

										occurrence				detection				mitigation				mitigation				
id	type	error	effect	Rate	Cause	severity	Rate		Rate	Method	Rate	Method	Rate	Method	Rate	Method	Rate	Method	Rate	Method	Rate	Method	Rate	Method		
							Rate	Method																	Rate	Method
[032d]	Labelling	Instructions for use are tampered	Misinterpretation	5	No paper instructions for use	5	1	None	10	50	IFU in app/IFU website/helpdesk/Software System Tests	3	1	15												
[05ab]	User	Misinterpretations of the product claims	Misinterpretation	3	User error: instructions for use overlooked	3	5	None	10	150	Description App Store/Terms of service/Privacy Policy/IFU in app	10	3	90												
[070d]	Technical	Hardware related problems	No measurements possible	3	Hardware error	3	3	None	10	90																
[0a62]	Design/Technical	Patient can not link to physician account	No measurements possible	3	Complex design/software error	5	5	None	10	150	Prescription/Clearly presented instructions/IFU in app/IFU in website/Usability Studies/Software system tests	5	3	45												
[0a30]	Labelling	User does not have enough knowledge or experience to open the instructions for use	No measurements possible	3	No paper instructions for use	5	5	None	10	150	Usability Engineering/IFU on website/helpdesk/IFU Button	5	3	45												
[112b]	Technical	Flash failure	No measurements possible	3	Hardware error	3	3	None	10	90																
[11c1]	Design	Poor mapping of controls to actions of displayed information to actual state	No measurements possible	3	Complex design	5	5	None	10	150	Usability studies	5	3	45												
[118b]	Labelling	Problems to use the application due to the fact that the environment requires paper instructions for use	No measurements possible	3	No paper instructions for use	1	1	None	10	30																
[11c1]	Technical	No diagnosis possible due to hardware related problems	No diagnosis possible	3	Hardware error	3	3	None	10	90																
[20c4]	Technical	Camera failure	No measurements possible	3	Hardware error	3	3	None	10	90	Software System Test/Software detection	3	3	27												
[20c4]	Technical	Use on children	No measurements possible	3	User error: instructions for use overlooked	3	3	None	10	90	Instructions for use in app	5	3	72												
[2155]	User	Use of FibrCheck by SUT's that didn't follow the instructions for use	No measurements possible	3	User error: instructions for use overlooked	3	3	None	10	90	Instruction screen/instructions on prescription/IFU in app/Software detection	8	3	45												
[2419]	Design	Complex or confusing control system	No measurements possible	3	Complex design	5	5	None	10	150	Usability studies	5	3	45												
[2497]	Technical	No analysis possible due to hardware related problems	No diagnosis possible	3	Hardware error	3	3	None	10	90																
[3699]	User	Poor finger positioning	No measurements possible	3	User error: instructions for use overlooked	8	8	None	10	240	Instruction screen/instructions on prescription/IFU in app/Software detection	3	5	45												
[3716]	User/Design	User can't adjust control of a measurement	Misinterpretation	3	User error: instructions for use overlooked or complex design	3	3	None	10	150	Instructions for use in app/Usability Studies/Software System Tests	5	3	75												
[375b]	Technical	No immediate diagnosis possible due to no data-communication signal available (e.g. WiFi, cellular data connection)	No diagnosis possible	3	Connectivity error	5	5	None	10	150	Software System Test/Software detection	8	3	72												
[3a4d]	User	User has forgotten pincode	No measurements possible	3	User error: instructions for use overlooked	5	5	None	10	150	Instructions for use in app/Forget pincode button	10	3	90												
[349c]	User	Measurement of bad quality	False positive result	3	User error: instructions for use overlooked	8	8	None	10	240	Prescription is used/ IFU in app/Education page/Pop-up measurement is sent to physician	10	1	30												
[446b]	Design	User can't set a new password	No measurements possible	3	Complex design	3	3	None	10	90	Clear instructions presented on smartphone screen/Software System Tests/Usability Studies/Instructions for use in App	5	3	45												
[481f]	Technical	FibrCheck does not launch	No measurements possible	3	Specifications overlooked	3	3	None	10	90	Software System Tests/IFU website	3	3	27												
[4842]	User	Misinterpretation of the obtained results	Misinterpretation	5	User error: instructions for use overlooked	5	5	None	10	250	Prescription is used/ IFU in app/Education page/Terms of service	10	3	150												
