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Medical Software Evaluation Guidelines

Medical Device Safety Bureau
Korea Food & Drug Administration

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1. Purpose and Scope of Application

1.1 Purpose

The purpose of this guideline is to clarify the contents on medical software as is required by “Korea Food & Drug Administration Bulletin No. 2007-55, Regulations on Evaluation of Medical Device Technical Documents”, to enable applicants to accurately prepare contents on medical software when preparing technical documents for medical devices. Also, the guideline serves to increase the fairness in evaluating medical software during technical document evaluations.

1.2 Scope of Application

This guideline is applied to “medical software” embedded in medical devices or used as stand-alone products. However, software used for production & development of medical devices or for quality assurance of medical devices shall be excluded from the scope.

2. Terms and Definitions

2.1 Medical Software

Software used in medical devices, whether embedded in medical devices or used as stand-alone products. However, software used for production & development of medical devices or for quality assurance of medical devices are excluded.

2.2 Stand-alone Software

Medical software operated in environments identical to generic computers, in terms of generic computer specifications and hardware.

2.3 Embedded Software

Medical software that is generally operated inside specifically designed hardware systems, and it does not include stand-alone software. Such software is dependent on the hardware environment of the given medical device.

2.4 Name

Type name or name given to medical software to identify them

2.5 Version

Number given according to a numbering system to manage the configurations of medical software

2.6 Structure

The internal configuration of medical software in the viewpoint of the software's major functions. The structure of medical software can be expressed through functional module units and status diagrams.

2.7 Major Functions

Function of medical software implemented for the purpose of the medical device.

2.8 Algorithm

The procedures and methodologies for operating the medical software within the medical device. The input/output at each stage of the procedures must be clear.

2.9 Operating Environment

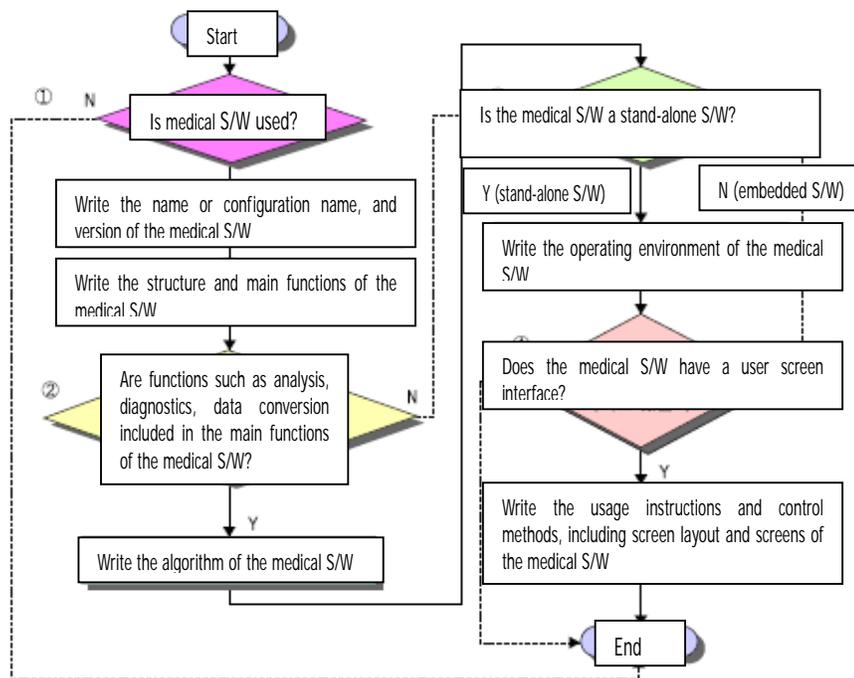
Hardware requirements required for the effective operation of medical software.

3. Methods for Evaluating Medical Software

3.1 Evaluation Procedures for Medical Software

The evaluation of medical software is performed through the evaluation of technical documents of the medical devices. Therefore, the contents of the medical devices' technical documents in relations to the medical software are critical in the evaluation of medical software.

In order to write the contents of the medical software accurately within the technical documents for the medical device, the features of the medical software must be analyzed to precisely understand what needs to be written in the documents. (Fig. 1) below illustrates the procedures for analyzing the features of medical software in order to identify them. Also, it shows the contents of the items that need to be written within the technical documents according to each feature. Therefore, evaluation of medical software is performed through the procedures and methods shown in (Fig. 1).



<Fig. 1> Evaluation Procedures for Technical Documents of Medical Software

(1) "Is medical S/W used?"

This checks whether medical software is used in the medical device. Since this guideline is applied only to cases in which medical software is used, it is not applied to cases where the answer is 'No.' As a general requirement, if medical software is used in the medical device, the structure, main functions, type name or name, and version of the medical software should be filled out according to each of the items of the technical document.

(2) "Are functions such as analysis, diagnostics, data conversion included in the main functions of the medical S/W?"

If functions such as analysis, diagnostics, and data conversion are included in the main functions of the medical software, an algorithm for the medical software must be prepared within the technical document for the medical device. The algorithm should be prepared as a diagram in the format of a flow chart, which provides an easy to understand description of the procedures and methods of the medical software's operations. Also, the input/output at each stage of the procedures should be defined to clarify the understanding of the internal processing procedures.

(3) "Is the medical S/W a stand-alone S/W?"

If the medical software is stand-alone software, the operating environment of the medical software should be described within the technical document of the medical device. The operating environment of the medical software is the required hardware specifications for the proper operation of the medical software, and the precise specifications for the hardware configuration should be written for this item.

(4) "Does the medical S/W have a user screen interface?"

If the medical software has a user screen, the user instructions or control methods should be prepared within the technical document of the medical device, including screen captures and diagrams of the medical software. User screens of the medical software that display measurement results and analysis results should accompany explanations for understanding the measurement values and analysis results that are displayed on the user screen.

3.2 Items for Technical Documents Related to Medical Software

Item Related to Medical S/W		Written Contents	Applied to
Configuration/ Structure and Dimensions	Structure	Classify the medical software into functional module units and draw illustrations and include descriptions, in order to identify the internal configuration status of the medical software	All medical S/W
	Main Functions	Describe the defined functions of the medical software according to the purpose of the medical device	All medical S/W
	Algorithm	Procedures and methods for operating the medical software within the medical device	Medical S/W which include analysis, diagnostics, and data conversion functions
Raw Materials	Type Name or Name, Version	Write the Type Name or name, and version of the medical S/W	All medical S/W
	Operating Environment	Write the hardware requirements for the proper operation of the medical S/W	All medical S/W (excluding embedded S/W)
User Instructions or Control Methods		Write the user instructions and control methods for the main functions, including descriptions of each item (result output elements) within the user screen of the medical S/W	Medical S/W with user screen interface

<Chart 1> Contents and Applied Items for Technical Documents related to Medical Software

[1] Configuration/Structure and Measurements

The structure or algorithm, and main functions of the medical software should be written for the Configuration/Structure and Measurements section of the technical documents for medical devices.

(a) Structure

The software should be classified into functional modules and illustrated into diagrams in order to provide an overall description of the medical software. In general, software structures can be presented in functional block diagrams, and may also be presented as status diagrams in the case of embedded software.

