EQUIPMENT SPECIFICATIONS

DRT-LETI-DTIS-SEMIV-PRISM-26-09-002104

Edition date 21/10/2026

« MICRODISPENSER »

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Version:**1**, Revision: **A**

Nb pages: **11**

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I. Introduction

I.1 Overview of this document

This document is aimed to define conditions and requirements related to user and technical requirements specification for microarray spotter for the account of the CEA. The evaluation of the proposal will be done on the technical level, safety level (EU regulation) using a weighted scoring system based on the criteria specified in the tender rules.

I.2 Equipment Localization

The equipment must be delivered in the site of CEA Grenoble

I.3 Specificity of the Working place

The equipment will be installed in a clean room (class 10000) Temp 21°C, Hr 50%

I.4 Delivery

The supplier shall indicate the expected delivery time from the date of issuance of the purchase order (PO) by CEA. A delivery time of 3 months is preferred.

The equipment and all of its associated devices should be cleaned before shipment and be delivered in clean room compatible packaging and crating.

All crates must include tilt and shock indicators.

The delivery should be made between 8h and 16h30 from Monday to Friday.

I.5 Installation

CEA will establish, in collaboration with the supplier and his subcontractors, the global safety plan for the installation and the start of the equipment.

The supplier and his subcontractors should supply the safety material necessary to avoid the specific risks generated by their intervention (Personal Protective Equipment)

II. Customer – Service Provider Interface

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III. Confidentiality

The supplier commits to keep confidential all information and/or knowledges of the CEA related to the use of such equipment.

IV. Substrate Specification

The equipment must be capable of performing localized spotting on substrate.

The equipment shall be compatible with a broad range of target substrates, including:

- Standard microscope glass slides;
- Silicon and semiconductor substrates;
- Quartz and other inorganic substrates;
- Polymer-based films and membranes;
- Chemically or biologically functionalized surfaces;
- Biosensor surfaces;
- Microstructured and nanostructured substrates;
- Microfluidic chips and lab-on-chip devices;
- Custom-designed substrates and non-standard formats.
- 48-well plates (spotting at the bottom of the wells)

The equipment shall be equipped with a vacuum chuck/stage to securely and reproducibly hold substrates of different sizes and formats during the spotting process.

V. Technical specifications of the equipment

V.1 Equipment concept

The equipment shall be a compact benchtop microarray spotting system designed for installation and operation on a standard laboratory workbench.

The system shall be enclosed in a protective housing suitable for laboratory operation and compatible with installation in a controlled cleanroom environment.

The system shall be designed for the precise and reproducible non-contact dispensing of biological and chemical solutions onto solid substrates.

The equipment shall include a motorized positioning system providing X, Y and Z motion, with high positioning accuracy and repeatability.

The system shall enable immediate machine start-up without priming or preliminary start-up procedures.

The equipment shall provide a pre-pattern spot quality control and recovery module using a head-mounted camera to automatically evaluate test spots for presence, number, position and droplet size against predefined acceptance criteria. In case of deviation, the system shall allow automatic re-spotting, sample skipping or retry, with the possibility of manual adjustment of dispensing and washing parameters before resuming the programmed process. Skipped samples shall be automatically reprocessed to prevent gaps in the final pattern.

The system shall include an integrated vision and alignment system for accurate and reproducible substrate positioning, registration, spot localization and process monitoring.

The system shall be designed as a stand-alone benchtop instrument, including all hardware and control components required for routine operation.

The equipment shall provide a post-spot quality control and respotting module using a head-mounted camera to automatically verify the presence and position of spots on various substrates, with results documented in an automatically generated HTML report. Missing spots shall be identifiable and, optionally, automatically re-spotted. The system shall also allow adaptation of the image analysis to application-specific substrates and low-contrast samples.

The equipment shall allow custom spot pattern import via CSV files, including arbitrary spot coordinates in µm, and support SubPattern Spotting with up to 500 sub-spots and 16 concentric rings per sample. Spot distribution shall be configurable either automatically with defined pitch or manually, enabling unconventional layouts, replicate printing and alignment with predefined target structures.

The equipment shall provide a custom piezo waveform generator allowing user-defined actuation waveforms to optimize droplet formation and dispensing according to liquid properties. The system shall support a broad range of dispensing volumes, viscosities and protein concentrations, enabling precise adjustment of spot volume and reliable dispensing of samples that may be difficult to dispense using standard waveforms.

The equipment shall include a high-resolution head-mounted camera with an extended field of view, capable of imaging an entire well of a 96-well MTP in a single image, while providing sufficient resolution for accurate inspection of substrates and droplets.

The supplier shall specify the overall dimensions, weight and footprint of the complete system, as well as the environmental and utility requirements for installation and operation.