[484f]	User	SUT is speaking during measurement	No measurements possible	3	User error: instructions for use overlooked	5	5	None	10	150	Instructions on prescription/IFU in app	10	3	90												
[486b]	User	User changes treatment/therapy based on obtained results	Misinterpretation	5	User error: instructions for use overlooked	5	5	None	10	250	Prescription is used/ IFU in app/Education page	10	3	150												
[4890]	User/Design	User can't set a pincode	No measurements possible	3	User error: instructions for use overlooked or complex design	3	3	None	10	90	Clear instructions presented on smartphone screen/Software System Tests/Usability Studies	5	3	45												
[5967]	Technical	Device contains non-authentic parts resulting in impaired device functioning	False positive result	3	Mis use of smartphone	3	3	None	10	90																
[5a2b]	Technical	Changes in SQUP	No measurements possible	3	Update of SQUP	5	5	None	10	150																
[5a41]	Technical	SUT is linked to wrong doctor	Wrong subject diagnosed	3	Software error	3	3	None	10	90	Software System Test/Prescription	5	1	15												
[612c]	User	SUT with conditions that impact the blood circulation in the fingers (e.g. perniois, cold fingers...)	No measurements possible	3	User error: instructions for use overlooked	3	3	None	10	90	Instructions for use in app	10	3	90												
[614d]	Design	Inadequate specification of hardware performance requirements	No measurements possible	3	Incomplete specifications or user error: instructions for use overlooked	5	5	None	10	150	Description App Store/IFU in app/Website	10	3	90												
[6892]	User	FibrCheck is used during activities that require undivided attention (e.g. driving, flying...)	No measurements possible	3	User error: instructions for use overlooked	5	5	None	10	150	Instructions on prescription/IFU in app/Software detects too much movement	8	3	72												
[6c78]	User	Use on non-humans	No measurements possible	3	User error: instructions for use overlooked	3	3	None	10	90	Instructions for use in app	10	3	90												
[708a]	User	Integration of results by the SUT	Misinterpretation	5	User error: instructions for use overlooked	8	8	None	10	420	Prescription is used/ IFU in app/Education page	10	3	150												
[70c1]	Labelling	Problems to use the application due to no access of a paper version of the IFU	No measurements possible	3	No paper instructions for use	3	3	None	10	90	Usability Engineering/Clearly presented instructions in App/ IFU in app/ IFU on website/helpdesk	5	3	45												
[71a3]	Labelling	Problems to use the application due to no access of the IFU on the website	No measurements possible	3	Server down or software error	3	3	None	10	90	Software monitoring	3	3	27												
[7194]	User	User tries to diagnose based on FibrCheck alone	Misinterpretation	3	User error: instructions for use overlooked	5	5	None	10	250	Prescription is used/ IFU in app/Education page/Pop-up measurement is sent to physician	10	3	150												
[7e4b]	Labelling	Inadequate specification of intended use	No measurements possible	3	Incomplete instruction for use	3	3	None	10	90	Description App Store/Terms of service/Privacy Policy/IFU in app	5	3	45												
[802a]	User	Deposits are present on the camera lens, flash or screen	No measurements possible	3	User error: instructions for use overlooked	5	5	None	10	150	Instructions for use in app/finger detection	10	3	90												
[8049]	User	Movements during measurement	No measurements possible	3	User error: instructions for use overlooked	8	8	None	10	240	Instruction screen/instructions on prescription/IFU in app/Software detection	8	5	120												
[809a]	Technical	Memory failure	No measurements possible	3	Device limitations	5	5	None	10	150																
[822a]	Labelling	User does not have enough knowledge or experience to use the device	No measurements possible	3	No paper instructions for use	5	5	None	10	150	Usability Engineering/Clearly presented instructions in App/ IFU in app/ IFU on website/helpdesk	5	3	45												
[824a]	User	User can't open the FibrCheck application	No measurements possible	3	Software error or user error: instructions for use overlooked	3	3	None	10	90	Software System Test	10	1	30												
[8465]	Design	Insufficient visibility, audibility and tactility	No measurements possible	3	Complex design	3	3	None	10	90	Usability studies	5	3	45												
[846a]	Technical	Environmental factors that can impair the hardware to perform the required processing for FibrCheck (i.e. Electromagnetic interference, temperature, moist, AC...)	No measurements possible	3	User error: instructions for use overlooked	3	3	None	10	90	Instructions for use in app	10	1	30												
