User, OHCA

From: Eric Hasel <eric.hasel@flex.com>
Sent: Thursday, April 13, 2017 3:38 PM
To: Lazarus, Steven; User, OHCA

Cc: Hansted, Kevin; Martone, Kim; Riggott, Kaila
Subject: RE: CT Scanner for Flex site in Manchester

Attachments: Flex Manchester CON Determination Form 2020.pdf; flex-cartagena-

m800-130-022017.pdf; zeiss_metrotom_en_60_022_0340viii.pdf

Steve,

Attached is the Form 2020.

Our controller has signed it given that we do not have a CEO or CFO on-site here in Connecticut. Please let me know if that is unacceptable.

I have also attached an information package about the machine (the model we are planning to purchase is the 800-130) as well as a copy of Zeiss' budgetary proposal in case either is helpful in determining the requirement for a CON.

Your help with this is greatly appreciated.

Regards, Eric

Eric Hasel Project Engineer/Quality Engineer 71 Utopia Road Manchester, CT, USA 06042

tel: +1 860 783 5107 mobile: +1 860 256-9541 email: eric.hasel@flex.com web: www.flex.com

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----Original Message-----

From: Lazarus, Steven [mailto:Steven.Lazarus@ct.gov]

Sent: Thursday, April 13, 2017 3:08 PM

To: Eric Hasel

Cc: Hansted, Kevin; Martone, Kim; Riggott, Kaila Subject: Re: CT Scanner for Flex site in Manchester

Good Afternoon Mr. Hasel,

As discussed over the phone, it would be best that you submit a completed CON Determination form to our office through ohca@ct.gov. This way we can make a formal determination as to whether a CON would be required for such acquisition and send you a written final action in about a week.

I'm copying OHCA's CON supervisor, the staff attorney by and OHCA's Director, so they are aware of your request in advance.

Thank you,

Steve

From: Eric Hasel <eric.hasel@flex.com> Sent: Thursday, April 13, 2017 1:26:44 PM

To: Lazarus, Steven

Subject: CT Scanner for Flex site in Manchester

Steven,

Thank you for taking the time to speak with me this morning.

While working on the CON Determination Form 2020 I received a call-back from Mr. Lenworth Williams with the DEEP.

He explained the registration process for a device like we are purchasing and said that because it is an industrial device only, it does not need require a CON (as it would if it were for a medical use).

Ultimately, this device will be used only as a sophisticated means of measuring small plastic parts.

I hope this is accurate, and I will follow the path that he recommended.

Please advise if you disagree or think that we should or need to still submit the CON determine form for documentation purposes.

Thank you, Eric

[cid:image003.png@01D22606.4218B360] Eric Hasel Project Engineer/Quality Engineer 71 Utopia Road Manchester, CT, USA 06042 tel: +1 860 783 5107 mobile: +1 860 256-9541

email: eric.hasel@flex.com<mailto:eric.hasel@flex.com>

web: www.flex.com<http://www.flex.com/>

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State of Connecticut Office of Health Care Access CON Determination Form Form 2020

All persons who are requesting a determination from OHCA as to whether a CON is required for their proposed project must complete this Form 2020. The completed form should be submitted to the Director of the Office of Health Care Access, 410 Capitol Avenue, MS#13HCA, P.O. Box 340308, Hartford, Connecticut 06134-0308.

SECTION I. PETITIONER INFORMATION

If this proposal has more than two Petitioners, please attach a separate sheet, supplying the same information for each Petitioner in the format presented in the following table.

Tagatal III and the Tagatal III and the Company	Petitioner	Petitioner
Full Legal Name	Advance Mold and Manufacturing, Inc.	Papara "
Doing Business As	Vision Technical Molding	
Name of Parent Corporation	Flex (formerly Flextronics)	
Petitioner's Mailing Address, if Post Office (PO) Box, include a street mailing address for Certified Mail	71 Utopia Road, Manchester, CT 06042	
What is the Petitioner's Status: P for profit and NP for Nonprofit	P	Searches describes describes of the property of the describes of the search of the sea
Contact Person at Facility, including Title/Position: This Individual at the facility will be the Petitioner's Designee to receive all correspondence in this matter.	Eric Hasel Quality Engineer/Project Engineer	

