HEALTHCARE SOLUTION USING RENESAS SYNERGY™

Accelerate Medical Device Design with IEC62304 Class C Pre-Certified Renesas Synergy™ Platform Safety Solution

Medical device companies allocate most of their design resources for validating whether their software meets certain standards, especially for Commercial-off-the-Shelf (COTS) software. Recently, the FDA recognized the extensive effort it takes for medical device companies to get their devices certified and started a pre-certified approval path to alleviate some of the burden and improve time to market.

Accelerate Medical Device Development

Renesas has developed an industry-leading IEC62304 Class C pre-certified safety solution using the Renesas Synergy™ Platform in an effort to reduce the certification burden on medical device companies.

Solution Highlights

- Improves time to market, total cost of ownership, and regulatory certification burden
- Integrated hardware and software platform
- Pre-certified Synergy Software Package (SSP) components, Express Logic X-Ware IoT Platform™, and IAR tool chain to IEC62304 Class C
- SSP is fully supported same as software product
- Safety claims backed by artifacts
- Application support provided

Renesas Synergy™

ACCELERATE DEVELOPMENT
Let us take care of everything below the API so you can focus on differentiating your product.

REDUCE TOTAL COST OF OWNERSHIP
Lower your costs from start to finish – technology, development, and maintenance are all included.
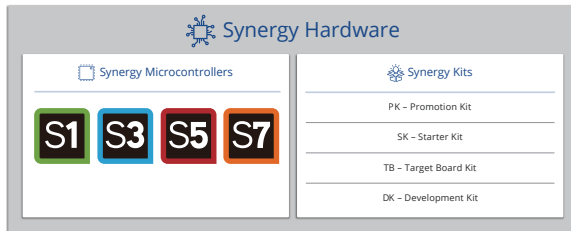
ELIMINATE BARRIERS TO ENTRY
Innovate without facing obstacles of upfront costs, complicated licensing, or starting from square one.
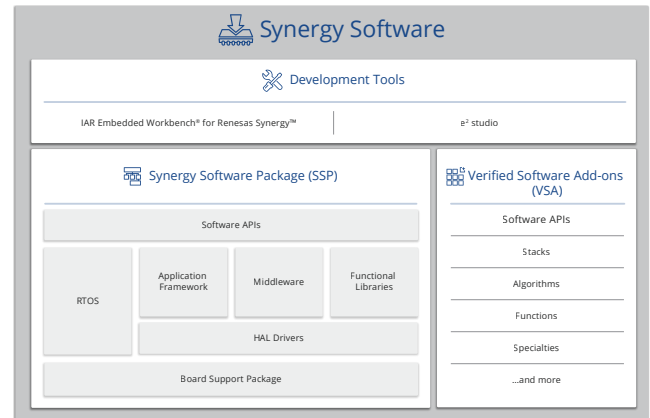
Renesas Synergy Platform

The scalable Renesas Synergy MCU family can be used to design a wide range of embedded systems and IoT devices, from efficient battery-powered applications to high-performance connected products.

Select a Synergy Kit to evaluate the full Synergy Platform, access functionality of Synergy MCUs, and prototype rapidly to save time and resources.

Software and tools are included in the Synergy Platform with no fees or royalties. The Renesas Synergy Software Package (SSP) is a complete MCU software framework with common APIs, add-on software components that complement the SSP with specialty functions, and two software development environments—e2 studio and IAR Embedded Workbench® for Renesas Synergy.

Synergy Hardware

Synergy Microcontrollers

S1 S3 S5 S7

Synergy Kits

PK – Promotion Kit

SK – Starter Kit

TB – Target Board Kit

DK – Development Kit

Learn more about our Healthcare Solutions:
www.renesas.com/en-us/solutions/home/healthcare.html

Learn more about Renesas Synergy: **renesas.com/synergy**

Synergy Software

Development Tools

IAR Embedded Workbench® for Renesas Synergy™	e² studio

Synergy Software Package (SSP)

Software APIs

RTOS	Application Framework	Middleware	Functional Libraries

HAL Drivers

Board Support Package

Verified Software Add-ons (VSA)

Software APIs

Stacks

Algorithms

Functions

Specialties

...and more

Renesas Safety Solution Claims & Supporting Arguments

1. Renesas uses an IEC 62304 compliant SDLC flow for the Synergy product line

- Based on ISO/IEC/IEEE 12207 SDLC process
- Developed with premium Software Quality Assurance (SQA) tools
- Validated and verified to best practices, which are audited and continuously improved
- Regular periodic maintenance releases
- Defined processes for development phases and transitions between each phase
- Established common framework for software lifecycle process

2. Renesas can support your ISO 13485 purchasing controls for the Synergy product line

- Maintain comprehensive product documentation & specifications
- Maintain organizational accreditations for Quality Management Systems (QMS)
- Maintain stringent downstream purchasing controls

3. Synergy Platform provides mechanisms to protect the integrity and confidentiality of critical data at rest

- Error detection & correction (DED), and parity checking in SRAM
- HW accelerated CRC to augment error detection
- Stuck-bit detection using high-speed RAM march tests (DOC)
- Early warning of brown-outs or power-supply glitches (LVD)
- Battery-backed regs. for critical data storage (Battery Backup Fn.)
- Fixed-key protection for special function registers

4. Synergy Platform provides mechanisms to enable self-checks for potentially critical hardware functions

- Hardware self-diagnosis functions on ADC (ADC Self Diagnosis)
- Clock accuracy reporting (CAC)
- Independent readback of port pin status (GPIO Readback Level Detection)
- Bounds checking at application level (Thread Monitor F/W with WDT/ IWDT)
- Error detection & correction (ECC), and parity checking in SRAM
- Certified Self-Test Library Options (IEC 60730 Class B & IEC 61508)

5. Synergy Platform provides "fail-safe" or "fail-secure" mechanisms

- Known system state reversion with exception handling (NMI, MOSC Stop Detect)
- Independent monitoring of system operation (IWDT)
- Detect & capture failure events with RTC (RTCIC)
- High-Z fail-safe for PWM pins (POEG)
- Documented cause of reset (Reset SFR)

6. Synergy Platform provides "fail-operational" mechanisms

- Partial system operation as fallback (CGC, MOSC Stop Detect)
- Known system-state reversion with exception handling (NMI, MOSC Stop Detect)
- Independent RTC operation for accurate timestamps (RTC, XCIN sub-osc)
- Battery-backed regs. for critical data storage (Battery Backup Fn.)

RENESAS

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