

designsafe Report

Application: defibrillator

Analyst Name(s):

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 | | Risk Reduction Methods /Comments | Final Assessment | | Status / Responsible /Reference |
|---------|---------------------------|--|----------------------|------------|--|----------------------|------------|---------------------------------|
| | | | Severity Probability | Risk Level | | Severity Probability | Risk Level | |
| 1-1-1 | All Users Common Tasks | electrical / electronic : shorts / arcing / sparking Incorrect placement of electrodes and an optimal environment for carrying current through the air (for example, high oxygen content) | Serious Unlikely | Medium | standard procedures, warning label(s) /Shorts and arcing are unlikely to occur with our configuration because both electrodes are internal. This risk can be made remote by training the operating room staff on proper electrode placement. | Serious Remote | Low | |
| 1-1-2 | All Users Common Tasks | electrical / electronic : water / wet locations Water from the patient's body as well as from solutions used during the procedure present an electrical hazard | Serious Likely | High | on-the-job training (OJT), standard procedures, warning label(s) /Wet towels/sponges are discarded during the surgical procedure. These should be placed far from the patient to avoid an accidental electrical connection to people or equipment. Operating staff are trained to clear during defibrillator operation. | Serious Remote | Low | |

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| 1-1-3 | All Users Common Tasks | fire and explosions : ignitable oxygen supply If the patient is on oxygen during the procedure, this increases the likelihood of sparking or fire when the defibrillator is used. | Catastrophic Likely | High | instruction manuals, special procedures, warning label(s) /Special training may be required to inform staff working with oxygen to check for leaks or open airflow systems before using the defibrillator. Circulation systems in the operating room should be checked to ensure they are functioning properly. | Catastrophic Remote | Low | |
| 1-2-1 | All Users clean up | biological / health : hazardous biological waste Being in the operating room always presents the risk of exposure to biological waste due to the nature of surgical procedures. | Serious Likely | High | standard procedures, gloves, special clothing /Operating rooms are kept very sterile. Training will be required to extend the standard procedures for operating room sterilization to use with the defibrillator electrodes. | Serious Remote | Low | |
| 2-1-1 | Doctor operate on patients | biological / health : blood borne diseases The surgeon will be in contact with the patient's blood during the procedure. Cuts in the surgeon's skin and through the surgical gloves could allow for the transfer of blood borne diseases. | Serious Remote | Low | special clothing, gloves, standard procedures /This is already an issue in the operating room, and once the doctor knows to check for sharp edges on the electrode (see cutting/severing, below), there is no additional risk of exposing the surgeon to blood borne illness. | Serious Remote | Low | |

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| 2-1-2 | Doctor operate on patients | mechanical : cutting / severing The surgeon will be using a scalpel during the procedure and in order to place the RV electrode. Additionally, the metal mesh electrode may have sharp edges if the insulating layer is defective. | Moderate Unlikely | Low | warning label(s), fixed enclosures / barriers, standard procedures /Warning labels will be used to remind the surgeon to check the electrode for sharp edges before handling it. The insulative layer will serve as a protective barrier between any sharp edges on the electrode metal mesh and the electrode users. Train... | Moderate Remote | Negligible | |
| 3-1-1 | Anesthesiologist inject / infuse / apply drugs | biological / health : blood borne diseases Handling needles and other drug administration devices could lead to transmission of blood borne diseases. | Serious Remote | Low | standard procedures, gloves, special clothing /This is already an issue in the operating room. If standard procedures are followed, the probability of the anesthesiologist contracting a blood borne is remote. | Serious Remote | Low | |
| 3-2-1 | Anesthesiologist monitor machines | electrical / electronic : energized equipment / live parts The anesthesiologists are responsible for charging and controlling the settings on the defibrillator unit. They may unplug/plug in the device. They may also hand the electrodes to the surgeon. | Serious Unlikely | Medium | instruction manuals, on-the-job training (OJT), warning label(s), standard procedures /Training and warning labels will be implemented to instruct the anesthesiologist on how to handle the electrical equipment with a remote probability of injury. The equipment should not be directly handled while energized. | Serious Remote | Low | |
| 4-1-1 | Nurse clean / sterilize instruments / equipment | biological / health : hazardous biological waste | | | /Risk assessment is the same as that under all users. The nurses are responsible for keeping the operating room and equipment sterile. | | | |

