



INVITATION TO SUBMIT A BID

for the small size public procurement for supplies

„ Nanoparticle Tracking Analyzer (NTA) instrument_TP16_510”

(“Public Procurement”) that is to be concluded in the procedure according to the Rules for applicants and beneficiaries (“Rules”) under the Research, Development and Education Operational Programme.

Name of the contracting authority:	Institute of Physics of Academy of Sciences of the Czech Republic, public research institution
Registered office:	Na Slovance 2, Praha 8, PSČ: 182 21
Identification No.:	68378271
Tax Identification No.:	CZ68378271
Person authorized to act on behalf of the contracting authority:	RNDr. Michael Prouza, Ph.D., director
Contact person:	David Pokorny
Telephone:	00 420 601 555 056
E-mail:	david.pokorny@eli-beams.eu

(“Contracting Authority”)

1. GENERAL INFORMATION

The subject matter of the Public Contract shall be funded from Research, Development and Education Operational Programme, the project reg. number: CZ.02.1.01/0.0/0.0/15_003/0000447,” name “Strukturní dynamika biomolekulárních systémů (Structural dynamics of biomolecular systems).“

- 1.1 The Contracting Authority does not follow the rules for public procurements set out in the act no. 134/2016 Coll., on public contracts awarding (“Act”), because the Public procurement is considered a small size public procurement within the meaning of Section 27 of the Act.
- 1.2 However, the award procedure is subject to Rules due to the fact that the Public Procurement is financed from the Research, Development and Education Operational Programme.



- 1.3 If the Contracting Authority uses references to the Act, it means that the Contracting Authority shall proceed analogically in relation to the Act. However, these links to the Act do not imply that the Public Procurement is awarded in accordance with the Act.

2. PUBLIC PROCUREMENT SPECIFICATION

The subject-matter of this Public Procurement is the delivery of a nanoparticle tracking analyzer instrument and provision of related services as specified in Annex No 3 hereto. The technology of Nanoparticle Tracking Analysis utilizes the microscope video records of light scattered by particles under Brownian motion to obtain the size distribution and concentration measurement of particles in liquid suspension (or emulsion and also nanobubbles). A laser beam is passed through a liquid cell with the sample, and the particles in suspension in the path of this beam scatter light and this light is captured via a microscope onto a digital camera. The camera operates at frame rate sufficient enough to capture a video file of the particles moving under Brownian motion. The software tracks each particle individually (all particles in a frame simultaneously) and calculates their hydrodynamic diameters using the Stokes-Einstein equation.

(“Products”)

- 2.1 The bidder shall include in its bid the description of the offered Products (e.g. product sheets, data sheets, etc.), so that the Contracting Authority may assess whether its requirements are fulfilled.

3. THE TIME AND PLACE OF DELIVERY

- 3.1 The supplier shall deliver the Products and carry out related services within 8 weeks from signature of the purchase contract.
- 3.2 The place of delivery is at the address: ELI Beamlines, Průmyslová 836, post code 252 41, Dolní Břežany, Czech Republic or other address in Dolní Břežany specified by the Contracting Authority prior to the delivery of Products.

4. BUSINESS AND PAYMENT TERMS

- 4.1 Business and payments terms and conditions for performing the Public Procurement are contained in the binding draft of the contract that forms Annex 2 hereto. After the most suitable bid placed within the Public Procurement is selected the Contracting Authority will conclude with the selected bidder the contract attached hereto as the binding draft contract with only missing parts completed in line with the selected bid (identification data of the selected bidder, price, etc.).
- 4.2 The bidder does not have to include the completed contract in its bid. By submitting its bid the bidder expresses its unconditional consent with wording of the contract which will be concluded after this procedure is completed.
- 4.3 If the bidder includes in its bid any additional business or legal terms or any reference thereto or the draft contract modified in any way such additional or contrary terms shall



be deemed irrelevant and the Contracting Authority will request that the bidder concludes the contract in line with art. 4.1 hereof.

- 4.4 If the selected bidder refuses to conclude the contract for Public Procurement performance in line with art. 4.1 hereof the Contract Authority will conclude the contract with a bidder on the second, third or other places always under the condition that all the bidders with higher ranking refused to conclude the contract.

5. THE DATE AND PLACE OF THE SUBMISSION OF BIDS

- 5.1 Bids must be submitted to the address: **Fyzikální ústav AV ČR, v. v. i. - ELI, DEP. 95 – David Pokorný, Za Radnicí 835, Dolní Břežany, post code: 252 41, Czech Republic, on 12. 7. 2018 until 14:00** at the latest.
- 5.2 Bids may be supplied by post, courier, or personally to the above mentioned address in working days between 8-15 hours. On the last day of the period for the submission for bids the bids may be submitted until **14:00** o'clock.

