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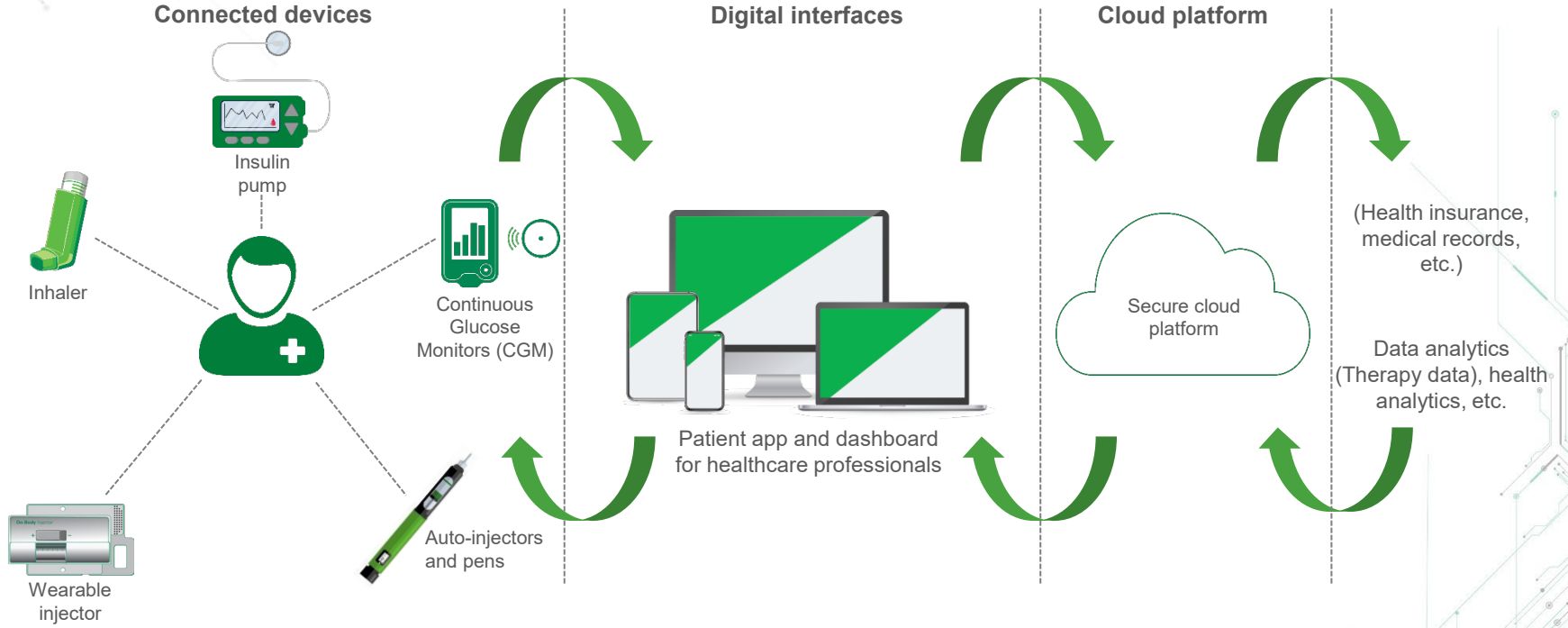
Drug Delivery Device Ecosystem

Healthcare Solutions

REV0425

Connected drug delivery systems are radically changing how services are being delivered to patients



Connected healthcare helps achieve lower healthcare costs, improves efficiency, and empowers patients.

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Drug delivery device ecosystem is growing at ~25% CAGR

Market trends and drivers

The market size growth for connected medical devices is projected to reach $251.57 billion by 2030, with CAGR estimated at 25.3% from 2021–'28.

Personal, portable, connected medical devices with CE* mark, FDA** approval, and NMPA*** certifications allow healthcare professionals to receive and act on data.

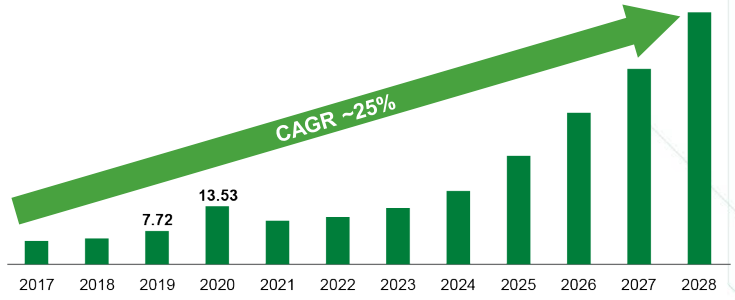
Connected auto-injectors and pens are new emerging tech in a mature, conservative, fast-growing drug market (Titrated Pens: 80% @ 10% CAGR; One-dose Auto Injectors: 20% @ 35% CAGR).