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| 4-2-1 | Nurse monitor patients | biological / health : blood borne diseases The nurse will be in contact with the patient's blood through handling towels/sponges and surgical equipment. The will also monitor the patient, so they may be in direct contact with the patient. | Serious Remote | Low | standard procedures, gloves, special clothing /This is already an issue in the operating room. If standard procedures are followed, the probability of the nurse contracting a blood borne is remote. | Serious Remote | Low | |
| 5-1-1 | Equipment Servicer install / setup equipment | electrical / electronic : energized equipment / live parts The technician will handle equipment that may be energized to set up the defibrillator and check for proper function. | Catastrophic Unlikely | Medium | special procedures, on-the-job training (OJT), instruction manuals /The technicians will be trained on how to handle the device during setup, maintenance, and troubleshooting. This will lower the probability of electrical injury to remote. | Catastrophic Remote | Low | |
| 5-2-1 | Equipment Servicer equipment maintenance | electrical / electronic : energized equipment / live parts | | | /same assessment as above | | | |
| 5-3-1 | Equipment Servicer trouble shooting | electrical / electronic : energized equipment / live parts | | | /same assessment as above | | | |
| 6-1-1 | Housekeeping disinfect / sterilize equipment / supplies | electrical / electronic : energized equipment / live parts Touching a defibrillator device that is on could lead to electrical injury. The housekeeper may be unaware of the danger of touching live electrical equipment. | Catastrophic Likely | High | restricted users, standard procedures, warning label(s) /They will be trained to clean the equipment. An access code is needed to charge the defibrillator. Restricted use and warning labels will prevent them from touching the device while on. Those allowed to use the device will power it off after use. | Catastrophic Remote | Low | |

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| | | | Severity Probability | Risk Level | | Severity Probability | Risk Level | |
| 7-1-1 | Facility Maintenance machine maintenance | electrical / electronic : energized equipment / live parts Attempting to repair an unfamiliar defibrillation device could lead to electrical injury. | Catastrophic Unlikely | Medium | restricted users, special procedures, warning label(s) /Maintenance staff should already be aware of the dangers associated with handling electrical equipment. They will be restricted from handling the device unless they are trained to repair it. | Catastrophic Remote | Low | |
| 8-1-1 | Patient rest | biological / health : unsanitary conditions The patient could be exposed to unsanitary conditions in the operating room due to improper sterilization techniques. | Catastrophic Unlikely | Medium | standard procedures /Standard sterilization procedures will be applied to the defibrillation electrodes. Once this training has been implemented, there will be only a remote probability of exposing the patient to unsanitary conditions. | Catastrophic Remote | Low | |
| 8-1-2 | Patient rest | mechanical : stabbing / puncture The patient's tissue could be stabbed or punctured unknowingly during the procedure because of the use of sharp tools like the scalpel. Any sharp edges on the electrodes would also cause this risk. | Catastrophic Unlikely | Medium | standard procedures, fixed enclosures / barriers, warning label(s) /Training the surgeon in checking for sharp electrode edges and proper placement technique will lower the probability of unintentionally puncturing the patient's tissue to remote. | Catastrophic Remote | Low | |
| 8-1-3 | Patient rest | electrical / electronic : overvoltage /overcurrent Incorrect electrode placement; Bad electrical contact between electrode and myocardium | Catastrophic Unlikely | Medium | on-the-job training (OJT), instruction manuals, restricted users, warning sign(s), standard procedures /OJT training and instruction manuals will be used together to train users on proper defibrillation technique. Only doctors are allowed to choose the defibrillation energy. A high impedance between the electrodes indicates incorrect placement. | Catastrophic Remote | Low | |

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