



# Addendum

## **Global Labeling Update for the Beckman Coulter Chemistry Analyzer AU480 User's Guide**

*For In Vitro* Diagnostic Use



C12120AA  
July 2017



Beckman Coulter, Inc.  
250 S. Kraemer Blvd.  
Brea, CA 92821 U.S.A.



## **Addendum**

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[www.beckmancoulter.com](http://www.beckmancoulter.com)



Beckman Coulter Ireland Inc.  
Lismeehan, O'Callaghan's Mills,  
Co. Clare, Ireland

Phone: +353-65-683-1100

FAX: +353-65-683-1122

Rx Only

Original Instructions

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## Contents

## Introduction



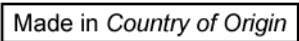


This symbols glossary addresses changes to global labeling requirements and identifies the symbols that relate to product identification, classification, cautions, and warnings. Use this symbols glossary with the User's Guide (UG) for the product.

This document applies to the latest software listed and higher versions.

- Software version 1.91

## Symbols Glossary



**Table 1.1** Symbols Glossary

Symbol	Description
	<p><b>CE Marking</b></p> <p>The CE marking indicates that a product has been assessed before being placed on the market, and has been found to meet the applicable directives relating to the European Union safety, health, and environmental protection requirements.</p>
	<p><b>cNRTLus Certification Mark</b></p> <p>This symbol indicates recognition by a Nationally Recognized Testing Laboratory (NRTL) that the instrument has met the relevant product safety standards for the United States and Canada.</p> <p><i>OSHA, CEC</i></p>
	<p><b>Country of Origin Symbol</b></p> <p>This symbol indicates the country that the product was manufactured.</p>
	<p><b>Moving Parts Symbol</b></p> <p>The moving parts symbol indicates that there are moving parts in the area. Only operate the system when all covers are in position and use caution to reduce the risk of personal injury.</p> <p>While the system is operating, do not touch the moving parts of the system. Do not insert fingers or hands into any system opening.</p>
	<p><b>RCM Symbol</b></p> <p>This symbol indicates compliance with the Australian Communications Media Authority (ACMA) requirements (safety and EMC) for Australia and New Zealand.</p>






**Global Labeling Update**

Symbols Glossary

**Table 1.1** Symbols Glossary (Continued)


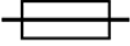




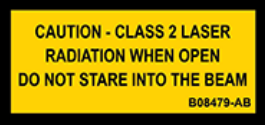
Symbol	Description
	<p><b>RoHS Caution Symbol</b></p> <p>This symbol indicates that this electronic information product contains certain toxic or hazardous elements, and can be used safely during its environmental protection use period. The number in the middle of the logo indicates the environmental protection use period (in years) for the product. The outer circle indicates that the product can be recycled. The logo also signifies that the product should be recycled immediately after its environmental protection use period has expired. The date on the label indicates the date of manufacture.</p> <p>These labels and materials declaration table (the Table of Hazardous Substance's Name and Concentration) meet People's Republic of China Electronic Industry Standard SJ/T11364-2006 <i>Marking for Control of Pollution Caused by Electronic Information Products</i> requirements.</p>
	<p><b>RoHS Environmental Symbol</b></p> <p>This symbol indicates that the product does not contain any toxic or hazardous substances or elements. The "e" stands for electrical, electronic, and environmental electronic information products. This logo indicates that this electronic information product does not contain any toxic or hazardous substances or elements, and is green and is environmental. The outer circle indicates that the product can be recycled. The logo also signifies that the product can be recycled after being discarded, and should not be casually discarded.</p>
<p>RxOnly</p>	<p><b>RxOnly Symbol</b></p> <p>This symbol is a required symbol from the FDA concerning the labeling for prescription devices.</p> <p><i>21 CFR 801.109(b)(1)</i></p>

**Table 1.1** Symbols Glossary (Continued)







Symbol	Description
	<p><b>Recycling Symbol</b></p> <p>This label is required by the Waste Electrical and Electronic Equipment (WEEE) Directive of the European Union. The presence of this label indicates that:</p> <ol style="list-style-type: none"> <li>1. The device was put on the European Market after August 13, 2005.</li> <li>2. The device is not to be disposed of via the municipal waste collection system of any member state of the European Union.</li> </ol> <p>Customers must understand and follow all laws regarding the correct decontamination and safe disposal of electrical equipment. For Beckman Coulter products bearing this label, contact your dealer or local Beckman Coulter office for more information on the take-back program that facilitates the correct collection, treatment, recovery, recycling, and safe disposal of these products.</p> <p>For the Japan market:</p> <p>This system is considered an industrial waste, subject to special controls for infectious waste. Before disposal of the system, refer to the <i>Waste Disposal and Public Cleaning Law</i> for compliance procedures.</p> <p><i>EU Directive 2002-96-EC: waste electrical and electronic equipment (WEEE)</i></p>
	<p><b>On Symbol</b></p> <p>This symbol indicates the on position of a disconnect device.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5007</i></p>
	<p><b>On or Standby Symbol</b></p> <p>This symbol indicates on or standby conditions. A green light can indicate that the power is on.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5010</i></p>
	<p><b>On or Reset Symbol</b></p> <p>This symbol indicates on or reset conditions.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5264</i></p>
	<p><b>Stop Button Symbol</b></p> <p>This symbol indicates a stop button that you can use to halt any hazardous condition.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5110A</i></p>