6. EXPLANATIONS REGARDING THE TENDER CONDITIONS

- 6.1 The supplier is entitled to require in written form explanations regarding the tender conditions from the Contracting Authority. The written request must be received by the Contracting Authority no later than 4 working days before the deadline for submission of bids.
- 6.2 The Contracting Authority sends explanations regarding the tender condition and possibly related documents no later than 2 working days after receiving written request from the supplier. If the request from the supplier is not delivered in time and despite this fact the Contracting Authority decides to provide explanations regarding the tender conditions, then the time limit in the preceding sentence does not need to be observed by the Contracting Authority.
- 6.3 The explanations regarding the tender conditions (including the exact wording of the request of the supplier) shall be provided to all suppliers at the same time and sent in the same manner as this invitation.
- 6.4 The Contracting Authority is entitled to provide explanations regarding the tender conditions without prior request. In such cases the Contracting Authority proceeds analogically according to the preceding paragraphs.
- 6.5 The Contracting Authority may modify the tender conditions before the deadline for submission of bids elapses. The modification has to be notified to the suppliers in the same manner as the tender conditions that was the subject of modification. If the Contracting Authority through explanations of the tender conditions makes modification of the tender conditions and the nature of the such modification requires it, the Contracting Authority shall reasonably extend the deadline for the submission of bids. In the event such a modifications, which may extend the range of potential bidders, the Contracting Authority will extend the deadline so that the potential bidders have the entire length of the original deadline for the submission of bid.



7. EVALUATION CRITERIA

- 7.1 Bids shall be evaluated on the basis of the lowest bid price criterion. The Contracting Authority shall (only for the purposes of evaluation and assessment) change bid prices into CZK. The exchange rate shall be the middle rate of Czech National Bank, which will be valid at the last day, on which bids could be submitted.
- 7.2 In the case that two or more bids contain the same lowest bid price, the time of the submission of the bid shall be a decisive element, i.e. the bid that was submitted earlier shall have priority over the bid that was submitted later.

8. BID PRICE

- 8.1 The Bidders must fill in the **COVER SHEET OF THE BID (ANNEX. 1 hereto)**. The bidder shall also fill in the currency, which must be EUR.
- 8.2 The bid price is the maximum price that cannot be exceeded and shall include all costs that the bidder shall incur during the performance of the Public Procurement.

9. FORMAL BID REQUIREMENTS

- 9.1 All bids must be submitted in writing in duly sealed envelope designated by the identification data of the bidder. The envelope must be designated by inscription “**DO NOT OPEN**” and by title of the Public Procurement „ **Nanoparticle Tracking Analyzer (NTA) instrument_TP16_510**”. On the envelope shall be address to which the Contracting Authority may send information regarding the Public Procurement.
- 9.2 The bid shall contain identification data of the bidder. This requirement is fulfilled by filling the cover sheet of the bid.
- 9.3 The bid must be submitted in Czech, Slovak or English language. This requirement is fulfilled if documents that by its nature cannot be in the required language are at least translated into one of the required languages.
- 9.4 All pages in the bid must be secured against unauthorized manipulation (e.g. bound by string and sealed), so that additional documents cannot be inserted nor any pages removed. The bid must be clearly readable, without any crossed words or other discrepancies.
- 9.5 The bidder must submit a bid in its original (paper) form.
- 9.6 The bidder must also include in the bid a CD-ROM, USB, or other generally used data carrier with an electronic copy of the bid (all paper documents in the bid).
- 9.7 If the bid is submitted jointly by several bidders (joint bid), a contact person authorized to represent all such bidders must be designated in the bid.
- 9.8 The bids must be structured in the following manner:

- a) **Cover sheet**



Bidders shall fill in cover sheet

b) **The description of the offered Products according to RSD**

10. **FINAL PROVISIONS**

- 10.1 The Contracting Authority is entitled to cancel the award procedure anytime prior to the signature of the contract.
- 10.2 The Contracting Authority does not allow alternative bids.
- 10.3 The Contracting Authority is entitled to change or supplement the provisions of this invitation.
- 10.4 The bidders shall bear all their costs connected with their participation in the award procedure initiated by this invitation.

11. **LIST OF ANNEXES**

- a) Annex 1 Cover sheet
- b) Annex 2 Draft of the contract
- c) Annex 3 Technical specification (RSD)

In Prague on26.6...... 2018

.....
RNDr. Michael Prouza, Ph.D., director



ANNEX 1

COVER SHEET OF THE BID - Part No. 1

Public procurement title: Nanoparticle Tracking Analyzer (NTA)
instrument_TP16_510

Contracting Authority: Fyzikální ústav AV ČR, v.v.i.
Registered office: Na Slovance 2, 182 21 Praha 8
Registration No.: 68378271

Person authorized to act on behalf of the bidder: RNDr. Michael Prouza, Ph.D., director

Contact person: David Pokorný

Telephone: 00 420 601 555 056

E-mail: david.pokorny@eli-beams.eu

Bidder:
Registered office:
Identification No.:
Tax Identification No.:
Person authorized to act on behalf of the bidder:
Contact person:
Contact address:
Telephone:
E-mail:

Bid price EUR without VAT

By submitting this bid the bidder expresses its consent to the binding draft contract of the Contracting Authority annexed to Invitation to bid for this Public Procurement and commits to conclude the contract with the Contracting Authority if this bid is selected as the most suitable one.

