



**Derma Vax™ Clinical Evaluation Intra-dermal 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

**Maximum Efficiency DNA Vaccination Delivery**

Effectively introduced DNA vaccines represent a powerful and safe means to stimulate immune responses against a wide variety of potentially fatal diseases. DNA vaccines work in essence by educating the immune system how to recognize unwanted foreign agents in the body and ultimately remove them. Practicality of such vaccines, however, is still largely inefficient due to the inadequacy of existing delivery systems, intra-muscular electroporation being too painful and gene gun too inefficient. Derma Vax™ is an exceptional intra-dermal electroporation system that features solutions to both.

Derma Vax™ is best suited when high doses and robust immune responses are desired such as for gene therapy and cancer vaccines. Electric fields are delivered following local anesthetic administration to the patient and injection of a therapeutic. The Derma Vax™ system primarily targets the dermis layer of skin where a variety of cell types can be transfected including dendritic antigen presenting cells and mesenchymal origin cells. Regardless of which cells are transfected, the secreted antigen is internalized by local antigen-presenting dendritic cells.

Derma Vax has a 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.

**Therapeutic Coverage** – Advanced electric field modeling software utilized by Cyto Pulse to determine optimal placement of needles in electrode assemblies prevent the appearance of cold spots, i.e. area where effective electric field intensity is too low. The areas absent of electric field have insignificant uptake of DNA into cells thus reducing overall vaccine efficiency. Uniform electric fields created by Derma Vax™ needle arrays offer the necessary coverage to ensure thorough expression in the entire treatment volume.

**Shorter is Better** – Tiny 2 mm length needles targeting dermal skin cells translate into a vastly more tolerable patient experience when compared to available intra-muscular (IM) electroporation systems.

**Quickly Done** – A strategically simple yet effective intra-dermal electrode design allows for delivery times to the patient of less than a second. Without any complicated or cumbersome electric field switching schemes between needles to slow delivery, the desired treatment area is covered with every pulse.

**Pulse Agile® Advantage** – While Derma Vax™ increases the level of protein production by in vivo transfection 100 fold over that seen with naked DNA delivery, the specialized use of *Pulse Agile®* waveform protocols also significantly enhances antigen specific CD8+ T-cell response when other standard protocols do not<sup>1</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 drive DNA vaccines into cells via electrophoresis, maintaining viability along the way.

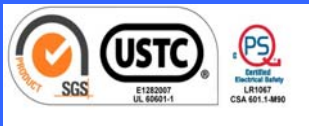


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<sup>1</sup> Roos, A.K., Moreno, S., Leder, C., Pavlenko, M., King, A. and Pisa, P., 2006, Enhancement of cellular immune response to a prostate cancer DNA vaccine by intradermal electroporation. *Mol Ther*, **13**, 320-7.

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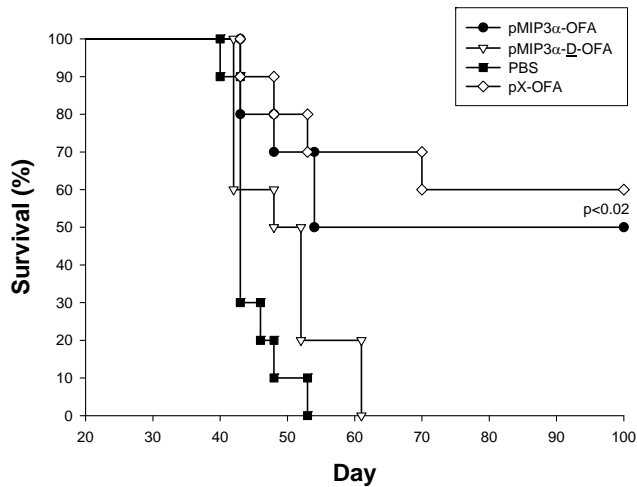
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## At a Glance – Lung Cancer

There are approximately 175,000 new cases of lung cancer each year in the United States alone. Correspondingly, there are approximately 163,000 deaths each year due to advancement of the disease. The strong correlation of deaths to incidence of new cases reflects the inability to treat lung cancer once it is metastatic; surgical removal of isolated primary tumors in the absence of metastatic cells is the only definitive cure in a limited number of cases. Thus, Cyto Pulse is collaborating with the National Institute on Aging (NIA) to develop a DNA vaccine solution based on an expressing oncofetal antigen/immature laminin receptor with chemokine fusion segment. This vaccine holds the ability to reduce the incidence of metastatic disease after surgery.

The figure below illustrates remarkable elimination of established tumors after immunization in an A20 (lymphoma) mouse model. While A20 is not itself a lung cancer model, it is a well defined aggressive tumor model of cancer cells that express the same OFA/iLRP, intimately resembling lung cancer.



## The Derma Vax™ Electroporation System Includes:

- CCEP-40 Waveform Generator
- IDA 4-4-2 or 4-6-2 Parallel row needle electrodes
- Electrode Connector Cable
- Footswitch for hands-free operation (Optional)
- Mobile Equipment Cart (Optional)
- User Manual

## Specifications

User Interface	Resistive Touch Screen Display, Footswitch
Pulse Amplitude	50 to 1000 volts
Pulse Width	0.050 to 10 ms
Pulse Interval	0.200 to 1000 ms (5 kHz to 1 Hz)
Data Access	USB Flash Key

- CCEP-40 Cabinet with handle 32 cm w x 20 cm h x 40 cm l  
12.6 in w x 7.9 in h x 15.7 in l
- Weight 25 pounds, 11.3 kg
- Operating temperature 10 to 40 °C
- Mains Voltage 100 to 250 VAC
- Fuse 5 Amp Slo-Blo®, 5 mm x 20 mm

## Cyto Pulse License Required

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

Specifications may change without notice