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TUTORIAL 4675

Important Considerations for Insulin Pump and Portable Medical Designs

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Abstract: This tutorial discusses critical considerations requiring attention when designing an insulin pump, including FDA regulation, form-factor requirements, and power-budget constraints. It also provides summary coverage of self-testing, flow sensing, alarms, and electrostatic-discharge variables.

Overview

Insulin pumps provide a precisely controlled rate of insulin delivery to diabetic patients who would normally need multiple daily injections to regulate blood glucose levels. Insulin pumps improve patient quality of life and reduce the incidence of long-term complications by providing tighter control of blood glucose levels. The firmware allows numerous modifications to the bolus dose and basal rate to enable patients to manage insulin levels in response to (and in anticipation of) events such as eating, sleeping, and exercise.

The insulin is contained in a user-replaceable cartridge held inside the pump. This reservoir is effectively a specialized syringe with a piston that is slowly pressed by the pump. The cartridge output is connected to flexible tubing going to the patient's subcutaneous injection site, usually on the abdomen.

A related product for managing diabetes is a continuous blood glucose monitor. This device provides real-time glucose-level monitoring through a subcutaneous sensor. The sensor can be left in place for several days at a time, which reduces the need for the patient to test multiple individual blood samples. Future developments are expected to

close the loop between these two systems by continuously monitoring the glucose level and, in response, automatically adjusting insulin dosage levels.

