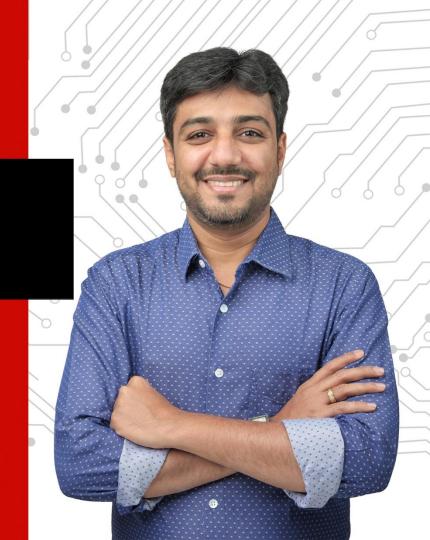


SANJAY PITHADIA PATIENT MONITORING

DESIGN WEARABLE HEALTHCARE SYSTEMS WITH ADVANCED SENSING AND EFFICIENT POWER FOR IMPROVED PATIENT MONITORING



Agenda



TI in medical



Market trends

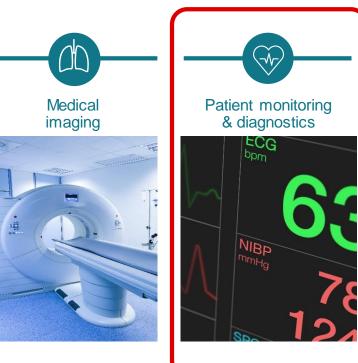


Fundamentals and challenges



Reference designs

TI semiconductors in every medical category





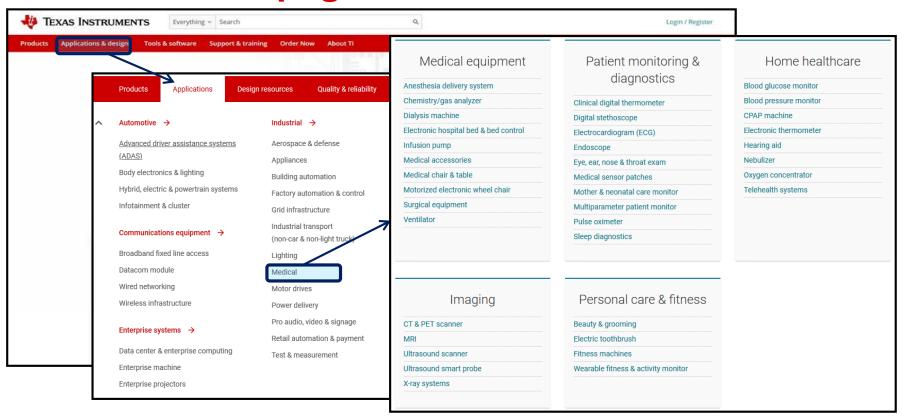




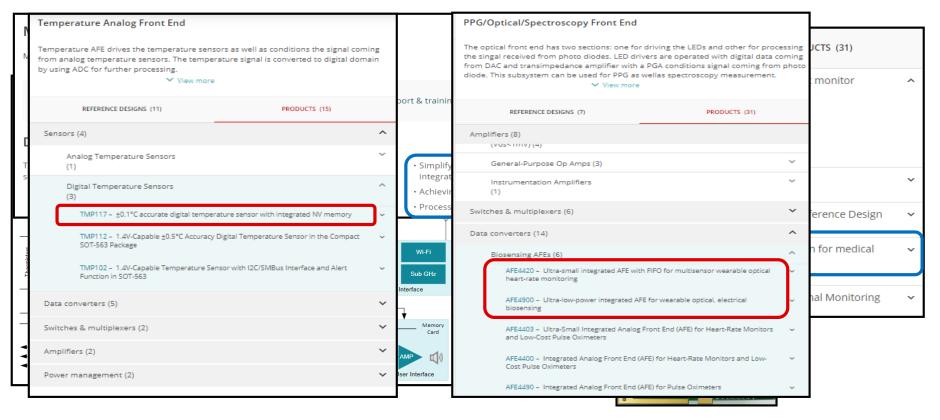




Medical sector page



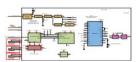
Medical sensor patches



Reference design

Design Guide: TIDA-01614 Multiparameter Front-End Reference Design for Vital Signs Patient Monitor









The following list provides details about the design:

- Supply Voltage = 5 V
- Charging current = 0.1 A

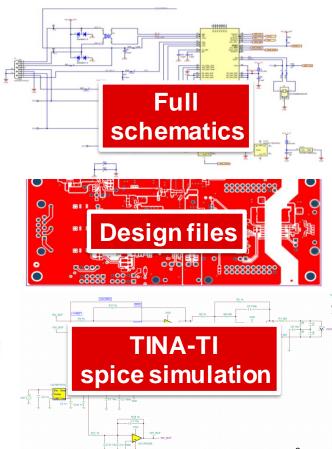
Detailed design considerations & applications info

How the input current limit (ILIM) is set:

- RLIM = KILIM / I1-MAX
- KILIM = 1530 AΩ

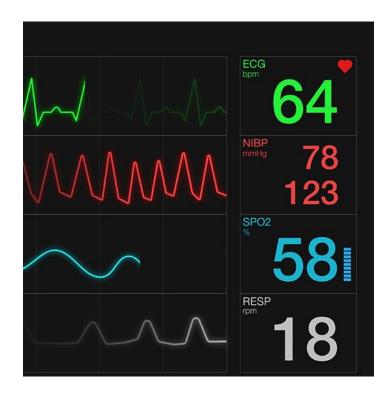








Patient monitoring market trend



Remote monitoring enhances quality of care and reduces healthcare cost

Wearable wireless medical technology enables accurate and reliable data in a smaller form factor: multimodalities, longer battery life, SHIP mode

