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To Whom it may concern,

The iGlucose GM291-v2 is battery operated and is handheld during measurement operation. The product is designed in such a way that data is only transmitted after a successful measurement of blood sugar content using the analysis function of the device.

As the device is minimally invasive and does not require strict privacy for use, data transmissions are possible when the device is carried next to the body of the patient and in the same vicinity as persons of general public. The device is turned On/Off manually with the On/Off button. In any normal use case, each use of the device will be separately by time of from one (1) to 24 hours. In an unusual use case of more frequent measurements, due to the time required for the device to complete a measurement and the preparation time needed on behalf of the patient, such an unusual measurement event will happen no more than 3 times within 6 minutes. This number was found conservative by our internal QM functional testing.

Whether the device is used in private or by medical professionals does not affect the above as the device is designed to be used by individuals after initial training through healthcare professional. The steps performed during a single measurement are outlined in detail in our owner's manual starting page 27.

Each measurement event is associated with a maximum 70 Byte data packet that is transmitted through the CAT M1 radio module as soon as a network connection can be established. Max application data in 2 minutes (1 blood sugar measurement) = 70 Bytes. Adding 20 Bytes TCP overhead and 20 Bytes IP4 overhead resulting packet size for 1 blood sugar measurement = 110 Bytes.

Worst case LTE settings are for TBS Index = 0 (maximum channel coding) and for 1 RB (maximum spread of transmissions over time) resulting in Transport Block size of 16kbps based on 3GPP TS 36.213.

To transmit 110 Bytes = 880 Bits on 16 kbps takes = $880 / (16 \times 1024) \text{ s} = 0.054 \text{ seconds}$. With the 120 sec each measurement takes this results in a maximum duty cycle of 0.00045. To then apply a safety factor of 81 as detailed below this results in a maximum duty cycle of 0.036

We are applying a safety factor of 81 to this with the following rationale:

- The LTE HARQ mechanism will retransmit if transport block not acknowledged (x3)
- The LTE Mac layer will retransmit if frames are not acknowledged (x3)
- The TCB layer will retry transmissions up to 3 times (x3)
- Measurements may be queued after a user enters back into network coverage (e.g. after a long camping trip). Our device is designed to transmit these stored readings after a successful measurement of blood sugar measurement where the device is back in coverage. There is no additional protocol overhead for the transmission of stored readings, thus this data is transmitted very quickly and efficiently.

The resulting maximum duty cycle originating from our device is DC = 0.036

Regards,  text here
Dick Kane