Decentralized healthcare relies on personal, wearable, and connected devices for patients to self-administer tests and medicines, necessitating precise data and high-performance Littelfuse parts like TMR, temperature sensing, switching, and ESD protection to generate precise data in robust environments.

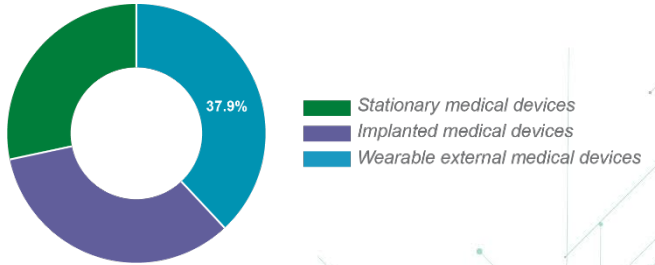
Healthcare is ready for disruption, and 5G, AI, and ML are essential for connected care. Accurate data are crucial, and Littelfuse's high-performance parts meet these demands.

High-performance and accurate Littelfuse products are for all medical device designs. The global market for decentralized connected health and wellness solutions is expanding rapidly, and no sub-segment is being left behind. Diagnosis and treatment (includes connected pharmaceutical delivery), wellness and prevention, monitoring, and others are all experiencing accelerated growth.

North America IoMT* market size, 2017 to 2028 ($B)



Global IoMT market share by product, 2020



Sources: Fortune Business Insights

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Country Oversight and Compliance to standards:
** CE Mark: Europe*
*** FDA Food and Drug Administration: USA*
**** NMPA National Medical Products Administration: China*

Acronyms:
CAGR – Compound Annual Growth Rate
TMR – Tunnel Magnetoresistance Effect
ESD – Electro-Static Discharge
AI – Artificial Intelligence
ML – Machine Learning
IoMT – Internet of Medical Things

Auto-injectors or drug delivery pens

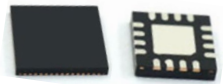
1 Dose dialing
Detect Switch

2 Activity detection
Tactile Switch, Detect Switch,
Reed Switch, TMR Switch

3 Drug Delivery Measurement
Plunger Position Sensor (TMR)/
Liquid Volume Sensor

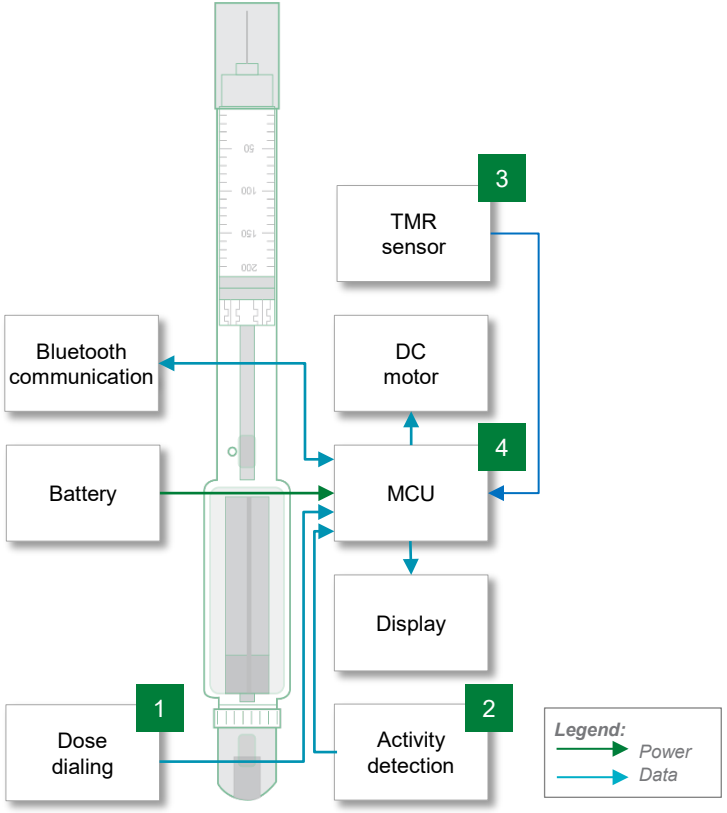
Under development

4 Control unit
Microcontroller



Click the product series in the table below for more info.

Auto-injectors or drug delivery pens



	Technology	Product series
1	Detect Switch	HDT, FDSD, FDSE
2	Tactile Switch	NanoT, KXT, KMT0, PTS, KMT0 D
	Detect Switch	HDT, FDSE, HDS
	Reed Switch	59177
	TMR Switch	TMR
3	Plunger Position Sensor (TMR)	Under development; contact sales
	Liquid Volume Measurement	Under development; contact sales
4	Microcontroller	Z8F1625*, Z8F3224 (No LCD) S3F8S19, Z8F6482 (With LCD)

Z8F1625 is under development

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Click the product series in the table below for more info.