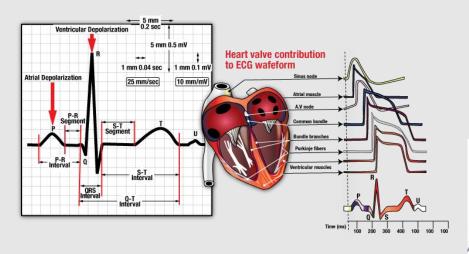
Artificial intelligence uses analytics and big data to improve decision making and early prevention

7

Patient monitoring basics

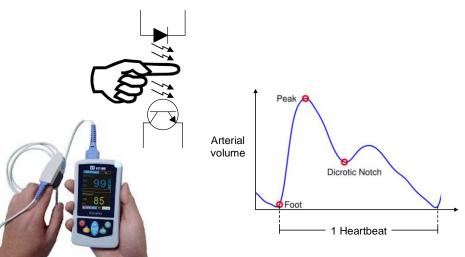
The electrocardiogram (ECG)

measures electrical activity of the heart



Photoplethysmography (PPG)

is an *optical* measurement of an organ's volume.



ECG vs. PPG

Feature Description	ECG	PPG
Measurement type	Electrical	Optical
Sensor type	Electrodes	Photodiode
Can measure heart rate?	Yes	Yes
Diagnostic information	Yes	Yes
Minimum number of skin contacts required?	2 (Across chest)	1 (Finger or wrist)
Number of ADC channels required	≥1	1

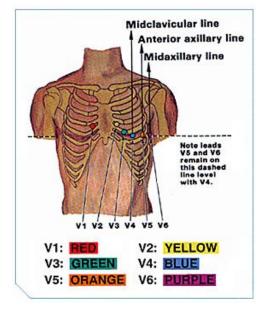
ECG lead and ADC channels

Number of Leads	Leads Used	Number of ADC Channels
1	Lead I	1
3	Lead I, Lead II, Lead III	2
6	Lead I, Lead II, Lead III, aVR, aVL, aVF	2
12	Lead I, Lead II, Lead III, aVR, aVL, aVF, V1 – V6	8

Standards Electrodes Needed

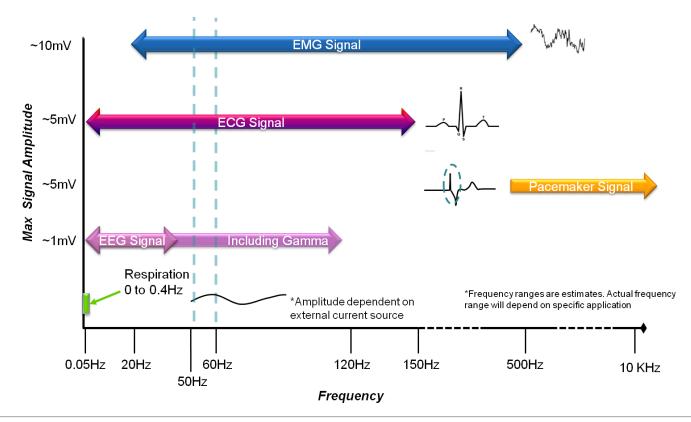
1 Lead LA, RA 3 Lead LA, RA, LL 6 Leads LA, RA, LL

12 Leads LA, RA, LL, V1-6



ECG characteristics

Frequency domain



Challenges in measuring ECG



Alternating Current (AC) Interference

Challenges in optical bio-sensing

- Low power for longer battery life
- Skin tone variation
- Best PPG signal for motion cancellation algorithms
- Performance with glass
- Low temperature performance
- Ambient light

TIDA-01614

Multiparameter front-end for vital signs patient monitor reference design

Features

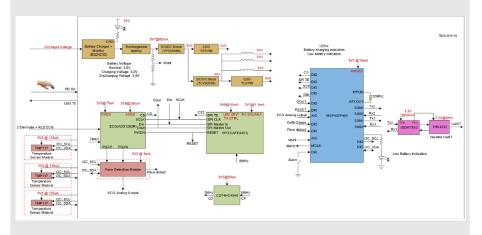
- System measures ECG, heart rate, SPO2, respiration rate using ADS1292R and AFE4403 and skin temperature using TMP117
- Circuit enables three electrode operation including right leg drive with good CMRR
- Pace detection circuit indicates presence of pacemaker
- Supports three 0.1° Celsius accurate sensors (TMP117) to measure the skin temperature
- Enables data transfer over isolated UART interface
- Works with 3.7V Li-ion rechargeable battery
- On-board memory for data logging

Applications

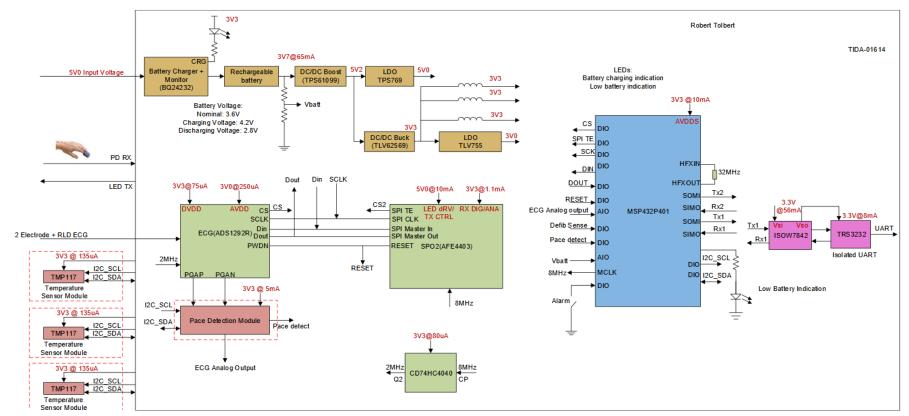
- Multiparameter patient monitor
- Medical sensor patches
- Pulse oximeter
- Electrocardiogram (ECG)