(b) Main Functions

The main functions of medical software should be filled out with descriptions that allow precise understanding of the names and roles of the main functions. Since the main functions of medical software are defined in functional module units within the medical software structure, they can be described along with the structure of the medical software.

(c) Algorithm

An algorithm describes the procedures and methods for the operation of the medical software within the medical device. Only medical software that includes analysis, diagnostics, and data conversion functions as its main functions require the preparation of such algorithms.

The preparation of algorithms can be presented in diagrams such as flow charts that provide a bird's eye view of the procedures for the activation of medical software, along with descriptions for the tasks performed at each stage. Also, the input/output at each stage must be clearly stated.

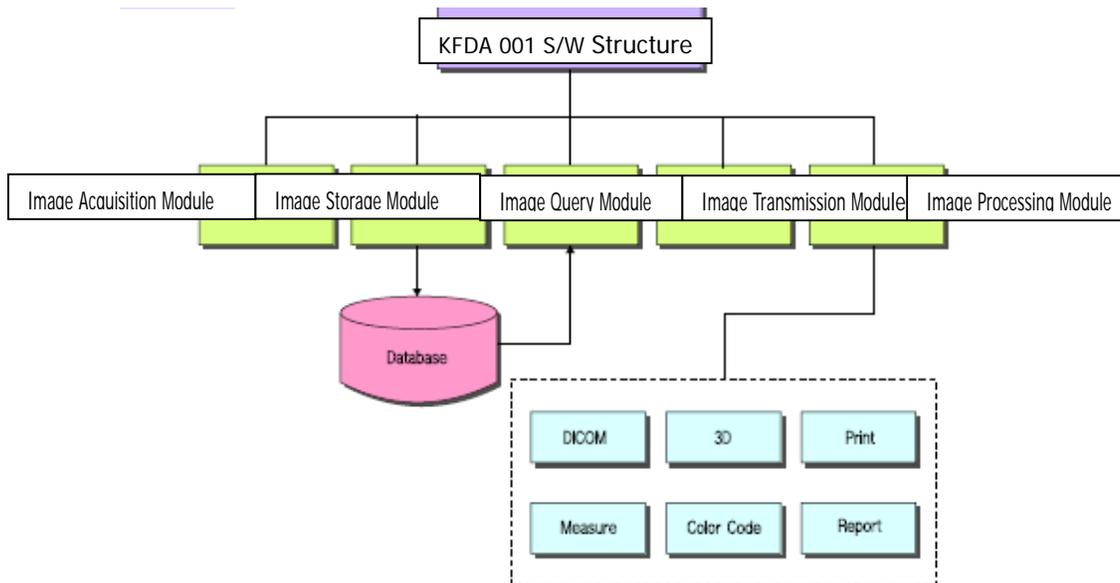
Sample Copy of Configuration/Structure and Measurements

This sample has been prepared to assist the understanding of how to write the structure, main functions, and algorithm of medical software, and may be different from the actual structure, main functions, and algorithms of actual medical devices. Also, this sample has been prepared based on 3 large classifications of "(a) medical software that uses generic PCs", "(b) medical software that has user screen interface", and "(c) medical software used for simple functional control", and therefore, the structure, main functions, and algorithms of medical software used for more complex and diverse medical devices should be prepared according to the features of the specific medical software.

(A) Medical Software that uses Generic PCs (Stand-alone Software)

This sample has been prepared for medical software used for 'medical image processing device/software (A26430 [2])' product.

[A-1] Structure

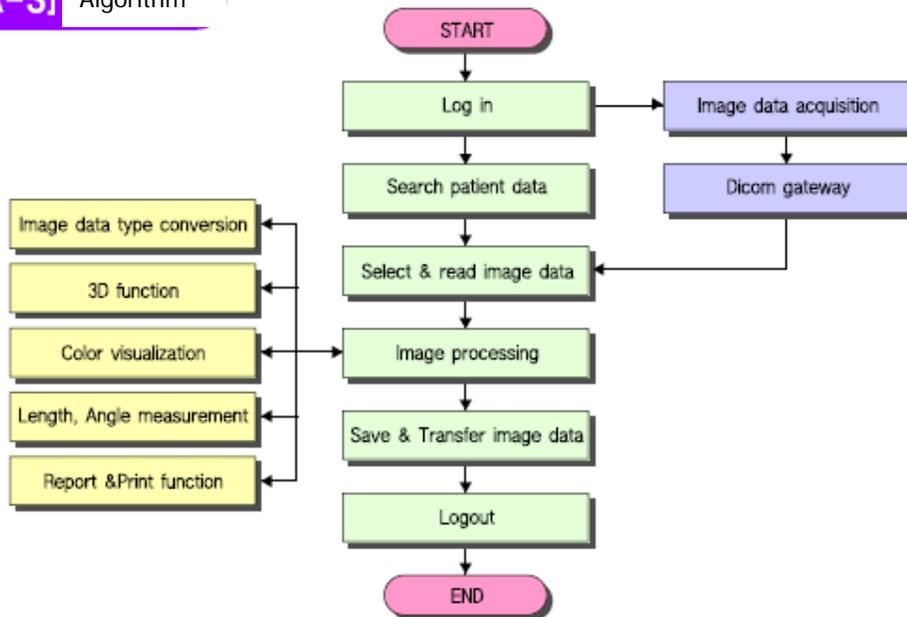


This medical software is configured in a structure that includes image acquisition module, image query module, image transmission module, and image processing module.

[A-2] Main Functions

Number	Main Function	Description of Main Function	
1	Image Acquisition Module	Module that acquires medical images for Modality, and includes functions such as 'image acquisition' and 'dicom conversion' within the module.	
2	Image Storage Module	Module that stores medical images that have been acquired or have been through image processing in the database, and includes functions such as 'image save' and 'image save as...' within the module.	
3	Image Query Module	Module that queries medical images from the database, and includes functions such as 'image search' within the module.	
4	Image Transmission Module	Module that transmits medical images to diffused systems at remote locations, and includes functions such as 'image send' and 'network identification' within the module.	
5	Image Processing Module	Module that processes medical images through image processing process to enable extraction of desired information from a queried medical image, and includes functions such as 'dicom', '3D', 'print', 'measure', 'color code', and 'report' within the module.	
		Dicom	Converts/processes non-DICOM medical images into DICOM 3-compliant images
		3D	Converts continuous medical images acquired from imaging devices such as CT into 3 dimensional images through modeling
		Print	Prints medical images according to set format
		Measure	Calls medical images to measure specific distance and angles of the actual image displayed on screen
		Color code	Analyzes the brightness value of each pixel in the medical image (black & white image) to visualize specific brightness values as specific colors
		Report	Prints medical images and comments in a report format

