PENTAX of America, Inc.
3 Paragon Drive
Montvale, New Jersey, 07645-1725
Toll-free: (800) 431-5880 T: (201) 571-2300
F: (201) 391-4189

June 30, 2025

URGENT MEDICAL DEVICE CORRECTION

For United States Customers

Re: PENTAX Medical Video Processors Software Update for EPK-i8020c for Light Limit Mode

Dear PENTAX Medical Customer,

This letter is to inform you that PENTAX Medical is conducting a field action regarding the PENTAX Medical Video Processor EPK-i8020c.

As previously announced in our Field Safety Notice of January 2025, (2025-001-C i20c Customer Advisory Notification Letter) when the PENTAX Medical i20c Video Endoscope Series are used in combination with the PENTAX Medical INSPIRA Video Processor EPK-i8020c, the following phenomenon may occur:

In certain cases, during endoscopic procedures using the EPK-i8020c Video Processor, the image may appear reddish or dark. Globally, Pentax has received fifty-nine complaints related to this issue.
Some users have observed smoke-like steam and noted that the light guide at the tip of the endoscope used is heated during or after use. In some cases, this phenomenon has been associated with patient mucosal irritation or injury. **Serious injuries have occurred due to the failure mode associated with this recall. We have reports of two serious injuries.**

PENTAX Medical is conducting a subsequent Field Corrective Action concerning the PENTAX Medical Video Processor EPK-i8020c.

PENTAX Medical updated the Video Processor EPK-i8020c software to add a new function called “Light Limit Mode.” This mode restricts the light output emitted from the distal end of the endoscope and is used to limit the maximum light intensity. When bleeding, such as hematemesis or hematochezia, is anticipated, activate the Light Limit Mode before inserting the endoscope. Additionally, if heavy bleeding is observed during the examination or treatment after inserting the endoscope, promptly activate the Light limit mode.

PENTAX Medical has also updated Instructions for Use (IFU) for the EPK-i8020c Video Processor to provide detailed information on the Light Limit Mode function.

Your PENTAX Medical representative will provide an overview of the Light Limit Mode software and will address any questions you may have.

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Customer Instructions:

PENTAX Medical will conduct the software update on the affected devices at your facility. Your local PENTAX Medical representative will contact you to schedule the required updates for your equipment.

- Please download the Instructions for Use (IFU) for the EPK-i8020c Video Processor from the PENTAX Medical online IFU library at https://ifu.pentaxmedical.com.
- Please complete the enclosed Field Correction Response Form upon receipt of this package, and email to PENTAX Medical at customeradvisories@pentaxmedical.com.

Contact Information:

PENTAX Medical regrets any inconvenience that this action may cause and appreciates your understanding and cooperation. Please be assured that maintaining product quality is our utmost priority.

Please indicate through the attached response form that you have received and understood this information, by completing it and returning it no later than July18, 2025 at: customeradvisories@pentaxmedical.com

If you have any questions regarding this action, please feel free to contact us at:

- Tel: 1-800-431-5880 (8:30 AM – 5:00 PM, Monday – Friday, EST)
- Fax: (800)-579-5432)
- Email: customeradvisories@pentaxmedical.com

Adverse events experienced with the use of this product should be reported as soon as possible to PENTAX Medical at vigilance@pentaxmedical.com.

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Sincerely,

Seiya Raiju

Seiya Raiju
Chief Quality Officer
PENTAX Medical

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Update to Instruction for Use (IFU).

The following descriptions shall be added to the Instructions for Use (IFU) of the EPK-i8020c Video Processor in accordance with the software update.

Light Limit Mode

- This mode limits the maximum light emitted from the distal end of the endoscope.
- This function is used to limit the maximum light intensity
- When bleeding, such as hematemesis or hematochezia, is expected, activate the Light Limit Mode before inserting the endoscope.
- If heavy bleeding is observed during the examination or treatment after inserting the endoscope, promptly activate the Light Limit Mode.

Light Limit Mode Compatible Endoscopes

The table below shows the compatibility of each endoscope with the Light limit mode.