Benefits

- Single IC does both ECG, respiration
- Pace detection
- ECG with 3 electrodes
- Three temperature sensors for temperature measurement



Detailed block diagram for TIDA-01614



Design challenges TIDA-01614 solves

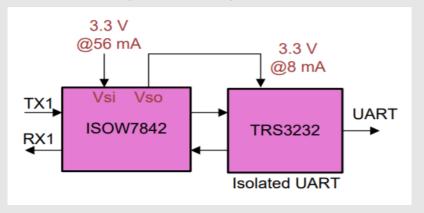
Design challenge 1

Integration of multiple modalities at optimum SNR levels and small form factor

- Monitoring of ECG, heart rate, SPO2, PTT, respiration rate and skin temperature
- Single lead ECG with RLD (ADS1292R)
 - > Signal amplitude: 0.2mV~2mV (p-p);
 - > BW0.05 Hz to 2000 Hz
- Supports 3 LED and 3 photodiodes with ambient subtraction for SPO2 and heart rate monitoring with AFE4403
- Supports three 0.1° Celsius accurate sensors to measure the skin temperature (TMP117)

Design challenge 2 Protection and isolation

Isolated UART interface using an onboard MSP432P401, ISOW7842, TRS3232



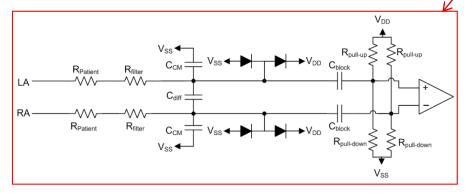
ECG analog front end

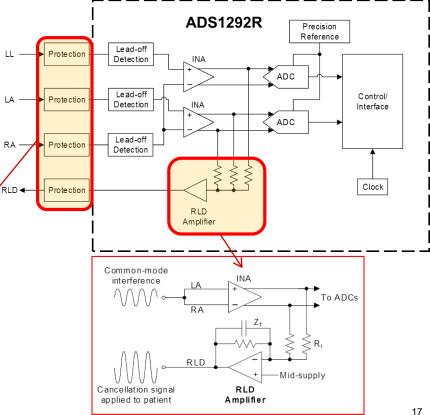
TIDA-01614: Multiparameter front-end reference design for vital signs patient monitor



Important parameters:

- Input bias current
- Input impedance
- Input current noise
- Input voltage noise
- Power consumption
- DC/AC CMRR





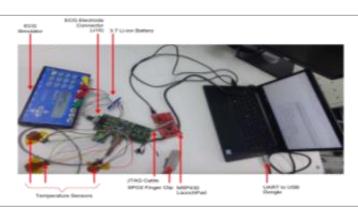


TIDA-01614 test setup and test results

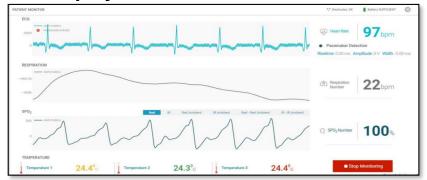
Design specs

CHARACTERISTICS	SPECIFICATIONS	
ECG	One lead ECG operation with RLD. Sampling rate of 500 samples per second, supports ECG sensitivity of 100 µV	
SPO2 Measurement	Works in transmissive SPO2, refresh rate of 500 Hz	
Skin Temperature Measurement	Three temperature sensor with 0.1 degree accuracy	
Pace pulse Rise-time (TR) measurement range	30–200 μs	
Pace pulse duration (TD) measurement range	0.1–2 ms	
Input Pace signal amplitude range	8 mV-700 mV	
Input Voltage (Vin)	5 V from Micro-USB	

Test setup



GUI display





Test pacemaker detection with TIDA-010005 & TIDA-01614



TIDA-01580

Wearable, wireless, multiparameter patient monitor reference design

Features

- Simple wearable multi-parameter patient monitor for photoplethysmography (PPG) and electrocardiography (ECG)
- Provides raw data to calculate heart-rate, oxygen concentration in blood (SpO2) and pulse-transit time (PTT)
- Uses single-chip bio-sensing front-end AFE4900 for synchronized ECG & PPG
 - PPG (Optical heart-rate monitoring and SpO2) supports 4 LEDs and 3 PDs with digital ambient subtraction to improve the SNR
 - ECG (LEAD I) signals
- Integrated ARM Cortex-M3 + 2.4GHz RF transceiver (CC2640R2F) supports wireless data transfer – BLE 4.2 and 5
- Operated from CR3032 (3V, 500mA coin cell battery) with battery life of 30 days using highly efficient DC/DC converters
- · Small form factor helps in easy adaptation to wearable applications

Target applications

- Wireless patient monitor
- Pulse oximeter

- Wearable fitness & activity monitor
- ECG

Tools & resources



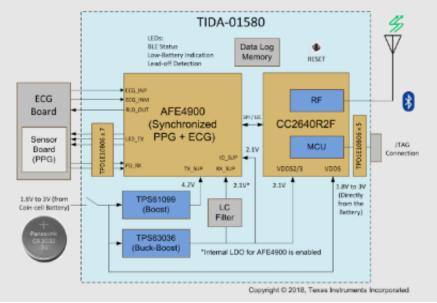


Device Datasheets:

