Devanshu Pal Consulting Group
Human Factors Evaluation Expert

Use-related Risk Analysis

Report produced by
Devanshu Pal

Devanshu Pal Human Factors Consulting Group

Natalie Davis
Director quality assurance,
Philips.

Dear Natalie and the quality assurance team,

I am writing to express our sincere appreciation for the opportunity to collaborate on the Use-Related Risk Analysis of the Philips HeartStart OnSite AED, as requested by your esteemed organization. Our team at Devanshu Pal Human Factors Consulting Group is enthusiastic about the prospect of contributing to the enhancement of safety and usability in healthcare technologies.

As a leading human factors consultancy with a proven track record in the medical device industry, we understand the critical importance of ensuring the usability and safety of life-saving devices such as the Philips HeartStart OnSite AED. Our team of experienced human factors professionals is dedicated to conducting comprehensive use-related risk analyses to identify and mitigate potential user errors and enhance the overall user experience.

If you require any further assistance with your current or future requirements, please do not hesitate to contact us at your convenience.

Best regards,

Devanshu Pal Human Factors Consulting Group
+1 (123) 456-7890

The comprehensive risk analysis report for the Philips HeartStart OnSite AED holds an amalgamation of risk matrix methods, task analysis, and Failure Modes and Effects Analysis (FMEA) to ensure a thorough evaluation of potential hazards and risks. The risk matrix method provides a visual representation of risks by plotting the likelihood and severity of identified hazards, enabling a clear prioritization of risks based on their potential impact. To achieve which, we conducted detailed task analysis, which plays a vital role in dissecting the complex user interactions associated with the AED. This approach allows for a detailed examination of each step, encountering potential human factors-related risks and providing valuable insights into user behavior. FMEA further contributes by systematically identifying failure modes, assessing their effects, and assigning risk priority numbers to prioritize mitigation efforts. By integrating these methodologies, the analysis achieves a holistic understanding of the AED's risk landscape, from technical failures to user-related challenges.

Click on the link to explore the detailed matrix of use-error risk classifications
https://docs.google.com/spreadsheets/d/1pXJGazPDXA8P3JDG9Gu7mS8cif8ioNpCrSggVclDle4/edit?usp=sharing

u-FMEA Table

Risk number	Hazardous scenario	Use error	Potential harm	Likelihood of failure	Severity of potential harm	Risk priority number (RPN)	Method of control	Effectiveness of control	Risk level with control	Risk acceptability
1	User failed to follow the instructions	User failed to provide CPR accurately	Patient may die	2	5	10	Audio feedback in case the CPR is ineffective or lack of pressure on chest.	2	20	Acceptable with review
2		Placing the pads in reverse with the wires facing outwards (Adults)	Device may not function due to which patient may die	2	5	10	Pads can be more versatile, they should sense the heart beat/rhythm form all ends	1	10	Acceptable
3		Misinterpreting the caution light and pressign shock button sooner than required or clearing off the environment	Patient may die	1	5	5	Caution light should be placed next to the shock button or should be integrated within the shock button	1	5	Acceptable
4	The zipper of the carry case gets stuck	Not removing the adhesive strips	Delay in life saving intervention which may lead to death	1	5	5	The case can have a different mechanism which can be easy to open and close the carry case	2	10	Acceptable
5	The patient is sweating excessively	The pads were not placed securely	Device may not function due to which patient may die	1	5	5	Audio feedback to clean the surface before placing on the pads	2	10	Acceptable
6	Provider or the patient removes the pads immediately after coming to conscious	Removing the pads immediately after the person moves	Patient will not be monitored	3	5	15	Audio feedback upon placement to inform the user to not take them off unless the mecial team arrives.	1	15	Acceptable with review
7	The patient collapsed on a metal bench	The patient was not relocated and intensity of shock may vary by the device	Patient may die	1	5	5	Audio feedback must guide to make sure patient is on ground	1	5	Acceptable
8	Provider is under stress	Pads pulled abruptly resulting in damaging of the pads	Device may not function due to which patient may die	2	5	10	Audio feedback prompting user to replace the damaged pads	1	10	Acceptable
9		Comes in contact with the person lying down in some form	Provider may be electrocuted	3	5	15	A warning signal either, visual or audio, given to the administrator prior to starting the process to tie up any loose clothing?	1	15	Acceptable with review
10		the user assumes an awkward hand posture and their fingers get entangled with the wires and disturbs the AED's function	Device may not function due to which patient may die	2	5	10	Audio feedback must guide to ensure the wires are not tangled anyway	1	10	Acceptable
11		Pressing the Information button instead of shock button while the caution light is blinking	Delay in life saving intervention which may lead to death	4	5	20	Caution light should be placed next to the shock button or should be integrated within the shock button	2	40	Acceptable with review
12	The patient didn't respond for long, or reacted very quickly	The administrator removes the pads assuming they are no longer needed while performing CPR	Device may not function due to which patient may die	2	5	10	Audio feedback upon placement to inform the user to not take them off unless the mecial team arrives.	1	10	Acceptable
13	The device was not reset for next use	User fails to connect the patch cartridges or fails to use the device in critical scenario	Device may not function due to which patient may die	1	5	5	Audio feedback upon the successful use of the device to help guide the reseting of the device for the next use.	1	5	Acceptable
14	Removing clothes of the patient	User doesnt have any sharp object or scissors	Defibrilation won't be performed	3	5	15	OnSite kit must have a blade or a small scissors to help cutting the clothes	2	30	Acceptable with review

Effectiveness of control		
5	Very ineffective	The method of control increases the delay in delivering care resulting in an increased probability of harm to the patient
4	Slightly ineffective	The method of control only slightly increases the delay in delivering care resulting in an increased probability of harm to the patient
3	No difference	The method of control neither reduces nor delays in delivering care to the patient.
2	Slightly effective	The method of control decreases delayed time for the administrator compared to the previous workings of the AED.
1	Very effective	The method of control doesn't delay time for the administrator compared to the previous workings of the AED.