

LOSSES

L1: Loss of life or life-threatening to the patient (acute incident of hypo/hyperglycemia, diabetic coma, and others);

L2: Loss of or damage to the AID system components;

L3: Loss of mission (automated insulin delivery);

L4: Loss of or corruption of sensitive information;

L5: Loss of connectivity between components of the system.

HAZARDS

H1: The BG sensor is unable to read BG data [L1, L3];

H2: The CGM is unable to send BG readings to the control application [L1, L3, L4, L5];

H3: The CGM physical integrity is lost [L1, L2, L3]; % with compromised physical integrity

H4: The control application cannot calculate or incorrectly calculates the insulin dose to place the BG into a target range [L1, L3];

H5: The control application cannot calculate or incorrectly calculates the insulin dose for meal-correction bolus [L1, L3];

H6: The control application cannot track or incorrectly tracks residual insulin [L1, L3];

H7: The control application does not provide an alarm for hypo/hyperglycemia limits [L1, L3, L4];

H8: The control application is unable to receive readings from the CGM [L1, L3, L4, L5];

H9: The control application is unable to send instructions to the IP [L1, L3, L4, L5];

H10: The patient does not provide meal data to calculate the meal-correction bolus [L1, L3];

H11: The IP delivers the wrong dose to the patient in either amount or timing [L1, L3];

H12: The IP with compromised physical integrity [L1, L2, L3];

H13: The IP is unable to pair and receive data to the control application [L1, L3, L4, L5];

H14: The IP reservoir volume is not monitored [L1, L2, L3].

THREATS

T1: Communications between components transmitted in clear text [L1, L3, L4, L5];

T2: Weak pairing protocol between components [L1, L3, L4, L5];

T3: Lack of mechanisms to prevent replay attacks or guarantee transmission [L1, L3, L4, L5].