended use outweigh the overall residual risk. If the evidence supports that the benefits outweigh the overall residual risks, the overall residual risk can be judged to be acceptable. Otherwise, the overall residual risk remains unacceptable; a rationale for why the product can be released in this situation must be documented and approved by Senior Management.

14. Risk Management Report

14.1. Prior to release of a new product or new device integration, Tidepool reviews the risk management process to ensure that it has been appropriately implemented and that the overall residual risk of the new product is accepted.

14.2. These results will be documented in a Risk Management Report and included in the Risk Management File.

15. Production and Post-production Information

15.1. On an iterative, ongoing basis, complaints, bug reports and other user feedback are compiled and evaluated per SOP-0004 Corrective and Preventive Action and SOP-0007 Complaint Handling. This information is reviewed under this Risk Management Process to determine whether new hazardous situations have been discovered and what risk control measures are appropriate.

15.2. Senior Management will be immediately notified and a CAPA will be opened when:

15.2.1. A new hazardous situation with an unacceptable risk is discovered, New information is discovered with respect to a previously identified hazardous situation that results in a re-evaluation of the risk to an unacceptable level, or

15.2.2. New information brings a previously completed benefit-risk analysis into question.

15.2.3. See SOP-0012 Field Actions for details on communicating such issues to users and to regulatory authorities when applicable.

16. Documentation

16.1. A compilation of risk management information for a product (risk analysis, traceability of requirements to risks, traceability of verification & validation activities traceable to risks, risk evaluation of unresolved anomalies, etc.) can be exported from Jira on request.

16.2. Documentation of risk management activities is maintained in perpetuity per SOP-0002 Control of Quality Records.