The equipment shall include an active humidity control system providing 99.9% germ-free humidification, dew-point-regulated relative humidity up to 70% RH with a CV ≤ 1%, without droplets or salt residues, with continuous monitoring and logging of humidity and temperature, and suitable for cleanroom operation.

V.2 Dispensing system

The system shall provide non-contact dispensing of biological and chemical solutions with high accuracy and reproducibility.

The equipment shall be supplied with one non-contact dispensing module suitable for the intended applications.

The system shall be compatible with alternative non-contact dispensing modules available from the supplier, allowing the dispensing technology to be changed or upgraded without replacement of the main platform.

The available dispensing technologies shall cover a droplet volume range from approximately 10 pL to 5 µL.

The dispensing system shall allow the relevant dispensing parameters to be controlled and adjusted through the system software.

The dispensing module shall provide automatic Z-height adjustment to maintain a controlled and reproducible distance between the dispensing element and the substrate surface.

The supplier shall specify, for each compatible dispensing technology, the droplet volume range, dispensing accuracy, repeatability, minimum achievable volume and compatible liquid properties.

The offer shall include three high-precision dispensing units, one for 300 pL max droplets, one for 2 nL max droplets, and one for 60 nL max droplets, as well as an additional dispensing head capable of dispensing volumes of up to 1 µL.

V.3 Spotting and dispensing path

The system shall allow the user to define and program customized spotting patterns according to the intended application.

The software shall allow the definition of spot positions, spot-to-spot spacing, spotting sequences and dispensing parameters.

The dispensing path shall be fully programmable, allowing the user to define the sequence and trajectory of the dispensing head between spotting locations.

The system shall allow the creation of multiple independent spotting patterns on a single substrate.

The dispensing path shall be optimized to minimize unnecessary movements of the dispensing head and reduce the overall spotting time.

The system shall provide accurate and reproducible positioning of the dispensing head according to the programmed spotting pattern.

The supplier shall specify the minimum achievable spot-to-spot spacing, positioning accuracy and positioning.

V.4 Substrate handling

The equipment shall be compatible with a broad range of substrates, including standard microscope slides, glass, silicon, quartz and polymer-based substrates and 48-well plates.

The system shall be suitable for spotting onto chemically or biologically functionalized and coated surfaces.

The system shall be capable of handling planar, microstructured and microfluidic substrates, within the dimensional and topographical limits specified by the supplier.

The system shall accommodate substrates of different sizes and formats, with the possibility of using custom substrate holders where required.

The supplier shall specify the minimum and maximum substrate dimensions and thicknesses, as well as the maximum acceptable substrate topography, compatible with the equipment.

The supplier shall specify the maximum number of substrates that can be processed in a single run.

V.5 Sample Handling

The equipment shall provide a flexible sample loading system suitable for handling multiple biological and chemical solutions.

The system shall be compatible with multiwell plates and individual microcentrifuge tubes. It shall accommodate at least 384-well microplates and if possible individual microcentrifuge tubes with volumes ranging from 0.5 mL to 2 mL, using appropriate racks or holders.

The sample loading system shall allow different sample source formats to be used without modification of the main equipment.

The system shall allow individual samples to be assigned to specific spotting positions, patterns and dispensing sequences through the control software.

The sample handling system shall minimize sample consumption and dead volume, while maintaining accurate and reproducible dispensing, including when using small sample volumes.

The system shall incorporate appropriate measures to minimize cross-contamination between samples during sample aspiration and dispensing.

The supplier shall specify the compatible multiwell microplate formats, tube types and racks, as well as the minimum recommended sample volume and typical dead volume for each compatible dispensing technology.

The supplier shall specify the compatibility of the sample handling system with aqueous solutions, biological samples, proteins, nucleic acids and other biomolecules.

V.6 Performance specifications

The equipment shall meet the following minimum performance specifications:

- Positioning resolution: ≤ 1 µm;
- Positioning accuracy in the X and Y directions: ≤ 5 µm;
- Droplet volume range for piezo-driven dispensing: 30 pL to 400 pL per droplet;
- Dispensing volume range for microdispensing: 10 nL to 5 µL per dispensed volume;
- Dispensing volume reproducibility: CV ≤ 2% under specified operating conditions.

The supplier shall specify the operating conditions and measurement methodology used to determine these performance values.

V.7 Vision and alignment

The equipment shall be equipped with an integrated optical vision system for substrate positioning, alignment and monitoring of the spotting process.

The vision system shall allow automatic or assisted alignment of the substrate prior to the spotting process.

The system shall allow the identification of reference marks or fiducial features on the substrate to ensure accurate registration of the spotting pattern.

The vision system shall enable the user to inspect and verify the position and quality of deposited spots during or after the spotting process.

The system shall allow large field image acquisition (and/or image combining to cover the spotted area) and storage for process monitoring and documentation.