Function	J10	90i/i10	i10c	90K	i20c	i20cW
Light limit mode	Y	Y	N*1	Y	Y	N*1

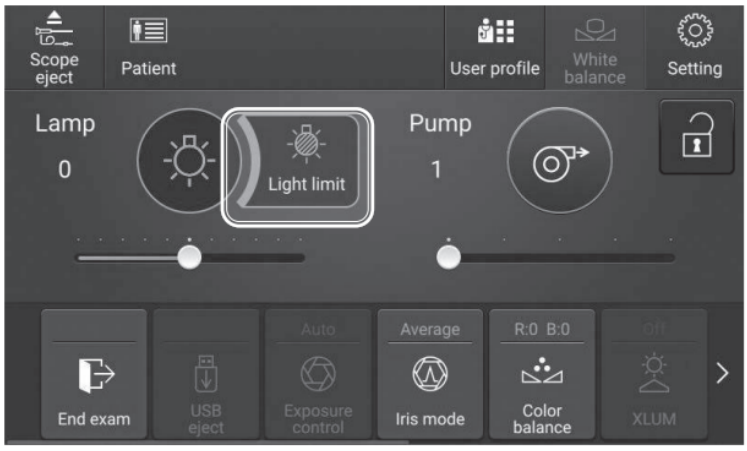
*1: The button is always grayed out and cannot be used.

Note:

- When Light Limit Mode is turned on, the amount of light decreases. If you notice reduced light output, please check that Light Limit Mode is not activated.
- White balance cannot be performed when Light Limit Mode is on.

How to Use Light Limit Mode

1. To activate Light Limit Mode, touch and hold the button. The button will turn blue, and the light emitted from the tip of the endoscope will decrease.



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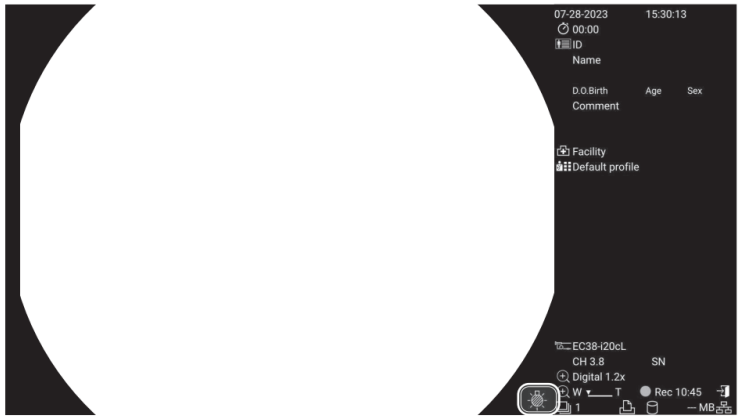
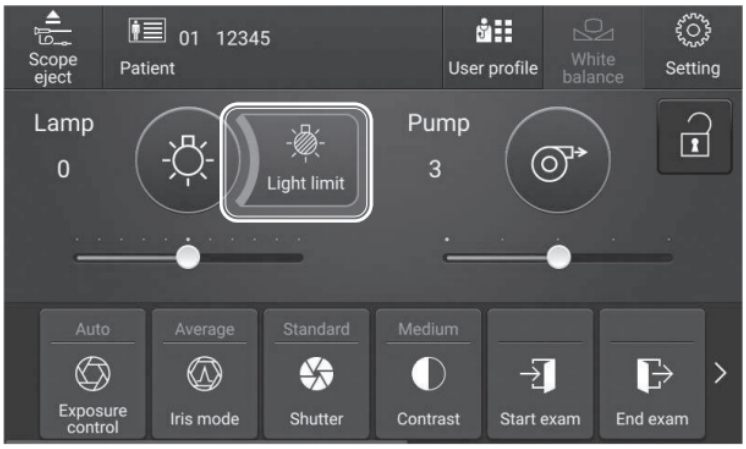
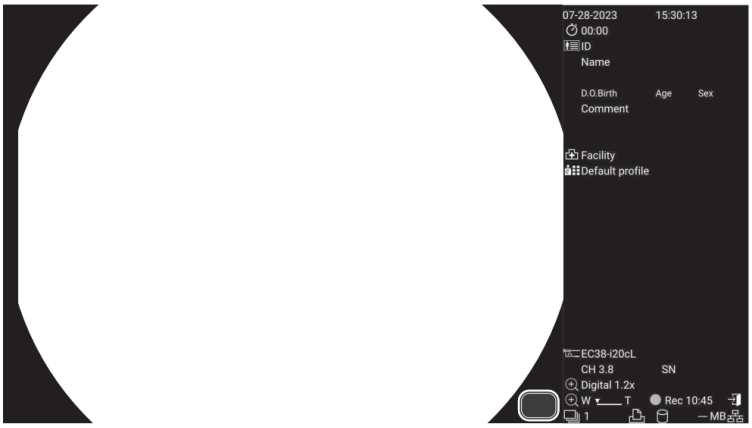
2. When Light Limit Mode is enabled, an icon will be displayed on the monitor screen.