Contact Person's Mailing Address, if PO Box, include a street mailing address for Certified Mail	71 Utopia Road, Manchester, CT, 06042	
Contact Person's Telephone Number	860-783-5107	
	non-polyleter and a second	
Contact Person's Fax Number		
Contact Person's e-mail Address	Eric.hasel@flex. com	

SECTION II. GENERAL PROPOSAL INFORMATION

- a. Proposal/Project Title:: Purchase and install of Zeiss Metrotom 800-130 CT Scanner
- b. Estimated Total Project Cost: \$550,000.00
- c. Location of proposal, identifying Street Address, Town and Zip Code: <u>20 Utopia Road</u>, Manchester, CT 06076
- d. List each town this project is intended to serve: Manchester
- e. Estimated starting date for the project: <u>01-May-2017</u>

SECTION IV. PROPOSAL DESCRIPTION

Please provide a description of the proposed project, highlighting each of its important aspects, on at least one, but not more than two separate 8.5" X 11" sheets of paper. At a minimum each of the following elements need to be addressed, if applicable:

- 1. If applicable, identify the types of services currently provided and provide a copy of each Department of Public Health license held by the Petitioner.
- 2. Identify the types of services that are being proposed and what DPH licensure categories will be sought, if applicable.
- 3. Identify the current population served and the target population to be served.

1. Advance Mold and Manufacturing, Inc dba Vision Technical Molding is an injection mold manufacturing company and custom injection molder.

We are a wholly owned Flex (formerly Flextronics) company within that corporation's "precision plastics" division. Our molding facility (Vision Technical Molding) serves the medical industry almost exclusively (~98% of our business), producing injection molded plastic components and offering ancillary assembly (post-molding) operations to our customers where applicable. Vision is an ISO 13485 certified and FDA registered company.

We do not currently possess any Department of Public Health licenses.

2. The piece of equipment that we are attempting to purchase and operate at our Manchester facility is a Zeiss Metrotom 800-130. This is a CT (computed tomography) Scanner machine which uses x-ray technology to create highly accurate 3 dimensional "point cloud" images of scanned components. This is a highly accurate metrology (measurement) tool allowing the measurement and analysis of complex plastic parts (including their internal geometry which otherwise would require the sectioning (and destruction) of the subject parts to obtain).

The CT Scanner will allow us to expand the profile of services which we can offer to our customers in-house. Currently we sub-contract this type of inspection on very complex molded components during our mold qualification/validation processes as necessary, or compromise with less technological inspection methods.

3. Our customer base includes medical/pharmaceutical companies such as: Alcon, Becton Dickenson, Halyard Healthcare, NP Medical, Smiths Medical, Avanir Pharmaceuticals and others. Our growth includes new programs with Insulet and Eli Lilly.

Summary:

The purchase of Advance Mold and Mfg and Vision Technical Molding by Flextronics (now Flex) in 2014 was part of a series of such purchases to build the corporation's footprint in the Precision Plastics (and Medical) industry. Significant investments have been made in the growth of the Manchester, CT site to better serve our customers, and the addition of a CT Scanner will continue to add to the technology portfolio that we can offer our customer base within the medical and pharmaceutical OEM communities.

CT Scanning will give us a competitive edge over many of our competitors due to its high degree of precision and accuracy, and will expand our capabilities to conduct complex measurements in-house. We have out-sourced approximately \$90,000 in metrology in each of the last two calendar years and this piece of equipment will allow us to conduct most or all of that inspection internally.

SECTION V. AFFIDAVIT

(Each Petitioner must subr	nit a completed Affi	davit.)	
Petitioner: Advance	Mold and	Mfg, Inc.	
Project Title: Parchase and	Installation of	Ziss Metatom	800-130
I, Nicole Brooks (Name)	,	(Position - CEO	or CFO)
of Adocuce Mold & M. (Organization Name)	anufactory IND	eing duly sworn, depose	and state that the
information provided in this C	CON Determination for	orm is true and accurate	to the best of my
knowledge.			
Signature Mach		<u>4//3//7</u> Date	20 F 8 20 F 8 20 T 10 2 2
Subscribed and sworn to be	fore me on <i>April</i>	1 13th 2017	23 1350
Parbare	Lefto		ya yari
Notary Public/Commissioner	r of Superio / Court		
My commission expires:	3-31-2026		

flex

71 Utopia Road
Proposal For: Manchester, CT 06042
Edgardo.cartagerna@flextronics.com

8607835147

Attention of: Edgardo Cartagena
Quality Engineer of Metrology

Proposal Number: #66355

Date: 2/3/2017

Christopher Daly
Regional Sales Manager
Carl Zeiss Industrial Metrology, LLC.
Submitted by: 6826 Kensington Rd
Brighton, MI 48116
Phone: 7047796360
E. mail: christ dalv@zeiss.com