[A-3] Algorithm

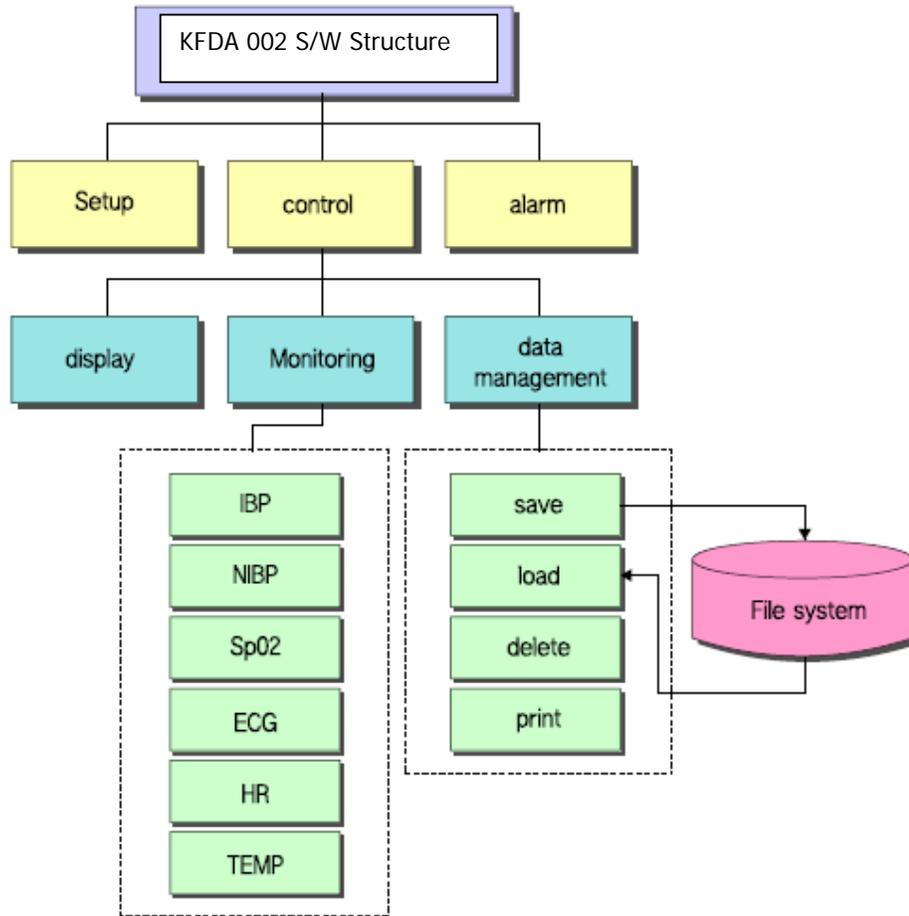


Number	Procedure	Procedure Description
1	Login	Login to image processing system
2	Image data Acquisition	Acquire image data from various modalities
3	Dicom Gateway	Standardize acquired image data through the Dicom gateway
4	Search patient data	Search patient data
5	Select & read image data	Select desired image data among the patient's image data to call up to the work screen
6	Image processing	Measure, analyze, and process the called image data through various image processing functions
7	Save&Transfer image data	Save image data in database or transfer to other system
8	Log out	Logout from the image processing system

(B) Medical Software that Includes User Screen Interface

This sample has been prepared for medical software used for 'patient monitoring device (A26090121)' product.

[B-1] Structure



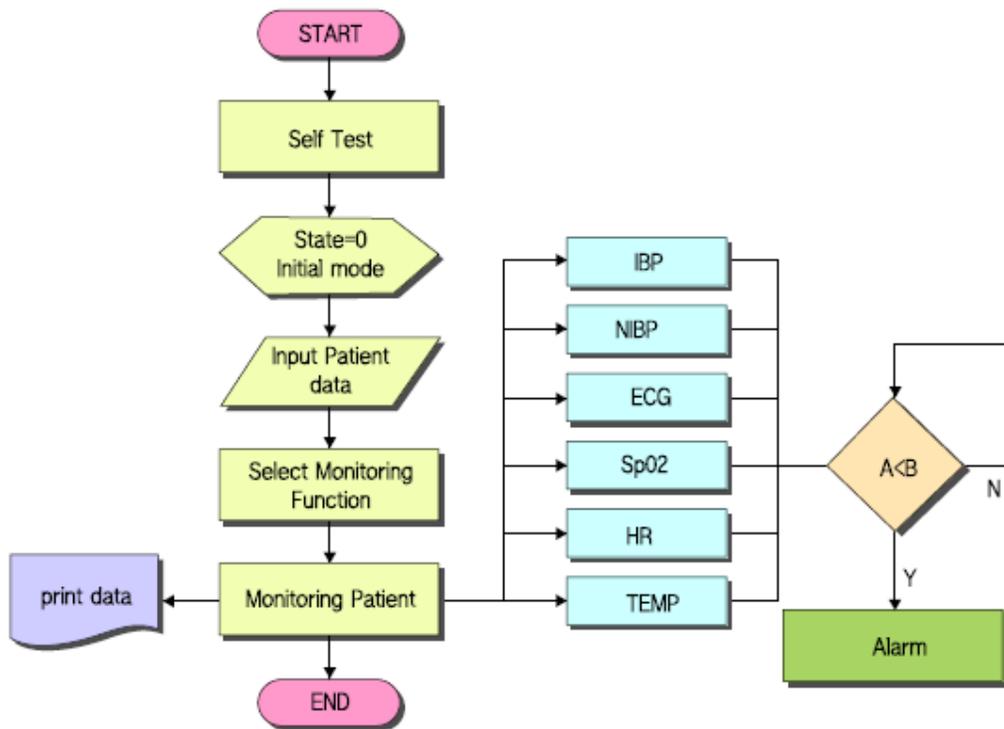
This medical software consists of setup module, control module, and alarm module, and the control module includes functions such as display control, life sign monitoring control, and data management.

[B-2] Main Functions

Number	Main Function	Description of Main Function	
1	Setup	Module for patient registration, system setup (time, alarm, records, data printout, etc.), IP address setup, and wireless network setup	
2	Control	Module for controlling user display management, life sign monitoring, and data management	
		Display	Functions for controlling user screen configuration and displaying patient's life signs on screen
		Monitoring	Function for measuring and analyzing patient's life signs to monitor the status of each patient
		Data Management	Function for managing patient's life sign data
3	alarm	Module for transmitting alarm signals when patient becomes unstable	

Number	Main Function (Detailed Function)	Description of Main Function	
1	Monitoring	IBP	Measures and analyzes IBP
		NIBP	Measures and analyzes NIBP
		ECG	Measures and analyzes ECG
		SpO2	Measures and analyzes SpO2
		HR	Measures and analyzes heartbeat rate
		TEMP	Measures and analyzes body temperature
2	Data Management	Save	Saves patient's life sign data
		Load	Loads patient's life sign data
		Delete	Deletes patient's life sign data
		Print	Prints out patient's life sign data

