

CliniMACS Electroporator

For use with CliniMACS Prodigy

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Recap – Prodigy Validated Applications



CE BM-133 Enrichment

CE LP-34 Enrichment

CE LP-TCRab/19 Depletion

CE CCS-IFN Enrichment

CE LP-14 Enrichment

MoDC Generation

CAR T process

Electroporation - Applications

Scope

- Transient gene expression (mRNA)
- Gene knock out: Nucleases (ZnF, TALEN, CRISPR...)
- Gene integration
 - Transposase (Sleeping Beauty, piggybac...)
 - ds break induced homologous recombination: Nucleases (...)

Applications

- DC loading for antigen presentation
- CAR expression
- Expression of survival / migration / costimulatory factors ...
- Knock out of endogenous TCR
- Knock out of inhibitory signalling proteins
- Safety switch (thymidine kinase, caspase 9)?
- Gene therapy (HSCs)

Electroporation - Module Addition

Cells provided from external source or from CliniMACS Prodigy

Bag for cells

Bag for Electroporation material



Electroporation cuvette
(4 mm or 2 mm)

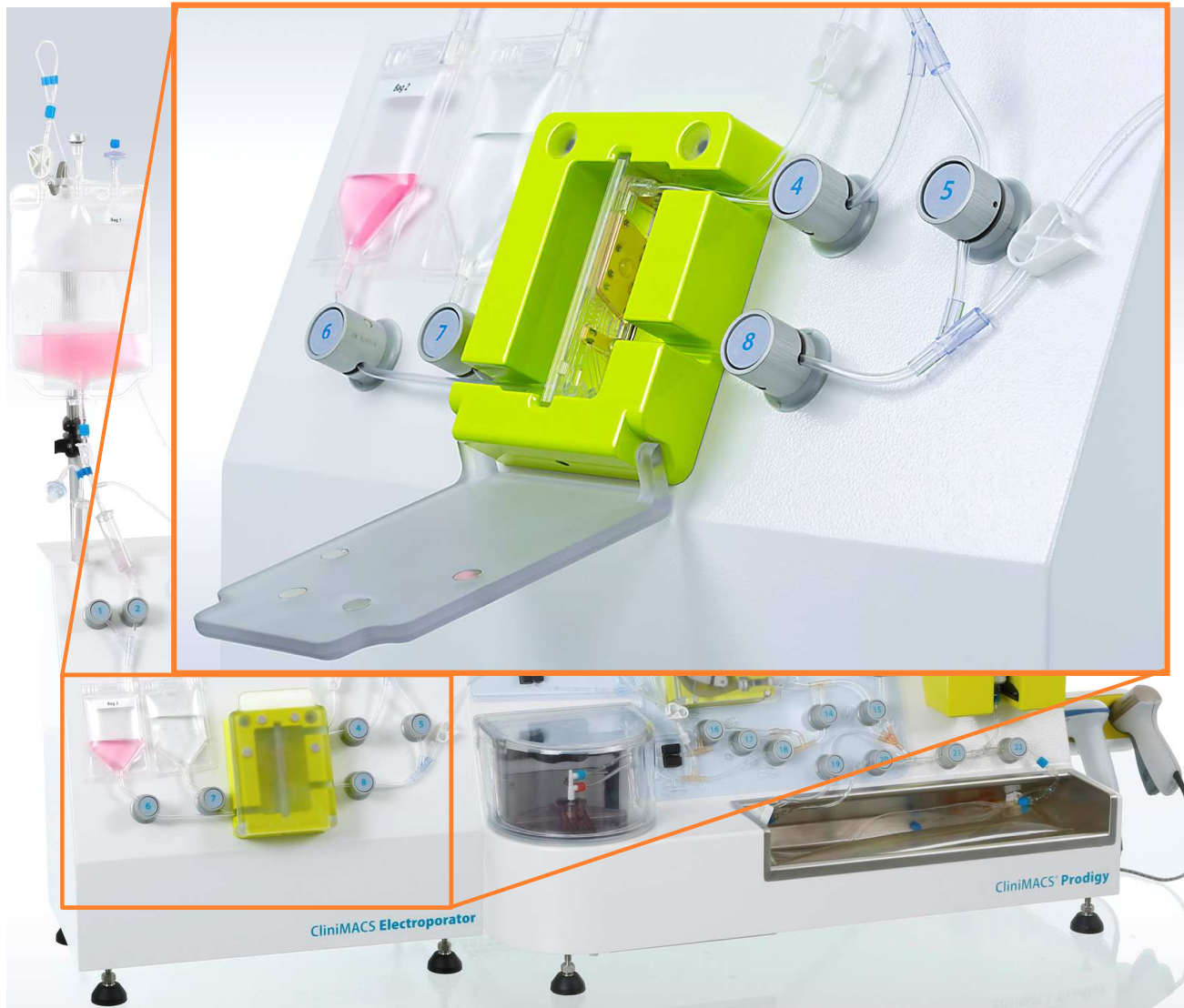
Two connections to Prodigy Tubing Sets

Validation - Test Cuvette Adapter (TCA)



- Included in delivery of the CliniMACS Electroporator
- Adapter to enable manual cuvettes to be used on Prodigy Electroporator
- Used for initial tests and demonstrations e.g. pulse optimisation, electroporation efficiency, viability etc.
- Easy upscaling for testing and transfer of electroporation parameters on the CliniMACS Electroporator
- Transfer of optimised conditions to tubing sets

