Risk Management Report - Corowell

Approval			
Role	Name	Function	Date/ Signature
Author	5.1.2e	5.1.2e	5.1.2e
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Revision History			
ECO	Date	Author	Status – Change(s)
C00	14. Oct 2020	5.1.2e	Initial version

References and related documents

No.	Document name	Revision /date
1	CW20-0025 System Description	C00
2	CW20-0012 Risk Consideration	C00
3	CW20-0026 System Requirement Specification	C00
4	CW20-0020 Design Document Corowell System	C00

Definition, acronyms and abbreviations

Abb	Description
PHA	Preliminary Hazard Analysis

Table of Content

1 Introduction

This document is assessing the risks associated with the project Corowell and the mitigation plan of these risks. The core of the project is software developed for a COVID-19 Symptom Screening Test device residing on a paper card and Mobile Phone platform such as an iPhone. The Mobile Phone is a standard device designed and manufactured by e.g. Apple and out of scope of this document. Only the software and the usage of it are evaluated in this document.

The audience for this document is QA personnel, auditors and senior management.

2 Evaluation Criteria and ranking System

2.1 Likelihood of Failure Occurrence

O: Occurrence of hazard

Formula: none

Definition:

O is the probability of occurrence of HARM.
This number considers of two aspects,
    P1: *the probability of a HAZARDOUS SITUATION occurring and*
    P2: *probability of a HAZARDOUS SITUATION leading to a HARM.*
These two aspects influence the probability that a harm occurs.

For estimating Software errors the probability of a "HAZARDOUS SITUATION occurs" must be assume with 100%. But that does not mean that the probability of "OCCURANCE OF HARM" is always estimated with 5. The second aspect can reduce the probability.

P1 - Probability of a hazardous situation occurring

P1 Value	Classification	General Definition	Reference point for *Corowell COVID-19 Symptom Screening Test*
5	**Frequently**	Extremely Likely to occur	*Likely to occur in 10% < x of all uses*
4	**Probably**	Very likely, to occur	*Likely to occur in 1% < x of all uses*
3	**Occasionally**	Likely to occur	*Likely to occur in 0.1% < x of all uses*
2	**Remote**	Unlikely, to occur	*Likely to occur in 0.01% < x ≤ 0.1% of all uses*
1	**Improbably**	Extremely unlikely to occur	*Likely to occur in x ≤ 0.01% of all uses*

P2 - Probability of a hazardous situation leading to harm			
P2 Value	**Classification**	**General Definition**	**Reference point for Corowell COVID-19 Symptom Screening Test**
A	High	Likely to happen, often, frequent	*approximately 1:10 < x of all uses*
B	Medium	Can happen, but not frequently	*approximately 1:1000 < x ≤ 1:10 of all uses*
C	Low	Unlikely to happen, rare, remote	*approximately x ≤ 1:1000 of all of all uses*
X	N/A		

Occurrence Index O (= Probability of Occurrence of Harm: O = P1 x P2) Numeric Values in table represent Probability of Occurrence of Harm				
P2 / P1	**Improbably**	**Remote**	**Occasionally**	**Probably**	**Frequently**
High	1	2	3	4	5
Medium	1	1	2	3	4
Low	1	1	1	2	3
N/A	1	2	3	4	5

2.2 Failure Severity

Severity (S)

Formula: none

Definition:

S is the severity level for a specific harm under the assumption that the harm will occur. The likelihood for the sequence of events leading to this harm is irrelevant and shall not be considered for the qualification of the severity level.

Figure	Classification	General Definition:	Software classification
5	**Catastrophic:**	Leads to death of the patient	C
4	**Critical:**	Leads to a permanent disability or to a life-threatening injury	C
3	**Serious:**	Leads to a temporary injury or disability that required experienced medical intervention	B
2	**Minor:**	Leads to an injury or disability that **does not** required experienced medical intervention	A
1	**Negligible:**	Cause inconvenience or temporary afflictions	A

2.3 Security relevance

Who is affected by the harm:

- Patient
- User
- 3rd Party
- Environment

Type of component, the hazard is caused:

- Usability   caused by use
- Software   caused by software
- Construction   caused by mechanical parts
- PEMS   cause by electrical parts

2.4 Criteria for Risk Acceptability

The risk acceptance criteria the following assessment criteria are given:

- S: Severity;

- O: Occurrence of harm; Probability that a harm accrues.

