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PP-AR50-V20-E01

ARIETTA 50 ARIRTTA 50LE

Product Presentation for Diagnostic Ultrasound System

November, 2020

US Business Operation Division, Ultrasound Diagnostic System Division, Hitachi, Ltd. Healthcare Business Unit

Innovating Healthcare, Embracing the Future



Contents

- 1. Probe
- 2. Workflow improvement
- 3. Function improvement
- 4. Preset default
- 5. Other

1. Probe – Probe connection and functions



The following probes are newly connected.

Functions	C41B	L64	C41RP	C22P	C41V
Tissue Harmonic (FmT)				V	
Tissue Harmonic (WbT)	ν	V		V	V
TDI					
Compound Scan		V			
Trapezoidal Scan / B Steer Scan		V			
Puncture Guide line	ν	V	ν	レ	V
Needle Emphasis		V			
Contrast Harmonic Imaging *1					
FAM *2	ν	V	ν	V	V
CW *3					

^{*1:} Option SOP-AR50-44

For connection of Probes listed above, PM-AR50-S200EXP/USA is required for each product of Ver.1.1 or before.

^{*2:} Option SOP-AR50-5

^{*3:} Option SOP-AR50-55

2. Workflow - Measurement menu improvement



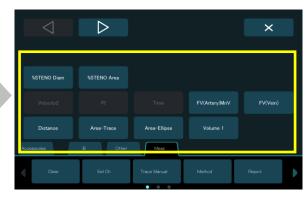
Display the measurement items on the touch panel

Assignable measurement item to touch panel
 Target: Basic measurements, Application measurements

In the conventional version, there was only a method to select an item from the measurement menu displayed on the viewing monitor by pressing the [Measurement] button on the touch panel.







Conventional Ver.

Measurement menu is displayed on the monitor only when pressing [Measurement] button, software buttons are no change.

Ver.2.0

The set measurement items are displayed as software buttons.

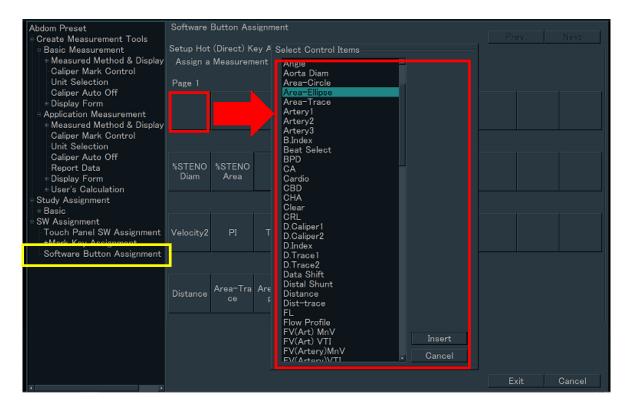
The measurement menu of the monitor is displayed as before.

2. Workflow – Measurement menu improvement



Setting:

Measurement Preset > SW Assignment > Software Button Assignment



Insert the measurement item from "Select Control Items"

Note:

- Assignment for each mode is not possible
 (Assigned measurement items are not changed by mode)
- •There are some restriction on Obstetrics measurement Region. Please refer to Preset section for details.

