



## Easy Vax™ Clinical Epidermal Electroporation System

Cyto Pulse™ Electroporation and Electrofusion Systems for:  
In vivo therapeutic delivery  
Gene therapy  
Immunotherapy  
Hybridoma production  
Vaccine delivery  
Nuclear transfer

mRNA delivery  
siRNA delivery  
plasmid delivery

### Highly Efficient DNA Vaccine Delivery

The recent promise of successful DNA vaccines has provided a breath of fresh air into advancing modern vaccination techniques. Loading genetic material directly to antigen presenting cells encourages the body to naturally jump start the human immune system, thus eliminating the costly need to produce artificial proteins. While classical protein and live virus vaccines have been criticized for long production lead times and safety concerns, the use of DNA as a protection agent is seen as inherently safe and inexpensive to mass produce. The main hurdle, being trail blazed at Cyto Pulse, is in making DNA vaccine delivery effective enough for field use around the world.

Electroporation technology has recently been shown to be the most effective form of DNA vaccine delivery, more than naked injection by hypodermic needle or ballistic particles utilized by gene gun<sup>1</sup>. However, due to electrical design constraints for muscular or even intradermal skin delivery systems, they are too large to be practical for mass immunization. First responders for example need a relatively inexpensive, easy to perform, and low pain solution to make deployment feasible. Cyto Pulse is solving this problem with the development of the portable Easy Vax™ vaccination system. Easy Vax™ is a portable electric field waveform generator for use in conjunction with disposable vaccine-coated needle arrays.

**Go Micro** – Several rows of micrometer length needles pack together to form a disposable delivery array. These short needle lengths target epidermal skin cells thus avoiding nerve endings to create a relatively pain-free patient experience. Vaccine parameters are stored electrically in an on-array smart chip and accessed automatically by the user interface, providing flexibility and prevention of multiple uses.

**What Cold Chain?** – Revolutionary technology advances made by Cyto Pulse allow the dry coating of DNA vaccines directly onto disposable micro-needle arrays, which are then sterile and individually packaged until administration. No additional hypodermic needles are necessary to deliver the therapeutic. DNA retains the desirable property of remaining stable even in non-ideal temperature conditions above room temperature. In contrast, all other vaccine delivery systems require a cold chain to preserve structural integrity of the vaccine while in storage.

**On the Move** – Reduced distance between micro-needle rows in Easy Vax™ disposable arrays results in a lower voltage requirement for achieving comparable electric fields with larger electrodes at higher voltage. Not only does this reduce perceived pain in the patient, but it also crosses a design threshold whereupon the pulse generator is shrinkable enough to be powered solely by battery. The Easy Vax system is designed in a comfortable handheld package for extended use.

**Pulse Agile® Advantage** – Considered to be the most efficient pulse delivery waveform for inducing antigen specific CD8+ T-cell response<sup>2</sup>, Cyto Pulse patented *Pulse Agile®* technology combines a unique sequence of short high-intensity pulses to porate cell membranes, followed by long low-intensity pulses to further transfer DNA vaccines into cells via electrophoresis.



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<sup>1</sup> Hooper, J.W, Golden, J.W., Ferro, A., King, A.D., 2007, Smallpox DNA vaccine delivered by novel electroporation device protects mice against intranasal poxvirus challenge. *Vaccine*, 25(10):1814-23.

<sup>2</sup> Roos, A.K., Moreno, S., Leder, C., Pavlenko, M., King, A. and Pisa, P., 2006, Enhancement of cellular immune response to a prostate cancer DNA vaccine by intradermal electroporation. *Mol Ther*, 13, 320-7.

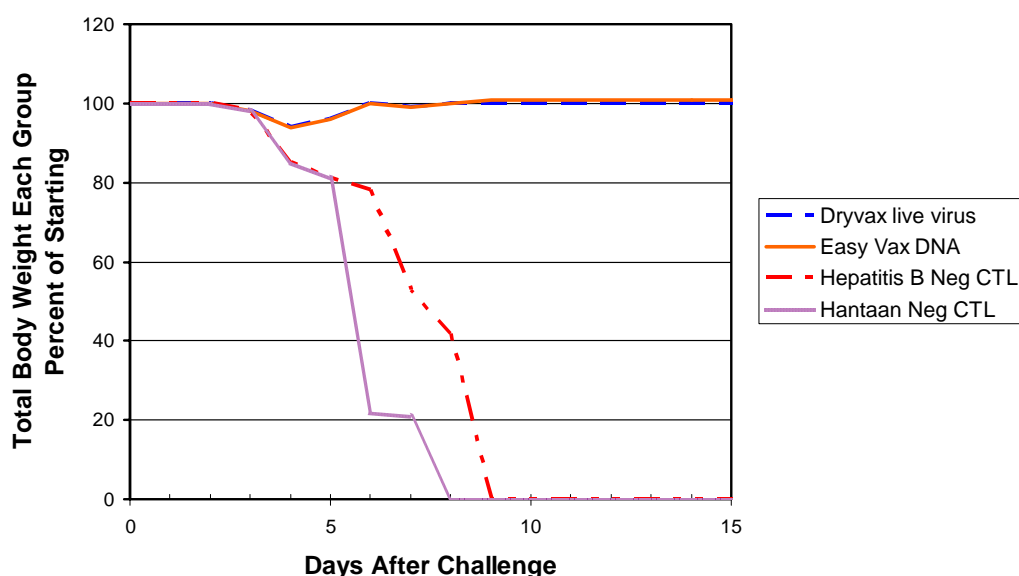
## At a Glance – Smallpox

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Cyto Pulse is currently developing a vaccination solution for Smallpox with members of USAMRIID and the National Institutes of Health. While smallpox has already been eradicated worldwide, the potential risk still remains of intentional malicious re-introduction. Therefore vaccine stockpiles must continue to be held in particular by the United States Department of Defense should an emergency situation arise. However, serious known side effects of the traditional live vaccinia virus Dryvax, including death, have opened up a new need for advanced technology such as DNA vaccines.

Through joint development, extensive mice and non-human primate studies have been conducted in preparation for clinical trials. Collected data so far has been remarkably encouraging and even further system optimizations continue to be made. The below figure represents a live smallpox challenge in mice observed over a fifteen day period. As can be ascertained, the Easy Vax™ vaccination performed identically to that of Dryvax and all mice survived.



## Specifications

Weight	17 oz (482 g)
Battery	Nickel Metal Hydride, Rechargeable
Vaccinations per Charge	Minimum 320 over 16 hrs of use
Pulse Amplitude	20 to 140 volts
Pulse Width	0.050 to 10 ms
Pulse Interval	0.200 to 1000 ms (5 kHz to 1 Hz)
User Interface	Liquid Crystal Display (LCD)
Data Access	Mini USB

## Cyto Pulse License Required

Cyto Pulse has patents, patents pending, and other intellectual property on the Easy Vax™ system and it is only supplied directly by Cyto Pulse under license agreement for clinical applications.

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