**Software requirements analysis**

**Model: SmartSONO MS-09**

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

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**Contents**

[1 Software Requirements Specification (SRS) 6](#_Toc426958791)

[1.1 Hardware Requirements 6](#_Toc426958792)

[1.1.1.1 Microprocessors 6](#_Toc426958793)

[1.1.1.2 Initialization (SRS-M01) 6](#_Toc426958794)

[1.1.1.3 Probe Setting (SRS-M02) 6](#_Toc426958795)

[1.1.1.4 System option setting (SRS-M03). 7](#_Toc426958796)

[**1.1.2** Memory devices 7](#_Toc426958797)

[1.1.2.1 Patient Information (SRS-D01) 7](#_Toc426958798)

[1.1.2.2 Save Cline Loop (SRS-D02) 7](#_Toc426958799)

[1.1.2.3 Save Image (SRS-D03) 7](#_Toc426958800)

[**1.1.3** Sensors 7](#_Toc426958801)

[1.1.3.1 Probe ID Selection (SRS-S01) 8](#_Toc426958802)

[1.1.3.2 Linear Probe Selection (SRS-S02) 8](#_Toc426958803)

[1.1.3.3 Convex Probe Selection (SRS-S03) 8](#_Toc426958804)

[1.1.3.4 Phased Probe Selection (SRS-S04) 8](#_Toc426958805)

[1.1.3.5 Sector Probe Selection (SRS-S05) 9](#_Toc426958806)

[1.1.3.6 Vaginal Probe Selection (SRS-S06). 9](#_Toc426958807)

[1.1.3.7 Energy sources 9](#_Toc426958808)

[1.1.3.8 Tx (SRS-E01) 9](#_Toc426958809)

[1.1.3.9 Rx (SRS-E02) 9](#_Toc426958810)

[1.1.3.10 Range gate (SRS-E03) 9](#_Toc426958811)

[1.1.3.11 Focus Delay (SRS-E04) 9](#_Toc426958812)

[1.1.3.12 Channel Acq (SRS-E05) 10](#_Toc426958813)

[1.1.3.13 Frequency (SRS-E06) 10](#_Toc426958814)

[**1.1.4** Safety features 10](#_Toc426958815)

[1.1.4.1 MI (SRS-S01) 10](#_Toc426958816)

[1.1.4.2 TI (SRS-S02) 11](#_Toc426958817)

[**1.1.5** Communications 11](#_Toc426958818)

[1.1.5.1 Power On/Off (SRS-C01) 11](#_Toc426958819)

[1.1.5.2 Freeze (SRS-C02) 11](#_Toc426958820)

[1.1.5.3 Vertical (SRS-C03) 11](#_Toc426958821)

[1.1.5.4 Horizontal (SRS-C04) 11](#_Toc426958822)

[1.1.5.5 Dynamic Range (SRS-C05) 11](#_Toc426958823)

[1.1.5.6 Patient Input (SRS-C06) 11](#_Toc426958824)

[1.1.5.7 Focus# (SRS-C07) 11](#_Toc426958825)

[1.1.5.8 Zoom (SRS-C08) 12](#_Toc426958826)

[1.1.5.9 Mode Selection (B mode, M mode, CMF mode, PDI mode) (SRS-C09) 12](#_Toc426958827)

[**1.1.6** External equipment 15](#_Toc426958828)

[1.1.6.1 DICOM (SRS-X01) 15](#_Toc426958829)

[1.1.6.2 External Printer (SRS-X02) 15](#_Toc426958830)

[**1.1.7** Imaging Processing and Motion (H/W) 15](#_Toc426958831)

[1.1.7.1 Demodulator (SRS-PH01) 15](#_Toc426958832)

[1.1.7.2 Clutter Filter & Hilbert (SRS-PH02) 16](#_Toc426958833)

[1.1.7.3 ADC (SRS-PH03) 16](#_Toc426958834)

