

Risk Level Report

Application: Head-Fixture Device product assessment
 Description:
 Product Identifier:
 Assessment Type: Detailed
 Limits:
 Sources:
 Risk Scoring System: designsafe Three Factor

Analyst Name(s): Debra Yen, Mengqian (Vera) Xiao, Taylor Tso
 Company: Pulse Therapeutics, Inc.
 Facility Location: 611 Olive Street
 St. Louis, MO 63101

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

Final Assessment

Final Assessment						Initial Assessment		Status / Responsible / Reference
Severity Exposure Probability	Risk Level	Item Id	User / Task	Hazard / Failure Mode	Risk Reduction Methods / Comments	Severity Exposure Probability	Risk Level	
Minimal Remote Unlikely	Low	1-1-1	adult normal use	mechanical : product instability If adhesive is not sufficient or 5 minutes have not passed after application, then device may be unstable on patient's head while elastic straps are hooked to opposite pedestal. This may irritate the patient by pulling on his/her hair or skin.	instruction manuals, video, on-the-job training (OJT)	Minimal Occasional Possible	Moderate	TBD
Minimal Occasional Unlikely	Low	1-1-2	adult normal use	slips / trips / falls : trip User may trip over probe cables.	warning label(s), special procedures (station ultrasound system in a standardized location away from traffic area around patient, make sure cables are placed out of the way)	Minimal Frequent Probable	High	TBD
Minimal Remote Unlikely	Low	1-1-3	adult normal use	slips / trips / falls : falling material / object The headset may fall off the patient's head after setup if not successfully adhered, or user may drop device. Falling device may harm the user.	instruction manuals, video, on-the-job training (OJT)	Minimal Occasional Possible	Moderate	TBD

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Severity	Exposure	Probability	Risk Level	Item Id	User / Task	Hazard / Failure Mode	Risk Reduction Methods / Comments		Severity	Exposure	Probability	Risk Level
Minimal	Remote	Unlikely	Low	1-1-4	adult normal use	ergonomics / human factors : physical discomfort Elastic straps may compromise blood circulation in the head if they are too tight for the patient. This may cause the patient discomfort and/or dizziness.	adjustable enclosures / barriers (provide option of switching to longer/shorter straps for increased comfort)	Minimal	Occasional	Possible	Moderate	TBD
Minimal	Occasional	Unlikely	Low	1-2-1	adult cleaning	chemicals and gases : acetone Acetone is used to dissolve the adhesive after use of the headset. It is highly flammable and irritating to the eyes. Vapors can cause drowsiness and dizziness.	warning label(s), instruction manuals, video, on-the-job training (OJT), special procedures (shield patient's eyes)	Minimal	Frequent	Probable	High	TBD
Minimal	Remote	Unlikely	Low	1-3-1	adult storage	slips / trips / falls : falling material / object Headset may fall from an improper storage location.	instruction manuals, fixed enclosures / barriers (designated storage area within therapy cart)	Minimal	Occasional	Possible	Moderate	TBD
Minimal	Remote	Negligible	Low	1-4-1	adult misuse	mechanical : drawing-in / trapping / entanglement User may become tangled in the probe cables.	warning label(s), special procedures (station ultrasound system in a standardized location away from traffic area around patient, make sure cables are placed out of the way)	Minimal	Remote	Unlikely	Low	TBD
Minimal	Remote	Unlikely	Low	1-4-2	adult misuse	mechanical : accidental adhesion Adding the adhesive before the probe is in desired position/angle and before plate is screwed downwards to the surface of patient's head may cause accidental adhesion to the user or patient.	instruction manuals, supervision, video, on-the-job training (OJT)	Minimal	Occasional	Possible	Moderate	TBD

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Severity	Exposure	Probability	Risk Level	Item Id	User / Task	Hazard / Failure Mode	Risk Reduction Methods / Comments		Severity	Exposure	Probability	Risk Level
Minimal Remote Negligible			Low	1-4-3	adult misuse	ergonomics / human factors : duration If probe is not locked in place, then user may need to hold the probe in place for the rest of the duration of the therapy (up to 90 min).	supervision, on-the-job training (OJT)	Minimal Occasional Possible			Moderate	TBD
Slight None Negligible			Low	1-4-4	adult misuse	ventilation / confined space : lack of fresh air If elastic straps cover patient's nose or mouth, then breathing would be difficult for the patient.	instruction manuals, video, supervision, standard procedures	Slight Remote Unlikely			Low	TBD
Serious None Negligible			Low	1-4-5	adult misuse	chemical : reaction to / with irritant chemicals One of the ingredients of colloidon, the adhesive used, is ethyl ether, which can cause irritation of the nose and eyes, dizziness, lung irritation, etc with acute exposure. OSHA permissible exposure limit for ethyl ether is 400ppm as 8-hour TWA.	standard procedures, instruction manuals, video, supervision, warning label(s), fixed enclosures / barriers (apply colloidon in tubes directly to adhesion sites), on-the-job training (OJT)	Serious Frequent Negligible			Moderate	TBD
Minimal Occasional Unlikely			Low	1-5-1	adult test / practice	mechanical : product instability If adhesive is not sufficient or 5 minutes have not passed after application, then device may be unstable on tester's head while elastic straps are hooked to opposite pedestal. This may irritate the tester by pulling on his/her hair or skin.	instruction manuals, video, supervision, substitute less hazardous material / methods (reexamine adhesive material or adhesion protocol)	Minimal Frequent Probable			High	TBD
Minimal Occasional Unlikely			Low	1-5-2	adult test / practice	slips / trips / falls : falling material / object The headset may fall off the tester's head after setup if not successfully adhered, or user may drop device. Falling device may harm the user.	instruction manuals, video, supervision	Minimal Frequent Probable			High	TBD

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Severity	Exposure	Probability	Risk Level	Item Id	User / Task	Hazard / Failure Mode	Risk Reduction Methods / Comments		Severity	Exposure	Probability	Risk Level
Minimal None Negligible			Low	1-5-3	adult test / practice	ergonomics / human factors : physical discomfort Elastic straps may compromise blood circulation in the head if they are too tight for the tester. This may cause the tester discomfort and/or dizziness.	adjustable enclosures / barriers (provide option of switching to longer/shorter straps for increased comfort), instruction manuals, supervision	Minimal Occasional Possible			Moderate	TBD
Minimal Occasional Unlikely			Low	2-1-1	passer-by / non-user walk near	slips / trips / falls : trip Passer-by may trip over probe cables.	warning label(s), special procedures (station ultrasound system in a standardized location away from traffic area around patient, make sure cables are placed out of the way)	Minimal Occasional Possible			Moderate	TBD
				2-2	passer-by / non-user observe / watch	<None>						