

User's Manual

2-Needle Array™ Electrode



MA1 45-0167	2-Needle Array, 10 mm kit
MA1 45-0205	2-Needle Array Handle, 10 mm gap, Model 530
MA1 45-0120	2-Needle Array Tip, 10 mm gap, pkg. of 6, Model 531
MA1 45-0168	2-Needle Array, 5 mm kit
MA1 45-0206	2-Needle Array Handle, 5 mm gap, Model 533
MA1 45-0121	2-Needle Array Tip, 5 mm gap, pkg. of 6, Model 532

BTX®

HARVARD APPARATUS

The Electroporation Experts

WEEE/RoHS Compliance Statement

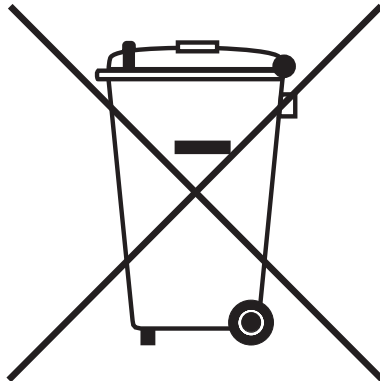
EU Directives WEEE and RoHS

To Our Valued Customers:

We are committed to being a good corporate citizen. As part of that commitment, we strive to maintain an environmentally conscious manufacturing operation. The European Union (EU) has enacted two Directives, the first on product recycling (Waste Electrical and Electronic Equipment, WEEE) and the second limiting the use of certain substances (Restriction on the use of Hazardous Substances, RoHS). Over time, these Directives will be implemented in the national laws of each EU Member State.

Once the final national regulations have been put into place, recycling will be offered for our products which are within the scope of the WEEE Directive. Products falling under the scope of the WEEE Directive available for sale after August 13, 2005 will be identified with a "wheelie bin" symbol.

Two Categories of products covered by the WEEE Directive are currently exempt from the RoHS Directive - Category 8, medical devices (with the exception of implanted or infected products) and Category 9, monitoring and control instruments. Most of our products fall into either Category 8 or 9 and are currently exempt from the RoHS Directive. We will continue to monitor the application of the RoHS Directive to its products and will comply with any changes as they apply.



- **Do Not Dispose Product with Municipal Waste.**
- **Special Collection/Disposal Required.**

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General Information

Warranty

BTX/Harvard Apparatus warranties this BTX 2-Needle Array™ Electrode for a period of 90 days from date of purchase. At its option, BTX/Harvard Apparatus will repair or replace the item if it is found to be defective as to workmanship or material. This warranty does not extend to damage resulting from misuse, neglect, or abuse, normal wear and tear, or accident. This warranty extends only to the original customer purchase.

IN NO EVENT SHALL HARVARD APPARATUS BE LIABLE FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES. Some states do not allow exclusion or limitation of incidental or consequential damages so the above limitation or exclusion may not apply to you. **THERE ARE NO IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE, OR OF ANY OTHER NATURE.** Some states do not allow this limitation on an implied warranty, so the above limitation may not apply to you.

If a defect arises within the 90 day warranty period, promptly contact: **BTX/Harvard Apparatus, 84 October Hill Road, Holliston, Massachusetts 01746-1388** using our toll free number **1-800-272-2775 (Outside the U.S. call 1-508-893-8999).**

Goods will not be accepted for return unless an RMA (Return Materials Authorization) number has been issued by our customer service department. The customer is responsible for shipping charges. Please allow a reasonable period of time for completion of repairs or replacement and return. If the unit is replaced, the replacement unit is covered only for the remainder of the original warranty period dating from the purchase of the original device. This warranty gives you specific rights, and you may also have other rights which vary from state to state.

IMPORTANT: Read all Instructions, Warnings and Precautions prior to use.

General Information (continued)

Technical & Customer Service

BTX® is the ultimate resource for technical information on the use of high voltage bacterial transformation and general electroporation of molecules and drugs into cells. We constantly track and monitor scientific publications in this area. Our Technical Service group extracts and enters pertinent information, such as results and parameters from these papers into a Protocol database. This database is available via the BTX website. Please visit www.btxonline.com.

For technical assistance, additional information or an inquiry/request for repair service, contact BTX/Harvard Apparatus Technical Support/Customer Service Group at:

BTX®

A Division of Harvard Apparatus

84 October Hill Road

Holliston, MA 01746-1388 U.S.A.

Toll Free: 1-800-272-2775 (US only)

Phone: 1-508-893-8999

Fax: 1-508-429-5732

E-mail: techsupport.btx@harvardapparatus.com

Internet: www.btxonline.com (click on customer service)

If outside the United States and Canada:

call **1-508-893-8999** or contact your nearest BTX Distributor.

A complete list of distributors is on our website.

General Safety Summary

Review the following safety precautions to avoid injury and prevent damage to this product or any products connected to it. To avoid potential hazard, use this product only as specified. Only qualified BTX personnel should perform service procedures.

To Prevent Hazard or Injury:

ARCING CAN OCCUR AT HIGH VOLTAGES

An unfavorable combination of parameters such as high voltage settings and a small sample volume with a highly conductive medium might lead to flashover between the electrodes (ARC) and/or explosive evaporation of the medium. Reduce voltage or pulse length to avoid repeating this condition.

