**WNR FMEA Mitigation Plan**

1. **Dislodgement of WNR cap from head**

The dislodgement of the WNR cap from the head is an unacceptable occurrence but potentially frequent event that will cause catastrophic failure to the WNR system and damage to the patient.

There are many causes to why the WNR cap can be dislodged:

1. WNR cap was not properly installed and secured by physician with retainers or adhesive
2. WNR cap was intentionally pulled out
3. WNR cap was unintentionally knocked loose and dislodged

The WNR team plans to mitigate the issues by:

1. Providing extensive training videos and instructional information containing best practices, recommended adhesives to physicians installing the devices.
2. We will also be providing pamphlets describing the device to the patients and how to best care for the device to ensure safety and optimal performance
3. We have designed the WNR system to be as compact as possible to ensure a fit as close to the top of the head as possible. The system will be less than 1.5 centimeters from the top of the scalp and will be safe from unintentional overhead collision risks. Additionally a hat may be recommended to ensure a layer of extra protection above the WNR system.
4. **WNR Device overheating**

The potential overheating of the WNR cap on the head is an potential but non-fatal risk. A change of 2 degree Centigrade on the scalp may cause skin cells to die and prolonged exposure may cause minor burns.

There are a couple of causes to why the WNR cap can overheat:

1. WNR cap was running for an extended period of time without adequate cooling such as circulation or ventilation
2. WNR current draw exceeded design maximum and drew abnormally high current from the battery.

The WNR team plans to mitigate the issues by:

1. While the WNR system is designed with insulating material to prevent overheating directly on the scalp and to radiate heat off the top of the cap, adequate circulation must be present to exchange heat. However the low power draw of the WNR system means the system can work for an extended period of time before heat becomes an issue. Ideal environment and device operating temperatures will be included in both physician and patient documentation.
2. The team has designed the WNR system to be safe with high quality, low current draw components and integrated current limiting circuits to prevent both excess current draw and reverse current.
3. **Electric Surge**

Any electric surge or feedback current is unacceptable as it may propagate down the electrode into the brain causing an electric shock or overstimulation.

A cause for the leakage current:

1. Circuit was incorrectly designed or incorrect components were used or incorrectly modified.

The WNR team plans to mitigate the issue by:

1. The WNR system is designed to be safe with high quality, low current draw components and integrated current limiting circuits to prevent both excess current draw and reverse current. There will also be a fuse on the battery board that shorts when power safety limits are exceeded. The WNR system will also be thoroughly tested before release.
2. **Contact with Water**

An excess exposure to water may lead to water entering the device may cause electronics inside the system to malfunction and potentially short. This may cause incorrect data readings or electric shock.

A cause for the water damage:

1. WNR device was submerged for an extended period of time
2. Torrential downpour of sweat, rain, or shower water
3. Battery screw top was incorrectly replaced

The WNR team plans to mitigate the issues by:

1. The housing and design of the device will be designed IP68 protected from dust and water thus mitigating issues with sweat, showering, and submersion around 1m.
2. Instructions and training video of the battery replacement will be highly detailed but succinct to ensure proper procedure of replacement of battery and watertight screw cap to device. Nurses and Physicians will be instructed to double check seal between cap top and base of cap to ensure IP68 seal.
3. **Electrode gets disconnected from WNR cap in head**

The detachment of the neural electrode to WNR cap from the head is an infrequent occurrence but potential event that will cause catastrophic failure to the WNR system and damage to the patient.

There are many causes to why the electrode may be disconnected from the cap:

1. WNR cap and electrode was not properly installed, connected and secured by physician
2. WNR cap and electrode was intentionally tampered with
3. WNR cap and electrode was unintentionally knocked or impacted loose and dislodged

The WNR team plans to mitigate the issues by:

1. Providing extensive training videos and instructional information containing best practices, recommended adhesives to physicians installing the devices.
2. We will also be providing pamphlets describing the device to the patients and how to best care for the device to ensure safety and optimal performance
3. We have designed the WNR system to be as compact and robust as possible to ensure a fit as close to the top of the head as possible. The system will be less than 1.5 centimeters from the top of the scalp and be made of a lightweight aluminum. The design of the WNR cap and its placement will be safe from unintentional overhead impact risks. Additionally a hat may be recommended to ensure a layer of extra protection above the WNR system.
4. **Data confidentiality compromise**

The loss of data to an unintended third party will be a significant violation of HIPPA requirements and will be detrimental to the patient’s privacy but poses no health risk.

The cause for the data leak may be:

1. Wireless protocol was compromised and a malicious third party was able to sniff packets over the air to receive the encrypted data

The WNR team plans to mitigate the issues by:

1. Encrypting data before transmission and decrypting data once received. All data sent over the air wirelessly will be encrypted to ensure privacy and security.
2. The WNR team will be monitoring wireless protocol bugfixes and updates to ensure the highest level of security. The WNR system will have periodic updates to ensure compliance with the latest security fixes and release information to the relevant purchaser of the WNR system on how to keep the device up to date and secure.
3. **Erosion of electrode inside brain**

The erosion of the electrode inside the brain would be a significant risk to the reliability of the data and the patient’s health may be at risk.

The cause for the erosion may be:

1. Supplier of ECoG electrode provided a poor quality product that missed QA inspection and should not have been certified for installation.
2. Electrode was damaged in shipping or storage

The WNR team plans to mitigate the issues by:

1. The WNR system is designed to be safe with high quality components both internal and external. The WNR system will also be thoroughly inspected and tested before sale.
2. The WNR team will be package the WNR cap and electrode securely and shipped via an insured carrier. Physicians will also be asked to physically inspect the electrode for any noticeable defects before installation.
3. **Electromagnetic pulse**

The WNR system uses an electrode probe to gather data and an antenna to communicate wirelessly and those components will be susceptible to electromagnetic interference.

The cause for the EMI may be:

1. Antenna is too long or improperly shielded
2. Internal components and are improperly shielded or grounded

The WNR team plans to mitigate the issues by:

1. The WNR team will be actively designing for electromagnetic compatibility and will be modeling its effects on the system as well as doing real world testing.
2. The WNR system is designed to be safe with high quality components both internal and external. The WNR system’s grounding and shielding will also be thoroughly inspected and tested before sale.
3. A warning in the instruction pamphlet will instruct patients to not go near places with high electromagnetic radiation.