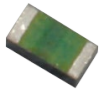
Features and benefits of Littelfuse products

	Technology	Function in application	Product series	Benefits	Features
1	Detect Switch	Detects position of the dose dial	HDT, FDSD, FDSE	Extremely small package size	Integrated mechanism and lever; lead free
2	Tactile Switch	For various types of activity detection (for example reliable navigation; dose dialing, dose counting, cap on/off detection, activation, detection of vial in correct position, contact with patient body/ skin contact)	NanoT, KXT, KMT0, PTS, KMT0 D	Board space saving and design flexibility; long life; compatible with harsh environment	Ultra-compact size; up to 1000 K life cycles; up to IP68 for sealed versions; compatibility with PCB coatings
	Detect Switch		HDT, FDSE, HDS	Micro-miniature; long life; up to IP 68 sealing properties; micro-detect switches; over-travel, low actuation magnetic stress; 35 g max; low profile	Excellent performance; response to touch and feel; design allows for top or side actuation; low-profile package; normally closed circuit (FDSE)
	Reed Switch		59177	Ease of integration within space-constrained environments; no degradation in performance; no leakage current in ‘open’ state−ideal for battery-powered IoT applications	Ultra-miniature size switch 9.0 mm x 2.5 mm x 2.4 mm (0.354"x 0.098" x 0.094"); capable of switching 170 Vdc or 0.25 A at up to 10 W; available in select sensitivities (operating distances)
	TMR Switch		TMR	Ultra-low power consumption; excellent thermal stability	Ultra-low power consumption: 200 nA at 50 Hz response or 1.5 uA at 1 kHz response
3	Plunger Position Sensor (TMR)	Under development; contact sales			
	Liquid Volume Measurement	Under development; contact sales			
4	Microcontroller	Bluetooth control for communication LCD display, and DC motor control	Z8F1625, Z8F3224 (No LCD) S3F8S19, Z8F6482 (With LCD)	Lower standby current; charging battery charges with high-resolution ADC; high-resolution PWM for motor control	8-bit MCU; 12- or 14-bit ADC and LCD controller

Continuous Glucose Monitor (CGM)

1 **Magnetic device activation**
TMR Switch*

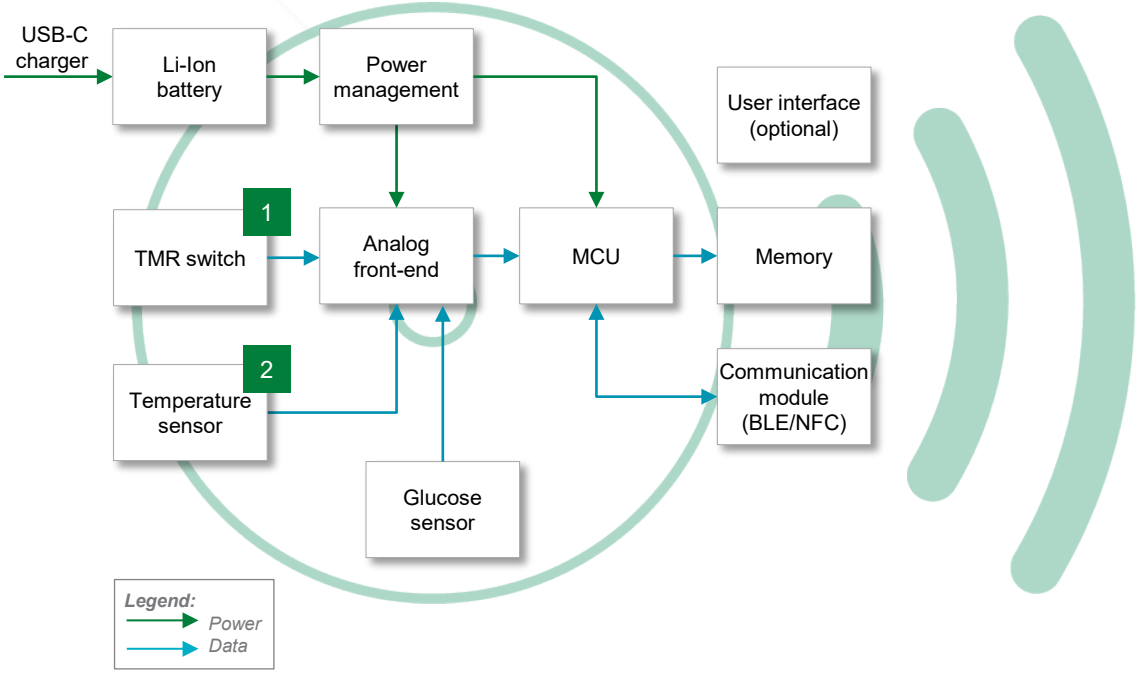
2 **Temperature detection**
Thermistor



* *LGA-4 package is under development. Contact Littelfuse Sales for more details.*

Click the product series in the table below for more info.