[B-3] Algorithm

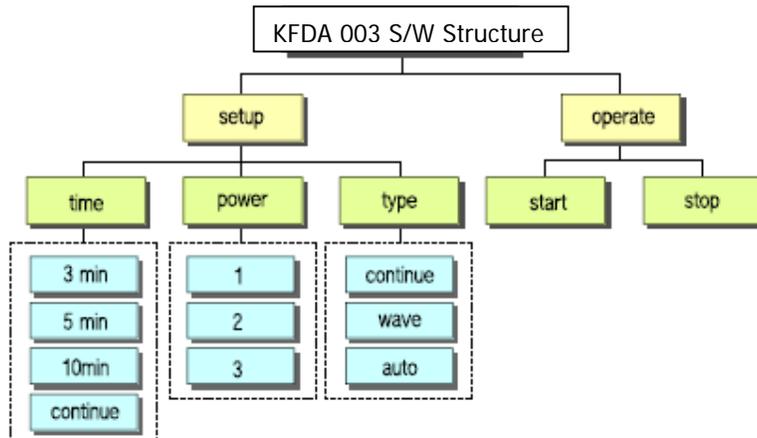


Number	Procedure	Procedure Description
1	Self Test	When the device is powered on, the medical software automatically inspects the status of the device
2	Initial mode	When the self test of the device is complete, the device enters standby mode to be used, and all entry variables are initialized at this time
3	Input Patient Data	Entry variables are set according to the status of the patient
4	Select Monitoring Function	The patient's life signs to measure are selected
5	Monitoring Patient	The patient's life signs are monitored
6	A<B, Alarm	A is the patient entry variable and B is the measurement value of the patient's life signs. If the measurement values exceed the entry variables, an alarm is generated
7	Print Data	Prints various measurements results of the patients

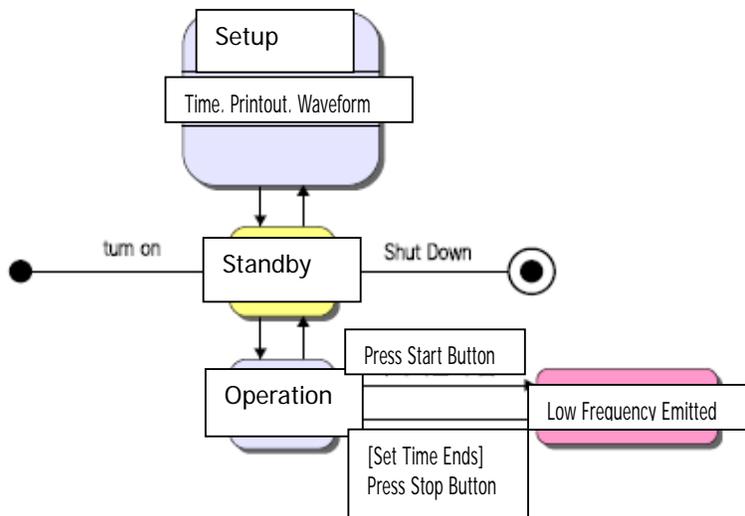
(C) Medical Software Used for Simple Functional Control

This sample has been prepared for medical software used for 'low frequency stimulator (A16010[2])' product.

[C-1] Structure



<When presenting as a functional block diagram>



<When presenting as a status diagram>

This medical software consists of setup module and operation module. The setup module includes functions such as time setup, output setup, and waveform type setup, and the operation module includes functions such as start activation and stop activation.

[C-2] Algorithm

Number	Main Function	Description of Main Function	
1	Setup	Module for patient registration, system setup (time, alarm, records, data printout, etc.), IP address setup, and wireless network setup	
		Time	Function for setting time to 3, 5 ,10 minutes or to continuous
		Power	Function for setting output to 1, 2, 3 stages (* when preparing an actual technical document, the precise output should be filled in for each of 1, 2, 3, along with descriptions.)
		Type	Function for setting continuous, wave-type and automatic stimulus
2	Operate	Module for the operation of the device	
		Start	Function for operating the device
		Stop	Function for stopping operation of the device

[C-3] Algorithm

* Not required

[2] Raw Materials

In the Raw Materials section of the technical documents for medical devices, the type name or name, version, and operating environment of the medical software must be filled out. The preparations can be divided largely into embedded medical software and stand-alone software, and filled out appropriately according to <Chart 2>.

The type name or name, and version must be filled out in order to identify the medical software. Also, the operating environment must additionally be filled out for stand-alone medical software because it is an important element for acquiring software performance.

For software such as PACS (Picture Archiving & Communications System) which use generic computers, the statement "compatible with identical or higher specifications" under the filled out "part management number", and an additional statement "only products that have acquired evaluation reports or certifications from the government or public certified organizations shall be used" for the "remarks" section.

Classification	Contents to Fill Out
Embedded Software	Configuration name or name, and version of the medical software
Stand-alone Software	Configuration name or name, version, and operating environment of the medical software

<Chart 2> Items to Fill Out for the Raw Materials Section by Type of Medical Software

Sample Copy of Raw Materials

This sample has been prepared to assist the understanding of how to write the raw materials of medical software, and may be different from the actual medical devices. Also, this sample has been prepared based on classifications of "(a) embedded software", "(b) stand-alone software", and "(c) stand-alone software (when using generic PCs)", and therefore should serve as a reference for preparing the documents according to the features of the medical software when preparing the actual technical documents.

(A) Embedded Software

Serial No.	Part Name	Part Management No.	Specification	Quantity	Remarks
1	Analysis S/W	KFDA-001	Version 1.2	1	

(B) Stand-alone Software

Serial No.	Part Name	Part Management No.	Specification	Quantity	Remarks
1	Operation S/W	KFDA-002	Version 1.04 Operating Environment -OS : Windows XP -HDD : 200GByte -RAM : 1GByte -FDD : 3/5" 1.44 MB -CD R/RW : 52x -I/O Device : Keyboard, Mouse -Network : 10/100Mbps -Monitor : LCD 20" (1280 x 1024)	1	

(C) Stand-alone Software (when using generic PCs)

Serial No.	Part Name	Part Management No.	Specification		Quantity	Remarks
1	Image Acquisition S/W	KFDA-001 (compatible with identical or higher specifications)	Version	1.41	1	Only products that have acquired evaluation reports or certifications from the government or public certified organizations shall be used
			Operating Environment	-OS : Windows XP pro -CPU : Intel Premium 3.0GHz -RAM :1GB -HDD : 80GB -FDD : 3/5" 1.44 MB -CD R/RW : 48x -I/O Device : Keyboard, Mouse -Network : 10/100Mbps Ethernet -Monitor : LCD 19" (1280 x 1024) -Dual Graphic Card (128MB or more) -HP DC7600CMT2		
2	Image Storage S/W	KFDA-002 (compatible with identical or higher specifications)	Version	1.8	1	Only products that have acquired evaluation reports or certifications from the government or public certified organizations shall be used
			Operating Environment	-OS : Microsoft Windows Server 2003 -CPU : Intel Xeon 2.0GHz -RAM : 512GB (8GB max.) -Storage : 500GB -FDD : 3/5" 1.44 MB -CD R/RW: 48x -I/O Device : Keyboard, Mouse -Network : 10/100Mbps Ethernet -Monitor : LCD 17" (1224 x 768) -Graphic Memory :8MB SDRAM -HP ML 1504		
3	Image Query S/W	KFDA-003 (compatible with identical or higher specifications)	Version	1.7	1	Only products that have acquired evaluation reports or certifications from the government or public certified organizations shall be used
			Operating Environment	-OS : Microsoft Windows XP pro -CPU : Intel Premium 3.0GHz -RAM :1GB -HDD : 80GB -FDD : 3/5" 1.44 MB -CD R/RW : 48x -I/O Device : Keyboard, Mouse -Network : 10/100Mbps Ethernet -Monitor : LCD 19" (1280 x 1024) -Dual Graphic Card (128MB or more) -Samsung DB-P55		

[3] User Instructions or Control Methods

User instructions or control methods are prepared for the technical documents of medical devices only when the software provides a user screen. The instructions for using and controlling the main functions should be prepared along with diagrams of the user screen for the main functions, and should also include descriptions on the user screen layout of the medical software.