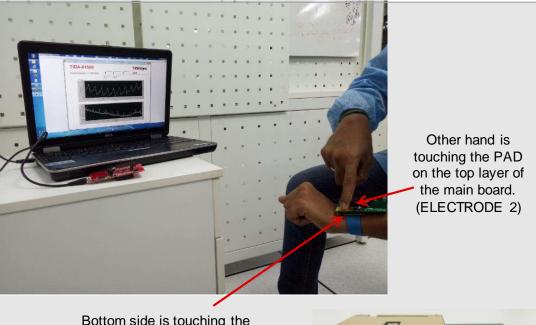
- AFE4900
- CC2640R2F
- TPS61098
- TPS63036
- TPD1E10B06

Benefits

- PPG supports 4 LEDs and 3 PDs with digital ambient subtraction to improve the SNR
- AC and DC lead off detection helps in correct measurement of vital signs
- Continuous monitoring with low er operating power ensures battery life of 30 days
- Flexibility of ultra low power modes and integrated FIFO can keep MCU into sleep to increase the battery operation time



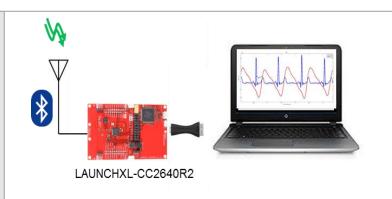
TIDA-01580 for medical patch



Bottom side is touching the wrist of one hand (ELECTRODE 1)



Side View



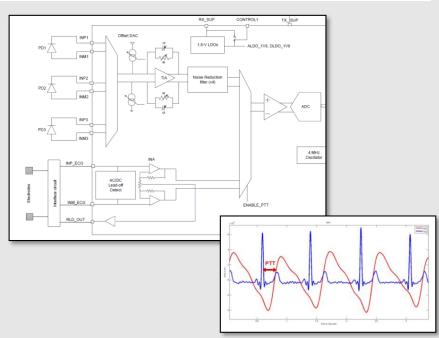
- LAUNCHXL-CC2640R2F receives the signals remotely and displays on LabView GUI
- The design uses BLE 5.0 with an advertising time = 100ms

Design challenges TIDA-01580 solves

Design challenge #1

Integration of multiple modalities at optimum SNR levels and small form factor

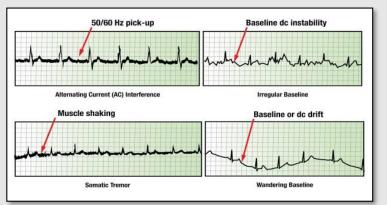
- Capturing synchronized ECG and PPG to enable PTT and BP calculations (non-invasive and without cuff)
- Pulse transit time (PTT): Time difference between the R-peak in the ECG waveform and the arrival of the blood pressure wave
- Simultaneous measurement of ECG and PPG together
- Along with other variables, such as the patient's size, weight, age, etc., algorithms show the correlation between PTT and systolic blood pressure
- Challenging to synchronize both measurements timing is the key! (powering up, clock timing, phase, drift with temperature)

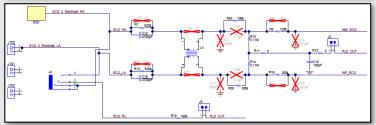


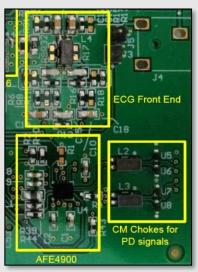
Design challenges TIDA-01580 solves

Design challenge # 2 BLE connectivity that does not interfere with measurement accuracy

- Signal amplitude: 0.2mV to 2mV (p-p)
- BW: as broad as 0.05 Hz to 300 Hz (pace detection increases the bandwidth further)
- Reject environmental electrical signals, such as ac mains, security systems and RFI to amplify and display the ECG signal
- Good CMRR of the signal chain and right-leg drive (RLD) for CM rejection
- Differential- and common-mode filtering, environmental shielding and algorithms







Design challenges TIDA-01580 solves

Selecting the extended barechargeable cells)

- Powering windevice insteam
 (bypass model)
- Sleep / shut for radio dev
- Selection of termination (important!)

Analog Design Journal

http://www.ti.com/lit/an/slyt763/slyt763.pdf

Power

Improving battery life in wearable patient monitors and medical patches

By Sanjay Pithadia

System Engineer, Medical Sector, System Engineering and Marketing

Introduction

The market for wearable patient monitors is growing fast. The two main attributes for wearable monitors are portability (or size) and operating time (or battery life). Today's wearable medical products not only measure vital signs but can also act as personal emergency-response systems.

Portable and wearable applications are typically battery powered, and for consumers, battery life is one of the key purchasing considerations. The life of the battery is critical because most patient monitors measure and monitor continuously.

Battery-powered systems require careful partitioning, tight space utilization and efficient use of the available charge. It is important to enable more functionality while delivering power more efficiently in a tight space for a longer time. Functions like standby, sleep, power save, hibernate and shutdown are critical for designers to

hydride (NiMH), lithium iron phosphate, lithium manganese and zinc are popular battery chemistries in medical devices, and each type needs a different charging circuit. It is also important to note that rechargeable batteries have a self-discharge rate. To reduce overall bill of materials (BOM) and size, designers may connect batteries directly to the radio module and other peripherals, but running directly from the battery voltage is not the most efficient way to use the battery.