Based on this evaluation criteria the following key figures are calculated:

- **RISK:** Estimated Risk is a product of O x S

Occurrence		Severity				
		Negligible 1	Minor 2	Serious 3	Critical 4	Catastrophic 5
Frequently	5	5	10	15	20	25
Probably	4	4	8	12	16	20
Occasional	3	3	6	9	12	15
Remote	2	2	4	6	8	10
Improbably	1	1	2	3	4	5

Criteria for risk acceptability		
Description	Symbol	Description
Broadly acceptable	$1 < RISK \le 10$	Risk is broadly acceptable ⇒no need to consider further risk reduction
Intolerable, not acceptable	RISK > 10	Risk is intolerable/unacceptable and must be reduced by reducing the severity and/or the likelihood/probability of the hazard (otherwise, stopping the project should be considered)

3 Risk Analysis

For the risk evaluation a Risk Analysis (Preliminary Hazard Analysis = PHA) was performed, see document *CW20-0012 Risk Consideration*

4 Intended Controls and Measures

Preventive actions and detection methods for the various potential hazards, hazardous situations have been listed within the scope of the performed Preliminary Hazard Analysis (PHA).

Part of the preventive and detective actions based on controls to be performed during development, manufacturing and/or assembly of 'Corowell COVID-19 Symptom Screening Test" or after assembly completion (final test and checks).

Intended Controls or Recommended actions are only given on first appearance.

This section describes the planned and taken measures used in risk analysis. These measures are grouped in 3 categories:

- Design (D)
- Verification Test or Protective Measure (V)
- Labeling (L) [e.g. warning message, notices in manual

ID-Risk Mitigation Measure	Description Risk Mitigation Measure / Requirement-ID (if applicable)	Subsystem
By Design (D)		
RM.D01	Using of Source Code Versioning systems like Bitbucket	Mobile App, Cloud Service
RM.D02	Choices of Scents shall use commonly known scents	Ticket
RM.D03	Using of role-based access and authorization system incl. Multi-Factor Identification	Cloud Service
RM.D04	Information on Product Label meet regulatory requirements & using of standard icons	Ticket, Mobile App, IFU
RM.D05	Encrypted communication via HTTPS, TLS v1.2	Mobile App, Cloud Service
RM.D06	Encryption of stored data at Cosmos DB	Cloud Service
RM.D07	using JSON data format for communication and storing of information	Mobile App, Cloud Service
By Protective Measure/Verification (V)		
RM.V01	App Verification by Apple/ Google before upload to Store	Mobile App
RM.V02	Scent Validation on printed samples, sampling of production lots (ANSI),	Ticket
RM.V03	Performing of Software Verification & Validation Tests	Mobile App, Cloud Service
By Information/ Labelling (L)		
RM.L01	IFU available in different languages on manufacturer website	IFU
RM.L02	Precaution at IFU: Due not use Corowell COVID-19 Symptom Screening Test in smell-intensive environment.	IFU
RM.L03	Precaution at IFU: Corowell COVID-19 Symptom Screening Test requires a proper connection to internet.	IFU

5 Summary

5.1 Residual Risk Evaluation

The PHA was performed during the design of *Corowell COVID-19 Symptom Screening Test.* The Risk Consideration has identified different potential hazards or hazardous situations that are related to safety or can cause harm. These potential harms are listed in *CW-20-0012 Risk Consideration* document. None were rated as critical after implementation of intended controls and suitable measures.

All intended measures are implemented, reviewed and lead to no other potential risks.

5.2 RISK /BENEFIT ASSESSMENT

Based on the evaluated low residual risk, the risk-benefit-ratio for the patient is considered to be acceptable.