Continuous Glucose Monitor (CGM) block diagram



	Technology	Product series
1	TMR Switch	LF21173TMR*
2	Thermistor	503-KR, 603-RB, 1206-LR

* *LGA-4 package is under development. Contact Littelfuse Sales for more details.*

Click the product series in the table below for more info.

Features and benefits of Littelfuse products

	Technology	Function in application	Product series	Benefits	Features
1	TMR Switch	Provides a digital signal to a microcontroller that wakes up the full circuitry	LF21173TMR*	Easy to integrate; board space saving	LGA-4 package, small footprint (1.45 mm x 1.45 mm), V_{ddmin} = 1.8 V
2	Thermistor	Monitors the temperature corrections in the blood glucose measurements	503-KR, 603-RB, 1206-LR	Precision, size, energy efficiency, durability	Surface mountable; small size; low cost; Nickel Barrier

* *LGA-4 package is under development. Contact Littelfuse Sales for more details.*

Insulin pump

1 Power management
eFuse, PPTC

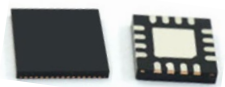
2 USB
TVS Diode Array

3 Keypad
Tactile Switch, Detect Switch

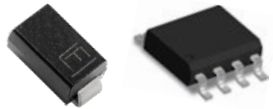
4 Drug Delivery Measurement
Plunger Position (TMR)/
Liquid Volume Sensor

Under development

5 Control unit
Microcontroller



6 Motor control
TVS Diode, Gate Driver



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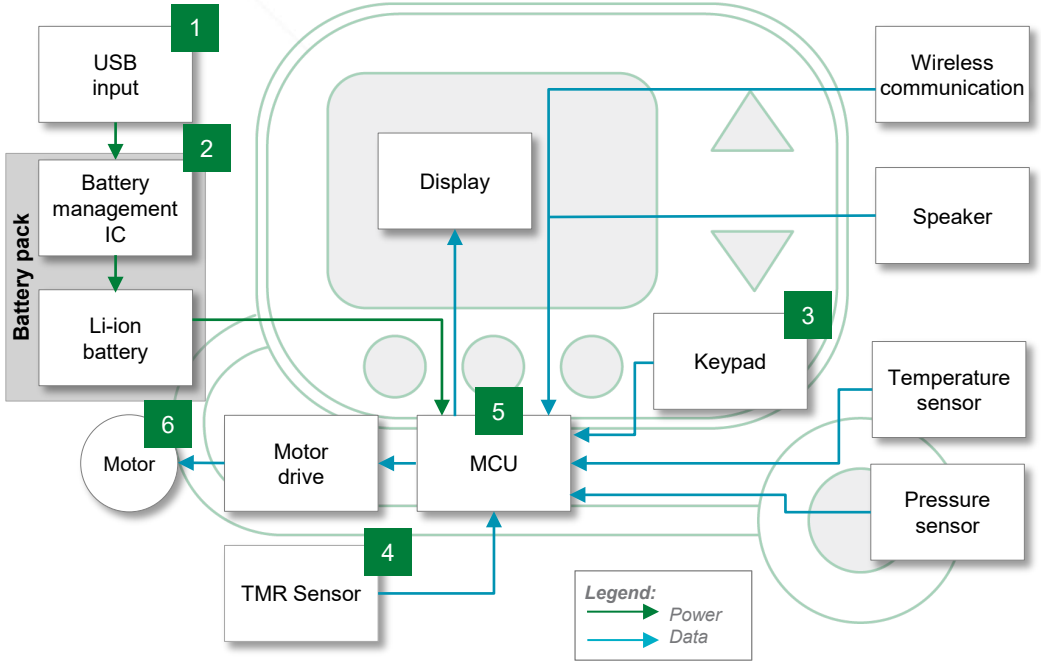
Click the product series in the table below for more info.

Insulin pump functional block diagram



	Technology	Product series
1	eFuse (USB-C)	LS0504EDD12
	PolySwitch® Device (for USB-A or -B)	Low Rho
2	TVS Diode Array	SC1205-01UTG, SP1006-01UTG
3	Switch	NanoT, KXT, KMT0, KMR, HDT, KMT0 D
4	Plunger Position Sensor (TMR)	Under development; contact sales
	Liquid Volume Measurement	Under development; contact sales
5	Microcontroller	Z8F3224, S3F8S19, Z8F6482, S3F8S7B
6	TVS Diode	SMAJ
	Gate Driver	LF2101N, LF2103N

Click the product series in the table below for more info.