If other person than a statutory representative of the bidder signs this cover sheet respective authorization in simple copy shall be provided in the bid.

In _____ on _____

Company name
Authorised representative



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ANNEX 2

DRAFT OF THE CONTRACT



PURCHASE CONTRACT

This purchase contract ("Contract") was concluded pursuant to section 2079 *et seq.* of the act no. 89/2012 Coll., Civil Code ("Civil Code"), on the day, month and year stated below by and between:

- (1) **Institute of Physics of the Academy of Sciences of the Czech Republic, a public research institution,**

with its registered office at: Na Slovance 2, Praha 8, PSČ: 182 21

registration no.: 68378271

represented by: RNDr. Michael Prouza, PhD. – director

("Buyer"); and

- (2) _____,

with its registered office at: _____,

registration no.: _____,

represented by: _____

("Supplier")

(The Buyer and the Supplier are hereinafter jointly referred to as "Parties" and individually as "Party".)

WHEREAS

- (A) The Buyer is a public contracting authority and the beneficiary of a grant of the Ministry of Education, Youth and Sports of the Czech Republic for the project „*Structural Dynamics of Biomolecular Systems*,“ registration number CZ.02.1.01/0.0/0.0/15_003/0000447 ("Project"), within the Operational Program Research, Development and Education.
- (B) For the successful implementation of the Project it is necessary to purchase the Object of Purchase (as defined below).
- (C) The Supplier's bid for the public procurement entitled "Nanoparticle Tracking Analyzer (NTA) instrument_TP16_510", whose purpose was to procure the Object of Purchase ("Public Procurement"), was selected by the Buyer as the most suitable.



IT WAS AGREED AS FOLLOWS:

1. BASIC PROVISIONS

1.1 Under this Contract the Supplier shall deliver to the Buyer a nanoparticle tracking analyzer instrument and provide the Buyer with related services and requested documentation as stipulated in Annex 1 (Technical Specification) and Annex 2 (Supplier's Bid) to this Contract ("**Object of Purchase**"), and shall transfer to the Buyer ownership right to the Object of Purchase, and the Buyer shall take over the Object of Purchase and shall pay the Supplier the Purchase Price (as defined below), all under the terms and conditions stipulated in this Contract.

1.2 The Supplier promises to the Buyer that if for the fulfillment of the requirements of the Buyer under this Contract or the proper operation of the Object of Purchase are necessary other deliveries and activities not expressly mentioned in this Contract, the Supplier shall procure such deliveries or shall carry out such activities at its own expense without any effect on the Purchase Price.

2. THE PLACE OF DELIVERY

The place of delivery is: Fyzikální ústav AVČR, v.v.i / ELI-Beamlines, Za Radnicí 836, 252 41 Dolní Břežany, Czech Republic.

3. THE TIME OF DELIVERY

3.1 The Supplier shall deliver the Object of Purchase and shall carry out related activities within 8 weeks from the signature of this Contract.

4. THE OWNERSHIP RIGHT

The ownership right to the Object of Purchase shall pass to the Buyer upon signature of the Acceptance Protocol (as defined below) by both Parties.

5. PRICE AND PAYMENT TERMS

5.1 The purchase price for the Object of Purchase is EUR ("**Purchase Price**") without value added tax ("**VAT**"). VAT will be paid in accordance with the applicable legal regulations.

5.2 The Purchase Price cannot be exceeded and includes all costs and expenses of the Supplier related to the performance of this Contract. The Purchase Price includes, among others, all expenses related to the handover of the Object of Purchase and execution of related activities, costs of copyright, insurance, customs, warranty service and any other costs and expenses connected with the performance of this Contract.

5.3 The Purchase Price for the Object of Purchase shall be paid in EUR on the basis of a tax document – invoice, to the account of the Supplier specified in the invoice. The Supplier is entitled to issue the invoice after signature of the Acceptance Protocol. Copy of the



Acceptance Protocol must be attached to the invoice. The invoice must be delivered to the Buyer without undue delay after the signature of the Acceptance Protocol. The invoice shall have only the electronic form and shall be submitted to the email address: efaktery@fzu.cz.

