



## A Valid Answer to IEC 62304 Cost

Creating medical device software within the IEC 62304 framework is estimated to cost \$75 to \$150 per line of code. One way to rein in software development costs is to utilize existing software where ever possible. Medical device developers routinely look to commercial software vendors for general purpose components such as real-time OS software. Since it is the compliance portion that drives costs, an ideal solution is one where both software and its certification artifacts are readily available.

In the past, it was difficult for light-weight users to justify the expense of commercial RTOS and certification artifacts when they only need one or two of the RTOS services. As a result, they take on the burden of creating the certification artifacts for their API subset, or they choose to forgo the use of a RTOS altogether.

## The Valid-62304 Approach

Valid-62304 (v62304) is the latest addition to VSC's line of verification, validation, and certification products. It was created as a low cost approach to rendering  $\mu$ C/OS-II certified in a medical device.

v62304 contains all of the essential certification artifacts necessary to render  $\mu$ C/OS-II certified to IEC 62304 in any class of a medical device:

- Complete set of  $\mu$ C/OS development life-cycle artifacts covering all APIs and services
- Processor specific life-cycle artifacts for the  $\mu$ C/OS port software
- All test results verified for your target processor\*

v62304 is created and packaged as a “drop-in” module. It is super easy to use. With no external dependencies on tools or software, integration is as simple as checking it in to revision control, followed by documenting it as the reference for all things  $\mu$ C/OS.

## Valid-62304 Value

Valid-62304 is an off-the-shelf item. Each variant is created for a specific combination of compiler and processor or processor family. The  $\mu$ C/OS-II version of Valid-62304 using IAR's EWARM is available today for a number of ST Micro's processors including the Cortex M3 based STM32L1 Value Line family.

For information about other processor and toolsets supported with Valid-62304 please contact us.

\*Physical processor target or equivalent

### Valid-62304 Features

- Less than \$2.5 to \$5 per LOC
- Support for any class of IEC or FDA medical device
- Artifacts cover Life-cycle Processes for
  - Planning though Release and maintenance
  - Risk Management, Configuration Management, and Problem Resolution
  - Includes over 2,000 additional supporting artifacts
- Comprehensive test coverage
  - 100% Feature/Function coverage
  - 100% Statement coverage
  - 100% Decision coverage
  - 100%  $\mu$ C/OS Object Code coverage
- Delivered complete and ready to use
- Development life-cycle artifacts and test reports recorded in PDF format
- Includes instrumented  $\mu$ C/OS-II source code and IAR Embedded Workbench® projects
- Contains all unit test code, integration test code and IAR EWARM projects – to verify prerecorded test results, and perform sanity checks and regression analysis

### Valid-62304 Benefits

- Reduce risk with proven certification solution
- Accelerates development and test schedules
- Frees up vital development and test personnel to work on value add features
- Eliminates up to 18 man-months of in-house efforts to create a similar level of support for  $\mu$ C/OS or comparable RTOS
- No special tools or software is needed





## Validated Software Corporation – Enabling Affordable Safety!

Valid-62304 Artifacts*					
Master Artifact Set	Core	Port	Standards (cont.)	Core	Port
Project Checklist	Yes	Yes	Port Requirements Document	NA	Yes
Software Safety Validation Plan	Yes	Yes	Software Problem Reporting Procedure	Common	
Software QA Plan	Common		Software Design Standard	Common	
Software Configuration Management Plan	Common		Software Requirements Standard	Common	
Software Validation Plan	Common		External Standards Referenced	Common	
Software Configuration Index	Yes	Yes	Supporting Artifacts		
Software Correlation Matrix	Yes	Yes	Audit	Core	Port
Software Requirements Document	Yes	Yes	QA Check Lists	Yes	Yes
Software Design Plan	Yes	Yes	Source Code review Sheets	Yes	Yes
Software Design Document	Yes	Yes	Unit Tests Code Review Sheets	Yes	Yes
Software Integration Test Plan	Yes	Yes	Integration Tests Code Review Sheets	Yes	Yes
Software Integration Test Procedure	Yes	Yes	Document review sheets	Yes	Yes
Software Integration Test Report	Yes	Yes	Requirements Trace Matrices	Yes	Yes
Software Unit Test Plan	Yes	Yes	Test Results	Core	Port
Software Unit Test Procedure	Yes	Yes	IT Test Results	Yes	Yes
Software Unit Test Report	Yes	Yes	UT Test Results	Yes	Yes
Software Accomplishments Summary	Yes	Yes	Lint Test Results	Yes	Yes
Safety Manual	NA	Yes	Code Coverage Results	Yes	Yes
Standards	Core	Port	Source Code	Core	Port
Micrium's "C" Coding Standard	Common		Source Code Projects - All	Yes	Yes
VSC "C" Coding Standard	Common		Source Code $\mu$ C/OS	Yes	Yes
ASM Coding Standard	Common		Source Code UT	Yes	Yes
Code Review Procedure	Common		Source Code IT	Yes	Yes
Document Review Procedure	Common		Source Code Coverage	Yes	Yes

\* There are over 2000 files in Valid-62304, exact contents and document names subject to change

Learn more at: <http://www.validatedsoftware.com>  
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