Features and benefits of Littelfuse products

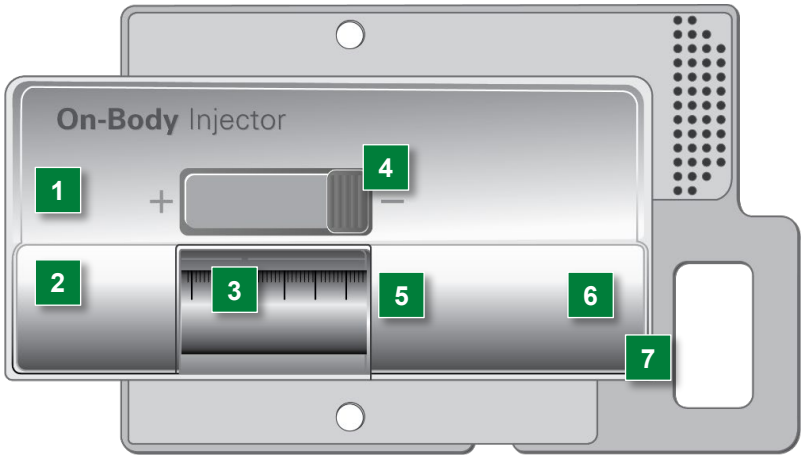
	Technology	Function in application	Product series	Benefits	Features
1	eFuse (USB-C)	Integrated overcurrent and overvoltage protection	LS0504EDD12	Wide input range from 1.8 V to 5.5 V; internal soft start	Hiccup mode for short circuits and overcurrents
	PolySwitch® Device (for USB-A or -B)	Protects 5 V DC power supply from overcurrent and over-temperature events	Low Rho	Offers fast response to overcurrent events; suitable for compact portable devices	Ultra-low internal resistance; higher current holding in smallest SMD package
2	TVS Diode Array	Protects against ESD on data lines	SC1205-01UTG, SP1006-01UTG	Enables compact design; reduces assembly time	Complies with IEC standards; low leakage current of 100 nA; compact form factor
3	Switch	Reliable navigation; dose dialing and activation	NanoT, KXT, KMT0, PTS, HDT, KMT0 D, FDSE, HDS,	Micro-miniature; long life; up to IP 68 sealing properties; micro-detect switches; over-travel, low actuation magnetic stress: 35 g max; low profile	Excellent performance; response to touch and feel; design allows for top or side actuation; low-profile package; normally closed circuit (FDSE)
4	Plunger Position Sensor (TMR)	Under development; contact sales			
	Liquid Volume Measurement	Under development; contact sales			
5	Microcontroller	Overall system control	Z8F3224, S3F8S19, Z8F6482, S3F8S7B	Lower standby power, high resolution PWM for Motor control, direct LCD display control	8 bit MCU, 12/14 bit ADC, LCD controller
6	TVS Diode	Surge protection	SMAJ	Offers board space saving; excellent clamping capability	Low profile package; IEC-61000-4-2 ESD 30 kV (Air) and 30 kV (Contact); fast response time
	Gate Driver	Controls the motor	LF2101N, LF2103N	Shoot-through protection; more precise control and lower torque ripple; board space saving	Logic inputs are 3.3 V logic level compatible; available in SOIC-8

Wearable injectors

1 Power management
eFuse, PPTC

2 USB
TVS Diode Array

3 Dose dialing
Detect Switch

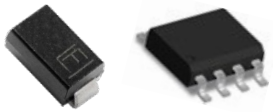


4 Activity detection
Tactile Switch, Detect Switch,
Reed Switch, TMR Switch

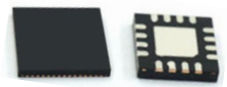
5 Drug delivery measurement
Plunger Position (TMR)/
Liquid Volume Sensor