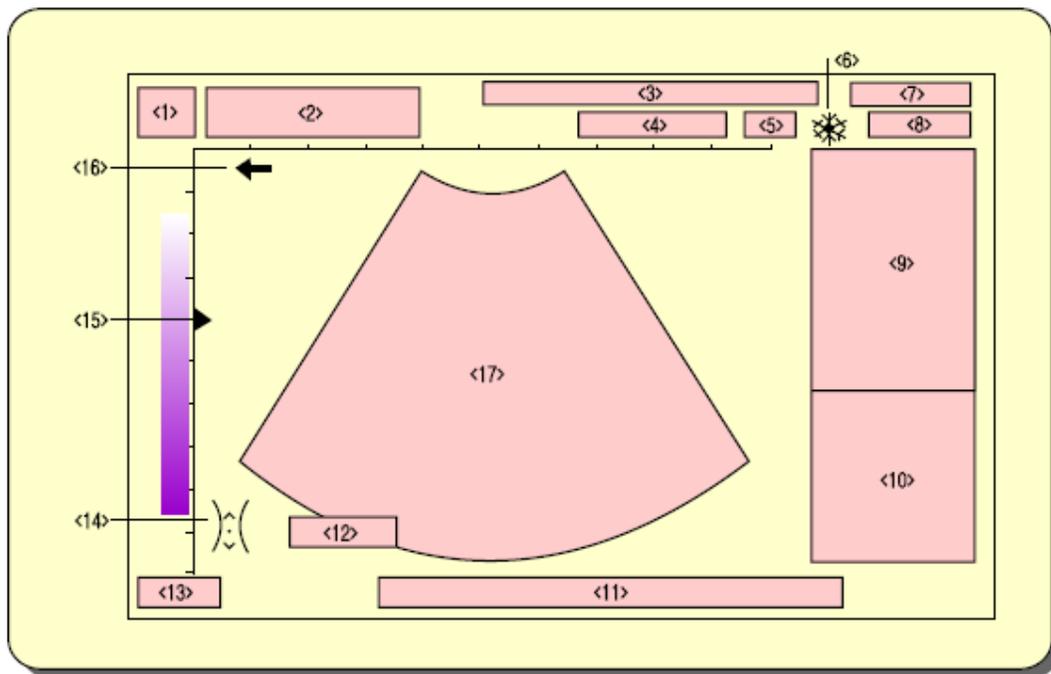
Sample Copy of User Instructions or Control Methods

This sample has been prepared to assist the understanding of how to write the user instructions or control methods of medical software. Also, this sample has been prepared based on "(a) ultrasonic image diagnostics device", "(b) ultrasonic brain scan device", and therefore should serve as a reference for preparing the documents according to the features of medical software with user screen interfaces when preparing the actual technical documents.

(A) Medical Software used for 'Ultrasonic Image Diagnostics Device'

This sample outlines the user instructions or control methods for medical software used for 'ultrasonic image diagnostics device (A26380[3])'

[A-1] Software Screen Layout



Number	Description
1	Manufacturer's logo
2	Hospital name, patient's name and ID display
3	Currently used image parameters display : BG, MG, AP, IP ,FR, etc.
4	Probe model name display
5	Probe's current frequency display
6	FREEZE icon (displayed during freeze)
7	Current date (displays date when screen is stopped)
8	Current time (displays time when screen is stopped)
9	Menu display area
10	Measurement value or calculation results display area
11	Operation information prompt display
12	Current image depth display
13	Current measurement mode display
14	Body mark icon
15	Focus icon (used for displaying the location and number of focuses)
16	Scanning line
17	Image display area

[A-2] User Instructions or Control Methods for Main Functions

Main Function	User Instructions	Contents
Exam	Select ABD/GYN/OB/SML keys from the control panel	Allow the self-test to execute automatically upon power up. Press the ABD/GYN/OB/SML keys to select the test mode.
Preset	Select [Preset] key from the control panel	Set the operating environment, status, and parameters for each test mode and store them in memory. The stored values can also be edited and deleted.
B.M gain	Rotate the [Gain] knob on the control panel to adjust	Adjust the gain of the B mode or M mode images.
Cine Review	Select the CINE key on the control panel	Function for paying back images prior to stopping the image for editing. Up to 128 images can be stored in high resolution scan mode, and up to 256 images can be stored in high frame rate scan mode. Automatic/manual settings are possible.
Comments	Press COMMENT key on the control panel to activate the [Comment] lamp and function.	Check the location to add comments to and use the trackball to move the cursor and enter the comments. Press [Del] key to delete the comments. There are symbols for various names stored in the Comment Library, which can be selected for use.
Body Mark	Press BODY MARK key on the control panel to activate the lamp and function.	Body marks refer to points on the body surface to be inspected, in order to detect the direction of the probe. Use the [Set] key to add, move, or delete body marks.
Measure	Press the Measure key on the control panel to activate the lamp and function.	When the Measure key is pressed, the measurement menu appears on the right side of the screen. Press the key again to close the screen and cancel the measurement. Various menus are provided for measurements and calculations.
File	Select the FILE key on the control panel	Press the FILE key to display the file related menus on screen. Set the related functions such as entering file names or storing files.

(B) Medical Software used for 'Ultrasonic Brain Scan Device'

This sample outlines the user instructions or control methods for medical software used for 'ultrasonic brain scan device (A26400[3])'

[B-1] Initial Screen

- Exam : Provides screen for measuring brain blood current.
- Search : Allows searching of previously measured patient information using various search conditions.
- Config : Performs configuration tasks related to program executions.
- Exit : Exits brain blood current measurement program.

[B-2] Measurement Screen

- Once measurement begins, the entered patient information is displayed on the upper left corner.
- Before starting the measurement, select the [Vessel] to measure.
- When [Vessel] is selected, the basic settings such as direction, depth, and power of the blood current are set according to the entered values.
- Click [Exam] button to begin measurement.
- Click [Freeze] button to stop measurement and [SAVE] the results.

A. Measurement Data

- V_p : Peak velocity
- V_d : Diastolic velocity
- V_m : Mean velocity

- PI : Pulsatility Index ($PI = (V_p - V_d) / V_m$)
- RI : Resistance Index ($RI = (V_p - V_d) / V_p$)
- S/D : Systole to Diastole ratio
- Hr : Heartbeat rate index

B. Measurement Graph

- The blood flow in the vessels can be checked in real-time through spectrum signals.
- Blood current incoming towards the probe are displayed in red, and blood current flowing away from the probe are displayed in blue.
- The size of the segments can be adjusted. Click the probe icon on the top of the graph to reverse the blood current direction display.

C. Vessel Auto Search

- This function searches for and displays the depth of blood current to enable easy identification of blood current signals.
- Parts with blood currents form curved lines according to the strength of the signal. Blood current incoming towards the probe are displayed in red, and blood current flowing away from the probe are displayed in blue. Blood current signals can easily be identified by adjusting the depth to the adjacent area of the curved lines.