- 5.4 The Buyer shall realize the payment on the basis of duly issued invoice within 30 days from its receipt. If the Supplier stipulates any shorter due period of the invoiced amount in the invoice such different due period shall not be deemed relevant and the due period stipulated herein applies. The invoice shall be considered to be paid for on the day when the invoiced amount is deducted from the Buyer's account on behalf of the Supplier's account.
- 5.5 The invoice issued by the Supplier as a tax document must contain all information required by the applicable laws of the Czech Republic. Invoices issued by the Supplier in accordance with this Contract shall contain in particular following information:
- a) name and registered office of the Buyer,
 - b) tax identification number of the Buyer,
 - c) name and registered office of the Supplier,
 - d) tax identification number of the Supplier,
 - e) registration number of the tax document,
 - f) scope of the performance (including the reference to this Contract),
 - g) the date of the issue of the tax document,
 - h) the date of the fulfilment of the Contract,
 - i) Purchase Price,
 - j) registration number of this Contract, which the Buyer shall communicate to the Supplier based on Supplier's request before the issuance of the invoice,
 - k) declaration that the performance of the Contract is for the purposes of a project "Structural Dynamics of Biomolecular Systems", registr. number CZ.02.1.01/0.0/0.0/15_003/0000447.

and must comply with the double tax avoidance agreements, if applicable.

- 5.6 In case that the invoice shall not contain the above mentioned information, the Buyer is entitled to return it to the Supplier during its maturity period and this shall not be considered as a default. The new maturity period shall begin from the receipt of the supplemented or corrected invoice to the Buyer.

6. SUPPLIER'S DUTIES

- 6.1 The Supplier shall ensure that the Object of Purchase is in compliance with this Contract including all its annexes



- 6.2 During performance of this Contract the Supplier proceeds independently. If the Supplier receives instructions from the Buyer, the Supplier shall follow such instructions unless these are against the law or in contradiction to this Contract. If the Supplier finds out or should have found out if professional care was exercised that the instructions are for any reason inappropriate or illegal or in contradiction to this Contract, then the Supplier must notify the Buyer.

7. **HANDOVER OF THE OBJECT OF PURCHASE**

- 7.1 Handover and takeover of the Object of Purchase shall be realized on the basis of an acceptance protocol ("Acceptance Protocol") after all conditions for issuing it are met (see mainly sec. 6 of Annex No 1 hereto).
- 7.2 If the Object of Purchase does not meet requirements of this Contract, the Buyer is entitled to refuse the takeover of the Object of Purchase. In such a case the Supplier shall remedy the deficiencies within ten (10) working days, unless Parties agree otherwise. The Buyer is entitled (but not obliged) to take over the Object of Purchase despite the above mentioned deficiencies, in particular if such deficiencies do not prevent the Buyer from the proper operation of the Object of Purchase. In such a case the Supplier and the Buyer shall list the deficiencies in the Acceptance Protocol, including the manner and the date of their removal (remedy). If the Parties do not reach agreement in the Acceptance Protocol regarding the date of the removal, the Supplier shall remove the deficiencies within ten (10) working days.

8. **WARRANTY**

- 8.1 The Supplier shall provide a warranty of quality of the Object of Purchase for the period of 12 months. If on the warranty list or other document is the warranty period of longer duration, then this longer warranty period shall have priority over the period stated in this Contract.
- 8.2 The warranty period shall begin on the day of the signature of the Acceptance Protocol by both Parties. If the Acceptance Protocol lists any deficiencies, the warranty period shall begin on the day, which follows the day, in which the last deficiency was removed.
- 8.3 The Supplier shall remove defects that occur during the warranty period free of charge and in the terms stipulated in this Contract.
- 8.4 If the Buyer ascertains a defect of the Object of Purchase during the warranty period, the Buyer shall notify the Supplier such defect without undue delay. Defects may be notified on the last day of warranty period, at the latest.
- 8.5 The Buyer notifies defects in writing via e-mail. The Supplier shall confirm within 2 working days from the receipt of the notification.
- 8.6 In the notification the Buyer shall describe the defect and the manner of removal of the defect. The Buyer has the right to:



- 8.6 In the notification the Buyer shall describe the defect and the manner of removal of the defect. The Buyer has the right to:
- a) ask for the removal of the defect by the delivery of new Object of Purchase or its individual parts, or
 - b) ask for the removal of the defect by repair, or
 - c) ask for the adequate reduction of the Purchase Price.

The choice among the above mentioned rights belongs to the Buyer. However, the Buyer is not entitled to request delivery of a new Object of Purchase or its parts in case of removable defects unless the same defect occurs repeatedly. The Buyer is also entitled to withdraw from this Contract, if by delivering the Object of Purchase with defects this Contract is substantially breached.

- 8.7 The Supplier shall remove the defect within 21 calendar days from its notification, unless Parties agree otherwise.
- 8.8 Parties shall execute a protocol on the removal of the defect, which shall contain the description of the defect and the confirmation that the defect was removed. The warranty period shall be extended by a period of time that elapses between the notification of the defect and its removal if the Buyer was prevented from using the Object of Purchase for the intended use due to the defect removal.
- 8.9 In case that the Supplier does not remove the defect within stipulated time or if the Supplier refuses to remove the defect for which it is responsible, then the Buyer is entitled to remove the defect at his own costs and the Supplier shall reimburse these costs within 10 days after the Buyer's request to do so.
- 8.10 The warranty does not cover defects caused by unprofessional manipulation or by failure to follow Supplier's instructions for the operation and maintenance of the Object of Purchase.

