

designsafe Report

Application: Head-Fixture Device product assessment Analyst Name(s): Debra Yen, Mengqian (Vera) Xiao, Taylor Tso
 Description: Company: Pulse Therapeutics, Inc.
 Product Identifier: Facility Location: 611 Olive Street
 Assessment Type: Detailed St. Louis, MO 63101
 Limits:
 Sources:
 Risk Scoring System: designsafe Three Factor

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

Item Id	User / Task	Hazard / Failure Mode	Initial Assessment		Risk Reduction Methods /Comments	Final Assessment		Status / Responsible /Reference
			Severity Exposure Probability	Risk Level		Severity Exposure Probability	Risk Level	
1-1-1	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.	Minimal Frequent Probable	High	instruction manuals, video, supervision, substitute less hazardous material / methods (reexamine adhesive material or adhesion protocol)	Minimal Occasional Unlikely	Low	TBD
1-1-2	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.	Minimal Frequent Probable	High	instruction manuals, video, supervision	Minimal Occasional Unlikely	Low	TBD
1-1-3	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.	Minimal Occasional Possible	Moderate	adjustable enclosures / barriers (provide option of switching to longer/shorter straps for increased comfort), instruction manuals, supervision	Minimal None Negligible	Low	TBD

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			Severity Exposure Probability	Risk Level		Severity Exposure Probability	Risk Level	
1-2-1	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.	Minimal Occasional Possible	Moderate	instruction manuals, video, on-the-job training (OJT)	Minimal Remote Unlikely	Low	TBD
1-2-2	adult normal use	slips / trips / falls : trip User may trip over probe cables.	Minimal Frequent Probable	High	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 Unlikely	Low	TBD
1-2-3	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.	Minimal Occasional Possible	Moderate	instruction manuals, video, on-the-job training (OJT)	Minimal Remote Unlikely	Low	TBD
1-2-4	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.	Minimal Occasional Possible	Moderate	adjustable enclosures / barriers (provide option of switching to longer/shorter straps for increased comfort)	Minimal Remote Unlikely	Low	TBD
1-3-1	adult repair tasks	mechanical : cutting / severing The elastic strips should be cut and replaced every 3 months. User may be harmed by scissors.	Minimal Remote Unlikely	Low	warning label(s)	Minimal Remote Negligible	Low	TBD

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1-4-1	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.	Minimal Frequent Probable	High	warning label(s), instruction manuals, video, on-the-job training (OJT), special procedures (shield patient's eyes)	Minimal Occasional Unlikely	Low	TBD
1-5-1	adult storage	slips / trips / falls : falling material / object Headset may fall from an improper storage location.	Minimal Occasional Possible	Moderate	instruction manuals, fixed enclosures / barriers (designated storage area within therapy cart)	Minimal Remote Unlikely	Low	TBD
1-6-1	adult misuse	mechanical : drawing-in / trapping / entanglement User may become tangled in the probe cables.	Minimal Remote Unlikely	Low	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 Negligible	Low	TBD
1-6-2	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.	Minimal Occasional Possible	Moderate	instruction manuals, supervision, video, on-the-job training (OJT)	Minimal Remote Unlikely	Low	TBD
1-6-3	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).	Minimal Occasional Possible	Moderate	supervision, on-the-job training (OJT)	Minimal Remote Negligible	Low	TBD

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1-6-4	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.	Slight Remote Unlikely	Low	instruction manuals, video, supervision, standard procedures	Slight None Negligible	Low	TBD
1-6-5	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.	Serious Frequent Negligible	Moderate	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 None Negligible	Low	TBD
2-1-1	passer-by / non-user walk near	slips / trips / falls : trip Passer-by may trip over probe cables.	Minimal Occasional Possible	Moderate	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 Unlikely	Low	TBD
2-2	passer-by / non-user observe / watch	<None>						