[1.2 Programming Language Requirements 17](#_Toc426958835)

[**1.2.1** Program Language 17](#_Toc426958836)

[1.2.1.1 Main UI & sequence (SRS-PP01) 17](#_Toc426958837)

[1.2.1.2 Firmware (SRS-PP02) 17](#_Toc426958838)

[**1.2.2** Programming Tools and Library (SRS-PP03) 17](#_Toc426958839)

[1.2.2.1 Editor: Microsoft Visual 2010 17](#_Toc426958840)

[1.2.2.2 C++ compiler: Microsoft Visual 2010 17](#_Toc426958841)

[**1.2.3** Program Size (SRS-PP04) 17](#_Toc426958842)

[1.3 Interface Requirements 18](#_Toc426958843)

[**1.3.1** Printers (SRS-I01) 18](#_Toc426958844)

[**1.3.2** Monitors (SRS-I02) 18](#_Toc426958845)

[**1.3.3** Keyboard (SRS-I03) 18](#_Toc426958846)

[**1.3.4** Mouse (SRS-I04) 18](#_Toc426958847)

[**1.3.5** Functions for checking DB size & compaction DB (SRS-I05) 18](#_Toc426958848)

[**1.3.6** USB (SRS-I06) 19](#_Toc426958849)

[**1.3.7** LAN (SRS-I07) 19](#_Toc426958850)

[**1.3.8** VGA (SRS-I08) 19](#_Toc426958851)

[**1.3.9** CP (Control Panel, SRS-I09) 19](#_Toc426958852)

[**1.3.10** TGC (SRS-I10) 21](#_Toc426958853)

[1.4 Software Performance and Functional Requirements 22](#_Toc426958854)

[**1.4.1** Device limitations due to software (SRS-SP01) 22](#_Toc426958855)

[**1.4.2** Internal software tests and checks (SRS-SP02) 22](#_Toc426958856)

[**1.4.3** Error and interrupt handling (SRS-SP03) 22](#_Toc426958857)

[**1.4.4** Fault detection, tolerance, and recovery characteristics Software detects the status of USB connection, and do re-connect if connection is lost. Software checks the validity of image and discards it if not valid. (SRS-SP04) 23](#_Toc426958858)

[**1.4.5** Safety requirements (SRS-SP05) 23](#_Toc426958859)

[**1.4.6** Timing and memory requirements. 23](#_Toc426958860)

[1.4.6.1 Memory Storage (SRS-MS01) 23](#_Toc426958861)

[1.4.6.2 System boot time (SRS-MS02) : 90 second 23](#_Toc426958862)

[1.4.6.3 Probe is connected to the system time (SRS-MS03) : second 23](#_Toc426958863)

[1.4.6.4 Time: a user to select a Probe (SRS-MS04) : second 23](#_Toc426958864)

[1.4.6.5 Time printer output (SRS-MS05) : 5 second 23](#_Toc426958865)

[**1.4.7** Identification of off-the-shelf software, if appropriate: Windows 23](#_Toc426958866)

[**1.4.8** Imaging Processing and Motion (S/W) 24](#_Toc426958867)

[1.4.8.1 DAS (SRS-PS01) 24](#_Toc426958868)

[1.4.8.2 Envelop Detection (SRS-PS02) 24](#_Toc426958869)

[1.4.8.3 Log Compression (SRS-PS03) 24](#_Toc426958870)

[1.4.8.4 Distal Scan Conversion (SRS-PS04) 24](#_Toc426958871)

[1.4.8.5 Base Line (SRS-PS05) 24](#_Toc426958872)

[1.4.8.6 BODY MARK (SRS-PS06) 24](#_Toc426958873)

# Software Requirements Specification (SRS)

## Hardware Requirements

* + - 1. Microprocessors

The main purpose, Ultrasound imaging system (MS-09) is check the lesion. This method is we use the B-scan. Regular Doppler B-scan instruments for this purpose are unwieldy and are not locatable at the bedside. Microprocessor based Ultrasound Display instrument with combined Doppler spectrum view was developed.