D. Control Panel

- Depth : Inspection depth
- Gain : Mode for gaining more accurate measurements
- Power : Power of ultrasonic waves currently in use
- Vol : Adjust volume

The control panel is a combination of control buttons that are used frequently during measurement of blood currents, and can also be manipulated using the arrow key (right, left, up, down) buttons.

E. Menu

- [VESSEL REPORT] Set measurement results report
- [SYSTEM CONFIG] Environmental settings function
- [Exit] : End measurement

- [REVIEW] : Function for viewing measured graphs using moving images

- [SAVE] : Function for storing measurement results

- [PRINT] : Function for printing measurement results

[B-3] Depth Measurement Screen

- Click [2 Depth] button to display the following screen.

- The 2Depth screen allows measurements using different depths, allowing the searching of more accurate depths, and also enables decisions regarding angiostenosis.
- Different depths, sound modes, and graphic modes can be used for graph 1 and graph 2.
- During Freeze, data is stored for graph 1.
- When the sound mode for graph 1 is adjusted, the sound mode for graph 2 is automatically muted, and vice versa.
- Power, Gain, and Volume are applied simultaneously to both Graph 1 and Graph 2.

[B-4] Storing Measurement Results

- If the vessel flow has been captured precisely during measurement, press the [Freeze] button and then click [SAVE] to store the measurement data.

- Once data has been stored, the stored screen is displayed in the bottom, as is shown in the above diagram.

- In the stored screen, the vessel and depth are indicated, as well as the original measurement graph.

- To measure other vessels, select [Vessel] and click [Exam Start] to commence measurement.

[B-5] Printing Measurement Results

- When all measurements have been completed, click [PRINT] button to display the printout preview screen.

- Click the [Print] button on the top of the printout preview screen to execute printout.
- When printing using the Print button, all results measured previously by the current user are disregarded, and the printout only contains the most recent measurement results performed today.
- To print a comprehensive copy of previous measurements and the recent measurement, use [Vessel Report] function to printout the report.
- The measurement values and graphs for the measured vessel are printed on the report, and a comparative analysis between the default range of each vessel that were entered previously are printed out on the report.

4. Submitting Attachments

When writing contents related to medical software in technical documents for medical devices, attachments must be submitted to provide proof for the contents written in the documents. Currently, attachments required for verification of contents related to medical software are materials for checking "type name or name, version", "structure", "algorithm", "main functions and function display screen", and "operating environment."

Such contents are all included in documents that are produced within the development life cycle of the software, such as the "manifest of requirements", "design specifications" or "software product descriptions" and "user manuals." Therefore, these documents may be attached when submitting the technical documents for medical devices.

Items for Submission in relation to Medical S/W		Whether Attachments are Applicable	Examples of Attachments
Attachments	Type Name or Name, Version	All must be submitted	Product Description, User Manual, Manifest of Requirements, Design Specifications
	Structure	All must be submitted	Product Description, User Manual, Manifest of Requirements, Design Specifications
	Main Functions	All must be submitted	Product Description, User Manual, Design Specifications
	Algorithm	If analysis, diagnostics, and data conversion functions are included in the medical S/W	Design Specifications
	Function Display Screen	If medical device has user screen	Product Description, User Manual
	Operating Environment	If S/W is stand-alone	Product Description, User Manual, Manifest of Requirements, Design Specifications

<Chart 3> Applicable Attachments for Medical Software

4.1 Type Name or Name, Version

Materials for checking the version of the medical software written within the technical document for the medical device must be submitted. Materials such as the Product Description, User Manual, Manifest of Requirements, Design Specifications in relation to the software may correspond to this requirement.

4.2 Structure

Materials for checking the structure of the medical software written within the technical document for the medical device must be submitted. Materials such as the Product Description, User Manual, Manifest of Requirements, Design Specifications in relation to the software may correspond to this requirement.

4.3 Algorithm

Materials for checking the algorithm of the medical software written within the technical document for the medical device must be submitted. Materials such as the Design Specifications in relation to the software may correspond to this requirement. However, this should be submitted only when filling out items in regards to the algorithm of the medical software within the technical document for the medical device.

4.4 Main Functions & Function Display Screen

Materials for checking the main functions and function display screens of the medical software written within the technical document for the medical device must be submitted. Materials such as the Product Description, User Manual, Manifest of Requirements, Design Specifications in relation to the software may correspond to this requirement. While materials related to the main functions must be submitted mandatorily, materials related to function display screens should be submitted only when the medical device is equipped with LCD, CRT monitors or additional display devices for providing information regarding the operation of the software and other information to the user as is requested.

4.5 Operating Environment

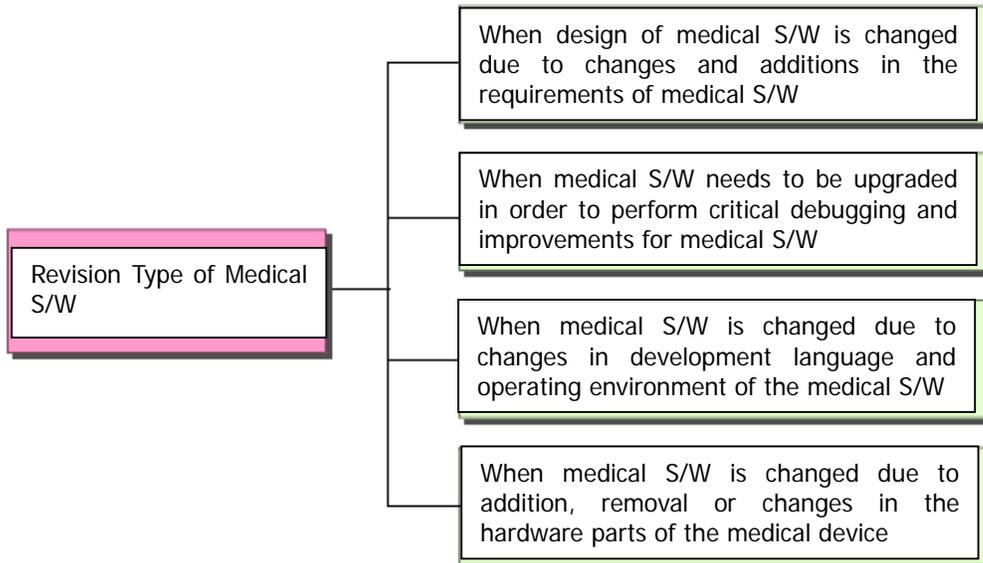
If the medical software is stand-alone, attachments for the operating environment must be submitted. Operating environment refers to the hardware requirements for the operation of the medical software, and are usually described in the Product Description, User Manual, Manifest of Requirements, or Design Specifications. Therefore, corresponding materials may be submitted as attachments.

5. Revising Technical Documents for Medical Software

This section provides detailed types of revisions of medical software that require revisions in technical documents for medical devices when revising medical software. Also, this section serves to provide a clear explanation on how and what parts of the technical documents for medical devices need to be changed when revising technical documents for medical devices by each revision type for the proposed medical software. Items related to the submission of related attachments shall also be covered.

5.1 Revision Types of Medical Software

Revision types of medical software that require revision of technical documents for medical devices can be classified largely into 4 types, as is shown in the diagram below.



