

Verification and Validation of Continuous Glucose Monitoring Devices

Business Organization of Dexcom

The software testing department lies between the product development and regulatory affairs.



Continuous Glucose Monitoring (CGM) Technology

- CGM technology allows patients to be take control of their diabetes.
- This technology consists of a transmitter attached to a subcutaneous sensor; gathered data is then displayed via a handheld device.
- CGM data includes the patient's estimated glucose value (EGV), rate at which their EGV is changing, and whether the EGV is deviating from the normal range.
- For accurate readings, this technology requires proper calibration using a standard blood glucose meter.





Verification and Validation

Verification is the process in which specification requirements are verified throughout each iteration step. Validation is the process in which the end-product is validated and the requirements are being met.

Regie Felix, Software Test Intern Tifo Hoang, Senior Manager Engineering – Software Test Issa Salameh, Supervisor Engineering – Software Test

• These two steps are included in the **Software Development Life Cycle** or **SDLC**. This process is divided into various phases and each phase includes an input and an output.

• Each phase is verified and ensured that the output meets the requirements of the input.



At Dexcom, our mission is to empower people to take control of diabetes.







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References

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