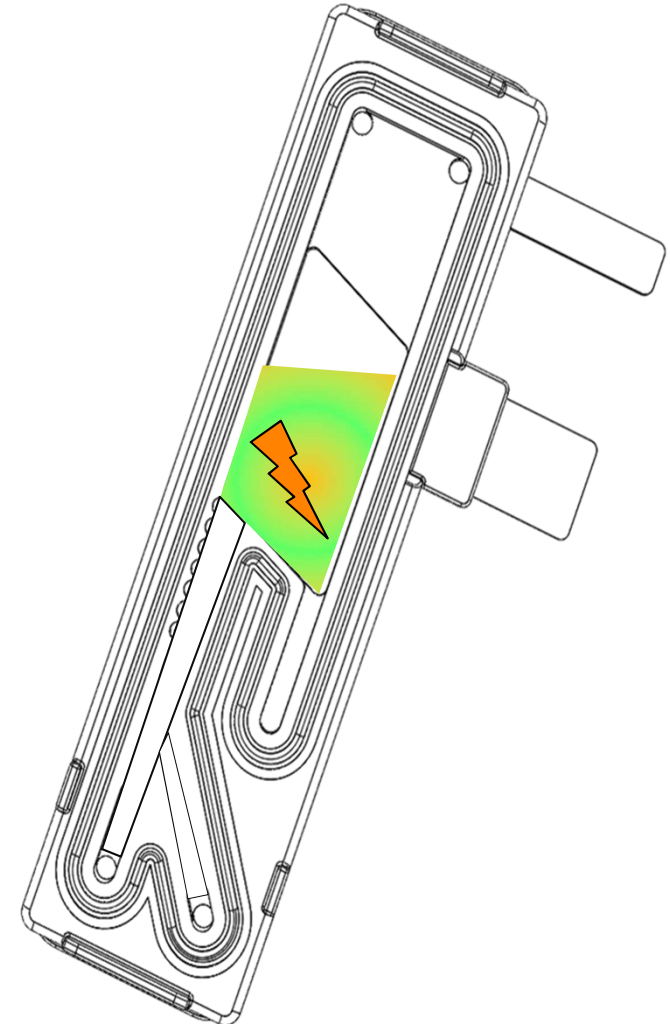
CliniMACS Prodigy and Electroporator - Tubing Set(s)



- EP-2 tubing set (2mm)
- EP-4 tubing set (4mm)
 - Electroporation cuvette (2 mm / 4 mm electrode distance)
 - 2 Cell bags
 - 1 material bag
- Combination of Prodigy and Electroporator tubing sets

CliniMACS Electroporator – Electroporation chamber

- CliniMACS Prodigy Controlled
- Closed system
- Automated, cyclic electroporation of 15-50ml
- Square wave pulse (single or double)
- Variable protocols and pulsing parameters (500V-1000V)
- **Wider facility of cell product manufacturing**
- **A broader platform for cell manufacturing**



Finding the right balance for parameter input

Sensitivity to electric pulse varies for different cell types

Optimal combination of electric field strength, time constant and ionic strength of buffer has to be determined for each cell type to produce maximum transfection rates and maintain cell viability!

CliniMACS Electroporator is parametrizable:

Voltage HV (0-1000V)

Duration HV pulse (10 μ sec-1sec)

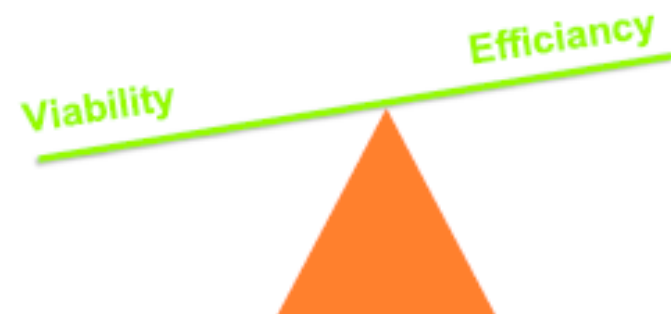
Voltage LV bank (50-500 V; condition: \leq Voltage HV)

Duration LV pulse (0 μ sec-1sec)

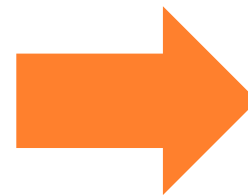
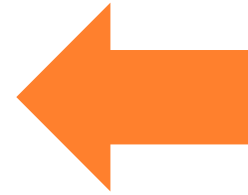
Pulse mode (burst y/n)

if burst mode = yes ; burst length (5 μ sec- durHV ; 1 μ sec sensitivity)

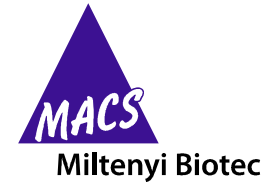
Pulse polarity (toggle y/n)



Electroporation - Process Indication by colour



Requirements and Solutions



Customer transfection needs	CliniMACS Electroporator solutions:
Viability > transfection efficiency	TCA for electroporation optimisation
Large amounts of cells to be electroporated	Automated loading for large volumes
Can be electroporated in a sterile, closed system	Sterile tubing sets
Cell expansion after electroporation	Cells directed to CCU
Enriched population	Process on Prodigy

Just like the Prodigy, the electroporator can be used from process development to clinical production.

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