The vision and alignment system shall be compatible with the different substrate types specified in Section I.4.

The supplier shall specify the optical resolution, field of view and alignment accuracy of the vision system.

V.8 Software and control

The equipment shall be operated through a dedicated and user-friendly software interface.

The software shall allow the user to create, modify, save and reuse spotting protocols.

The software shall allow the definition and management of:

- spotting patterns and spot coordinates;
- spotting sequences and dispensing paths;
- sample-to-spot assignments;
- dispensing parameters;
- substrate configuration and alignment;
- sample source configuration, including multiwell plates and individual tubes.

The software shall allow the user to import and export spotting patterns and relevant process data using commonly used file formats.

The software shall provide access to the relevant equipment parameters and allow monitoring of the spotting process and equipment status during operation.

The software shall allow the storage and retrieval of application-specific recipes, including dispensing, spotting and substrate parameters.

The system shall provide appropriate user access and data management functions to ensure traceability and reproducibility of experiments.

The software shall support the different dispensing technologies compatible with the equipment and allow the corresponding dispensing parameters to be configured and controlled.

The supplier shall specify the supported file formats, software architecture, data export capabilities and software update/support policy.

V.9 Computer material

In case of an equipment delivered with a PC computer, this one should have an operating system Windows 11 Enterprise or above and should support the antivirus SYMANTEC Endpoint Protection 11.

The computer should be connectable to a network and should have at least 3 USB ports available.

V.10 Environmental and operating requirements

The equipment shall be suitable for operation in a controlled cleanroom laboratory environment.

The supplier shall specify the required operating temperature and relative humidity ranges.

The equipment shall be designed for continuous and reliable operation under the specified environmental conditions.

The supplier shall specify all required utilities and connections, including electrical power, compressed air, vacuum and any other services, where applicable.

The equipment shall be compatible with the available laboratory infrastructure and shall not require dedicated infrastructure beyond the utilities specified by the supplier.

The supplier shall provide the overall dimensions, weight, footprint and installation requirements of the complete system.

The supplier shall specify the noise level of the equipment during normal operation.

The supplier shall specify any environmental restrictions or special requirements related to the operation of the equipment in a cleanroom.

The equipment must be compliant to 3 phases, N, 400V, 50 Hz or two phases 230V 50 Hz.

VI. Cleaning, maintenance and service

The equipment shall be designed to allow easy cleaning and routine maintenance of all components involved in the dispensing process.

The system shall provide appropriate procedures for cleaning and rinsing the dispensing system between spotting runs and/or when changing samples or dispensing technologies.

The cleaning procedures shall minimize the risk of cross-contamination and carry-over between successive samples.

Components requiring regular cleaning, maintenance or replacement shall be easily accessible to the user.

The dispensing components shall be replaceable without requiring major intervention on the main equipment.

The supplier shall provide detailed cleaning, maintenance and troubleshooting procedures, including recommended cleaning solutions and maintenance intervals.

The supplier shall specify all consumable and replacement parts required for routine operation, together with their expected lifetime and indicative cost.

The supplier shall specify the recommended preventive maintenance schedule and associated costs.

The supplier shall provide technical support and service for the equipment during its lifetime, including access to spare parts and software updates.

VII. Safety, EU and French regulation compliancy

As explained in the general information section, security is key for the selection of the equipment manufacturer. On the proposal, the supplier shall explain how the plan to address the safety aspect of the equipment and its compliancy to EU and French regulations.

1. The equipment including its safety enclosure must comply with the laws and regulations into force at the time of the delivery in Europe and France.
2. Especially, the equipment must fulfil the European Union (EU) and French safety regulations. Among them a non-exhaustive list is given here after
    - Machinery" Directive 2006/42/EC,
    - Electromagnetic Compatibility 2004/108/EC and 2004/40/EC
    - “RoHS2” 2011/65/CE Restriction of the use of certain Hazardous substances in electrical and electronic equipment,
    - Directive “Pressure” 97/23/CE,
    - Directive “Low tension” 2006/95/CE,
    - Low tension wiring will be compliant with NF C 15-100 regulation and implementing legislation
    - The conception, implementation and labeling of lasers should be in accordance with the standard EN 60825. The lasers should have the CE marking
3. To achieve this goal, CEA requests that the manufacturer proceed to the analysis by a CE advisor (such as VERITAS – APAVE, …) of a standard equipment in order to list all mismatches with CE regulations. This analysis will be paid by the equipment manufacturer.