**Global Labeling Update**  
**Symbols Glossary**

**Table 1.1** Symbols Glossary (Continued)

Symbol	Description
	<p><b>Off Symbol</b></p> <p>This symbol indicates the off position of a disconnect device.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5008</i></p>
	<p><b>Fuse Symbol</b></p> <p>This symbol is used to identify a fuse location and rating.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5016</i></p>
	<p><b>Caution, Risk of Electric Shock</b></p> <p>This symbol indicates an area of the system to not access under any circumstances, due to possibility of high voltages and the risk of electrical shock.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5036</i></p>
	<p><b>Protective Earth; Protective Ground Symbol</b></p> <p>This symbol is used to identify the main terminal which is intended for connection to an external conductor for protection against electric shock if there is a fault, or the terminal of a protective earth (ground) electrode.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5019</i></p>
	<p><b>Caution, Hot Surface</b></p> <p>This symbol indicates that there is a hot surface or component (such as a lamp) in the area that, if touched, can cause a burn.</p> <p><i>IEC 60417: Graphical symbols for use on equipment - Overview and application, #5041</i></p>
	<p><b>Laser Compliance</b></p> <p>This label indicates that the product is a Class 1 Laser Product and is in compliance with international standard and US requirements.</p> <p><i>21 CFR 1040</i></p>
	<p><b>Laser Class 2 Panel Label</b></p> <p>The panel marking indicates that there is Class 2 laser light radiation beyond the panel it is placed on. Use caution and do not stare into the beam when laser light is in the area.</p> <p><i>IEC 60825: Safety of laser products - Part 1: Equipment classification and requirements</i></p>





**Table 1.1** Symbols Glossary (Continued)

Symbol	Description
	<p><b>Legal Manufacturer Symbol</b></p> <p>This symbol identifies who the legal manufacturer of the product is.</p> <p><i>ISO 15223-1: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements, clause 5.1.1</i></p>
	<p><b>EC Representative</b></p> <p>This symbol indicates the European Community Representative for the product.</p> <p><i>ISO 15223-1: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements, clause 5.1.2</i></p>
	<p><b>Part, Model, or Catalog Number</b></p> <p>This symbol indicates the model number, catalog number, or part number of the equipment.</p> <p><i>ISO 15223-1: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements, clause 5.1.6</i></p>
	<p><b>In Vitro Diagnostic Use</b></p> <p>This symbol indicates that the instrument is an in vitro diagnostic medical device.</p> <p><i>ISO 15223-1: Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements, clause 5.5.1</i></p>
	<p><b>Caution, Read Manual Symbol</b></p> <p>This symbol indicates that the operator must read the manual to identify and understand that there is a potentially hazardous situation which, if not avoided, could cause injury or serious physical damage.</p> <p><i>ISO 7000: Graphical symbols for use on equipment - Registered symbols, #0434A</i></p>
	<p><b>Biohazard Symbol</b></p> <p>This is the international symbol for biohazardous material. This label indicates the use of biohazardous materials in the area. Use caution when working with possible infectious samples.</p> <p>Wear Personal Protective Equipment (PPE) such as gloves, eye shields, and lab coats. Handle and dispose of biohazardous materials according to your laboratory procedures.</p> <p><i>ISO 7000: Graphical symbols for use on equipment - Registered symbols, #0659</i></p>

**Global Labeling Update**

Other

**Table 1.1** Symbols Glossary (Continued)

Symbol	Description
	<p><b>Consult the Instructions for Use Symbol</b></p> <p>This symbol indicates to read the Instructions For Use before using the system.</p> <p><i>ISO 7000: Graphical symbols for use on equipment - Registered symbols, #1641</i></p>
	<p><b>Date of Manufacture</b></p> <p>This symbol indicates the date the system was manufactured.</p> <p><i>ISO 7000: Graphical symbols for use on equipment - Registered symbols, #2497</i></p>
	<p><b>Serial Number Symbol</b></p> <p>This symbol indicates the serial number of the product.</p> <p><i>ISO 7000: Graphical symbols for use on equipment - Registered symbols, #2498</i></p>
	<p><b>Laser Radiation Symbol</b></p> <p>The laser radiation symbol indicates that there can be laser light radiation in the area. Take precautions to prevent exposure.</p> <p><i>ISO 7010: Graphical symbols - Safety colours and safety signs - Registered safety signs, #W004</i></p>

**Other**




**California Proposition 65 warning**

**This product can expose you to chemicals including Phthalates, which are known to the State of California to cause cancer and cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).**



Noise level generated by the instrument:

- 60 dBA

**Table 1.2** Button Label Update:

Original	Update
ON	

**Table 1.2** Button Label Update: (Continued)

Original	Update
EM STOP	
RESET	

**Global Labeling Update**

Other



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