designsafe Report

Application:	Bloodless Glucose Monitor		Analyst Name(s):	Tom Zhou
Description:			Company:	
Product Identifier:			Facility Location:	
Assessment Type:	Detailed			
Limits:				
Sources:				
Risk Scoring System:	ANSI B11.0 (TR3) Two 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 Severity Probability	Risk Level	Risk Reduction Methods	Final Assessment Severity /Comments	Probability	Status / Responsible Risk Level /Reference
1-1-1	Doctor conduct tests	electrical / electronic : improper wiring	Moderate Unlikely	Low	Protect circuit from physical contact	Moderate		
1-1-2	Doctor conduct tests	lasers : eye exposure	Serious Unlikely	Medium	Add warning label	Serious		
1-2-1	Doctor calibrate / test / troubleshoot medical monitoring equipment	electrical / electronic : improper wiring	Moderate Unlikely	Low	Protect circuit from physical contact	Moderate		

1-2-2	Doctor	lasers : eye exposure	Serious	<mark>Medium</mark>	Add warning label	Serious
	calibrate / test / troubleshoot medical monitoring equipment		Unlikely			
2-1-1	Patient	electrical / electronic : improper wiring	Moderate	<mark>Low</mark>	Protect circuit from physical contact	Moderate
	All Activities		Unlikely			
2-1-2	Patient	lasers : eye exposure	Serious	<mark>Medium</mark>	Add warning label	Serious
	All Activities		Unlikely			

Page 1