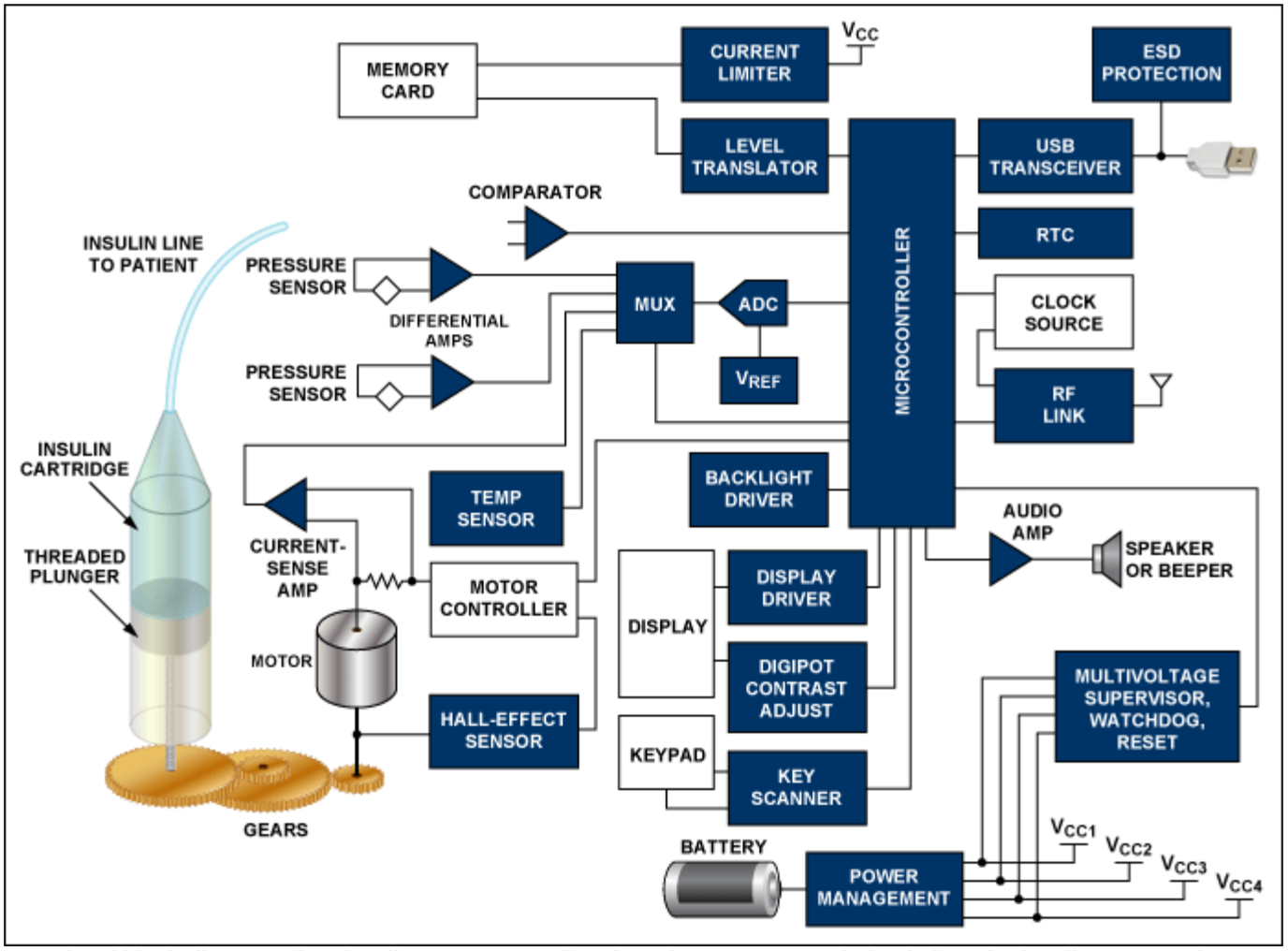
FDA-Regulated Medical Equipment

Insulin pumps are portable medical equipment whose design and manufacture is regulated by the Food and Drug Administration (FDA). This means that their design and construction must follow precisely documented processes, and their performance must meet stringent documentation, development testing, production testing, and field maintenance requirements.

The equipment also must contain comprehensive self-test and fault-indication capabilities, which require additional circuitry and the use of components that include self-test features.

Given the time and expense required to achieve FDA approval, manufacturers must select a supplier with a customer-oriented discontinuance policy to ensure that system components will be available for many years.

Medical customers rely on Maxim products because over the years we have carefully avoided discontinuing parts. We realize how devastating product discontinuance can be to a customer, so we work diligently to transfer some products to newer production lines, create wafer buffers, allow last-time purchases, or develop upgrade devices. Very few Maxim parts have ever been discontinued while demand still existed. Maxim's Discontinuance Policy is one of the most flexible among our peer supplier companies.



Functional block diagram of an insulin pump. For a list of Maxim's recommended solutions for insulin pumps, please visit: www.maximintegrated.com/insulin.

Portability

Insulin pumps are wearable devices and, thus, must be very small and lightweight. They typically measure about 2in x 3in x 0.75in, and they weigh in the 2oz to 4oz range. These form-factor requirements lead designers to put size and power consumption as high priorities when selecting components.

To save space, system designers require highly integrated solutions and extremely small packages, such as UCSP™ and wafer-level packaging (WLP). To keep batteries as small as possible, designers must reduce power consumption and improve efficiency wherever possible. If possible, any circuitry that is not in use at any given time is shut down until needed.

Insulin Pump Solutions

Pump Mechanism

Insulin is measured in "units" where there are 100 units per cc (or mL), assuming the standard U-100 concentration. This means that one unit is 10µL. Basal rates are on the order of one unit/hour administered every three to ten

minutes, while bolus doses are several units. Typical cartridge volumes are 200 to 300 units.

Due to these ultra-low flow rates, the motor is geared down, and a screw drive is used to advance the cartridge piston very slowly with many revolutions of the motor. Consequently, only coarse angular measurements of the motor are needed. Most major insulin pump manufacturers use optical encoders and DC motors, although stepper motors can also be used. Other possible approaches include the use of MEMS-based pumps to miniaturize the system, or pressure pumps to eliminate motors and piston-based reservoirs.

Flow Sensing

Pressure sensors are used to ensure normal operation and detect occlusions. Based on silicon strain gauges, these sensors provide signals in the millivolt range, rather than the microvolt level provided by bonded-wire strain gauges. The strain gauges use a typical bridge configuration, which provides a differential signal at a common-mode voltage that is roughly half of the supply voltage.