This system employs a 6502 microprocessor along with a BASIC interpreter as part of the firmware, so that the calculations particular for Doppler spectrum evaluation could be handled.

* + - 1. Initialization (SRS-M01)

When to power equipment, it will be operated through the first set value. MS-09 is setting the initial state of the HW and SW via the Microprocessor. When the first execution, check whether the operating state of the system is normal. Check whether the problem also occurs in the system by performing the checks Protocol between HW and SW. Through abovementioned processes, it can be checked the problem in the equipment and recognized the system state.

* + - 1. Probe Setting (SRS-M02)

There is a Probe of the sensors that are used in medical devices. It is possible to determine the disease status of the patient through a Probe. Therefore, it should the verification whether or not Probe is recognized to the system. Therefore, it should the verification of whether the probe is disconnected from the system.

If the probe is not connected or incorrectly connected, any measures needed to allow users to check.

Probe is classified as in several types in accordance with the intended use. Thus, each set is needed with respect to the Probe. It reads the ID value through recognized set value of the Probe. The probe is set by the read ID value and it provides information to the user.

* + - 1. System option setting (SRS-M03).

Ultrasound imaging system can be used with different purposes by users. In this regard the system option must set up. The HW configuration should be to match the diagnostic imaging. Through this configuration it is possible to change the options according to the purpose of each user.

### Memory devices

MS-09 basically confirms the lesion by B-mode. When checking, it usually displays in real-time on the screen. The Memory is required to store the image displayed patient information and images. Typically, more than 60GB Memory is required.

* + - 1. Patient Information (SRS-D01)

It can be stored and can be modified of the patient information. Also it can be recalled the information later and can be modified again. Through patient information user (eg the doctor) can be compared to the diagnosis later.

* + - 1. Save Cline Loop (SRS-D02)

The measured information can be stored as the moving picture. It can call up the stored data and can be deleted again.

* + - 1. Save Image (SRS-D03)

The measured patient information can be stored as the picture. It can call up the stored data and can be deleted again.

### Sensors

Probe is required to get Data regarding the patient lesion. The Probe will be used in accordance with the observation target. That’s because the frequency and power will be changed according to depth and range of measured area. MS-09 is generally used an array type transducer (Transducer Array). It can be used among Linear, Convex, and Phased Probe. Each usage is as follows.

|  |  |  |  |
| --- | --- | --- | --- |
| Linear | D:\METABIOMED\1_System\Ultrasound_MS09\2.SW\System변경\배포용\Probe Image\7.5MHzL40-1.jpg | Center Frequency:  5~10 MHz  Peripheral vascular  Skeleton-muscular |  |
| Convex | D:\METABIOMED\1_System\Ultrasound_MS09\2.SW\System변경\배포용\Probe Image\3.5MHzR50-1.jpg | Center Frequency: 3.5MHz  Abdomen |  |
| Phased | D:\METABIOMED\1_System\Ultrasound_MS09\2.SW\System변경\배포용\Probe Image\3.5MHzP30-1.jpg | Center Frequency: 3.5MHz  cardiac |  |

It is required to be using the same sensor (Probe) aforementioned.

MS-09 diagnostic ultrasound system can be used the sensor among Linear, Convex, Phased, Sector and Vaginal Probe.

* + - 1. Probe ID Selection (SRS-S01)

MS-09 will have the four ports to connect the Probe. Therefore, when the user selects a different probe during use of the system, it should be changed to. It must be prepared to the choice about this.

* + - 1. Linear Probe Selection (SRS-S02)

As a kind of Probe, it should be selected when connecting to the Linear Probe from the outside.

* + - 1. Convex Probe Selection (SRS-S03)

As a kind of Probe, it should be selected when connecting to the Convex Probe from the outside.