Under development

7 Motor control
TVS Diode, Gate Driver



6 Control unit
Microcontroller



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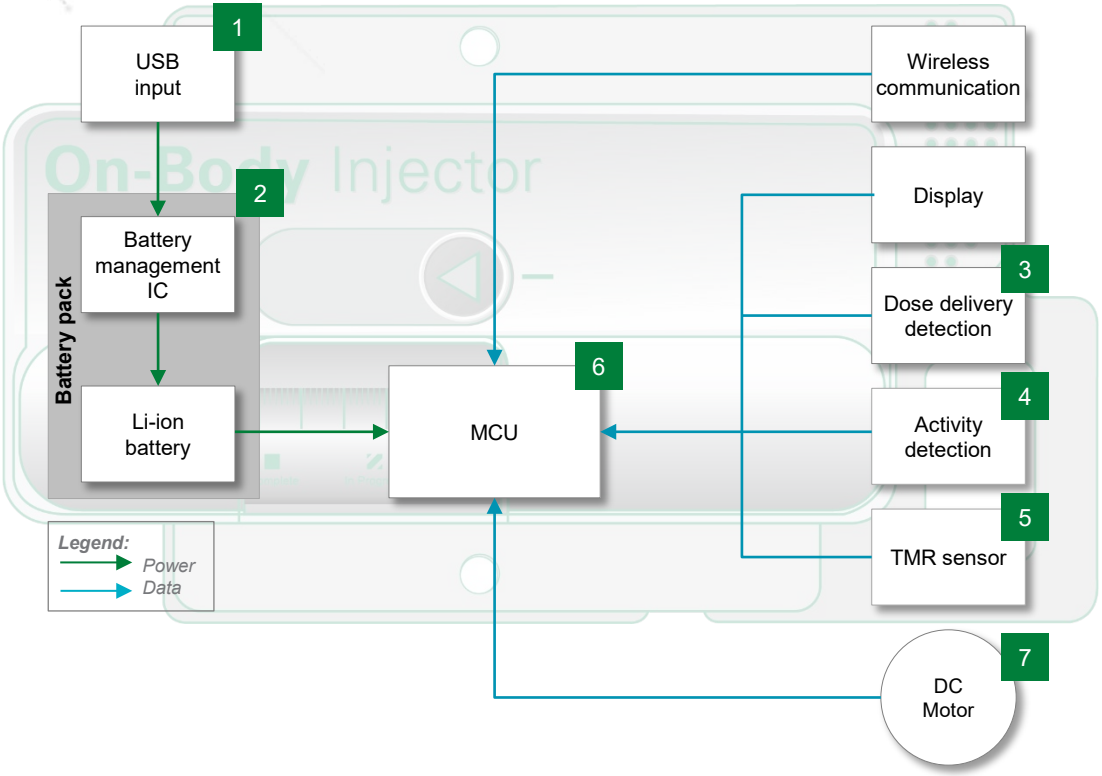
Click the product series in the table below for more info.

Wearable injectors functional block diagram



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	TMR Switch	TMR
5	Plunger Position Sensor (TMR)	Under development; contact sales
	Liquid Volume Measurement	Under development; contact sales
6	Microcontroller	Z8F1625*, Z8F3224 (No LCD) S3F8S19, Z8F6482 (With LCD)
7	TVS Diode	SMAJ
	Gate Driver	LF2101N, LF2103N

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2	TVS Diode Array	Protects against ESD on data lines	SC1205-01UTG, SP1006-01UTG	Enables compact design; reduces assembly time	Complies with IEC standards; low leakage current of 100 nA; compact form factor
3	Detect Switch	Detects the position of the dose dial	HDT, FDSD, FDSE	Extremely small package size	Integrated mechanism and lever; lead free
4	Tactile Switch	For various types of activity detection (for example reliable navigation; dose dialing, dose counting, cap on/off detection, activation, detection of vial in correct position, contact with patient body/skin contact)	NanoT, KXT, KMT0, PTS, KMT0 D	Board space saving and design flexibility; long life; compatible with harsh environments	Ultra-compact size; up to 1000 K life cycles; up to IP68 for sealed versions; compatibility with PCB coatings
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6	Microcontroller	Bluetooth control for communication, LCD display, and DC motor control	Z8F1625*, Z8F3224 (No LCD) S3F8S19, Z8F6482 (With LCD)	Lower standby current; battery charges with high-resolution ADC and high-resolution PWM for motor control	8-bit MCU; 12- or 14-bit ADC and LCD controller
7	TVS Diode	Surge protection	SMAJ	Offers board space saving; excellent clamping capability	Low-profile package; IEC-61000-4-2 ESD 30 kV (Air), 30 kV (Contact); fast response time
	Gate Driver	Controls the motor	LF2101N, LF2103N	Shoot-through protection; more precise control and lower torque ripple; board space saving	Logic inputs are 3.3 V logic level compatible; available in SOIC-8

Driving device design: personal, portable, & connected

Understanding these standards and the impact on the device during development is critical

Standard	Title	General scope	Market
ISO 11608-1	Needle-based injection systems for medical use. Part 1: Needle-based injection systems	Specifies requirements and test methods for Needle-Based Injection Systems (NISs) for single-patient use intended to deliver discrete volumes (bolus) of medicinal product, which can be delivered through needles or soft cannulas for intradermal, subcutaneous, and/or intramuscular delivery, or all three incorporating pre-filled or user-filled, replaceable, or non-replaceable containers.	Global
ISO 11608-4	Needle-based injection systems for medical use. Part 4: Needle-based injection systems containing electronics	Specifies requirements and test methods for NISs containing electronics with or without software (NIS-Es).	Global
IEC 60601	Medical Electrical Equipment Testing and Certification	Part 1-11: General requirements for basic safety and essential performance−Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.	Global
IEC 60529	Degrees of protection provided by enclosures (IP Code)	Developed to rate and grade the resistance of enclosures of electrical and electronic devices against the intrusion of dust and liquids. It also rates how easy it is for individuals to access the potentially hazardous parts within the enclosure.	Global
IEC 60068-2-XX	Environmental testing of electrotechnical products	A collection of methods for environmental testing of electronic equipment and products to assess their ability to perform under environmental conditions including extreme cold and dry heat.	Global

CE Mark, FDA Approval, and NMPA certifications provide for actionable data for medical professionals.

