**Software integration**

**and integration testing**

**Model: SmartSONO MS-09**

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| **META BIOMED CO., LTD.** |

**Revision History**

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| Date | Revision | Description | Author |
| 2014.10.30 | 0 | Modification of changing a monitor’s panel  Modification of probes’ fixed position | 정현우 |
| 2015.02.05 | 1 | IEC 62304의 수정으로 인하여 | 정현우 |
| 2015.03.05 | 2 | 오타 및 내용 수정 | 정현우 |
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# Code Review

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| --- | --- | --- | --- | --- |
|  | Software Requirement | Implemented? (Y/N) | Module | Remark |
| CR-U01 | System initialize | Y | Main UI / Scan process | -Create SW components  -Connect to scan process & perform initialization  -Check DB status |
| CR-U02 | Task area switching | Y | Main UI | - Scan / Image view / Database task switching |
| CR-U03 | System option setting | Y | Main UI | -Save categorized system options to local files |
| CR-U04 | Time & disk status display | Y | Main UI | -Refresh time & disk information according to predefined interval |
| CR-U05 | Scan status display | Y | Main UI | - Display status message and progress information |
| CR-U06 | Patient call display | Y | Main UI | - Display patient call message |
| CR-U07 | Patient /study Registration | Y | Scan UI | -Input or import patient/study information  -Check mandatory information |
| CR-U08 | Scan series management | Y | Scan UI | -Create /Delete/Copy series  -Reserve series |
| CR-U09 | Scan parameter management | Y | Scan UI | -Create/delete/ modify parameters  -Import/export parameters  -Check parameter limit & display error message. |
| CR-U010 | Scan plane localization | Y | Scan UI | -Using DICOM coordinate |
| CR-U011 | Scan protocol management | Y | Scan UI | -Create/delete/modify protocol information  -Import/export protocol parameters. |
| CR-U012 | Scan operation | Y | Scan UI / Scan process | -Scan load / start / stop  -Pre-scan functions  -Check & display MI, TI  -Display real time Ultrasound signal |
| CR-U013 | Image reconstruction | Y | Scan UI / Scan process | -Independent Image reconstruction  -Support extensible post processing interface |
| CR-U014 | HW status checking | Y | Scan UI / Scan process | -Check Ultrasound HW & display error message.  -Reset Ultrasound HW |
| CR-U015 | View result images | Y | Image view UI | -Support various layout & view mode ( 1x1 ~ 2x2, custom, Exam/Series/Stack mode )  -Create various graphic ROI |
| CR-U016 | Image processing | Y | Image view UI | -Support basic tools for image processing (width/level, zoom, flip, inverse, rotation, 2D etc.) |
| CR-U017 | Send images to DB | Y | Image view UI | -Independent process. -Support queuing function  -Show status. |
| CR-U018 | DB optimization | Y | Database UI / Database | -DB compaction function |
| CR-UH01 | System initialize Tx | Y | Main UI / Scan process | - Create Frequency  - Create Tx Power  - Connect to scan process & perform initialization  - Check DB status |
| CR-UH02 | System initialize Rx | Y | Main UI / Scan process | - Create Gain Value  - Calculation: Gain, Amplitude |
| CR-UH03 | System initialize Probe | Y | Main UI / Scan process | - Selection Probe ID  - Check the ID |
| CR-UH04 | System initialize Printer | Y | Main UI | - Check the Print ID number |
| CR-UH05 | System initialize Monitor | Y | Main UI | - Compatible the monitor  - Setting the Resolution |
| CR-UH06 | Interface Requirements (USB) | Y | Main UI, USB | - Confirm to the USB connection |
| CR-UH07 | Interface Requirements (LAN) | Y | Main UI, LAN | - Confirm to the LAN connection |
| CR-UH08 | Interface Requirements (VGA) | Y | Main UI, VGA | - Confirm to the VGA connection |
| CR-UH09 | Interface Requirements (CP) | Y | Main UI, CP | - Confirm to the CP connection |
| CR-UH10 | Interface Requirements (TGC) | Y | Main UI, TGC | - Confirm to the TGC connection |
| CR-F01 | RF waveform generation | Y | Tx | * Change the phase of RF waveform * Change the center frequency * Modulate the RF waveform * Output to RF amplifier |
| CR-F02 | Dynamic Range | Y | DR | * Select Dynamic Range |
| CR-F03 | Receiving signals | Y | Rx | * Demodulate received signal * Process multi-channel input * Send received signal to host system |
| CR-S01 | Pulse sequence | Y | TOF | * Calculate and generate   + RF shape and timing sequence   + ADC information   + Other scan parameters |