9. PENALTIES

- 9.1 If the Supplier is in delay regarding the delivery of the Object of Purchase, i.e. the Supplier breaches its duty to perform this Contract in time and due manner, the Supplier shall pay to the Buyer a contractual penalty in the amount of 0.05% from the Purchase Price (excl. VAT) for each (even commenced) day of delay.
- 9.2 If the Supplier is in delay with removal of a defect of the Object of Purchase, the Supplier shall pay to the Buyer a contractual penalty in the amount of 0.02% of the Purchase Price of the Object of Purchase for each (even commenced) day of delay.
- 9.3 The Supplier shall pay contractual penalties within fifteen (15) days from the day, on which the Buyer enumerated its claims. The payment of contractual penalties shall not affect the right of the Buyer to damages in the amount in which such damages exceed the contractual penalty.



9.4 Total amount of contractual penalty that the Buyer is entitled to claim for late delivery of the Object of Purchase shall not exceed 5 % of the Purchase Price.

9.5 The Buyer is entitled to unilaterally set off claims arising from the contractual penalties against the claim of the Supplier for the payment of the Purchase Price.

10. RIGHT OF WITHDRAWAL

10.1 The Buyer is entitled to withdraw from this Contract without any penalties, if any of the following circumstances occurs:

d) the Supplier is in delay with the fulfilment of this Contract and such delay lasts more than two (2) months

e) The Object of Purchase does not repeatedly fulfil the requirements stipulated in this Contract, in particular in Annex 1 (Technical Specification) and Annex 2 (Supplier's Bid)

f) the insolvency proceeding is initiated against the Supplier; or

g) the Buyer ascertains that the Supplier provided in its bid for the Public Procurement information or documents that do not correspond to the reality and that had or could have had impact on the result of the tendering procedure, which preceded the conclusion of this Contract.

11. SPECIAL PROVISIONS

By signing this Contract, the Supplier becomes a person obliged to cooperate during financial controls within the meaning of Section 2 letter e) of the act no. 320/2001 Coll., on finance control in the public administration, and shall provide to the Managing Body of the Research, Development and Education Operational Program or other control bodies access to all parts of the bid, Contract or other documents that are related to the legal relationship formed by this Contract. This duty also covers documents that are subject to protection in accordance with other acts (business secrets, secret information, etc.) provided that control bodies fulfil requirements stipulated by these acts.

12. FINAL PROVISIONS

12.1 This Contract is governed by the laws of the Czech Republic, especially by the Civil Code.

12.2 All disputes arising out of this Contract or out of legal relations connected with this Contract shall be preferable settled by a mutual negotiation. In case that a dispute is not settled within sixty (60) days, such dispute shall be decided by courts of the Czech Republic in the procedure initiated by one of the Parties.

12.3 The Supplier is not entitled to set off any of its claims or his debtor's claims against the Buyer's claims. The Supplier is not entitled to transfer its claims against Buyer that arose on the basis of or in connection with this Contract on third parties. The Supplier is not entitled to transfer rights and duties from this Contract on third parties.



- 12.4 All modifications and supplements of this Contract must be in writing.
- 12.5 If any provision of this Contract is invalid or ineffective, the Parties are bound to modify this Contract in such a way that the invalid or ineffective provision is replaced by a new provision that is valid and effective and to the maximum possible extent corresponds to the original invalid or ineffective provision.
- 12.6 This Contract is executed in four (4) counterparts and every Party shall receive two (2) counterparts.
- 12.7 Integral parts of this Contract are Annex 1 (*Technical Specification*) and Annex 2 (Supplier's Bid). In case of any discrepancy between provisions of this Contract and provisions of Annex 1 or Annex 2 provisions of this Contract shall prevail. In case of any discrepancy between Annex 1 and Annex 2 the more favorable option for the Buyer shall prevail.
- 12.8 This Contract shall become valid on the date of the signature of both Parties and effective on the day of its publication in the register of contracts according to the respective legal regulation.



IN WITNESS WHEREOF attach Parties their handwritten signatures:

Buyer

Signature: _____

Name: RNDr. Michael Prouza, PhD.

Position: Director

Date:

Supplier

Signature: _____

Name:

Position:

Date:



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ANNEX 1
TECHNICAL SPECIFICATION
(REQUIREMENTS SPECIFICATION DOCUMENT FOR THE PUBLIC PROCUREMENT)



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ANNEX 2
SUPPLIER'S BID

NOTE: the part of the bid of the Supplier submitted in the public procurement procedure which describes the Object of Purchase from the technical point of view to be attached here.

