

May 13, 2015

URGENT: FIELD SAFETY NOTICE
Error in WIZARD² Barcode ID Label #023 Content

Product code	Product name	Serial Numbers
2470-0010	WIZARD ² 1-detector, 550 samples	See attached list
2470-0020	WIZARD ² 2-detector, 550 samples	
2470-0050, 3470-0050	WIZARD ² 5-detector, 550 samples	
2470-0100, 3470-0100	WIZARD ² 10-detector, 550 samples	
2470-0150, 3470-0150	WIZARD ² 5-detector, 1000 samples	
2470-0200, 3470-0200	WIZARD ² 10-detector, 1000 samples	
2480-0010	WIZARD ² 1-detector,3", 1000 samples	

Dear Customer,

The purpose of this letter is to advise you that PerkinElmer is voluntarily implementing a correction to the PerkinElmer WIZARD² Gamma Counter. The serial numbers of the affected WIZARD² Gamma Counters are provided as an attachment to this document.

Reason for the Voluntary Correction

We have become aware through a customer complaint that the content of the second of the two #023 barcode ID labels provided on each page of the Barcode ID Label Binder are incorrect. The second barcode ID label #023 symbol incorrectly identifies as #024 when scanned. In the event measurement protocols have been programmed for both ID #023 and #024, and the WIZARD² Gamma Counter scans the affected barcode label, the protocol associated with barcode ID #024 is executed. If the error is undetected, the WIZARD² Gamma Counter may produce erroneous results.

Risk to Health

The impact on health is dependent on the clinical application in which the WIZARD² Gamma Counter is being used.

In the event where no protocol has been programmed for barcode ID label #024, the WIZARD² Gamma Counter will fail to execute protocol #024 when the affected barcode ID label #023 is used. The issue will lead to a delay in reporting results due to the delay to resolve the issue and retest the samples or test new samples.

In the event both protocols #023 and #024 are programmed, protocol #024 must also have the results exported to a directory to generate a measurement results file. In addition, protocol #024 will only run if the isotope(s) associated with the protocol are normalized. With these constraints met, the WIZARD² Gamma Counter will execute protocol #024 when the affected barcode ID label #023 is scanned. The count measurements in the generated .CSV file will be incorrectly identified as from the protocol programmed for ID #024.

Dependent on the software used to analyze the count measurements, the following outcomes may result;

- When WorkOutPlus data analysis software is used, the WIZARD² protocol name must exactly match a corresponding WorkOutPlus protocol name for data analysis to occur. The WIZARD² Gamma Counter User Interface (“WizIU”) software prevents any two WIZARD² measurement protocols from having the same protocol name. Therefore, data analysis results will not be generated by WorkOutPlus software.

The issue will lead to a delay in results due to the need to resolve the issue and retest the samples or test new samples.

- When the Autoprint Macro utility is used for CPM (count per minute) only data, a user selectable subset of the system generated result csv file is printed. The protocol name and protocol ID are prominently displayed as part of the printout header and cannot be suppressed. The isotope measured is displayed in the column header for CPM and Counts reported. If the error is undetected, the sample measurement result would be incorrect. Dependent on the clinical application, the incorrect result may lead to the patient;
 - Being administered a second dose of radioactive material so the nuclear medicine procedure can be repeated where an insufficient amount was initially given,
 - Being administered a greater dose of radioactive material than necessary for the nuclear medicine procedure.
 - Being administered an insufficient chemotherapy dosage where the GFR determined was under estimated,
 - Being administered an increased chemotherapy dosage where the GFR determined was over estimated.
- Dependent on individual patient clinical status an incorrect result may impact disease progression or renal function.

Actions to be taken by the Customer

Until the PerkinElmer correction has been completed, we request you immediately destroy all barcode ID labels #023 in your possession. The WIZARD² Gamma Counter barcode label binder contains a total of 20 barcode labels identified as #023 (i.e. 2 labels on each of 10 pages). Please ensure to you remove the barcode labels ID #023 from all barcode label binders in your possession. Please be sure to inspect all sample racks to remove and destroy any barcode ID labels #023 already affixed to racks.

Actions to be taken by PerkinElmer

A WIZARD² Gamma Counter barcode label binder with corrected barcode labels ID #023 will be provided upon request and return of the completed Correction Response Form to PerkinElmer.

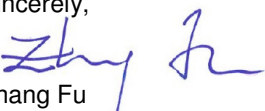
Other Information:

Please distribute this information immediately to any staff that may be affected by this WIZARD² Gamma Counter barcode label ID issue.

To comply with regulatory requirements we request that you complete the enclosed Correction Response Form and return it by scan and e-mail to QMresponse.SG@perkinelmer.com as soon as possible, but no later than June 15th, 2015.

We regret the inconvenience this issue may cause and appreciate your assistance. For further information, please contact your local PerkinElmer representatives.

Sincerely,


Zhang Fu
Quality and Compliance Manager,
Singapore
PerkinElmer Inc.

RESPONSE FORM

Please complete this response form and send it by scan and e-mail to QMresponse.SG@perkinelmer.com.

Product(s) affected:

Product code	Product name	Serial Numbers
2470-0010	WIZARD ² 1-detector, 550 samples	See attached list
2470-0020	WIZARD ² 2-detector, 550 samples	
2470-0050, 3470-0050	WIZARD ² 5-detector, 550 samples	
2470-0100, 3470-0100	WIZARD ² 10-detector, 550 samples	
2470-0150, 3470-0150	WIZARD ² 5-detector, 1000 samples	
2470-0200, 3470-0200	WIZARD ² 10-detector, 1000 samples	
2480-0010	WIZARD ² 1-detector,3', 1000 samples	

1. Have you read the letter accompanying this form? The letter provides information of the Field Safety Corrective Action by PerkinElmer of the above listed instruments.

Yes No

2. Please record the serial numbers of the WIZARD² Gamma Counters in your possession in the table below.

WIZARD ² Gamma Counter Serial Number	WIZARD ² Gamma Counter Serial Number

3. Please record the number of WIZARD² barcode ID label binders in your possession and the number of barcode labels ID #023 destroyed. (Destruction should be permanent to prevent any accidental use of the affected #023 barcodes).

Quantity of Binders	Quantity of #23 Labels Destroyed

4. Please record the serial numbers of any WIZARD² Gamma Counters that you previously owned but are no longer in your possession.

Enter WIZARD ² Serial Numbers Below	Disposition of Unit (check one)				
	Returned to PKI	Destroyed	Sold /Given away	Other	Please describe "other" if selected

Please provide the following information.

Signature / Date _____ / _____

Clarification of signature _____

Laboratory / Clinic _____

State / Country _____

**Serial Number Attachment for WIZARD2 Gamma Counter FIELD SAFETY
CORRECTIVE ACTION**

Model	Serial Number
2470-0020	DG08129575