4. At the Customer Site acceptance, the CE compliancy of the equipment must be validated by the CE advisor. This final review will be paid by CEA. The report must be free from any mismatched with the EU (European Union) and French regulations. In case of mismatch, the supplier of equipment must perform the modification of the equipment without any compensation from the CEA.
5. Commitment of the supplier to store in Europe based company all CE documents, the risk analysis and the contingency plan. The proposal must include the company name, address, contact name, telephone number, email. The absence, incorrect or partial information will automatically reject the proposal.
6. An CE certificate, edited and signed by the equipment manufacturer, must be available at the acceptances of the equipment.
7. An CE label attesting that the equipment fulfils the regulations must be fixed on the equipment.
8. The supplier will explain on the equipment documentation all appropriate individual and collective protections which are useful especially those related to mechanical and electrical risk.
9. The equipment must be free from asbestos, cadmium and lead.
10. The lift points of the equipment modules must be clearly identified.
11. For safety requirements, the equipment will include an enclosure with doors or a safety fence linked to emergency stop by safety interlocks. The enclosure will be designed to be connectable with factory exhaust. If it is necessary to open the door (ex: loading and unloading substrates) the entire equipment must be in a safe mode according to CE regulation.

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VIII. Documentation

One set of the manual will be supplied. The document will be written on clean room compatible paper and will contain the following chapter:

- Safety instructions during operations with special focus on servicing in **French**
- Instructions and operating manual. It will describe how to program and setup the equipment.
- Maintenance manual it will include:
  - The electric and pneumatic drawings.
  - Explanation in order to diagnose the problem in case of failure and also to allow possible future software upgrade.
  - A list with commercial reference of all components part numbers.
  - The method to adjust the equipment parameters and the mechanical parts.
  - A back-up copy of the software which enable to reload the PLC configuration in case of failure.
  - Adjustment procedures, mechanical, electrical.
  - Maintenance procedures, including preventive maintenance planning and the description of operations, with the relevant spare parts needed (reference and price).
  - Troubleshooting procedures based on experience on similar equipment.

An CE certificate, edited and signed by the equipment manufacturer.

IX. Acceptance conditions

IX.1 Customer site acceptance

The Customer Acceptance is pronounced at CEA in the presence of the technical representatives of CEA, and CE advisor paid by the CEA

Customer acceptance shall be granted following successful completion of the Site Acceptance Test (SAT) and confirmation that the equipment complies with the technical specifications and contractual requirements defined in this document.

Acceptance shall be based on the following criteria:

- Analysis review of the CE compliancy. No mismatch with the CE regulation is authorized
- Successful installation, commissioning and operation of the equipment at the customer's site;
- Compliance with the specified X–Y positioning resolution and accuracy;
- Compliance with the specified dispensing volume range and reproducibility;
- Successful operation of the vision and alignment system;
- Successful operation of the spotting and dispensing path programming functions;
- Compatibility with the specified substrate formats and sample source formats;
- Successful operation of the supplied dispensing module;
- Successful operation of the control software and associated functions;
- Delivery of all required documentation, operating procedures and maintenance instructions;
- Completion of the agreed user training.

As part of the acceptance test, the supplier shall demonstrate the ability of the equipment to perform localized and reproducible spotting of oligonucleotide solutions onto structured sensor chips. The supplier shall demonstrate the deposition of an oligonucleotide solution at a concentration of 10 µM onto structured sensor

chips comprising individual sensor structures with diameters ranging from 200 to 400 µm, with a center-to-center spacing ranging from 400 to 600 µm.

Any deviation from the specified requirements shall be documented and assessed by the customer. Customer acceptance shall not be pronounced until all critical non-conformities have been resolved.

The final acceptance shall be formally documented and signed by both the supplier and the customer.

At the issue of the Customer Acceptance, a report will be signed:

A report will be signed by the CEA and the supplier.

X. Training

After completion of the trainings, CEA staff must be able to setup and use the equipment to perform successfully the requested processes. As an option, the training may also cover preventive maintenance, troubleshooting, fault diagnosis and corrective actions for failures that may occur on the equipment.

X.1 Use of the equipment

The supplier undertakes to give a training on the use of the equipment to CEA employees. The number of days will be given by the supplier in its proposal

X.2 Maintenance and safety

The supplier undertakes to give a training on the first level maintenance to CEA employees. The number of days will be given by the supplier in its proposal

XI. Warranty

Notwithstanding the legal warranty, the equipment is warranted one (1) year(s) against defective materials, manufacture, assembly and operation, in accordance with the technical specifications, from the date of provisional acceptance.

As an option, the supplier shall provide a quotation for an additional one (1) year warranty under the same conditions.

This warranty covers parts (excluding consumables), labour, transport and travel.

During the warranty period, the supplier undertakes to intervene for repair within 72 hours (in case of line down) after receiving a fax or an email of request for assistance from the CEA

During the warranty period, the supplier undertakes to answer to question within 24 hours after receiving a fax or an email of request for assistance from the CEA.

In case of the unavailability, the warranty period is extended by a period equivalent to the downtime of equipment.

XII. Spare parts

All the components or equivalent parts must be available on the market for at least 10 years after the end warranty period.