2. Workflow – Increase in Custom SW



Supports [M]key and [CW]key customization

•Function can be assigned in the same way as the [User1]key to [User3]key

Increased range of customization

e.g.) U1: B/W Printer,

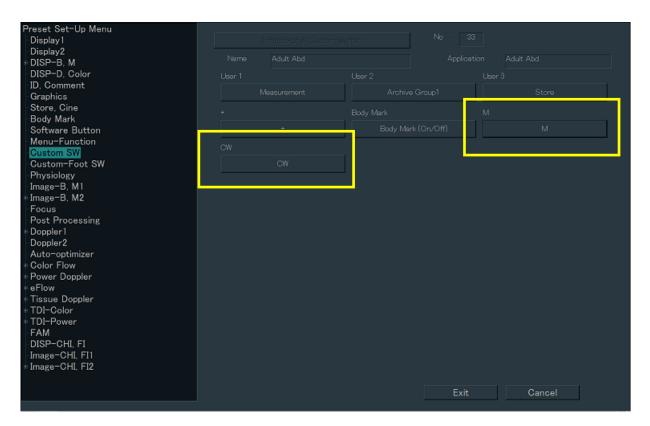
U2: HDD,

U3: DICOM,

M: Next Probe,

CW: Puncture



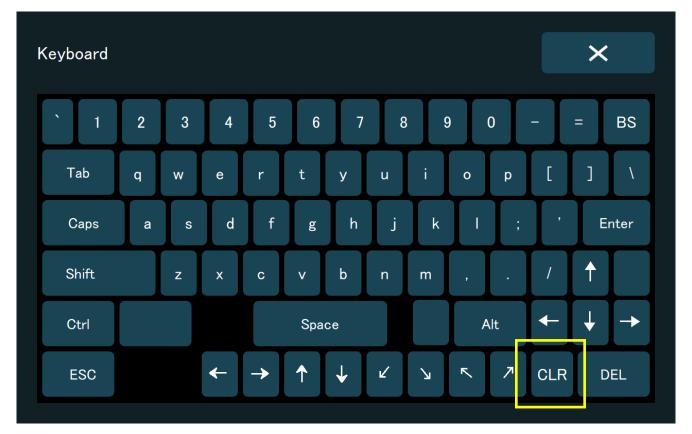


2. Workflow – Software keyboard improvement



Added "CLR" key to software keyboard

• Clarification of how to delete all comments displayed on the screen In the conventional Ver., It was difficult to understand the operation such as pressing the "DEL" key twice for batch erasure.



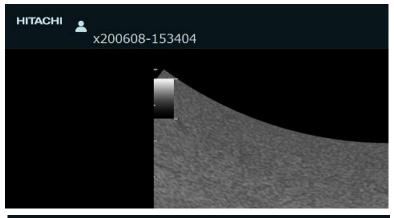
2. Workflow – Scanning screen display information improvement

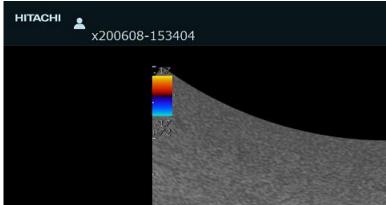


Improved display of grayscale / color scale bar

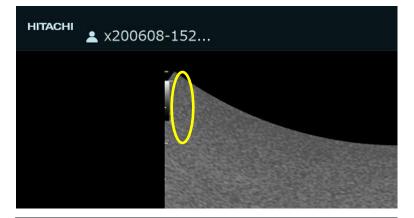
- Thinner display than conventional Ver
- Reduces overlap on ultrasound image

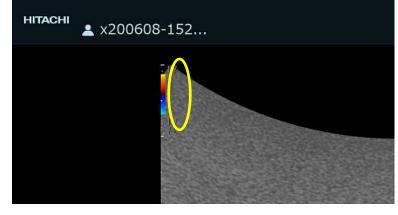
Conventional Ver.