3. To deactivate Light Limit Mode, touch and hold the button again. The button will return to its original color, and the light emitted from the distal end of the endoscope will return to its previous intensity.



4. After deactivating Light Limit Mode, the icon will disappear from the monitor screen, indicating that the light emission has returned to its normal intensity.



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Operation When Light Limit Mode is Enabled or Disabled

Light limit mode is Enabled:

Function	Status	Disabled Functions	Control Details
Light limit mode	On	Exposure control	Not Available *1
		OE	Not Available *1
		Red density	Not Available *1
		ND mode	Not Available *1
		Twin mode	Not Available *1
		XLUM	Not Available *1
Light limit mode	Off→On	OE	Off (switches to White Light)
		Red density : On	Off (switches to White Light)
		Twin Mode	Off (switches to White Light)

*1: The touch panel items are grayed out, and when the Endoscope button, Footswitch, or keyboard is configured, an error beep and message will be displayed.

i -SCAN Profile Settings While Light limit mode is Activated

The i -SCANProfile can be modified or loaded during Light Limit Mode; however, functions restricted by Light Limit Mode cannot be used through the i-SCANProfile. For further details, please refer to the table below.

i-scan setting function	Light limit mode On	Control Details
OE	Not Available	It is disabled in Light limit mode and cannot function
Red density		

Light limit mode is Disabled:

The display switches to a single - screen White Light state, regardless of the state prior to activation.

Conditions Preventing Activation of Light Limit Mode:

Light Limit Mode will be disabled and cannot be used if any of the following conditions are met:

Function	Status
Exposure control	Manual
ND mode	On
XLUM	On

OE (Optical enhancement)

- OE cannot be used while the Light Limit Mode is activated.
- OE is disabled when the scope is removed, and it does not automatically switch to OE mode when the scope is reconnected.

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FIELD CORRECTION RESPONSE FORM
RESPONSE IS REQUIRED

Name

Address,

State, Zip

REF: 2025-002-C

PENTAX Medical EPK-i8020c Video Processors Software Update for Light Limit Mode

Contact Information
Name
Title
Telephone
Fax Number
Email address

☐ I have read and understood the instructions provided in the customer notification letter.

☐ I have received the PENTAX Medical weblink and instructions and have downloaded the Instructions for Use (IFU) for EPK-i8020c.

According to our record the following product/serial numbers are affected by this notification

Model	Serial Number(s)
EPK-i8020c	

Signature of Receipt and Acknowledgement: Date:

Upon completion of the form and signing, please return the form by either one of the following methods:

- Faxing this completed form to PENTAX Medical QA/RA Department at 201-799-4063 (alternate 201-391-4189)
- Email a pdf copy of the completed form to customeradvisories@pentaxmedical.com.

If you have any questions regarding this action, please feel free to contact your PENTAX Medical Territory Manager or PENTAX Medical Customer Service at 800-431-5880 (8:30am – 5:00 pm EST, Monday – Friday).