Choosing the right battery charger to improve battery life

Battery charging for wearables is challenging because batteries must be both small in size and capacity. Charge currents vary greatly depending on whether a 50-mAh, 100-mAh or 200-mAh battery is used, and whether to charge at 0.5 C-rate (C), 1 C or 2 C. The key is to include



TIDA-01624 Bluetooth-enabled high accuracy skin temperature measurement flex PCB patch

Features

- High accuracy, low power temperature sensor
- BLE 4.2 and 5 enabled microcontroller
- Thin-film flexible battery power, enabling entirely flexible design
- Integrated PCB antenna
- Temperature updates every second

Applications

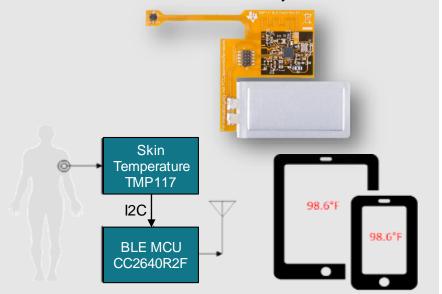
- Medical sensor patches
- Multiparameter patient monitors
- Smart patches

Tools & resources

- TIDA-01624 and/or tools folder
- Design guide
- Design files: Schematics, BOM, Gerbers, Software, etc.
- Device datasheets:
 - TMP117
 - CC2640R2F

Benefits

- Low power consumption and long battery life
- Extremely long shelf life (3+ Years)
- Small, flexible form factor
- Connects to smart device
- Zero-calibration to ±0.1°C accuracy



TMP117x Ultra-high accuracy digital temp sensor with integrated non-volatile memory

Features

Accuracy

• 16-bit resolution

(0.0078°C) Minimum PSRR: 1LSB = 7.8 m°C/V

Π Part	Accuracy (°C)	Accuracy Full Range
TMP117M	±0.1°C @ (30°C to 45°C)	±0.2°C @ (0°C to 85°C)
TMP117	±0.1°C @ (-20°C t 50°C)	±0.3°C @ (-55°C to 150°C)
TMP117N	±0.2°C @ (-40°C t 100°C)	±0.3°C @ (-55°C to 150°C)

Integrated EEPROM Low power consumption

- 140uA lq during conversion
- 3.5uA Average lg @ 1Hz
- 150nA Shutdown Ia
- 1.8V 5.5V



Digital feature: automatic offset NVW soft reset

Interface: Single wire

Packaging

- 6pin WSON (2 x 2) mm
- 6pin WCSP (1.6 x 1) mm

Applications

- Gas meter
- Medical

Instrumentation & test

Cold chain

• Thermocouple – reference

Wearables

Benefits

Ultra-high accuracy

- Meets ASTM E1112 & ISO medical standards:
 - 0.1°C acc. range 35.8°C to 42°C
- No calibration needed: NIST traceable

Integrated non-volatile memory

- Store configuration even after losing power
- 64 bits of general-purpose scratch pad memory

Low power consumption

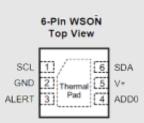
- 3.5uA average lq @ 1Hz; serial bus inactive
- 150nA shutdown lq; serial bus inactive

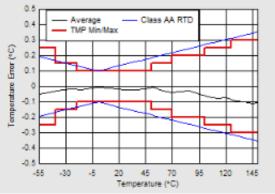
Digital feature & I2C interface

- Programmable temperature alert & offset value
- Soft device rest

Smallest package

6 PIN, QFN & CSP







Full system: Multiparameter patient monitor + wireless sensors



Why TI SimpleLink[™] for multiparameter patient monitor + sensor patch?

Low power



- BLE SoC with integrated ultra low power sensor controller
- Wi-Fi low power loT
- Best-in-class standby current

Ease of use



- CC3135/CC3235 Wi-Fi modules
- 5GHz Wi-Fi to reliably connect to hospital network
- BLE multirole support, up to 32 simultaneous connections

Secure



- FIPS 140-Level 1 validation
- Offload CPU bandwidth – HW crypto accelerators
- Secure boot

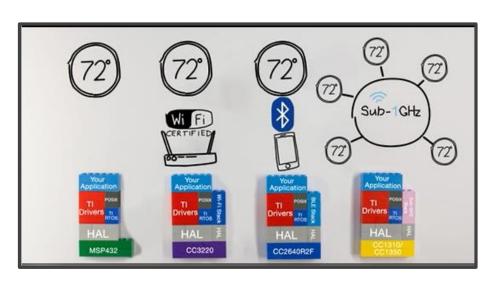
Small size



- BAW: first crystal-less wireless BLE SoC – 12% area savings in reference design
- Tiny BLE SoC: CC2640R2F – 2.7mm x 2.7mm DSBGA

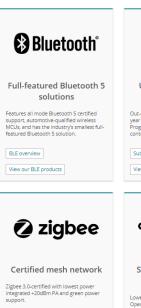


Invest once, reuse effortlessly



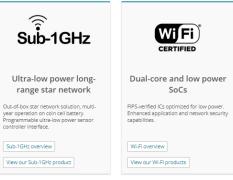
- Learn more about SimpleLink code portability
- SimpleLink medical resources
- CC2640R2F: How do I design an accurate and thermally efficient wearable temperature monitoring system?