* + - 1. Phased Probe Selection (SRS-S04)

As a kind of Probe, it should be selected when connecting to the Phased Probe from the outside.

* + - 1. Sector Probe Selection (SRS-S05)

As a kind of Probe, it should be selected when connecting to the Sector Probe from the outside.

* + - 1. Vaginal Probe Selection (SRS-S06).

As a kind of Probe, it should be selected when connecting to the Vaginal Probe from the outside.

* + - 1. Energy sources

A diagnostic ultrasound system is generating higher than the audible frequency to view the site the user wants to see. To generate the ultrasonic waves, the Probe as the sense should be adjusted from inside the System. In addition, regarding the deepest area, closest area and difference in impedance, it required to be controlled diversely. In this regard, Tx is charge of this process, and this process is referred to as the reflected signal and call it Rx by and large. It must perform a variety of functions internally.

* + - 1. Tx (SRS-E01)

According to the probe options to meet user purpose, Tx cycle and signal processing must be changed to match.

* + - 1. Rx (SRS-E02)

In the process of received signal, determine the gain according to the noise and Amplitude by H/W setting.

* + - 1. Range gate (SRS-E03)

As a function of PW (Pulse Wave), it is used when the acquisition and processing of the information about a particular input field. It is used mainly to obtain information about blood flow.

* + - 1. Focus Delay (SRS-E04)

Each signal must be delayed in order to obtain the information user want to see. It may amplify the value of such signal (phase) through a Delay.

* + - 1. Channel Acq (SRS-E05)

As storing section to obtain information about the Channel of the Probe, it can be used to further improve the image.

* + - 1. Frequency (SRS-E06)

Every probe has its own Frequency to use. By using this Frequency, it can be obtain information of the desired value.

### Safety features

* + - 1. MI (SRS-SM01)

By calculating Mechanical index, it indicates the size of the mechanical impact on the tissue of ultrasound. If it is out of specification, it can increase reliability of equipment by generating a warning.

MI (Mechanical Index) <1.9, will display on the screen. Therefore, if this value is lower than the warning occurred to increase the stability.

,

= maximum value of negative pressure

F = center frequency

If more than 1.9, there is a risk of breaking the cells by generating cavitation. Thus it should not exceed that value in any case.

* + - 1. TI (SRS-ST01)

By calculating the Thermal index, it indicates the size of the temperature effects on body tissue of ultrasound. If it is out of specifications, it can increase reliability of the equipment by generating a warning.

### Communications

* + - 1. Power On/Off (SRS-C01)

The power should be the On / Off by Hardware.

* + - 1. Freeze (SRS-C02)

When imaging, stop the screen when you want to focus a desired image. By the stopped image, the user can be observed and stored image.

* + - 1. Vertical (SRS-C03)

The video screen shows the vertical symmetry. It can be provided to vary the user's point of view, through a variety of digital effect.

* + - 1. Horizontal (SRS-C04)

The video shows the screen horizontally symmetrical. It can be provided to vary the user's point of view, through a variety of digital effect.

* + - 1. Dynamic Range (SRS-C05)

TGC and overall screen brightness can be adjusted through the Dynamic Range internally. In general, the deep section comes to relatively dark due to a weak signal. It is used to complement of it.

* + - 1. Patient Input (SRS-C06)

A variety of patient information can be stored and managed by save. By providing information diagnosed to the user, it aids medical treatment.

* + - 1. Focus# (SRS-C07)

The Focus position can be changed in order to exactly see Lesions that user want to investigate. In addition, two or three parts can be focused to see exactly the number of lesions in one image.

* + - 1. Zoom (SRS-C08)

It can be viewed by expanding lesion that you want to investigate exactly.

* + - 1. Mode Selection (B mode, M mode, CMF mode, PDI mode) (SRS-C09)

It allows the user to view and to select the desired Mode. MS-09 provides a B mode, B / M mode, CMF mode, and PDI mode.