<Fig. 2> Revision Types of Medical Software

(1) "When design of medical S/W is changed due to changes and additions in the requirements of medical S/W?"

When design of medical S/W is changed due to changes, additions, or removals in the requirements of medical S/W, the technical documents for the medical device must be revised. This is the most typical revision type for medical software, and affects the performance, safety, and effectiveness of the medical software.

(2) "When medical S/W needs to be upgraded in order to perform critical debugging and improvements for medical S/W?"

When medical S/W needs to be upgraded in order to perform critical debugging and improvements for medical S/W, the technical documents for the medical device must be revised. While hardware defects can be eliminated through the recall of the medical device product, defects in software can be removed through the distribution of software patches. Therefore, the removal of critical bugs and defects within the software must be verifiable through the revision of the technical documents for the medical device, and the removal of the defect must not cause other defects.

(3) "When medical S/W is changed due to changes in development language and operating environment of the medical S/W?"

When medical S/W is changed due to changes in development language and operating environment of the medical S/W, the technical documents for the medical device must be revised. This is because software performance may change according to the development language and operating environment of the software. Therefore, the fact that the medical software shows identical performance under the changed development language and operating environment must be verifiable through the revision of the technical documents for the medical device.

(4) "When medical S/W is changed due to addition, removal or changes in the hardware parts of the medical device?"

When medical S/W is changed due to addition, removal or changes in the hardware parts of the medical device, the technical documents for the medical device must be revised. Such added hardware parts are used through changes in the medical software, which can directly affect the performance, safety, and effectiveness of the product. Also, the addition of hardware parts can affect the electric/mechanical safety and electronic emission safety.

5.2 Revision of Technical Documents and Submission of Attachments

Submission of attachments in relation to software takes effect on October 1st, 2007. Attachments must be submitted to provide verification for revised contents when medical software is revised as well. The requirements for attachments submitted for evaluation of changes in technical documents for medical devices due to revisions in medical software are identical to those for the initial evaluation of technical documents for medical devices. <Chart 4> shows the materials required for submission for the types of revisions for medical software. The related materials should be submitted when such revisions are made.

Classification	Revision Type of Medical S/W	Materials to be Submitted upon Revision
Changes in Technical Documents for Medical Devices	<ul style="list-style-type: none"> - When design of medical S/W is changed due to changes and additions in the requirements of medical S/W - When medical S/W needs to be upgraded in order to perform critical debugging and improvements for medical S/W - When medical S/W is changed due to changes in development language and operating environment of the medical S/W - When medical S/W is changed due to additions in hardware parts 	<ul style="list-style-type: none"> - Submit materials corresponding to the revised portions when changes occur in the type name or name, version, structure, main functions and function display screens, operating environment, or algorithms - Submit materials related to the safety and performance due to S/W changes

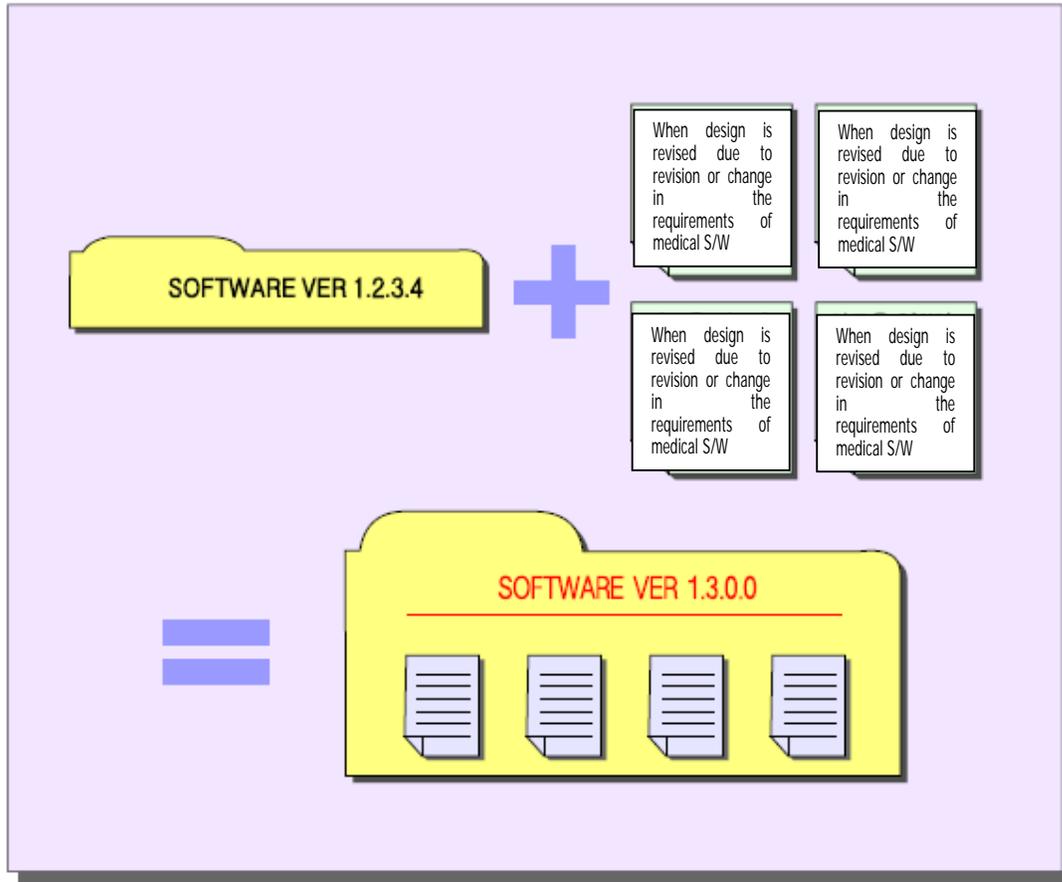
<Chart 4> Revision Types of Medical Software and Materials to be Submitted for Revisions

In particular, materials for verifying the changed performance must be submitted as well when the safety and performance of medical software is changed due to a revision type in medical software. However, such revision type of medical software and the submission of attachments are limited to when the purpose of the medical device is not changed due to the revision in medical software.

5.3 Version Management Scheme for Medical Software

The versions of software are changed continuously through the process of developing, revising, deleting, and upgrading the software. The purpose of managing the version of the software is to enable identification of the software that is continuously being changed. Therefore, software version management is critical since it is a method for tracking revisions such as revisions, additions, and deletions in the software.

If revisions such as revision types of medical software occur, the version of the medical software must be revised.

