



Addendum

AU480, AU680, and AU5800 In Vitro Diagnostic Regulation Requirements

For In Vitro Diagnostic Use



C79006AA
January 2021



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



Addendum

AU480, AU680, and AU5800 In Vitro Diagnostic Regulation Requirements

PN C79006AA (January 2021)

© 2021 Beckman Coulter, Inc.

All Rights Reserved.

Trademarks

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

All other trademarks are the property of their respective owners.

Find us on the World Wide Web at:

www.beckmancoulter.com

EC	REP
----	-----

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

Contents

AU480, AU680, and AU5800 Updates, v

Contents

AU480, AU680, and AU5800 Updates

Updates based on IVDR Requirements

Introduction

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

- AU480: Software version 1.A
- AU680: Software version 4.0
- AU5800: Software version 5.1

This addendum is a separate document containing additions to the AU480 User's Guide, AU680 Instructions for Use, and AU5800 Instructions for Use required by In Vitro Diagnostic Regulation (IVDR).

The following are the updates based on the IVDR Requirements:

Notice to Users (Troubleshooting Section)

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact a Beckman Coulter Representative.

Service Coverage (Warranty Section)

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

- For United States and Canada customers, call the Beckman Coulter Customer Support toll-free number at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

- For international customers, contact your local Beckman Coulter Customer Support.

Restricted Use (Safety Notice Section)

- Samples and reagents: Refer to each reagent Instructions for Use used for measurement.
- Consumables: Refer to Chapter 6 Maintenance in the analyzer Instructions for Use.
- Computer Connectivity (LIS, Automation, Pro Services): Refer to the System Overview > Hardware Overview > Computer section.

Use Statement (Safety Notice Section)

- The system is for indoor use only.

- Do not use the system in a way not specified by Beckman Coulter, as the protection provided by the system can be impaired and incorrect results or system failure can occur.

Summary of Hazards (Safety Notice Section)

Consumables

Be sure all consumables are unopened before use. If the consumables appear to be opened or contaminated, contact Beckman Coulter.

Batch to Batch Variation (Calibrate Tests Section)

Calibrator set points can vary with new lots. Be sure to inspect the calibrator value assignment sheets to ensure the correct set points are in use.

For calibrator information, refer to the calibrator IFU and value assignment sheet.

Batch to Batch Variation (Process Quality Control (QC) Section)

Quality control material mean, range, and standard deviation can vary for each test with new lots. Be sure the correct values for control material lot are in use.

Benefits and Limitations (Intended Use Section)

The Beckman Coulter Clinical Chemistry Analyzer is an automated chemistry analyzer that measures analytes in samples, in combination with appropriate reagents, calibrators, quality control (QC) material, and other accessories. This system is for in vitro diagnostic use only. Applications include colorimetric, turbidimetric, latex agglutination, and ion selective electrode.

Intended Purpose (Intended Use Section)

This product measures the chemical components in the sample (serum, plasma, urine, whole blood (HbA1c only)) by mixing (stirring) the sample and reagent. Refer to the reagent Instructions for Use for details of the measurement requirements.

Minimum Software Requirement (System Overview Section)

Software usage environment: Use only on the PC included with this product.

Store Pack Ship Transport (SPST) Transportation Codes (Temperature and Humidity Conditions When Not in Use Section)

When transporting the analyzers, the following specifications are recommended:

- Temperature: -30 to 60 degrees Celsius (-22 to 140 degrees Fahrenheit)
- Humidity: 10% to 95% RH

Installation (System Specifications Section)

- Before installing the system, refer to the System Specifications for the installation requirements.

- A Beckman Coulter Field Service Engineer must be present when the analyzer is removed from the shipping crate.
- A qualified Beckman Coulter Field Service Engineer must install the system. If the analyzer must be relocated, contact Beckman Coulter Customer Support.

A Beckman Coulter Field Service Engineer performs the following system verification:

- Photocal
- Water testing
- Dye testing
- If the ISE option is installed, ISE performance (ISE Calibration, ISE Selectivity Check, ISE Accuracy test)

Maintenance procedures required by the customer:

Refer to the Maintenance chapter.

Analytical performance characteristics (Analytical Method Specifications Section)

Refer to the reagent Instructions for Use used for measurement.

Specimen Preparation (Sample Preparation Section)

For sample handling, refer to the reagent Instructions for Use.

Training and Education Resources

Go to the Beckman Coulter Training and Education website (<https://www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm>) to find the following items:

- eLearning Training Modules:
Engaging interactive training provides an overview of the system software, hardware components, ISE, and reaction process.
- Job Aid Booklets and Additional Job Aids:
Easy to use instructions and flowcharts for frequently asked questions.
- Training Competency Checklists:
To ensure that trainees in your lab are proficient in basic system operations.

AU480, AU680, and AU5800 Updates
Updates based on IVDR Requirements

www.beckmancoulter.com



© 2021 Beckman Coulter, Inc.
All Rights Reserved.