* B mode
  + Measurement should carry on as per the following steps:
    - Record and check the relevant information of the patient. Verify system settings (probe and preset).
    - Scanning the patient.
    - Collect all the data to complete the examination.
    - Press B/Gain on the keyboard to enter into B mode, use menu function to set image parameter in real time state. Carry on various measurements in frozen state.
  + Function Explanation and Adjustment in B Mode
    - Power  
      Range of transmitting power: 0 ~15
    - Frequency  
      Different probes have different Frequency
    - Line Density  
      Scanning density rang: FPS×Hz in the information area will change according to the scanning density.
    - Dyn Range  
      Dyn Range: 0dB~160dB
    - Smooth  
      Processing of image noise
    - Persist  
      Frame averaging
    - THI  
      Enhanced penetration rate: OFF/ON Frequency XXM will show in the information area.
    - Focus#  
      Focus numbers: 0~4. FPS×Hz in the information area will change according to the numbers.
    - Rector  
      Width: 5%~100%. FPS×Hz in the information area will change according to the parameters.
    - iClear  
      This is processing for image signal.
    - Edge Enhance   
      Enhance the edge of the organs.  
      Range: 0~7
    - Gray Map  
      To control the image signal that below a certain gray scale.
    - Horizontal  
      Left/right flips: OFF/ON
    - Vertical  
      Up/down flips: OFF/ON
* B/M mode
  + The examination in B/M mode is generally carried on as follows
    - Obtain a higher quality image in B/M mode. Observe the anatomical structure, and place the interested area in the center of B mode.
    - Move the trackball and place the sampling line in the display area of M mode.
    - Press B/M again to enter into M mode.
    - If necessary, adjust scanning speed, TGC, gain, acoustical power, focus, Dyn Range and so on.
    - Press Freeze can stop the M track.
    - Press Freeze can continue the imaging.
    - Press M can back into B/M mode.
* CMF mode
  + Checks with color bloodstream mode are generally carried out as follows:
    - Choose the interested anatomical area as per the procedure in the B mode.
    - Add color bloodstream after image optimization in B mode.
    - Move the area of interested color bloodstream, close to the center of the image as far as possible.
    - Optimize the parameters of color bloodstream to obtain a higher frame rate and display the appropriate blood flow velocity.
    - Press Freeze and store the image.
    - Record color bloodstream image if necessary.
    - For more information, please carry on as per the process of Doppler mode.
    - The following functional description is based on real time state.
  + Parameter Adjustment in CF Mode
    - Power

Range of transmitting power

* + - Frequency

Probe Frequency

* + - Display mode

Parameters for brightness, color, contrast, and other parameters.

* + - Steer

The angle of sampling box, select Steer.

* + - PRF

Select PRF, “FPS×Hz” and “PRFC×Hz” in information area will change as per the value. Speed range/ pulse repetition frequency (PRF) determines the maximum speed which can be observed. If the speed is too high, the accuracy will decrease. It is needed to decrease PRF in high frequency mode.

* + - Baseline

Select Baseline. It is mainly used to increase the scope of Doppler bloodstream velocity and reduce confusion of spectral direction.

* + - Threshold

It is the critical value of gradation and contrast. It is mainly used to enhance image contrast.

* + - Wall Filter

Select Wall Filter

* + - C Persist

Select C Persist

* + - Ensemble

Select Ensemble. FPS×Hz” in information area is changed according to the value.

* + - C Speed

Select C Speed.

* PDI mode
  + PDI (power Doppler Imaging) mode (B+ C+ D mode) is a kind of color flow imaging technique, which reflects Doppler signal strength instead of signal frequency shift. The ultrasonic system draws color flow based on the reflector numbers of motion regardless of the speed. PDI mode cannot reflect the speed of imaging, so there is no aliasing.

### External equipment

* + - 1. DICOM (SRS-X01)

It provide to DICOM for sharing information between users and hospitals.