Ver.2.0



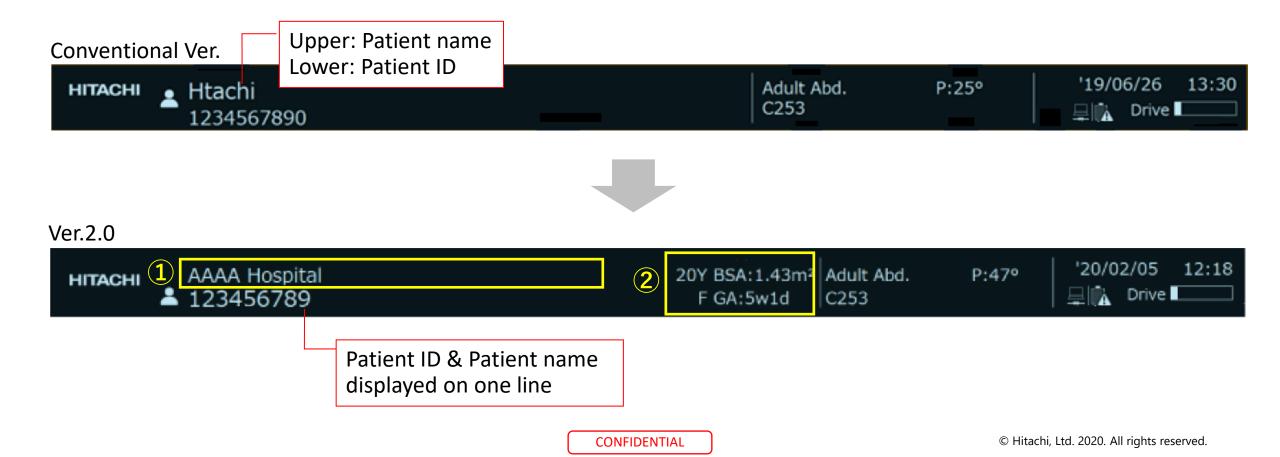


2. Workflow – Scanning screen display information improvement



Additional items displayed in the Information Area

- 1 Supports hospital name display
- 2 Supports patient Age, Gender, BSA and GA display
- * The displayed contents of the information area are also output to peripheral devices.



3. Function – Multi-lingual



The following languages supported.

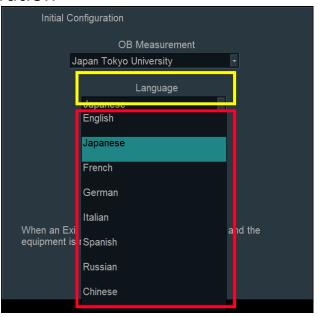
	French	Spanish	Germany	Italian	Chinese	Russian	Japanese
- Display							
Message	✓	✓	✓	✓	✓	✓	✓
Preset screen	✓	✓	✓	✓	✓	✓	
Touch panel menu	✓	✓	✓	✓	✓	✓	
ID/Review screen	✓	✓	✓	✓	✓ (Review only)	✓ (Review only)	
Main monitor	✓	✓	✓	✓			
Measurement (Preset, Touch panel, Report)	✓	✓	✓	✓			
- Software keyboard	✓	✓	✓	✓			
- Input							
Comment	✓	✓	✓	✓			
Annotation	✓	✓	✓	✓			
ID / Review screen	✓	✓	✓	✓			
Worklist	✓	✓	✓	✓			
Comment input on report screen	✓	✓	✓	✓			
- Output							
DICOM	✓	✓	✓	✓			
DICOM SR, CSV	✓	✓	✓	✓			

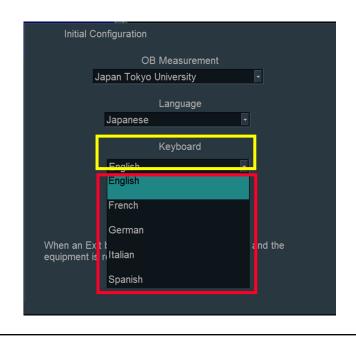
3. Function – Multi-lingual



How to switch languages

Switch Language, Keyboard **Initial Configuration**





Import/Export preset, exam information, image data

- 1) Export Preset.
- 2) Initialize : Ctrl+R in Preset screen → Select "Preset"
- 3) Select languages
- 4) Import Preset.

NOTE:

When performing preset import/export between systems with different language settings, If a full backup/restore at the Maintenance screen is performed, the language settings will also return to the settings at the time of backup.

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Addressing information security requirements in each country and facility by improving information security levels

Supported functions in Ver.2.0

- 1. Password lock of the patient database
- 2. IPv6
- 3. Audit Logs
- 4. BitLocker for Removable Media *
- 5. BitLocker for Built-In Storage *
- 6. DICOM communication encryption*

* USA only



Password lock of the patient database

- Improved the security of user data including patient information
- •The password is applied from the factory default or from upgrading to Ver.2.0.
- * The password will not be disclosed externally.



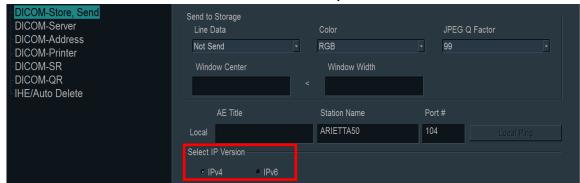
IPv6

AR65 V2.0

Improved security level against attacks such as brute force.

Setting:

Common Preset > DICOM-Store, Send > Select IP Version



The IP address entering field for IPv4 or IPv6 is switched depending on the IP Version (IPv4, IPv6).