Littelfuse purposely built parts for drug delivery device ecosystem

Purposely built parts

- Platform-based design
- Tailored to existing assembly space
- Broad technology portfolio (mechanical micro-switches, magnetic switches & sensors, and temperature, power, and voltage level sensing)

Co-design/customer-specific design

- Partner from development through design verification process to product launch: IATF16949 & EN9100, used to ISO13485 environment
- Following ISO11608-1, ISO11608-4, IEC60601, IEC60529, IEC60068-2, etc.
- Avoid complexity, streamline development, and minimize cost

Miniaturization

- High-precision mass production experience
- World's smallest tactile switches
- xMR parts in semiconductor packages
- SMT components

Full vertical integration

- Full quality control
- Cost known upfront
- Reduce time to market
- Customized haptics
- Signal Integrity

FEM Modeling

- Mechanical, magnetic, and electrical modeling
- Modeling for construction, dimensioning, and design
- Modeling on part and system levels
- Application-specific integration

Quality and reliability

- Switches designed to meet IP67 or IP68 standard
- Harsh environmental compatibility
- Sweat-resistance testing
- SO2 and SO4 gas testing

Sustainability: Environment, Social, and Governance

More information can be found in our Littelfuse 2023 Sustainability Report on www.littelfuse.com

Environment

24%
reduction in GHG intensity since 2019

Goal: 38% by 2035

46%
of our manufacturing sites utilize renewable energy

Established site-level annual GHG and water targets

37%
increase in water recycling

Three-year consecutive reduction in hazardous waste

Social

22.5%
females in leadership, an increase of 1.5% from the prior year

Enhanced leadership training and coaching program

3 Sites
Maintained zero workplace injuries for 3+ consecutive years

805
Critical suppliers screened for ESG risk

91%
of employees agree their manager sets a good example for ethical behavior

Governance

Local ethics ambassadors program launched at 28 largest locations

30,200
hours ethics and compliance training

Gold Rating Ecovadis Program (94th percentile)

Obtained third-party verified GHG data

Enhanced Workplace Investigation Program and Training

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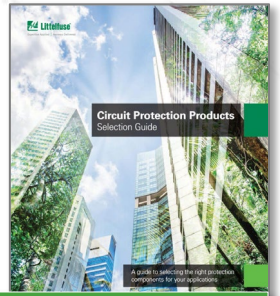
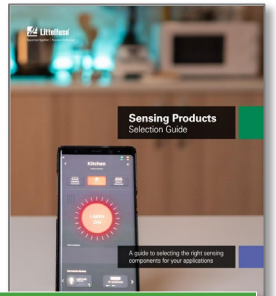
More information can be found at Littelfuse.com

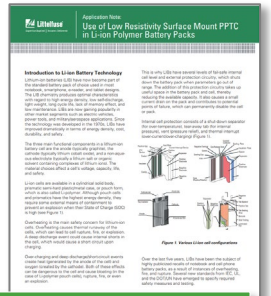
Explore the world of Littelfuse with the electronic ecatalogs (ecatalogs.littelfuse.com)



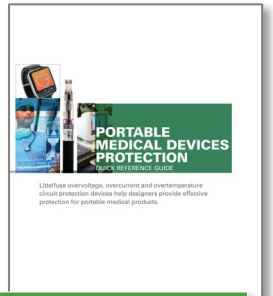
Circuit Protection Selection Guide



Sensing Products Selection Guide



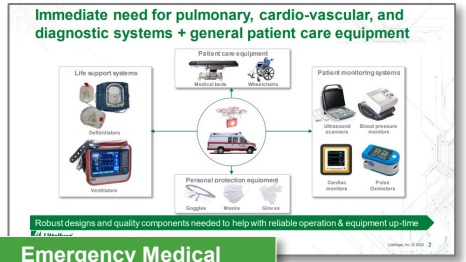
Lithium-Ion Battery Pack Protection with PPTC



Portable Medical Devices Protection Guide

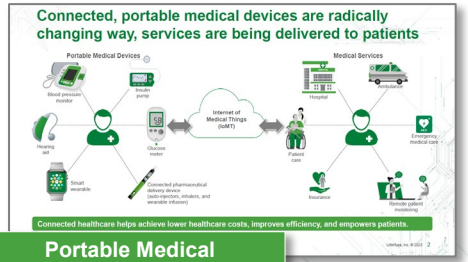
Switches for Medical Applications

Click the images for more information



Emergency Medical Equipment Spotlight

Personal Care Solutions Spotlight



Portable Medical Devices Spotlight

Scan the code to learn more!