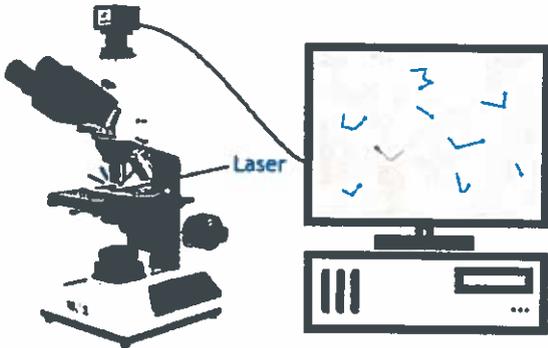


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ANNEX 3

TECHNICAL SPECIFICATION

Confidentiality Level	<i>BL - Restricted for internal use</i>	TC ID / Revision	00168895/C
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PBS code	<i>EBIO.EQBL.NANO.1</i>		
Project branch	<i>Engineering & Scientific documents (E&S)</i>		
Document Type	<i>Specification (SP)</i>		
<p>[RSD product category A]</p> <p>Nanoparticle Tracking Analyzer (NTA) instrument TP16_510</p>  <p>Keywords Microscope, nanoparticle, laser scattering</p>			
	Position	Name	
Responsible person	Researcher, RP4	Martin Přeček	
Prepared by	Researcher, RP4	Martin Přeček	

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Reviewed By

Name (Reviewer)	Position	Date	Signature
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Jakob Andreasson	RP4 team leader	NOTICE (RSD product category A)	
Martin Laub	Chief Engineer	NOTICE (RSD product category A)	
Ladislav Půst	Manager installation of technology	NOTICE (RSD product category A)	
Rachael Jack	Lab Manager, ELIBIO	NOTICE (RSD product category A)	
Roman Kuřátko	Facility Manager	NOTICE (RSD product category A)	
Veronika Olšovcová	Safety Coordinator	NOTICE (RSD product category A)	
Viktor Fedosov	SE & Planning group leader; Quality Manager	NOTICE (RSD product category A)	

Approved by

Name (Approver)	Position	Date	Signature
Georg Korn	Science and Technology Manager, Scientific coordinator of RP2-6	29.05.2018	

Revision History / Change Log

Change No.	Made by	Date	Change description, Pages, Chapters	TC rev.
1	M. Přeček, A.Kuzmenko	10.05.2018	RSD draft creation	A
2	M. Přeček, A.Kuzmenko	23.05.2018	RSD update, version for internal review	B
3	A.Kuzmenko	29.05.2018	RSD update, final version for approval	C

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1. Introduction

1.1. Purpose

This Requirements Specification Document (RSD) lists the technical requirements and constraints for the selection of a Nanoparticle tracking analyzer instrument. The technology of Nanoparticle Tracking Analysis utilizes the microscope video records of light scattered by particles under Brownian motion to obtain the size distribution and concentration measurement of particles in liquid suspension (or emulsion and also nanobubbles). A laser beam is passed through a liquid cell with the sample, and the particles in suspension in the path of this beam scatter light and this light is captured via a microscope onto a digital camera. The camera operates at frame rate sufficient enough to capture a video file of the particles moving under Brownian motion. The software tracks each particle individually (all particles in a frame simultaneously) and calculates their hydrodynamic diameters using the Stokes-Einstein equation.

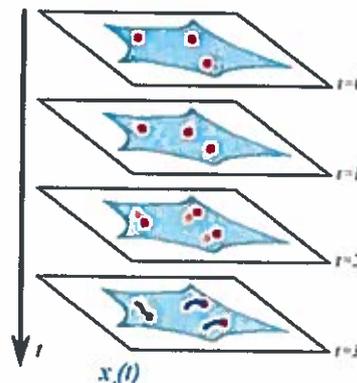


Figure 1: Example of the particles moving in liquid sample under Brownian motion over a time period.

1.2. Scope

This RSD contains all of the technical requirements: functional, performance and design, transportation and installation, safety and quality requirements for the following product (tender TP16_510): **Nanoparticle Tracking Analyzer (NTA) instrument**.

The NTA instrument is considered to be the standalone technology and will be placed in the ELIBIO bio-lab and the BioChemLab at the ELI Beamlines facility. The NTA instrument is registered in the PBS software under the following PBS code: *EBIO.EQBL.NANO.1 (1 pcs)*.

This Product is a **product Category A** according to the ELI Beamlines RSD categories. The category A is an Off-the-shelf Product without necessity of modifications and necessity to be subjected to a verification programme (review of design, inspection and testing) for ELI applications by the actual project

specifications. All verification activities performing by a supplier shall be executed in accordance with the supplier's plan of outgoing inspection and tests. The verification of all specified parameters listed in this RSD shall be undertaken by the supplier before delivery to the ELI Beamlines facility and the NTA Instrument shall be furnished with a declaration of conformity. Furthermore, NTA instrument will be subject to testing and verification after delivery and installation at ELI Beamlines premises to reflect their proper characteristics. All non-conformances (if any) must be addressed by the supplier in a timely manner.