Common Preset > DICOM-Server



To enter IPv6 address, press button and show "Enter IPv6 Address" dialog



Audit Logs

AR65 V2.0

Supports investigation when unauthorized access to patient data occurs

- Access to the Audit Log window and log files are limited to users with Level1 access permissions when user authentication is turned on.
- The following information is recorded as audit log data:
 - All operations on the User Authentication screen. Except for operations related to the audit log settings window.
 - Attempts (success or failure) to log in to, and log off from, user authentication.
 - Search, update, delete, and register patient data.
 - Importing and exporting of images and patient data from system to external media.
 - Search, update, delete, and store images.
 - Access to time server.
- Audit Log file storage address: F:\(\frac{1}{2}\)pc_data\(\frac{1}{2}\)log\(\frac{1}{2}\)AuditLog

NOTE:

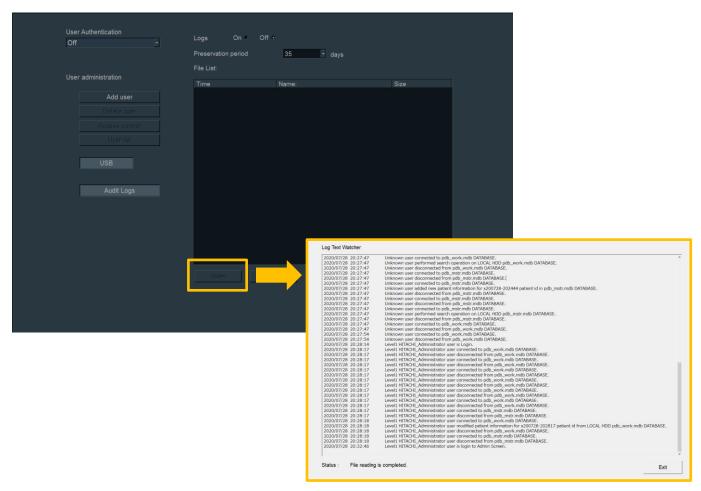
When All User Data is selected at Initial Configuration, the entire Audit Log folder is deleted.



AR65 V2.0

Audit Logs

Setting: Preset Setup > User Admin > Audit Logs



- Logs: Logging On/Off
- Preservation Period:Log file preservation period
- File list: List log files
- Open:Display selected log file
- Delete:Delete selected log file
- Save to USB:External output of selected log file

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BitLocker for Removable Media

AR65 V2.0

Data protection of external removable media by encryption using BitLocker function

* USA only

Encryption procedure

- Security preset with "USB Media Encryption/Decryption" button is added in Common Preset.
- Password Screen will appear when encrypted external media is connected to the PC.
- The external media can be accessed by entering the password.



NOTE: The external media encrypted in XTS-AES mode can not be decrypted by the US system.



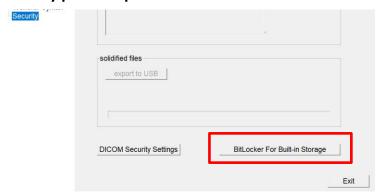
BitLocker for Built-in Storage

AR65 V2.0

Data protection of internal HDD by encryption using BitLocker function

* USA only

Encryption procedure





BitLocker Tool



1. Select 'Security' in the Maintenance screen and press 'BitLocker For Built-in Storage' button.

2. Set the password or password key for decryption.

NOTE: Enter a password consisting of 8 to 30 characters.

NOTE:

- Please do not remove the connection media or turn off the system power while encryption is in process.
- In order to be accessible, decryption or disabling of the function is required. (See next slide)



BitLocker for Built-in Storage

Decryption procedure

- In case of setting decryption password: When stating up the system, the screen shown on the right appears. Please enter decryption password.
- In case of setting decryption password key: Connect the external media storing the decryption password key to the system and start up.