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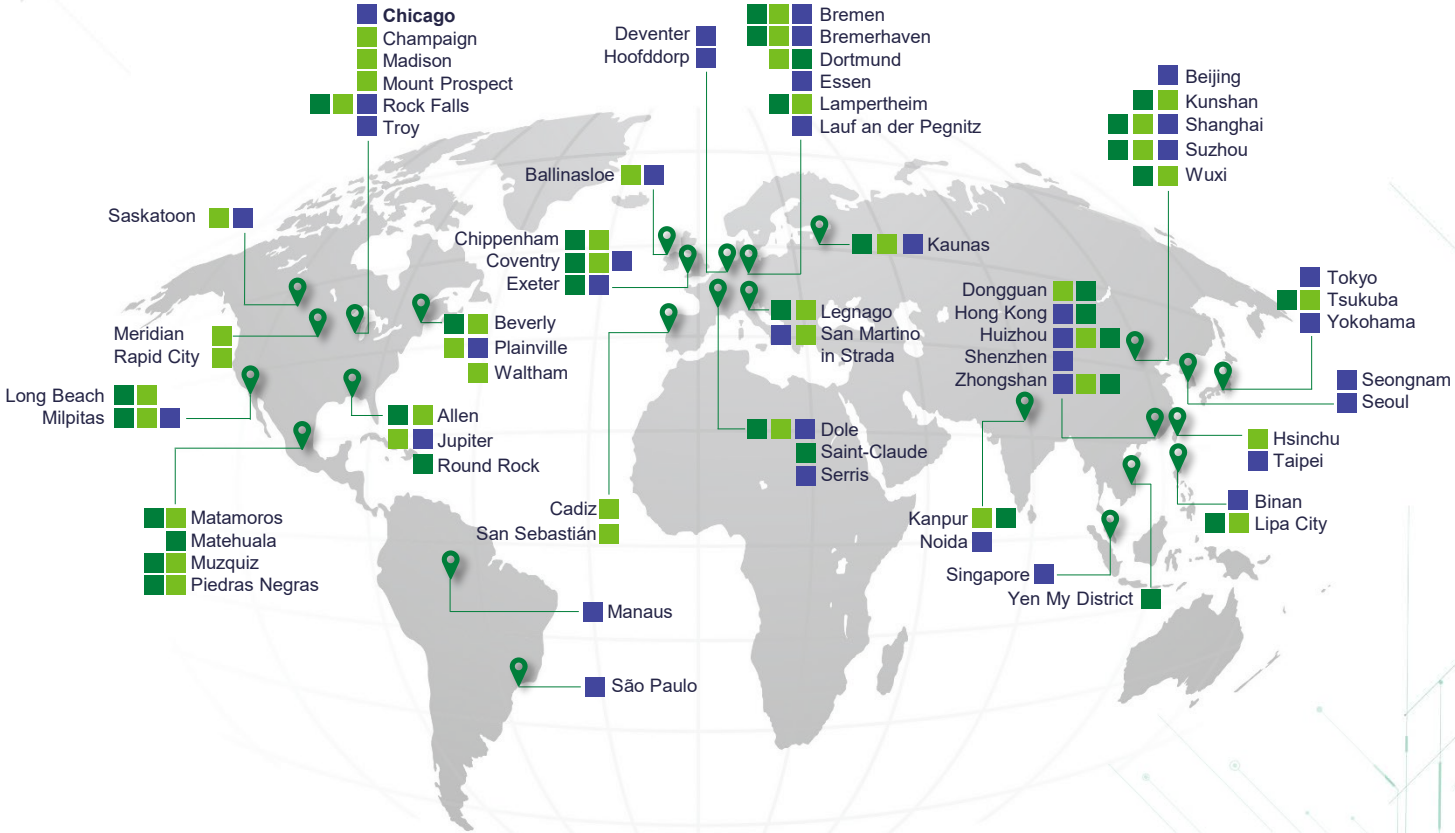
Local resources supporting our global customers



Legend

- ***Sales***
- ***R&D***
- ***Manufacturing***

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Partner for tomorrow’s electronic systems

Broad Product Portfolio

We are an industrial technology manufacturing company empowering a sustainable, connected, and safer world

Testing Capabilities

We help customers get products to market faster, we offer certification testing to global regulatory standards

Application Expertise

Our engineers partner directly with customers to help speed up product design and meet their unique needs

Compliance & Regulatory

We help customers in the design process to account for requirements set by global regulatory authorities

Global Customer Service

Our global customer service team is with you to anticipate your needs and ensure a seamless experience

Global Manufacturing

High-volume manufacturing that is committed to the highest quality standards

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