* + - 1. External Printer (SRS-X02)

It can be connected the outside to print the large sheet of the paper.

### Imaging Processing and Motion (H/W)

* + - 1. Demodulator (SRS-PH01)

In PDI Mode, the demodulator will be used to determine the information on the blood flow.

* + - 1. Clutter Filter & Hilbert (SRS-PH02)

The received echo signal via Hardware can be reduced by using Filter and Hilbert.

* + - 1. ADC (SRS-PH03)

Analog signal can be read as a signal by converting to the Digital.

## Programming Language Requirements

### Program Language

* + - 1. Main UI & sequence (SRS-PP01)

Editor : MS visual studio

Debugger : MS visual studio

Compiler

C compiler : MS visual studio

Assembler : MS visual studio

Linker : MS visual studio

* + - 1. Firmware (SRS-PP02)

Editor : Visual DSP

Compiler

Assembler : Visual DSP

C compile : Visual DSP

Linker : Visual DSP

Editor : FPGA

Compiler

Assembler : Xilinx FPGA

Linker : Xilinx FPGA

### Programming Tools and Library (SRS-PP03)

* + - 1. Editor: Microsoft Visual 2010
      2. C++ compiler: Microsoft Visual 2010

### Program Size (SRS-PP04)

- Main UI & sequence: about 10MB

- Firmware: about 1MB

## Interface Requirements

### Printers (SRS-I01)

MS-09 is commonly used for SONY-UP-D898MD. The image can be preserved and provided by printing.

### Monitors (SRS-I02)

15 inch monitor is used.

### Keyboard (SRS-I03)

QWERTY key type Keyboard is used. The keyboard is the same as the conventional keyboard and it may be used with no resistance to the user. It also provides an additional option for the user's convenience.

* Annotation
* Application
* Body Mark
* Setting
* 4B
* Flips
* Puncture
* Middle Line
* Close Body Mark
* Probe Selection
* ATGC

### Mouse (SRS-I04)

Mouse used the Track Ball Type.

Used to select, adjust, and move objects on the screen. For example, it controls the caliper position, CPD/Color box position and size, floating cursor, and more. The arrow keys control much of the same functionality as the trackball.

### Functions for checking DB size & compaction DB (SRS-I05)

DB is used to check the version management and further information modified of Software.

### USB (SRS-I06)

It provides a USB ports to connect the external memory and other equipment connection.later.

* Version 2.0 : 2 pcs

### LAN (SRS-I07)

It provides a communication device for connection to the external environment.

* RJ-45

### VGA (SRS-I08)

It provides the connector for user to connect an extra monitor as a user convenience.

### CP (Control Panel, SRS-I09)

System should be changed for user to obtain the desired information. At this time, the service panel is provided for changing easily. Mainly in the panel, the options user want are provided.

* Depth  
  scanning depth
* Focus  
  Multi- Focus & Adjusting focus position
* Zoom  
  Multi- Focus & Adjusting focus position
* Angle  
  Adjusting scanning area & Move M-Mode Line
* Filter  
  Wall Filter
* BFV  
  Blood velocity
* Patient  
  Access to patient information
* Printer  
  Prints the active image to the printer
* Adjust  
  Adjustment knob for the six keys on the Upside (【Depth】【Focus】【Zoom】【Angle】【Filter】【BFV】)
* Doppler  
  In real time, response to black and white pulse Doppler and pulse Doppler in bloodstream mode
* CFM  
  Press once to enter into bloodstream mode (C mode), gain adjustment
* B/Gain  
  Press once to enter into brightness mode (B mode), gain adjustment
* Probe  
  Probe conversion
* B/B  
  Entering B/B or 4B mode
* B/M  
  Entering B/M mode
* Steer  
  Image rotation
* Change  
  Change the live image on the 2B and 4B Mode
* Update  
  Revision, correction
* Clear  
  Clear
* Esc  
  Equivalent to the right mouse button.
* Set  
  Confirming, equivalent to the left mouse button.
* Distance  
  Distance measurement
* GA  
  Application Area for measurement
* Upper Arrow  
  Upward
* Under Arrow  
  Downward
* on the left of Arrow  
  Leftward/ Decrease
* on the right of Arrow  
  Rightward/ Increase
* Cine Save  
  Saving video
* Cine Loop  
  Cineloop, or press this key after press Freeze to enter into the selection menu.
* Save  
  Saving image
* Report  
  Entering the current patient report.
* Freeze  
  Freezing or unfreezing an image.