AR65 V2.0

USA only



Disable the function procedure



1. Select 'Security' in the Maintenance screen and press 'BitLocker For Built-in Storage' button.



2. Press 'Disable' button.

NOTE: Use recovery key to decrypt it when you forget decryption password or lose a decryption password key. Please do not lose recovery key. CONFIDENTIAL



BitLocker for Built-in Storage

* USA only

NOTE:

- Time required
- OS drive encryption/decryption requires about 1 hours and 30 minutes.
- Data drive encryption/decryption requires about 4 hours per 100GB.
- Disable procedure requires the both of the above times to consider.
- Be sure to connect/to set the start-up-key or the recovery key to start the device. If the device is left without connecting/setting the key, the system will restart repeatedly. (Precautions peculiar to AR50/50LE)



DICOM network connection authentication

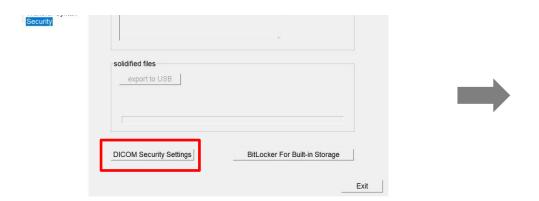
Protect DICOM communication by encryption

AR65 V2.0

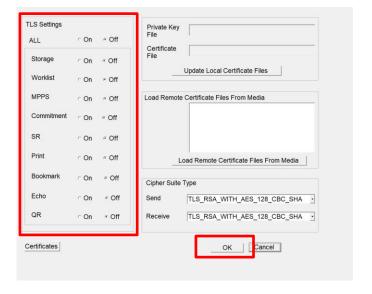
* USA only

Encryption procedure

1. Select 'Security' in the Maintenance screen and press 'DICOM Security Settings' button.



2. Select the target from 'TLS Setting' and press 'OK' button.



NOTE:

- PM-AR50-S003 must be installed separately.
- Certificate file and private key file are needed to perform encrypted communication.
- Please prepare certificate file and private key file on site and install them on the system.

4. Preset – Probe preset



Assigned preset to the probes as follows:

Conventional Ver. Probe	Preset		
L53K	Abd.ope.LN		
C41V1	Obstetrics TV	Gynecology TV	

Probe added in Ver.2.0	Preset			
C41B	Obstetrics TV	Gynecology TV		
L64	Thyroid	Breast		
C41RP	*1			
C22P	Adult Abd			
C41V	Obstetrics TV	Gynecology TV		

^{*1:} For C41RP, Preset registration is required separately



Assignment of measurements to software buttons

Assignment concept:

- In consideration of the easy-to-understand layout, the Basic measurement* was assigned to the upper row of the software button, and a space is provided between it and the Application measurement.
 - *Although the upper row is far from the operator, Basic measurement can also be activated from the [+]key on the operation panel.
- The order was assigned from left to right in consideration of the eye movements, the frequency of use and the flow of examination.

Restrictions on obstetric measurements:

- In obstetrics measurement, it is necessary to switch the study according to the measurement when selecting from the touch panel as well as when selecting from the conventional measurement menu.

 e.g.) NT can only be measured with Study Early
- The following settings are required to enable the table for obstetric measurements starting from the software button.
 Register GA table on "Measurement Preset > Study Assignment > (Study name) > OB Program > GA FW Ratio"

NOTE:

Due to the significant change in the Preset structure of Measurement in Ver.2.0, the Default layout of Software Button is not reflected correctly when copying the Measurement Preset from the old Ver. to Ver.2.0. (This matter will be resolved in Ver.2.1)

If you Initialize the Measurement Preset after Preset copy, it will be initialized including the Software Button Assignment. Please set the necessary items manually as appropriate.



The assignment of the Software button menu for each measurement region has been revised as follows:

Abdom

Page 1	Distance	Area-Trace	Area- Ellipse	Volume 1	
	%STENO Diam	%STENO Area			
	Velocity2	PI	Time	FV(Artery) MnV	FV(Vein)

Small Parts

	Page 1	Distance	Area-Trace	Volume1	Angle	
		Velocity2	PI	Time		
		Rt.Lesion1	Lt.Lesion1	Rt.D/W ratio1	Lt.D/W ratio1	
		Rt.Thyroid V	Lt.Thyroid V			

·URO

Page 1	Distance	Area-Trace	Volume1	
	Velocity2	PI	Time	
	PSA Volume	PreBldrVol	PstBldrVol	

•GYN

Page 1	Distance	Area-Trace	Volume1		
	Velocity2	PI	Time		
	Uterus	Endom-T	Cervix		
	Rt.Ovary	Lt.Ovary	Rt.Follicles	Lt.Follicles	



