

Nightscout Hazards Analysis

DRAFT

Nightscout Foundation

This is open source.

DRAFT

Contents

0.1	some hazards	3
0.1.1	special controls	3

0.1 some hazards

Hazard	Mitigation
Incorrect glucose value reported on the secondary display or glucose value missed	special control 1
Treatment recommendations are made based on data presented by secondary display device.	special control 2
Individual with diabetes loses self management discipline	special control 3

0.1.1 special controls

- (b) Classification. Class II (special controls). The device is exempt from the pre-market notification procedures in subpart E of part 807 of this chapter subject to the limitations in §862.9. A continuous glucose monitor secondary display must comply with the following special controls:
1. Devices being marketed must include appropriate measures to protect against unauthorized access to data and unauthorized modification of data.
 2. The labeling must prominently and conspicuously display a warning that states “Dosing decisions should not be made based on this device. The user should follow instructions on the continuous glucose monitoring system.”
 3. The labeling for the device must include a limitation that states “This device is not intended to replace self-monitoring practices advised by a physician.”