1.3. Terms, Definitions and Abbreviations

For the purpose of this document, the following abbreviations apply:

Abbreviation	Meaning
AC	Alternating Current
CA	Contracting Authority (Institute of Physics AV CR, v. v. i.)
CPU	Central Processing Unit
DDR	Double Data Rate
ELI	Extreme Light Infrastructure
NTA	Nanoparticle Tracking Analyzer
PC	Personal Computer
RAM	Random Access Memory
RSD	Requirements Specification Document
NCR	Nonconformity Report

1.4. Reference documents

Number of document	Title of Document/ File
RD-01	00163567-B_1.2_Q_M_Guide_for_Instructions_for_Use_Ver-9_EN_fully_signed.pdf

1.5. References to standards

If this document includes references to standards or standardized/ standardizing technical documents the CA allows/permits also another equal solution to be offered. If a supplier offers another equal solution the CA shall not reject its bid, once the supplier by appropriate means in the bid proves that the offered supplies, services or works meet in an equivalent manner the requirements including references to standards or technical documents.

2. General requirement

REQ-023212/A

The Supplier shall deliver a nanoparticle tracking analyzer (NTA) instrument consisting of the following parts (for further details see chapter 3 below):

- an optical unit, comprising of
 - an optical microscope system,
 - a laser light source,
 - and a liquid cell with temperature control;
- a digital camera;
- a desktop PC station equipped with monitor, keyboard and a computer mouse;
- a computer software for controlling the optical setup and performing the analysis of the acquired camera footage.

3. Functional, Performance and Design requirements

3.1. General requirements

REQ-023213/A

The NTA instrument shall be capable of observing the movement of small particles suspended in a liquid sample in the concentration range between 10^6 to 10^9 particles per milliliter in the size range between 10 nm and 1000 nm. For a monodispersed sample (single-size population) the instrument shall be capable of determining the mean size of the studied particles with an accuracy of +/- 5 % (standard deviation).

NOTE: It is understood that performing the analyses of samples at these limits and achieving the sizing accuracy may be possible only for certain samples.

REQ-023214/A

All parts of the NTA instrument shall be able to operate with provided single phase electric power at 230 V AC and at 50 Hz with 16 A maximum current.

REQ-023215/A

The NTA instrument shall be able to work under the following conditions:

- 10 to 40 °C of ambient temperature;
- 10 to 90 % of humidity.

REQ-023216/A

The NTA instrument shall have the capability of optional upgrading its hardware and software.

3.2. Optical unit of the NTA instrument

3.2.1. Optical microscope system

REQ-023217/A

The optical microscope system of the optical unit shall be equipped with an appropriate optical objective capable of imaging suspended particles in a liquid sample.

REQ-023218/A

The optical microscope system shall be equipped with an appropriate two-axis translation stage if the measurement assembly requires from the user to actively locate the optimal focus in the horizontal direction.

REQ-023219/A

The optical unit shall make it possible to adjust the focus of the optical microscope system's objective to locate the portion of the beam traversing the liquid cell chamber which gives the best image.

REQ-023220/A

The NTA instrument shall be equipped with a removable optical filter for fluorescence imaging which can be introduced or removed into the optical unit during measurement procedure without the need to manually replace any other components.

REQ-023221/A

The NTA instrument shall be provided with at least one compatible long-pass cut-off filter capable of filtering out the scattered light of the 405 nm laser before it enters the digital camera, while letting red-shifted emitted fluorescence light through.

3.2.2. Laser light source

REQ-023222/A

The laser light source shall have a central wavelength of 405 nm at a laser power of > 30 mW.

REQ-023223/A

The enclosure containing the laser light source shall be classified as a class 1 product according to the standard ČSN EN 60825-1 (equivalent to EN 60825-1).

REQ-023224/A

The optical unit shall have the capability to be upgraded with laser light sources operating at different wavelengths than 405 nm.

3.2.3. Liquid cell

REQ-023225/A

The liquid cell shall be capable of working with non-corrosive aqueous samples as well as with sample suspensions in some non-aqueous solvents.

REQ-023226/A

The minimum liquid sample volume with which it is possible to perform an analysis shall be at most 700 microliters.

REQ-023227/A

The liquid cell shall be equipped with a system for temperature control in the range between 5 °C below the ambient temperature and up to +50 °C absolute.

REQ-023228/A

The liquid cell shall have the possibility of introducing the liquid samples into the cell from a syringe with a Luer fitting.

REQ-023229/A

The liquid cell shall have the possibility to use the loading syringe to non-destructively recover a loaded sample after analysis from the liquid cell.

REQ-023230/A

The liquid cell shall be capable of being disassembled, cleaned and reassembled.

3.3. Digital camera

REQ-023231/A

The digital camera shall be mounted on the optical unit in such a way to allow image recording of the tracks of individual particles.

REQ-023232/A

The digital camera shall be of sufficient sensitivity and resolution to allow the detection of biological particles in aqueous solutions down to the diameter of 30 nm.

