

## AgilePulse™

### IN VIVO SYSTEM TECHNICAL SPECIFICATIONS

#### MAXIMUM EFFICIENCY DNA VACCINATION DELIVERY

Effectively introduced DNA vaccines represent a powerful and safe means for stimulating an immune response that recognizes and eliminates target molecules in the body. However, traditional DNA vaccine delivery systems such as gene gun delivery electroporation suffer from poor efficiency. The BTX AgilePulse™ In Vivo System used in DNA Vaccination Delivery provides an intra-dermal electroporation solution to produce maximum transfection efficiency.

DNA vaccination through the dermal layer is preferred since it is an easily accessible site that is immunologically active. After direct injection of plasmid DNA in the dermal layer, a programmed sequence of electric pulses is applied through a miniature parallel-needle electrode array to promote cellular uptake and transfection. All cells in the surrounding tissue are transfected, including dendritic antigen-presenting cells and mesenchymal origin cells.

Gene expression simulates the immune system to respond to the secreted antigen. Gene expression in skin is 100-fold higher when delivery is enhanced by electroporation compared to simply injecting plasmid DNA.

#### FEATURES & BENEFITS

AgilePulse™ is well-suited for applications requiring high doses and robust immune responses such as gene therapy and cancer vaccines. AgilePulse™ includes a user-friendly, programmable waveform generator with patented Pulse Agile® technology and a miniature parallel-needle electrode array.

**Simple User Interface** – Touch screen user interface, USB key data storage, and Windows® Mobile 6.0 operating system. The system automatically stores a digitized record of all pulse parameters for quality control. EN 60601-1, EN 60601-1-1 EN 60601-1-2, UL60601-1 and CSA 601.1 compliant.

**Pulse Agile® Advantage** – Our patented Pulse Agile® technology combines a unique sequence of short, high-intensity pulses to open pores in cell membranes, followed by long, low-intensity pulses to further drive the DNA into cells via electrophoresis. The dual-phase of pulses improves efficiency while maintaining cell viability. The specialized use of Pulse Agile® waveform protocols has shown to significantly enhance antigen specific CD8+ T-cell response when standard protocols do not .

**Uniform, Reliable Electroporation** – AgilePulse™ parallel-needle arrays produce uniform electric fields across the treatment volume for a more thorough transfection of the tissue. Electrode impedance is monitored through software analysis to ensure reliable electrode placement in tissue each and every time.

**Simple, Fast Treatment** – Simple yet effective intra-dermal electrode design allows for shorter delivery times of less than a second. The electrodes provide a uniform pulse to cover and target larger areas of tissue using a single application.

**Optimal Design** – Miniature, 2-mm length needles easily penetrate the layers of skin and to target dermal skin cells for high efficiency gene delivery

**Safety** – Each needle electrode array comes with a safety cover and easy grip sides to make the electrode insertion procedure simple and safe.

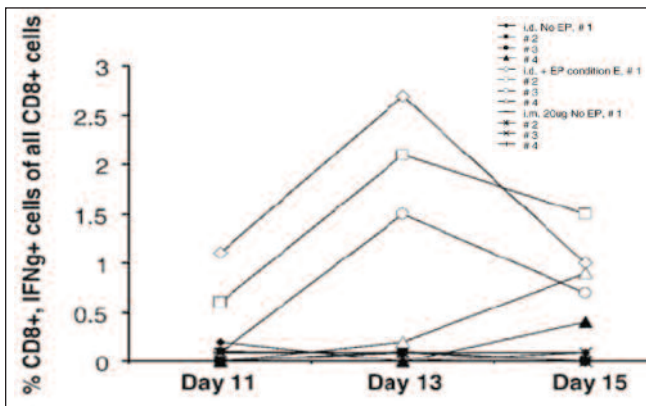
# AgilePulse™ TECHNICAL SPECIFICATIONS

## At a Glance – Electroporation Increases the Immune Response

Dermal delivery of DNA vaccine along with electroporation using the AgilePulse™ In Vivo System increases the immune response of PSA-specific CD8+ T cells over intradermal (i.d.) alone or intramuscular injection (i.m.), with or without electroporation (see figure below).

**Methods:** C57Bl/6 mice were immunized once with 10 mg pVax-PSA/20 ml PBS intradermally (i.d.) on each flank with or without electroporation (EP) or intramuscular (i.m.) in each TA muscle. Blood was collected on days 11, 13 and 15 and effector cells were stimulated for 4 h with 100 nM PSA-derived peptide psa65-73 or a control peptide GP33. The activated CD8+ T cells were quantified by intracellular cytokine staining for IFN $\gamma$  and analyzed by flow cytometry.

*Roos, A-K, et al., 2006 Molecular Therapy 13(2):320-327.*



## THE AGILEPULSE™ VACCINE DELIVERY SYSTEM INCLUDES

- AgilePulse™ Complete System (47-0400)
- AgilePulse Waveform Generator (47-0401)
- Footswitch for hands-free operation (Optional) (47-0320)
- Parallel-Needle Electrode Array, specify type:
  - 4 x 2 electrode array, 4 mm spacing (47-0040)
  - 6 x 2 electrode array, 4 mm spacing (47-0050)
- Electrode Connector Cable
- User Manual

## WAVEFORM GENERATOR SPECIFICATIONS

User Interface	Touch Screen Display, Footswitch
Voltage Range	50 to 1000 volts
Pulse Width Range	0.050 to 10 ms
Pulse Interval	0.200 to 1000 ms (5 kHz to 1 Hz)
Data Export	USB Flash Key
Dimensions (with handle)	32 cm w x 20 cm h x 40 cm (12.6 in w x 7.9 in h x 15.7 in)
Weight	25 pounds, 11.3 kg
Operating Temperature	10 to 40 oC
Mains Voltage	100 to 250 VAC
Fuse	5 Amp Slo-Blo®, 5 mm x 20 mm

## TECHNICAL & CUSTOMER SERVICE

For further references regarding specific applications and optimization, please contact BTX Technical Support:

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