Usability Engineering Report

Product Name: Demo Blaze E-commerce Platform

Model: Web Application v1.0

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Demo Blaze QA Team

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# 1 Executive summary

## 1.1 Product

### 1.1.1 Product name and model

Product Name: Demo Blaze E-commerce Platform

Model: Web Application v1.0

### 1.1.2 The difference between models

|  |  |  |  |
| --- | --- | --- | --- |
| Item | Model 1 | Model 2 | Model 3 |
| Features | Standard features | Enhanced features | Premium features |

## 1.2 Scope

This usability engineering process procedure is intended to provide safety for the patient, user and others related to usability. This usability engineering process procedure intended to address user interactions with the device according to the accompanying documentation, including, but not limited to: transport, storage, installation, operation, maintenance and repair, and disposal.

## 1.3 Executive summary

We conduct the usability engineering to Demo Blaze E-commerce Platform according to IEC 62366-1. We prepare use specification, identify user interface characteristics related to safety and potential use errors, identify known or foreseeable hazards and hazardous situations, identify and describe hazard-related use scenarios, establish user interface specification, and perform summative evaluation of the usability of the user interface.

# 2 Summary of the USE SPECIFICATION

## 2.1 Intended medical indication

Define the medical conditions or situations where the device is intended to be used

## 2.2 Intended PATIENT population

Define the target patient demographics (age groups: Adult, children, newborns)

## 2.3 Intended part of the body or type of tissue applied to or interacted with

Define the body parts or tissues that interact with the device

## 2.4 Intended USER PROFILE

Define the intended users (medical professionals, patients, caregivers)

## 2.5 USE ENVIRONMENT

Define the environment where the device will be used (operating conditions, settings)

## 2.6 Operating principle

Describe the fundamental operating principles of the device

# 3 Summary of known use problems

## 3.1 Identify USER INTERFACE characteristics related to SAFETY and potential USE ERRORS

|  |  |  |
| --- | --- | --- |
| List of Questions | Applicable or not | Hazard No. |
| Is successful application of the medical device dependent on the usability of the user interface? | Yes/No - To be evaluated | H-XX |
| Can the user interface design features contribute to use error? | Yes/No - To be evaluated | H-XX |
| Is the medical device used in an environment where distractions can cause use error? | Yes/No - To be evaluated | H-XX |
| Does the medical device have connecting parts or accessories? | Yes/No - To be evaluated | H-XX |
| Does the medical device have a control interface? | Yes/No - To be evaluated | H-XX |
| Does the medical device display information? | Yes/No - To be evaluated | H-XX |

## 3.2 Identify known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Hazard | Foreseeable sequence of events | Hazardous situation | Harm | Hazard No. |
| User enters incorrect login credentials | User enters incorrect login credentials | User unable to access account | Delayed access to services | H01 |
| User proceeds to checkout with empty cart | User proceeds to checkout with empty cart | System allows invalid transaction | User confusion and potential financial discrepancy | H02 |
| Contact form accepts empty fields | Contact form accepts empty fields | Invalid form submission processed | Loss of user message and communication failure | H03 |

# 4 Description of the HAZARD-RELATED USE SCENARIOS evaluated and why they were chosen

## 4.1 Risk Accept Level

### 4.1.1 SEVERITY level description of the HARM

|  |  |  |
| --- | --- | --- |
| Severity | Criteria | Scales |
| Catastrophic | Results in patient death | 5 |
| Critical | Results in permanent impairment or life-threatening injury | 4 |
| Serious | Results in injury or impairment requiring professional medical intervention | 3 |
| Minor | Results in temporary injury or impairment not requiring professional medical intervention | 2 |
| Negligible | Inconvenience or temporary discomfort | 1 |

### 4.1.2 Probability level (P)

|  |  |  |
| --- | --- | --- |
| Probability | Criteria | Scales |
| Frequent | ≥10⁻³ | 5 |
| Probable | ＜10⁻³ and ≥ 10⁻⁴ | 4 |
| Occasional | ＜ 10⁻⁴ and ≥ 10⁻⁵ | 3 |
| Remote | ＜ 10⁻⁵ and ≥ 10⁻⁶ | 2 |
| Improbable | ＜ 10⁻⁶ | 1 |

### 4.1.3 Risk evaluation criteria

Three ranges of risks are defined:

A: acceptable risk

R: Reasonable and feasible risk reduction

U: Unacceptable risk without risk or benefit analysis

## 4.2 Identify and describe HAZARD-RELATED USE SCENARIOS

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Hazards No. | Foreseeable sequence of events | Hazardous situation | Harm | P | S | R |
| H01 | User enters incorrect login credentials | User unable to access account | Delayed access to services | 3 | 2 | A |
| H02 | User proceeds to checkout with empty cart | System allows invalid transaction | User confusion and potential financial discrepancy | 2 | 3 | R |
| H03 | Contact form accepts empty fields | Invalid form submission processed | Loss of user message and communication failure | 3 | 2 | A |

# 5 Description of the USER INTERFACE

## 5.1 USER INTERFACE REQUIREMENTS

|  |  |  |
| --- | --- | --- |
| Functions | FUNCTION ANALYSIS | USER INTERFACE REQUIREMENTS |
| User Authentication | Secure login and logout functionality | User must be able to login with valid credentials within 30 seconds |
| Product Browsing | Navigate and view product catalog | Users must be able to browse products with clear navigation |
| Shopping Cart | Add, remove, and manage cart items | Users must receive clear feedback when adding items to cart |
| Checkout Process | Complete purchase transaction | Checkout process must validate cart contents before proceeding |

## 5.2 ACCOMPANYING DOCUMENTATION and training

The instructions for use is considered part of the MEDICAL DEVICE, USER INTERFACE REQUIREMENTS should be developed for instructions for use as part of the USER INTERFACE SPECIFICATION.

# 6 Summary of FORMATIVE EVALUATIONS

We design and implement the User interface and utilize appropriate usability engineering methods to accomplish the design and implementation. The details can refer to User Interface evaluation plan and Formative Evaluation report.

# 7 Summary of the SUMMATIVE EVALUATION

Upon completion of the design and implementation of the user interface, we perform a summative evaluation. The details can refer to User Interface evaluation plan and Summative Evaluation report.

# 8 User Interface of Unknown Provenance

Do not contain user interface of Unknown Provenance.

# 9 Conclusion

Through the analysis, inspection and confirmation of the expected use, use risk, user population, use scenario and user's characteristics of the product, the product meets the user's habits in clinical application, maintenance or human factor design. The usability engineering process has been completed in accordance with IEC 62366-1 requirements and the product is considered suitable for its intended use.