REQ-023233/A

The frame rate of the digital camera shall be sufficient enough to capture a video file of the particles moving under Brownian motion to allow for detection, counting and sizing of particles within the general functional requirements specified above.

REQ-023234/A

The digital camera shall be capable of connecting its output into the control PC.

3.4. Control PC station

REQ-023235/A

The PC station shall be equipped with:

- at minimum 4 GB of DDR RAM;
- a storage drive with at least 750 GB capacity;
- a graphical card unit (may be integrated) with output compatible with the monitor;
- interface adapter for the input from the digital camera;
- a full keyboard (Czech or English) and a mouse;
- a monitor with a diagonal of at least 23 inch;
- connection cables necessary to connect all the peripherals mentioned above and the NTA instrument.

REQ-023236/A

The NTA instrument control software shall be installed on the PC station.

3.5. NTA instrument control software

REQ-023237/A

The NTA instrument control software shall be able to perform the following functions:

- real-time dynamic nano-particle visualization;
- particle-by-particle analysis;
- particle concentration and sizing;
- particle size distributions;
- data output to spreadsheet and video clip export.

REQ-023238/A

The NTA instrument control software shall have the capability to be used on different PC stations.

NOTE: The CA will install and run the software and control the NTA instrument on at least 2 other ELI Beamlines PC stations than the one that is provided. However, it can be so that a unique physical hardware key would need to be transferred to use the software on these other PC stations for the control of the NTA instrument.

REQ-023239/A

Any NTA instrument control software updates or technical support shall be provided by the Supplier without additional cost at least until October 2022.

4. Transportation and Installation requirements

REQ-023240/A

The transportation to the final destination at the ELI Beamlines, the installation and final verification of the NTA Instrument shall be conducted by the Supplier.

NOTE: The bid price will be considered by the CA as the final price, including both transportation and installation costs.

REQ-023241/A

The transportation and Installation procedures shall be discussed and can be reviewed by the CA's installation officer.

5. Safety requirements

REQ-023243/A

The Supplier shall supply a Declaration of Conformity or any other equivalent document legally recognized and accepted in the Czech Republic for each product type if the appropriate legislation determines the Supplier's obligation to have a Declaration of Conformity (or the equivalent document) for the purposes of a Product sale in the Czech Republic to fulfil the requirements of 2001/95/EC directive or applicable Czech law.

6. Quality requirements

6.1. General Quality requirements

REQ-023244/A

The Supplier shall provide Instructions for use (Product User Manual) as part of the delivered Product. The Instructions for use shall be written in accordance with standard ČSN EN 82079-1 (equivalent to EN 82079-1) and shall include the instructions and descriptions regarding the following:

- transport, handling and storage;
- installation, cleaning and calibration;
- general use of provided control software;
- safe operation and maintenance procedures.

NOTE: As an alternative to standard ČSN EN 82079-1 (equivalent to EN 82079-1) an internal ELI "Instructions for use" methodology can be used (see RD-01; chapter 1.4) which will be provided to the Supplier upon request.

REQ-023246/A

The Supplier shall provide a declaration of conformity with technical requirements defined by the product RSD and ensure completeness of the product.

REQ-023252/A

The Supplier shall provide a verification protocol outlining the results of any testing executed on NTA instrument after installation at ELI Beamlines premises to confirm specification conformity.

REQ-023247/A

The Supplier shall establish and maintain a nonconformity control system compatible with standard ČSN EN ISO 9001 (equivalent to EN ISO 9001).

6.2. Specific Quality requirements

REQ-023248/A

As part of the delivered Product, the Supplier shall provide certified sizing standards or reference materials (i.e., samples with particles of known size).

REQ-023249/A

The Supplier shall provide basic training at ELI Beamlines premises on how to operate, maintain and calibrate the NTA instrument. This training shall take place after the successful installation and final verification of the Product.

REQ-023250/A

In case of the NTA instrument repair by the Supplier within the validity of warranty, the Supplier shall recalibrate and verify the NTA Instrument once the repair is completed. The results of this process shall be provided to the CA.

6.3. Acceptance

Acceptance will be carried out by the CA upon installation and final verification of the NTA instrument at ELI Beamlines premises. The basis for acceptance will be verification protocol summarizing the overall verification results together with relevant documentation supporting the verification (see REQ-023243/A, REQ-023244/A, REQ-023246/A and REQ-023252/A).

In case of successful acceptance phase the CA will provide to the Supplier signed acceptance protocol. In case of unsuccessful acceptance stage the CA will provide to the Supplier Nonconformity Report (NCR) and process in accordance with REQ-023247/A will be applied.

REQ-023251/A

The Acceptance phase shall demonstrate the following:

- Final (installed) NTA instrument has been successfully verified by the Supplier and the results of this process has been documented in an appropriate way through verification protocol (see REQ-023252/A);
- All detected non-conformities have been solved in accordance with REQ-023247/A;
- Final NTA Instrument is free of fabrication errors and is ready for the intended operational use.