### TGC (SRS-I10)

It is provided for the user to be assigned a gain value with regards to the desired point.

## Software Performance and Functional Requirements

### Device limitations due to software (SRS-SP01)

|  |  |  |
| --- | --- | --- |
| Device | Description | Range |
| Display monitor | Display device supporting min.  Resolution 1280\*1024. | -Monitor: 15 inch |
| CPU | MS-09 is used for efficient image processing. | -Support SCUS |
| RAM | Minimum memory size for efficient image reconstruction is required. | -1GB or above |
| Mother board | - PCI slot for plugging SICC card  - RS232 communication port to connect OCB and RGU | -VGA slot: 2 or above |

### Internal software tests and checks (SRS-SP02)

|  |  |  |
| --- | --- | --- |
| Check items | Description | Valid condition |
| License validity | Check license validity to be used by permitted users only. | - Within the term of validity  - Permitted system |
| DB compatibility | Check DB fields for DB compatibility. | - The presence of field supported |
| Patient information | Check the number of patient records and recommend to back up in case of more than the limitation. | - Less than the fixed value of option |
| Disk space | - Check available memory size of disk frequently and display the warning message continuously if the remaining capacity is not enough. | - Less than 10% for free space |

### Error and interrupt handling (SRS-SP03)

Software handles no interrupt and internal timer interrupt.

### Fault detection, tolerance, and recovery characteristics Software detects the status of USB connection, and do re-connect if connection is lost. Software checks the validity of image and discards it if not valid. (SRS-SP04)

### Safety requirements (SRS-SP05)

|  |  |
| --- | --- |
| Item | Requirement |
| MI | * Mechanical index can be used as an estimate for the degree a given set of ultrasound parameters will induce. Show range display. |
| TI | * Thermal Index (TI) a metric associated with the tissue heating. Show range display |

### Timing and memory requirements.

* + - 1. Memory Storage (SRS-MS01)

The remaining space of memory should be checked when storing RF Data and video. When 85% of the total space is used, it will be warning to inform the user of it.

* + - 1. System boot time (SRS-MS02)  
         : 90 second
      2. Probe is connected to the system time (SRS-MS03)  
         : second
      3. Time: a user to select a Probe (SRS-MS04)  
         : second
      4. Time printer output (SRS-MS05)  
         : 5 second

### Identification of off-the-shelf software, if appropriate: Windows

Imaging Processing and Motion (S/W)

* + - 1. DAS (SRS-PS01)

This is modified task for the RF-Data received to DAS (Delay And Sum) is modified by task according to in Time.

* + - 1. Envelop Detection (SRS-PS02)

The signals are gathered + or -. In this case, the image will have a rough phase model. Therefore, correct this problem by changing the signal -into +.

* + - 1. Log Compression (SRS-PS03)

The deeper has the smaller value relatively. Due to that Log scale becomes smaller, compensate for the gain to match the depth.

* + - 1. Distal Scan Conversion (SRS-PS04)

The number of pixels are different from the number of pixels in the ultrasound monitor. Therefore, DSC is needed to overcome the disadvantages.

* + - 1. Base Line (SRS-PS05)

It is mainly used to increase the scope of Doppler bloodstream velocity and reduce confusion of spectral direction.

* + - 1. BODY MARK (SRS-PS06)

It displays a body mark to indicate the portion of the user’s measurement point. At this time UI can be displayed to identify.