# Module Review

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|  | Software Specifications | | | | Implemented? (Y/N) | Remark |
|  | Module | Function | | Function related |
| MR-U01 | Main UI | Initialization | | CreateSystemObjects ()  CheckDatabaseFields() | Y | Verify that HW control / Scan UI /Image Viewer / DB manager are created and displayed properly  Verify that database checking perform normally.  If errors exist, appropriate messages show up. |
| MR-U02 |  | Initialization | | InitializeScanModule() | Y | Verify that scan process is connected normally.  If errors exist, appropriate messages show up. |
| MR-U03 |  | Initialization | | InitializeSystem() | Y | Check the system initialization  If errors exist, appropriate messages show up. |
| MR-U04 |  | Task area switching | | OnButton\_\_\_ () | Y | Verify that correspondent task window shows up and other processing windows are hidden. |
| MR-U05 |  | System option setting | | CSystemOptionsDlg ::OnInitDialog()  CSystemOptionsDlg::OnOK() | Y | Verify that options from local files are loaded normally.  Verify that option changes are saved to local files |
| MR-U06 |  | Time & disk status display | | RefreshSystemDateTime()  RefreshDiskInfo() | Y | Verify that time update is done normally  Verify that disk information update is done normally |
| MR-U07 |  | Scan status display | | OnAddStatusMsg()  OnSetCurStep() | Y | Verify that status message is displayed normally.  Verify that scan step progress is displayed normally. |
| MR-U08 |  | Patient call display | | ProcessEvent () | Y | Verify that patient call message is displayed clearly and blink periodically. |
| MR-U09 | Scan UI | Patient /study Registration | | OnBnClickedButtonPatregImportStudy()  OnBnClickedButtonPatregRegister ()  CheckInformationValidity() | Y | Verify that patient/study information is imported normally.  Verify that mandatory information exist.  If errors exist, appropriate messages show up. |
| MR-U10 |  | Scan series management | | OnScanMaintNewScansession()  OnButtonScanDeleteScan()  OnScanMaintCopyScansession()  OnClickScanSessionList()  ProcessReconEnd () | Y | Verify that creation /deletion/ cloning of series is done normally.  Verify that series reservation is done normally and the series run automatically. |
| MR-U11 |  | Scan parameter management | | OnScanParaMaintImportPara()  OnScanParaMaintExportPara()  VerifyScanParameters() | Y | Verify that creation /deletion/ modification of parameter is done normally.  Verify that importing / exporting parameter is done normally.  Check parameter limit & display error message |
| MR-U12 |  | Scan plane localization | | AddNewRenderer()  LayoutRenderer( mode ) | Y | Verify that renderer is created normally.  Verify that renderer's layout is done normally according to layout mode. |
| MR-U13 |  | Scan protocol management | | OnProtomanipulationCopy()  OnProtomanipulationSaveAs()  OnProtomanipulationRemove()  OnProtomanipulationImportprotocols()  OnProtomanipulationExportprotocols() | Y | Verify that copying /saving/deletion/modification of protocol is done normally.  Verify that importing / exporting protocol is done normally. |
| MR-U14 |  | Image processing | | OnLButtonUpCreating (...)  OnDelete\_ROI\_From\_Selected\_Card(...)  OnZoom\_mode(...)  OnPan\_mode(...)  OnMag\_mode(...)  OnWindowWidthLevel\_mode(...)  OnFlip(...)  OnMirror(...)  OnNagative(...)  OnRotate\_Right(...)  OnRotate\_Left(...)  OnRotate(...)  EnhanceImage() | Y | Verify that image processing functions (width/level, zoom, pan, flip, inverse, rotation) re executed normally. |
| MR-U15 |  | DB optimization | | OnCompactDatabase () | Y | DB size is reduced and error condition is cleared if exist.  Verify that DB is compacted normally |
| MR-F01 | Tx | Output the RF and gating signal | | CreateRFShape()  CreatePulseSequence()  Pulse() | Y | Change the input signal’s amplitude and timing, verify an output signal |
| MR-F02 |  | Control the RF signal’s phase | | CalculateOffsetPhase() | Y | Change the input signal’s phase and verify an output signal |
| MR-F03 |  | Control the center frequency | | ChangeTuningFrequency() | Y | Change the input signal’s center frequency and verify an output signal’s spectrum |
| MR-F04 | Rx | Acquire the signal | | Pulse() | Y | Verify the ADC timing  Verify the number of samples  Verify the acquired signal according to the change of the input signal |
| MR-F05 | Channel Acq | Channel Acq | | Ch\_acp() | Y | Channel timing and DAS.  Make to the Scanline. |
| MR-F06 | Probe  Selection | Probe Selection Mode | | Probe\_s()  Mode\_s() | Y | First, Probe select Mode.  (Linear, Convex, Sector, Vaginal, Micro Convex) |
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| MR-S01 | | TOF | Ultrasound compensation | Calc\_TOF() | | Y | Time of Flight |

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# Integration Review

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|  | Software Specifications | | | Implemented? (Y/N) | Remark |
|  | Status | Function | Module |
| IR-001 | Initialization | System Initialization | Main UI  Scan process | Y | Verify that following functions are performed normally.  -SW components are created and initialized.  -Check DB status.  -Connection to scan process is established.  -If the connection is successful, system initialization request is sent to scan process.  -If system initialization is successful, default task area show up and current disk status & time information is displayed. |
| IR-002 | HW checking | HW status checking | Scan UI  Scan process | Y | Verify that following functions are performed normally.  -If errors exist, error message show up and HW reset command is provided to user.  .-If user select HW reset, current scan is stopped. |
| IR-003 | Scanning | Scan planning | Scan UI  Scan process  Pulse sequence  Database UI | Y | Verify that following functions are performed normally.  -Select scan parameter from protocol DB and save it to scan series.  -Set up scan plane and save plane information at scan series.  -Display scan time by load command. if the value of scan parameter and SAR is not adequate, display the message. |
| IR-004 |  | Scan | Scan UI  Scan process  Pulse sequence  Database UI | Y | Verify that following functions are performed normally.  -Start scanning by scan command.  -Display scan step and its progress along scanning.  -Display series status while scanning.  -when the pre-scan option is turned on, optimization process is performed normally.  -when the scan is completed, start reconstruction.  -when the reconstruction is completed, start post processing.  -Add the completed series & image information to database and refresh database UI. |
| IR-005 |  | End Scan | Scan UI  Scan process  Pulse sequence  Database UI | Y | Verify that following functions are performed normally.  -After all scan are completed, back up DB information and images at the secondary DB.  -Initialize scan task area. |