

Technical specifications

The **Ntensify[®] midi flex** is an equipment suitable for GMP manufacturing of mRNA or saRNA at a scale that is ideal for clinical development and commercial production at scale.

In less than one day, the system can produce 0.1 up to 4 g of purified mRNA or 0.2 up to 8 g of purified saRNA in Quantoom's proprietary reactors using single-use consumables.



Specifications

	PER BATCH	PER YEAR
Input	1 to 40 mg of linear DNA	8.3 g of linear DNA
Output (drug substance)	0.1 to 4 g of purified mRNA 0.2 to 8 g of purified saRNA	Up to 832 g of purified mRNA Up to 1.66 kg of purified saRNA
Volume IVT	20 to 800 mL (1 well to 4 reactors)	Up to 166 L
Batch	1 per day	208 per year
Doses (50 µg for mRNA) (drug product)	from 1,600 to 64,000 doses	From 13M to 15M doses
Doses (50 µg for saRNA) (drug product)	from 32.000 to 1.3M doses	From 266M to 300M doses

Disposables

All disposables

- Are biocompatible according to following requirements: USP <87> Biological Reactivity Tests, In Vitro (Cytotoxicity) and/or USP <88> Biological Reactivity Tests, In Vivo, and/or ISO 10993-5 Tests for in vitro cytotoxicity and/or ISO 10993-6 Tests for local effects after implantation + ISO 10993-10 Tests for skin sensitization + ISO 10993-11 Tests for systemic toxicity.
- Are TSE/BSE free in accordance with EMA/410/01 Rev.3 (OJ C 73, 2011), Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products.
- Are latex-free.
- Do not contain Substances of Very High Concern (SVHC) above the applicable thresholds, in accordance with REACH Regulation (EC) No 1907/2006.
- Where applicable, irradiated components are sterilized by gamma irradiation at a minimum dose of 25 kGy.

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Installation and Utilities

The **Ntensify[®] midi flex** includes both transcription and purification steps, and have a small footprint of ~ 2 m²
Dimension: 2.7 m (width) x 2.4 m (height) x 0.8 m (depth), Weight: approx. 940 kg

The electrical requirements are limited to:

- 400 VAC / 50 Hz Triphase+N 16 Amp in Europe
- 480 VAC / 60 Hz Triphase+N 32 Amp in the US
- Consumption for a run of 1 reactor: 30kWh
- Instant consumption 2.5kW
- An UPS system is required to ensure continuous operation during electrical shortage

The utilities requirements are limited to:

- Wired IT/Ethernet Network for printer, data back-up, etc
- Integrated data storage. An external backup system might be required
- Fridges for reagent temporary storage
- Freezer for product long term storage

The systems can be operated in:

- Temperature: 20°C +/- 5°C
- Humidity: 60 RH +/- 20%
- Grade D with air change: min. 15 ACH (ISO8)
- Clearance: >1.2 m (front), 0.5 m (sides), >10 cm (top), >15 cm (back)
- Heat Dissipation of equipment: 1.5kW

Installation:

- Equipment to come partially disassembled
- Installation functional verification in 10 business days
- Door opening must be at least 0.93 m x 2 m