The assignment of the Software button menu for each measurement region has been revised as follows:

• OB (for JSUM)

Page 1	GS	CRL		NT	Cervix
	FW1	BPD	AC	FL	
	AFI	AF Pocket		CTAR	FHR
	MCA	UmA	Rt-UtA	Lt-UtA	PLI

Page 2	Distance	Area-Trace	Area- Ellipse	Volume1	
	Velocity2	PI	Time		

• OB (for Tokyo)

Page 1	GS	CRL		NT	Cervix
	BPD	APTD	TTD	AxT	FL
	FW1	AFI	AF Pocket	CTAR	FHR
	MCA	UmA	Rt-UtA	Lt-UtA	PLI

Page 2	Distance	Area-Trace	Area- Ellipse	Volume1	
	Velocity2	PI	Time		



The assignment of the Software button menu for each measurement region has been revised as follows:

• OB (for Osaka)

Page 1	GS	CRL		NT	Cervix
	FW1	BPD	FTA	FL	
	AFI	AF Pocket	HL	CTAR	FHR
	MCA	UmA	Rt-UtA	Lt-UtA	PLI

Page 2	Distance	Area-Trace	Area- Ellipse	Volume1	
	Velocity2	PI	Time		



The assignment of the Software button menu for each measurement region has been revised as follows:

• OB (for America)

Page 1	mGS	CRL		NT	Cervix
	FW1	BPD	НС	AC	FL
	FW2	AFI	AFV	CTAR	FHR
	MCA	UmA	Rt-UtA	Lt-UtA	PLI

Page 2	Distance	Area-Trace	Area- Ellipse	Volume1	
	Velocity2	PI	Time		
	BPDo	OFDo			

· OB (for Germany)

Page 1	mGS	CRL		NT	Cervix
	FW1	BPD	HC2	AC	FL
	FW2	AFI	AFV	CTAR	FHR
	MCA	UmA	Rt-UtA	Lt-UtA	PLI

Page 2	Distance	Area-Trace	Area- Ellipse	Volume1	
	Velocity2	PI	Time		
	BPDo	OFDo			



The assignment of the Software button menu for each measurement region has been revised as follows:

• OB (for UK)

Page 1	mGS	CRL		NT	Cervix
	FW1	BPD	НС	AC	FL
	FW2	AFI	AFV	CTAR	FHR
	MCA	UmA	Rt-UtA	Lt-UtA	PLI

Page 2	Distance	Area-Trace	Area- Ellipse	Volume1	
	Velocity2	PI	Time		
	BPDo	OFDo			

For OB measurement, the assigned measurement differs depending on the Initial Configuration





The assignment of the Software button menu for each measurement region has been revised as follows:

Cardio

Page 1	Distance	Area-Trace	Velocity1	Time	P1/2T
	Simpson(D isc)	Teichholz	Pombo	LA/AO	IVC
	Trans M Flow	TDI-PW MA	LVOT	RVOT	AS Flow

Vascular

Page 1	Distance	Area- Trace	PI	RI	
	Velocity2	Time	ACC	FV(Artery)	FV(vein)
	Mean IMT	Max IMT	%Stenosis- D	%Stenosis- A	

Page 2				
	ICA	ECA	VERT	



The assignment of the Software button menu for each measurement region has been revised as follows:

Other

Page 1	Distance	Area-Trace	Area- Ellipse	Volume1	
	Velocity2	PI	Time	FV(Artery) MnV	FV(Vein)

5. Other – Version upgrade & Probe connection SOP



Version upgrade kit

Туре	Name	Remarks
PM-AR50-S200EXP	Version upgrade kit	 Sales upgrade kit Probe connection SOP* Components Installation procedure Product Card
PM-AR50-S200USA		 Instruction manual CD set Hardcopy(Instruction for use) `NOTE: Software pack for version upgrade is not included

NOTE: Please refer to SIB for upgrading to Ver.2.0

*Probe connection SOP

Enables connection of additional five probes in Ver.2.0

SOP model name	SOP Installation display	SOP name
SOP-ARIETTA50-142	Probe V2.0	Probe Connection V2.0 software

Make sure to proceed version upgrade referring to installation procedure.

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