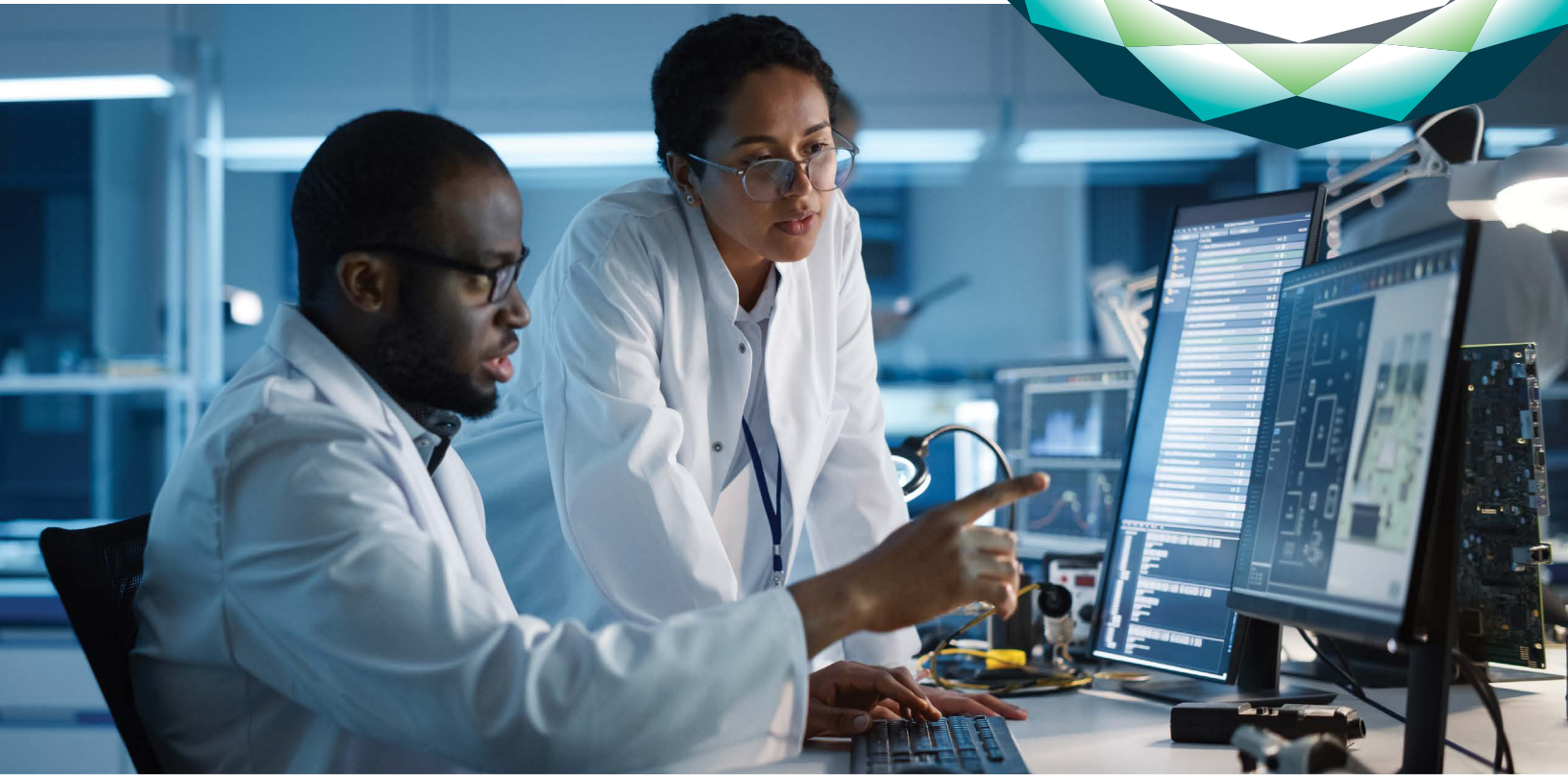


# BTX ECM 830 Instruments

Installation Qualification (IQ) /  
Operational Qualification (OQ) Services



## Manufacturer Expertise

Our highly skilled team is directly involved with the development and manufacturing of our equipment, working with us eliminates risks of third-party errors due to insufficient instrument knowledge.



## Flexible Offerings

Whether your lab needs regular compliance validation services or full repair and coverage for the instruments, we are ready to provide a custom service program to work with you at your lab onsite.



## Qualification Coverage

Our expert personnel ensure the instrument is properly installed and system operation is verified to validate system performance to the original specification. In the event of inspection failures, our team works closely with you.

# BTX<sup>®</sup>

An Affiliate of Harvard Bioscience, Inc.



Labs are involved with sophisticated electroporation techniques that require accurately calibrated, cutting-edge equipment to be successful.

With the BTX Electroporation System, your lab gains a complete partnership with BTX, an affiliate of Harvard Bioscience. This partnership allows your lab to have a dedicated, first-class technical service and support team. From validating operational best practices, to

meeting compliance requirements, and even restarting instruments, your lab can count on our engineers and technical support team to complete the necessary IQ/OQ validation to keep your lab running smoothly.





## What does the IQ/OQ validation service include?

### Your IQ/OQ validation service includes performance of the following tests:

#### Visual inspection of the instrument

Identifies any signs of damage

#### Verification of time and date

Ensures correct timestamping of logs and data

#### Verification of display and user interface

Ensures proper operation and control of the device

#### Verification of instrument installation process

Completes checklists, documents sign-off of the Installation Procedure

#### Verification of pulse accuracy throughout the voltage range

Ensures voltage and resistance measurement accuracy

#### Verification of pulse duration

Ensures accuracy of pulse length measurement

#### Verification of operation with media

Ensures proper operation of the safety stand or chamber holder and pulse accuracy in a sample

#### Log file storage and retrieval

Ensures that logs are accurate and stored appropriately and that the USB link is working properly

#### Verification of footswitch operation

Ensures proper hands-free operation

#### Verification and replacement of the system battery

Ensures accuracy of battery lifespan

### Your IQ/OQ service includes the following post-session summary documentation

#### Signed Qualification Reports detailing:

- Unit tested location and serial number
- Tests performed and measurement results
- Indication of “Pass” or “Fail” for each test
- Date of the qualification
- Staff that performed the qualification

#### Electronic logs files from the tests



“The BTX team came to our lab and tested our four installed units and ensured that they were performing to the full factory specifications. The staff was diligent, knowledgeable, and performed a thorough review of all our instruments”

BTX Customer



### Ordering information

- ECM 830 IQ\_OQ Document & Kit (requires Service below to be ordered at the same time).
  - 470681 ECM 830 IQ\_OQ Service (EU/UK)
  - 470659 ECM 830 IQ\_OQ Service (US/Canada)
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- 470644 ECM 830 OQ Document & Kit (requires Service below to be ordered at the same time).
  - 470676 ECM 830 OQ Service (EU/UK)
  - 470649 ECM 830 OQ Service (US/Canada)



**BTX**  
84 October Hill Rd.  
Holliston, MA 01746 USA  
Telephone: 508-893-8999  
Fax: 508-429-5723

**Sales:**  
[sales@harvardapparatus.com](mailto:sales@harvardapparatus.com)  
**Technical Support:**  
[support@hbiosci.com](mailto:support@hbiosci.com)

**Web:** [www.btxonline.com](http://www.btxonline.com)