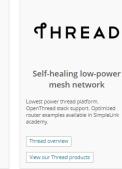
100% code reuse



Zigbee overview

View our Zigbee products











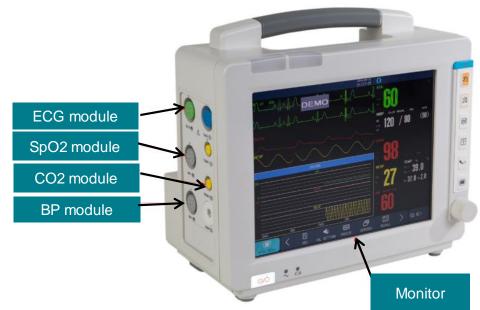
SDK

Multi-standard products

Achieve isolation and help enable patient safety

Patient safety

 Patient safety is a global health priority. Recalling resolution WHA55.18 (2002), which urged Member States to "pay the closest possible attention to the problem of patient safety and to establish and strengthen science based systems, necessary for improving patients' safety and the quality of health care", the seventy-second World Health Assembly (WHA72), in May 2019, adopted WHA72.6, a resolution on 'Global action on patient safety'. (Source: https://www.who.int/patientsafety/en/)



Isolation requirements and safety limits

- IEC60601-1: International basic safety and essential performance standard for electrical medical equipment and medical electrical systems
 - Regional compliance
 - Editions and versions
- Levels of isolation patient focus
- Spacing creepage & clearances
- Safety insulation for transformers
- Leakage current limits
 - Isolation at the sensing side
 - Isolation at the data/power side

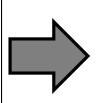
Data and power isolation

Characteristic	Value		
Input voltage range	Option – 1: 3.3 V to 24 V from AC/DC power supply	Isolate	d 🔪
	Option – 2: From 1S-4S battery (i3.7 V to 16 V)	Programmable Power Su	^{1pply} 5V/12V/18V
Output Voltage	Option – 1: 3.3 V or 5 V		
	Option – 2: 3.5 V or 5.5 V to be followed by an Low Drop-out Regulator (LDO)	(typ. 3.5V/5V/12V ← 3 (Or 2S/3S/4S (7.2V
Output power	Typical 5 watts to 7 watts	1 1 1	
Isolation	5 kV and above	@ 1A max)	to 16.8V)
	ECG electrodes RLD electrode Signal input' output protection ECG module example	Amp Pga ADC Signal isolation RLD Summer (resistive)	MPU/DSP . Digital processing
		5kV Iso	lation

Key design challenges

- Input voltage ranging from 3.3V to 24V
 - Regulated input vs. non-regulated input
- Output voltage ranging from 3.3V to 6V
- Output power up to 5W
- Open-loop or closed-loop (voltage/current)
 - achieving < 1% load regulation
- Isolation ~1kV to 5kV
- Emission (CISPR22/25, IEC60601-1)
- Small form factor (new trend electronics in cable and portable MPMs)
 - reduced BoM
- Low cost

One size doesn't fit all the requirements

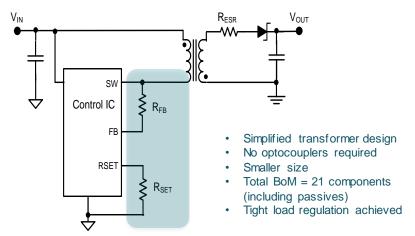


Possible architectures

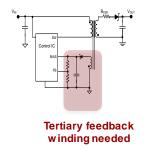
- Flyback
- Push-pull
- Isolated power module
- Isolated power and data module

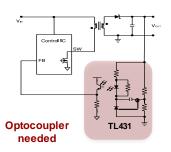
PSR flyback topology

Primary-side regulated flyback



Conventional flyback





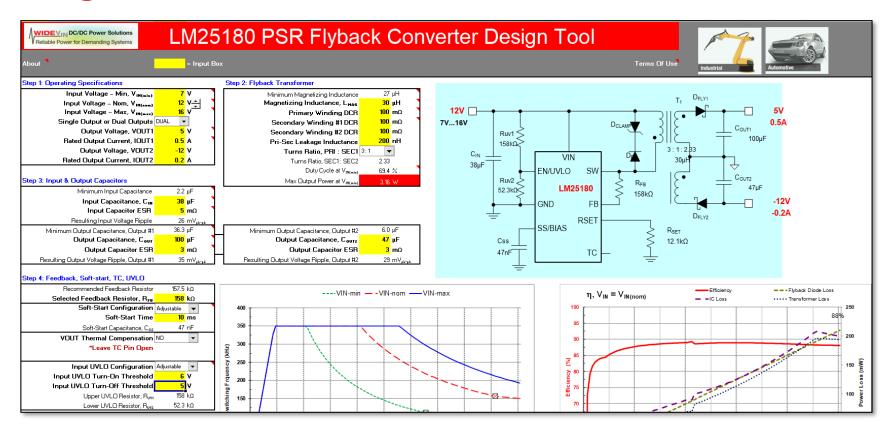
Parameter	Value
Input voltage (Vin)	4.5V to 65V (70V max)
Output voltage (Vout)	Adjustable
Output power (Pout)	7W max
Isolation level	5kV (can be tuned as per transformer design)
Size	45mm x 25mm x 11mm (Depends on transformer design)
Output regulation	1% achievable

Suggested TI devices: LM5180 LM25180 Refer to "Design Calculator" for complete schematics, BoM and simulation results



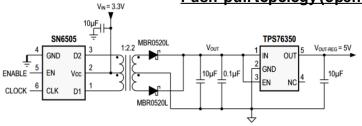
Design Calculator

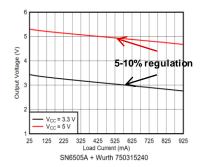
Design calculator for LM25180



Push-pull topology

Push-pull topology (open-loop)