[8678]	User	FibrCheck App is used on body parts different than targeted fingers	No measurements possible	3	User error: instructions for use overlooked	3	3	None	10	90	Instruction screen/instructions on prescription/IFU in app	5	3	45												
[889a]	User	Use of software emulators	No measurements possible	3	Mis use	1	1	None	10	30																
[8a7e]	User	Interpretation of self-diagnosis based on "raw signal"	Misinterpretation	5	User error: instructions for use overlooked	8	8	None	10	420	Prescription is used/ IFU in app/Education page	10	3	150												
[8a7d]	User/Design	FibrCheck account can't be verified	Wrong contact details	3	User error: wrong emuladores or type	3	3	None	10	90	IFU in app/Usability Studies/helpdesk	5	3	45												
[967f]	Technical	Changes or updates in Operating System	No measurements possible	3	Software error	3	3	None	10	90	Software System Test	3	3	27												
[984b]	Technical	Erroneous data transfer	No diagnosis possible	3	Connectivity error	3	3	None	10	90																
[9c87]	User	FibrCheck used while drinking or eating	No measurements possible	3	User error: instructions for use overlooked	5	5	None	10	150	Instructions on prescription/IFU in app	10	3	90												
[a40f]	Design	Inadequate disclosure of limitations	No measurements possible	3	Device limitations	5	5	None	10	150	IFU in app/Usability Studies/helpdesk	5	5	75												
[a49b]	Technical	Screen failure	No measurements possible	3	Hardware error	3	3	None	10	90																
[a67c]	Technical	Smartphone model is not compatible with FibrCheck	No measurements possible	3	User error: instructions for use overlooked	3	3	None	10	90	Description App Store/IFU in app/Website	3	3	27												
[a6b6]	Labelling	No access to the instructions for use due to hardware fault	No measurements possible	3	Hardware error	1	1	None	10	30	Device compatibility	8	1	24												
[b18b]	User	Too much ambient noise to perform a high quality measurement	No measurements possible	3	User error: instructions for use overlooked	5	5	None	10	150	Instructions on prescription/IFU in app/Software detection	5	3	45												
[b245]	Labelling	No access to the instructions for use due to software fault	No measurements possible	3	Software error	1	1	None	10	30	Software System Test/IFU in app/website/helpdesk	1	1	3												
[b32c]	Technical	FibrCheck does not perform the indicated function	No measurements possible	3	Software error	3	3	None	10	90	Software System Test	3	3	27												
[b32a]	User/Design	User can't register	No measurements possible	3	User error: instructions for use overlooked or prescription overlooked or complex design	3	3	None	10	90	Instructions on prescription/IFU in app/Clear design/Website/Usability Studies/Software system test	5	3	45												
[b54a]	User	FibrCheck used while performing activities other than sitting	No measurements possible	3	User error: instructions for use overlooked	5	5	None	10	150	Instructions on prescription/IFU in app	10	3	90												
[b92d]	User	Unclear fingers	No measurements possible	3	User error: instructions for use overlooked	3	3	None	10	90	Instructions for use in app	10	3	90												
[b94f]	Technical	Device temperature exceeds normal operating conditions impairing the correct functioning of FibrCheck	No measurements possible	3	Device limitations	3	3	None	10	90	IFU in app/Website/helpdesk/App description	8	1	24												
[ba23]	Design	Unable to login to FibrCheck	No measurements possible	3	Software error or user error: instructions for use overlooked or software error	5	5	None	10	150	Software System Tests/IFU in app/website/helpdesk/usability studies	5	3	45												
[c440]	Labelling	No access to instructions for use due to no data-communication signal available (e.g. WiFi, cellular data connection) when lagged off	No measurements possible	3	Connectivity error	3	3	None	10	90	IFU in app/IFU on website/Software System Tests	5	1	15												
[c68b]	User	Wet or damp fingers	No measurements possible	3	User error: instructions for use overlooked	3	3	None	10	90	Instructions for use in app	10	3	90												
[c81f]	Labelling	Problems to use the application due to the fact that the user does not receive a requested paper IFU in time	No measurements possible	3	No paper instructions for use	3	3	None	10	90	Complaint handling/IFU on website for printing/XPI	3	3	27												
[c833]	Labelling	User has no rapid access to electronic IFU at the time of use	No measurements possible	3	No paper instructions for use	5	5	None	10	150	Usability Engineering/IFU on website/helpdesk/IFU Button	5	3	45												