Designs will use either analog-to-digital converters (ADCs) with a differential programmable gain amplifier (PGA) input, or ADCs internal to the microcontroller with external differential or instrumentation amplifiers for signal conditioning. Precision pressure measurements are not needed since pressure readings are used for indicating normal operation and not for calculating drug delivery.

Power Supplies

Insulin pumps typically use a step-up regulator to boost the low voltage (1.5V, nominal) from a single alkaline cell up to 2V or more. In order to get the most life from the cell, these boost regulators should run down to the lowest input voltage possible. Maxim offers regulators that can run down to 0.6V, with startup-voltage minimums as low as 0.7V, to maximize battery-capacity utilization.

In devices that require tightly regulated power-supply voltages, it may be necessary to regulate down from the boosted supply discussed above. Linear voltage regulators can be more efficient in extremely low-power applications, since they do not suffer from the switching losses of switch-mode power supplies. Buck regulators with skip mode will have good light-load efficiency; however, low-dropout linear regulators (LDOs) yield physically smaller solutions, which is very important in these pumps. LDO efficiency is very close to the ratio V_{OUT}/V_{IN}, so efficiency can be high if V_{IN} is fixed slightly above the LDO dropout-voltage specification.

If voltage regulation is required for the motor, system designers use switch-mode converters. To minimize size and weight, these converters should run as fast as possible. Power-management ICs (PMICs) can also be used to save space when multiple power-supply outputs are needed.

Battery Management

Insulin pump manufacturers have made great strides in reducing power consumption to maximize battery life. Today's pumps can operate for three to ten weeks at a time before the batteries need to be replaced or recharged. Many pumps on the market use single AA or AAA alkaline or lithium batteries. Primary (nonrechargeable) cells are common, but secondary (rechargeable) cells can be used to save the patient long-term cost. Since secondary cells have lower capacities than primary cells, they provide reduced runtime between charges.

Given size constraints and the wide usage of primary cells, insulin pumps do not include battery chargers. Since there are not fuel gauges for primary cells, battery-life indicators rely on simple battery-voltage and, sometimes, temperature measurement. These readings of voltage and temperature will be sent to the ADC to be digitized. The microcontroller will process this data and use a lookup table to determine the remaining capacity within three or four bins. It will then drive the display, typically a battery symbol with a number of bars indicating remaining capacity. When down to the last bar, the insulin pump will issue a low-battery warning.

Programmability

As mentioned above, a sophisticated array of options is provided to users to tailor basal and bolus dosages to their needs. This is all done through a fairly simple interface using just a few keys for user inputs. Users can also set reminders to help manage insulin doses.

Displays/Keyboards

Monochrome, custom alphanumeric, backlit liquid-crystal displays (LCDs) are commonly used, although some pumps use color screens. The display provides information about insulin dosages and rates, remaining battery life, time and date, reminders, and system alarm conditions (e.g., blockages or low-insulin reserves). Display self-test at power-up is an FDA requirement, so designers require drivers with built-in self-test features. Visible and audible response to user touch inputs is also usually needed.

Newer pumps include continuous monitoring displays. For these systems, a separate continuous monitor with a radio transmitter measures and reports blood glucose levels to a sensor-enabled pump. The pump, in turn, displays trend information with graphical charting of glucose history to aid insulin dosage calculations.

Self-Test

All insulin pumps must perform power-on self-test (POST) to meet FDA requirements. This includes tests of all critical processors, critical circuitry, indicators, displays, and alarm functionality. Some POST operations can require user observations, but additional circuitry is used for self-checking to reduce the risk of undetected failures.

For example, some models use a safety processor to monitor the performance of the main processor and generate an alarm if unexpected behavior is detected. Another example of self-test is the simple monitoring of current through light-emitting diodes (LEDs) as they are turned on and off. If currents fall outside the acceptable range, a fault is indicated. Probably the most common self-test is the watchdog timer (WDT). Microprocessor supervisors with WDT

functions are commonly used to ensure that the processor executes within proper code boundaries. In medical devices it is usually not acceptable to have the supervisor on the same IC as the microprocessor, as this approach would subject the supervisor to the same transient errors as the microprocessor.