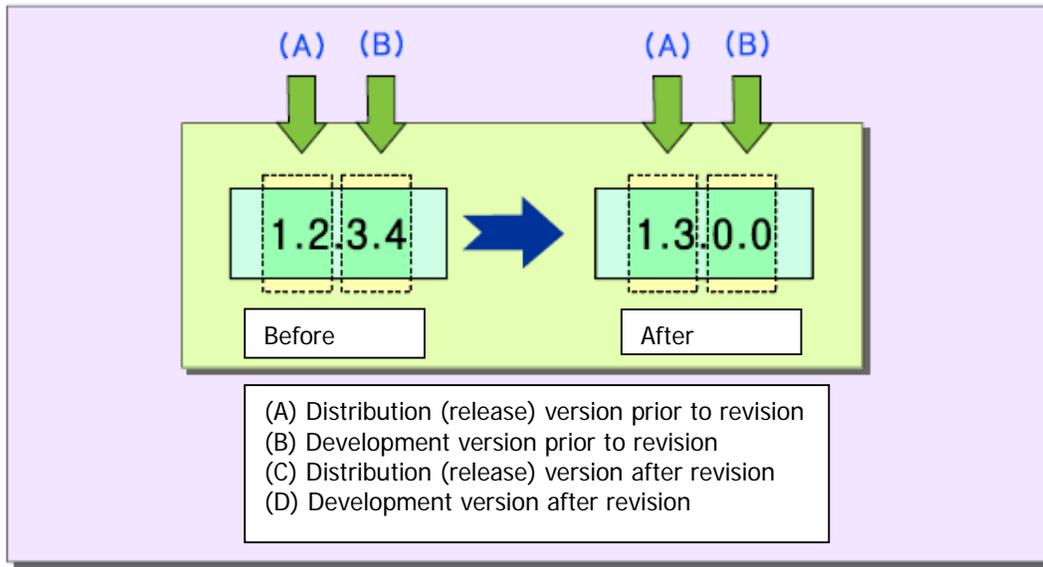


<Fig. 3> Revision Types of Medical Software and Version Revisions

In the above (Fig. 3), the version of the medical software prior to revision is 1.2.3.4, which is changed to 1.3.0.0 with the occurrence of a change such as a revision type of the medical software. Does this mean that the version of the medical software should be written as 1.3.0.0 in the technical document? No. In conclusion, write 1.3 for the version of the medical software inside the technical document.

Software versions can largely be classified into distribution (release) version and development version. The distribution (release) version refers to a version that has completed software development and revision, and allows normal use of the software. However, a development version is a version that is in-progress, and thus cannot guarantee normal use of the software. Such versions are made for internal administration purposes.

The distribution (release) version of the medical software must be written in the technical document for the medical device. In (Fig. 4), the first two digits "1.2" in the version "1.2.3.4" of the medical software version prior to revision refers to the distribution (release) version, the last two digits indicate the development version given for internal administration of medical software. Therefore, the two digit distribution (release) version "1.2" should be written on the front of the technical document prior to the revision of the medical software. After revision, the distribution (release) version "1.3" should be written.



<Fig. 4> Method for Writing Version of Medical Software

Since the numbering system for the version of medical software should be defined according to the size, features, and development tools of medical software, all medical software cannot be administered according to the identical numbering system. However, the development department responsible for the development of medical software must have the contents documented, and all members of the development team should be sharing this in order to perform a systematic administration of software versions.

6. Related Bulletins

Regulations on Evaluation of Medical Device Technical Documents (KFDA Bulletin No. 2007-55, Revised July 20, 2007)

Article 7 (Attachments Requirement)

c. Materials on electric/mechanical safety

(2) If the software is embedded in the corresponding product, or if the software is stand-alone, materials which include type name or name, version, algorithm or structure, main functions and functional display screens, and operating environments.

Article 11 (Configuration/Structure and Dimensions)

2. For electronic devices that use electric/mechanical principles, the function of each part, operational principles, electric specifications, protective method against lightning and level of protection, safety equipment, structure or algorithm of embedded software should be written out in addition to the configuration/structure/weight and dimensions stated in paragraph 1, and the electric circuit diagram and operational safety diagrams should be attached to provide electric/mechanical safety.

Article 12 (Raw Materials or Composition and Makeup)

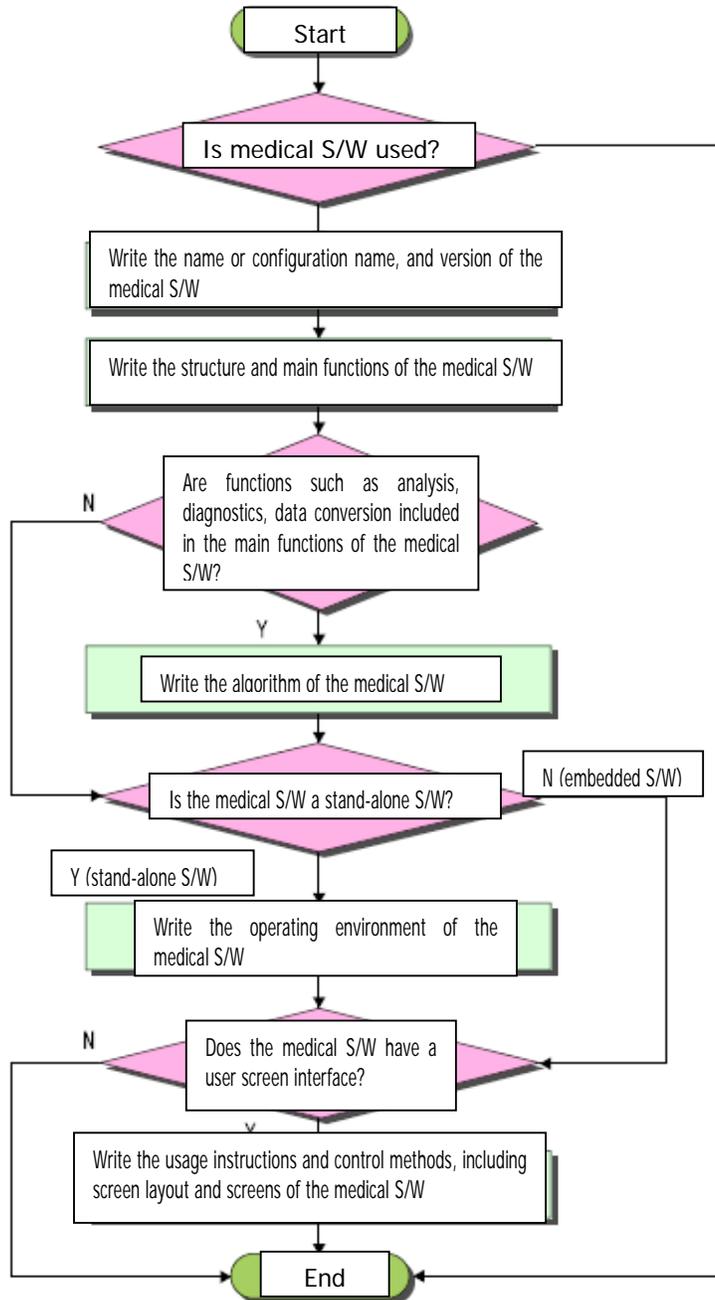
2. Fill Outs for Electric or Mechanical Devices

g. When software is embedded in electronic devices, or are used as stand-alone, write the type name or name, version, and operating environment according to a.

Article 15 (User Instructions or Control Methods)

1. Write the prerequisites, control methods, user instructions, and post-usage storage/management methods, and in particular, if the product must be sterilized before use, the conditions and methods for sterilization. If the software is embedded in the medical device or is stand-alone, a screen capture along with the program functions for checking the program's functions should be attached, and the usage instructions for the function should be written accurately.

[Appendix] Procedures for Evaluating Technical Documents Related to Medical Software



Medical Software Evaluation Guidelines

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