DO NOT OPERATE WITH SUSPECTED FAILURES

If you suspect there is damage to the product, have it inspected by qualified BTX service personnel.

DO NOT CONTACT ELECTRODES

To avoid fire or shock hazard, observe all ratings and markings on the product or in this manual before using the device.

AVOID EXPOSURE TO CONTACT

Do not insert fingers or try to remove electrode or sample during pulsing sequence.

WEAR PROPER EYE PROTECTION DURING ELECTROPORATION

DO NOT OPERATE IN AN EXPLOSIVE ENVIRONMENT

DO NOT OPERATE IN WET/DAMP CONDITIONS

Safety Terms and Symbols:

Terms that appear in this manual:



WARNING. Warning statements identify conditions or practices that could result in injury or loss of life.



CAUTION. Caution statements identify conditions or practices that could result in damage to these products or other property.

Symbols that may appear on the products:



Danger
High
Voltage



Attention
Refer to
Manual



Protective
(Earth)
Terminal



Functional
Ground
Terminal

Introduction

The 2-Needle Array Electrode is a needle style electrode specifically designed for in vivo gene delivery in muscles. The electrode consists of a reusable 2-Needle Array Handle and sterile disposable two-needle array tips. The needle array tips are conveniently packaged in “Six Packs,” allowing for guaranteed sterility, and designed to fit conveniently in a sterile hood. The needles themselves are made of medical grade stainless steel. To secure the needle array tip to the Needle Array handle, simply position the handle over a needle array tip and push to secure onto the handle. Attach the handle to a BTX electroporator via the high voltage banana cables. Remove the needle safety shield, place into the tissue, and deliver the pulse. Discard the needle array tip and prepare for the next experiment. The 2-Needle Array comes in 5 mm and 10 mm electrode spacing.

U.S. Patent #5, 273, 525

U.S. Patent #5, 702, 359

IMPORTANT: Read all Instructions, Warnings and Precautions prior to use.

FOR RESEARCH PURPOSES ONLY



2-Needle Array

CAUTION
FOR RESEARCH USE ONLY
NOT FOR CLINICAL
USE ON PATIENTS

Operation: Getting Started



WARNING HIGH VOLTAGE

Make sure the BTX electroporator is switched off before continuing.

1. Grasping the 2-Needle Array Handle, position the handle over a 2-Needle Array Tip and push to secure the 2-needle array to the handle.
2. Attach the handle to a BTX electroporator via the high voltage banana cables.
3. Following instructions for the electroporator set the appropriate parameters on the generator. Set up The Enhancer 3000 Monitoring System at this time if in use.
4. Prepare tissue and sample for electroporation. Apply sample to tissue just before electroporation.
5. Remove the safety shield protecting the needles, place into the tissue, and deliver the electroporation pulse.
6. Discard the 2-needle array tip in a typical biohazard sharps container. Refer to your country's waste management organization for proper disposal practices.
7. Clean the 2-Needle Array Handle with a soft cloth or tissue. If necessary, moisten the cloth or tissue with a dilute detergent solution.

Note: The 2-Needle Array Tips are designed for single use. If re-using these electrodes, sterilize with ethanol or ethylene oxide. DO NOT autoclave. Maximum usage is three sets of pulses.

Appendix A: Specifications

2-Needle Array™ Electrode Electrical & Technical Specifications

Standard Capabilities*:

Voltage Range	0 to 500 VDC
Pulse Length/Time	
Constants Range	1 µsec to 99 msec
Pulse Number Range	1 to 99
Operating Temperature	5° to 40°C
Intended Use	Indoor use only
Relative Humidity	20 to 80%
Maximum Altitude	2,000 m (6,562 ft)
Pollution Degree	II
Insulation Category	CAT I

Physical Characteristics:

Model	530/531	532/533
Needle Spacing	10 mm	5 mm
Needle Length	20 mm	20 mm
Needle Material	Stainless Steel	Stainless Steel
Handle Length	8 cm	8 cm

Compatibility:

Generators	ECM® 630, 830 and 2001
Monitoring	The Enhancer 3000® Monitoring System recommended

*Notes: Depending on buffer composition and generator capability

Appendix B: Replacement Parts

Catalog No.	Model	Description
MA1 45-0167	530KIT	2-Needle Array Kit, 10 mm
MA1 45-0205	530	2-Needle Array Handle, 10 mm gap
MA1 45-0120	531	2-Needle Array Tip, 10 mm gap, pkg. of 6
MA1 45-0168	532KIT	2-Needle Array Kit, 5 mm
MA1 45-0206	532	2-Needle Array Handle, 5 mm gap
MA1 45-0121	533	2-Needle Array Tip, 5 mm gap, pkg. of 6
MA1 45-0059	VIP3000SC	The Enhancer 3000® Monitoring System

Appendix C: Troubleshooting

Please contact BTX Technical Service at any of the numbers listed below in the event of any failure.

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2-Needle Array



**The Enhancer 3000 Monitoring
System**

MA1 45-0059 (110V)

(Shown with communications
module not installed)