Supervisory functions are critical for ensuring that the pump is operating properly during patient use. Microcontrollers must be held in reset until all power supplies are within tolerance and stable. Power supplies are monitored with voltage supervisors for undervoltage and overvoltage conditions. Motor loading is monitored and motor-stall detection is needed. (Motor stall is a critical failure causing a top-priority alarm.) ADCs, either internal or external to the microprocessor, are needed to digitize sensor readings such as temperature, motor loading, insulin-line pressure, and battery voltage.

Alarms

Insulin pumps require audible and visible alarms to alert users when a fault is detected, a specific time arrives, or a warning condition is triggered. Individual LEDs can be used as visual indicators in glucose monitor remotes and insulin pumps. A flashing green LED usually indicates normal operation, while a red LED signals an alarm or warning.

The audio beeper must include a self-test feature, which can be implemented either indirectly by monitoring for a speaker impedance within range or directly by incorporating a microphone near the speaker to register the audio output and confirm that it is at the proper level. Designers commonly use a variety of operational amplifiers, comparators, audio amplifiers, microphone amplifiers, and other components to implement the alarm and self-test functions. Audio digital-to-analog converters (DACs) can be used to generate unique alarm outputs.

Newer pumps may also include an eccentric rotating mass (ERM) motor to implement a vibrating alarm. The drive to the ERM motor is not critical, but an amplifier or voltage regulator of some type might be used. The ERM should self-test at battery installation by spinning briefly.

Timekeeping

Due to the criticality of proper insulin dosing, pumps typically log and time stamp all activity and programming changes. A real-time clock (RTC) is required for this and, of course, for timer alarms.

Electrostatic Discharge

All insulin pumps must pass IEC 61000-4-2 electrostatic discharge (ESD) requirements by either using electronics with built-in protection or by adding ESD line protectors to exposed traces. Maxim offers many interface parts with this high ESD protection built-in, as well as stand-alone ESD diode arrays.

Interfaces

Data ports are provided on most insulin pumps to allow data transfer to a computer and to download firmware upgrades. This allows history files to be pulled into application programs and sent to caregivers to aid in insulin therapy. USB interfaces are commonly used. These interfaces should include features such as ESD protection, current limiting, and logic-level translation for memory cards.

RF Interface

As mentioned above, some pumps have RF receivers to obtain data from continuous glucose monitors. Most pumps will use either Bluetooth® or unlicensed-ISM-band receivers.

Related Parts		
MAX1396	1.5V to 3.6V, 312.5ksps, 1-Channel True-Differential/2-Channel Single-Ended, 12-Bit, SAR ADCs	Free Samples
MAX1947	Low Input/Output Voltage Step-Up DC-DC Converter with Active-Low RESET	Free Samples
MAX6445	µP Reset Circuits with Long Manual Reset Setup Period	Free Samples
MAX6446	µP Reset Circuits with Long Manual Reset Setup Period	Free Samples
MAX6449	µP Reset Circuits with Long Manual Reset Setup Period	Free Samples
MAX6450	µP Reset Circuits with Long Manual Reset Setup Period	Free Samples
MAX9617	High-Efficiency, 1.5MHz Op Amps with RRIO	Free Samples
MAX9618	High-Efficiency, 1.5MHz Op Amps with RRIO	Free Samples
MAX9619	High-Efficiency, 1.5MHz Op Amps with RRIO	Free Samples
MAX9620	High-Efficiency, 1.5MHz Op Amps with RRIO	Free Samples
MAX9700	1.2W, Low-EMI, Filterless, Class D Audio Amplifier	Free Samples
MAXQ2010	16-Bit Mixed-Signal Microcontroller with LCD Interface	Free Samples

More Information
For Technical Support: http://www.maximintegrated.com/support
For Samples: http://www.maximintegrated.com/samples
Other Questions and Comments: http://www.maximintegrated.com/contact

Application Note 4675: http://www.maximintegrated.com/an4675
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