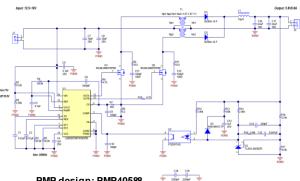




- No opto-couplers required
- Smaller size, total BoM = 10 components (including passives)
- Needs regulated input

Push-pull topology (closed-loop)

- Tight output regulation due to feedback
- Total BoM = 46 components (including passives)
- Optocoupler based design reliability

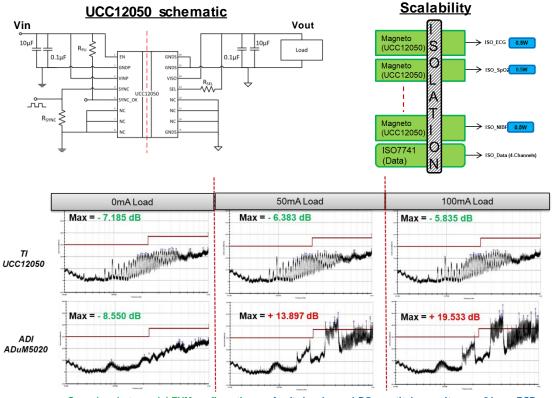


PMP design: PMP40588

Parameter	Value		
Input voltage (Vin)	2.2V to 5.5V		
Output voltage (Vout)	5V unregulated		
Output power (Pout)	5W max		
Isolation level	5kV (can be tuned as per transformer design)		
Size	30mm x 25mm x 6mm (Depends on transformer design)		
Output regulation	5 to 10%		

Suggested TI devices: SN6505A SN6505B

Isolated power module

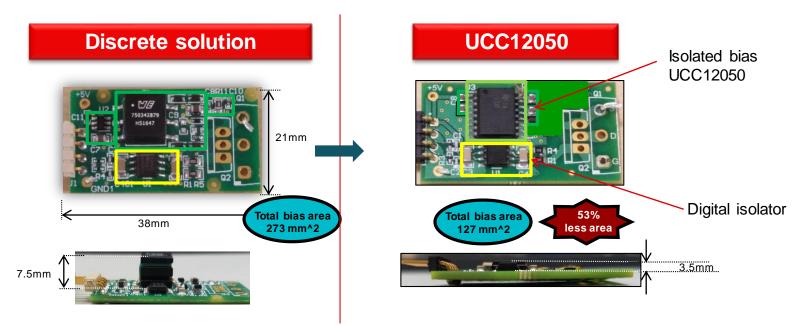


Parameter	Value			
Input voltage (Vin)	4.5V to 5.5V			
Output voltage (Vout)	Regulated 3.3V or 5V			
Output power (Pout)	0.5 W			
Isolation level	5kV RMS reinforced			
Size	10.3mm x 7.5mm x 2.65mm			
Output regulation	1.5%			

Suggested TI device: UCC12050

Same (apple-to-apple) EVM configuration: no ferrite beads, no LDO, no stitch capacitors, on 2 layer PCB
Tested to CISPR32 Limit, in 10m chamber, on same day, in same certified lab.

Integrated transformer technology benefits

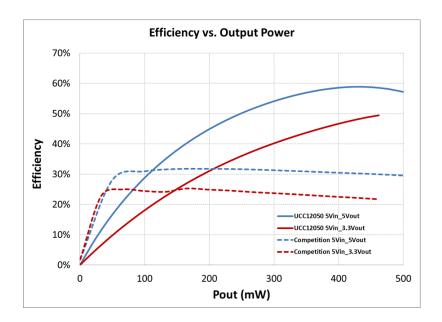




Single chip solution (UCC12050) advantages:

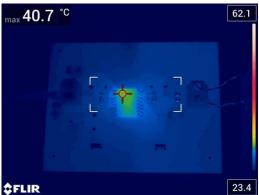
- ✓ Smaller size and low profile
- √ Very low isolation capacitance Cps for better CMTI and less noise
- ✓ Simplify design with less components and easy board layout

Efficiency and thermal Image

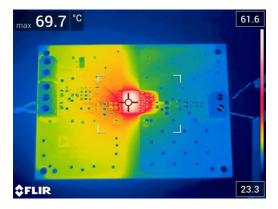


■ Thanks to the 2X peak efficiency, temperature rise of magnetic core solution is ~30°C lower than air-core solution when operating at 5 V_{IN}/5 V_{OUT}100 mA

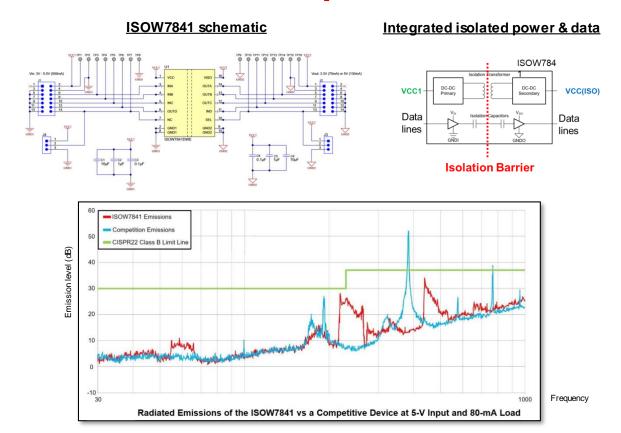
Magnetic core (UCC12050)



Air core



ISOWatt – Isolated power and data

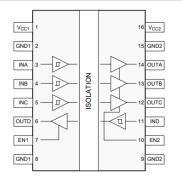


Parameter	Value		
Input voltage (Vin)	3V to 5.5V		
Output voltage (Vout)	Regulated 3.3V or 5V		
Output power (Pout)	0.65 W		
Isolation level	5kV RMS reinforced		
Size	10.3mm x 7.5mm x 2.65mm		
Output regulation	1%		

