Level of concern

Nightscout contributors

Nightscout Foundation

This is open source.

Contents

1 Level of concern

1.1 Description of device

1.2 Mitigations

1.3 Severity

Software "level of concern" – Estimate (in the absence of mitigations) of the severity of injury that a device failure or latent design flaw could permit or inflict, either directly or indirectly, on a patient or device operator: • Major: could directly result in death or serious injury • Moderate: could directly result in minor injury • Minor: unlikely to cause any injury

    http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/U