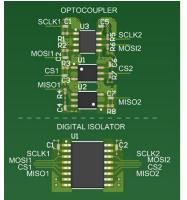
Suggested TI device: ISOW7841 ISOW7821

Digital isolators – signal isolation

ISO7741DW & ISO7841DWW

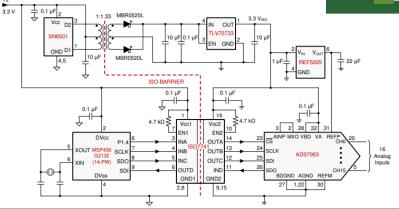


SPI Isolation: ISO7741DW vs traditional optocoupler solution



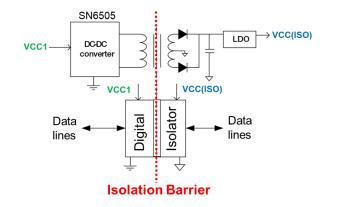
ISO7741DW	ISO7841DWW	
5kVrms	5.7kVrms	
8 mm	14 mm	
100 Mbps	100 Mbps	
2 MOPP up to 240Vrms	2 MOPP up to 400Vrms	
10.3 x 7.5 mm	10.3 x 14.0 mm	
	5kVrms 8 mm 100 Mbps 2 MOPP up to 240Vrms	

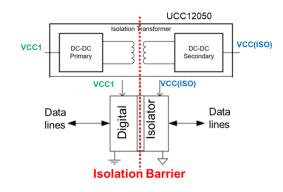
Application diagram:

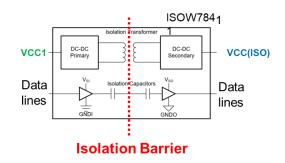


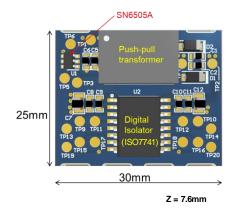
Suggested TI device: ISO7741DW ISO7841DWW

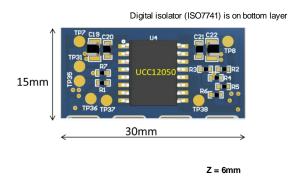
Layout comparison – power and 4-ch data isolation

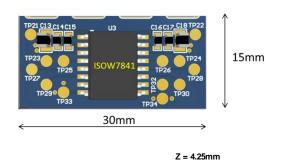












Summary

Topology Parameter	Conventional flyback	PSR flyback (LM25180)	Open-loop push- pull (SN6505)	Closed-loop push-pull (LM25037)	Isolated power module (UCC12050)	Isolated power with digital isolator (ISOW7841)
Output power level	Flexible (transformer and PWM controller dependent)	5 W to 7 W	5 W	Flexible (transformer and PWM controller dependent)	0.5 W	0.65 W
Input voltage range	Up to 42V/65V	Up to 42V/65V	Up to 5.5V	Up to 75V	Up to 5.5V	Up to 5.5V
Output regulation	1% or less	1%	5 to 10%	1% or less	1.5%	1%
No. of discrete components	More than 30	21	10	46	Less than 10	Less than 10
Isolation rating	Flexible (transformer dependent)	Flexible (transformer dependent)	Flexible (transformer dependent)	Flexible (transformer dependent)	5000 Vrms reinforced	5000 Vrms reinforced
Emission	High	High	Low	High	Low	Moderate to high

Application report

http://www.ti.com/lit/an/sloa285a/sloa285a.pdf

Application Report

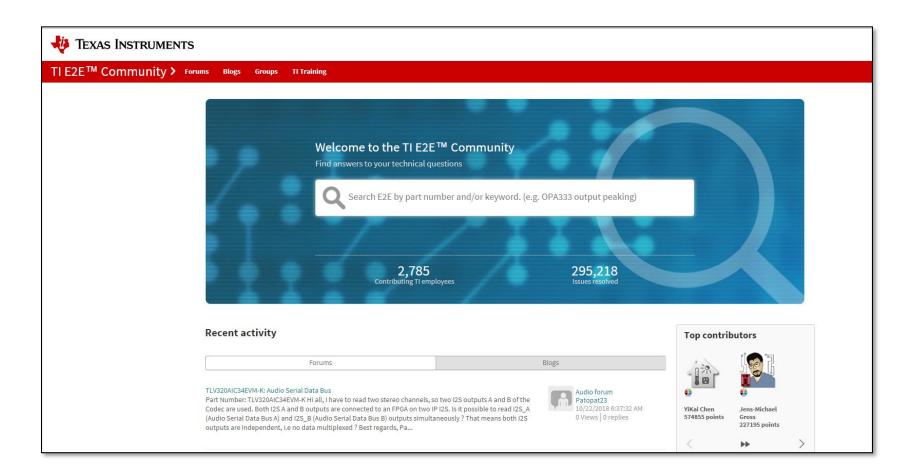
Topology Selection for Isolated Power Supplies in Patient Monitor



Sanjay Pithadia

ABSTRACT

Multiparameter Patient Monitors measure vital signs and use isolated modules for achieving the patient safety. These modules are small in size as they are inserted into the main monitor and support up to 5kV isolation. The data and power both are isolated using digital isolators and isolated power supplies, respectively. This application report talks about different topologies for isolated power and data. It dwells deeper into the critical design challenges associated with isolated power and data such as output regulation, feedback mechanism, input voltage range, output power and size considerations along with suitable power architectures. Finally, it compares the topologies on the basis of all these different parameters.





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