E-mail: chris.daly@zeiss.com





Proposal Number: #66355

Date: 2/3/2017

Description & Pricing

Description SKU

METROTOM

METROTOM 800 130kV

- For Non Destructive visualization and measurement of hidden internal artifacts
 - · Quality control blueprint layouts
 - 3D visualization and Reverse engineering
 - Material and Assembly Analysis
 - Defect Control Porosity analysis
- MPE system accuracy per VDI / VDE 2630 1.3, from 18 22 Deg C, is
 - Distance Measurement: MPESD = 2.9+ L/100 mm
 - Size Measurement:MPEPS=3 microns
 - Form Measurement:MPEPF = 4 microns
 - Overall Measurement (Distance, Size & Form): MPEE =6.9 + L/100 microns
- Objects must fit in an imaginary cylinder that is 170 mm Wide x 150 mm High.
- CAA corrected system calibration with infinitely adjustable magnification.
- Operator can view live images during scanning.
- Includes license for V3.2 METROTOM Operating System, VAST CT scanning and beam hardening (scattered radiation correction) software.
- Includes 1536 x 1920 pixel flat panel detector. (127 um pixel pitch)
- Includes PC-bonded license of CALYPSO CNC Software and SMA.
- Includes PC-bonded license of CALYPSO METROTOM Software and SMA.
- Includes highly integrated reconstruction data system, consisting of HP Z840
 Reconstruction Workstation with 2 nVidia Tesla GPUs, HP E272q 27" diagonal
 Elite monitor, keyboard and speakers, switch-set with patch cables, installation
 and system test.

Estimated Delivery: 12-16 weeks after receipt of order

Controller

Zeiss M800 Controller with metal cable trays. (Same 120V compatible, industrial 32bit, digital controller used on many Zeiss CMMs)



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611620-6661-000

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660032-0000-000

660032-0000-315

Services

Our service technician will supervise the riggers while the crates are opened and the components are spotted within your facility. The technician will then install, test & calibrate your METROTOM. You will be provided with a hardcopy of the calibration report.



636506-0000-100

Packaging

The Metrotom is crated in a highly protective & secure overseas shipping package to protect the contents from salt water seafreight challenges. The crate includes shock watch sensors to monitor the complete journey.

600006-0900-000



Accessories

Much like CMM styli are qualified using a reference sphere, users qualify the Metrotom on a weekly basis using a reference artifact. Shipped in a custom made, foam lined transportation case.



636506-9830-000

Metrotom Reconstruction System

The multi-part seperation module add-on to METROTOM OS 3.0 automatically separates parts scanned together into individual files. The files can then be imported into CALYPSO or VG StudioMax for individual analysis.



661401-0300-300

Metrotom Data Analysis Systems

CT Data analysis can be performed using the ZEISS CALYPSO and/or the Volume Graphics StudioMax software. While both of these products can be installed on the same computer, it will limit access to one or the other. Our recommendation is to install CALYPSO on its own workstation.

This bundle includes the following:

- HPZ840 Workstation running Windows 7 64bit Operating System
- 27" HP Elite E272g Monitor
- · Keyboard and Speakers
- · Installation and System Test



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CT Data analysis can be performed using the ZEISS CALYPSO and/or the Volume Graphics StudioMax software. While both of these products can be installed on the same computer, it will limit access to one or the other. Our recommendation is to install VG StudioMax on its own workstation.

This bundle includes the following:

- HP Z840 Workstation running Windows 7-64 Operating System
- nVidia Tesla GPU (2 Included)
- Frame Grabber Card (614303-8001-000)
- HP 27" diagonal E272q Elite Monitor
- Switch-Set with patch cables
- Keyboard and Speakers
- Installation and System Test



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CALYPSO Software

CALYPSO Metrotom Value Analyzer bundle allows you to create CALYPSO measurement programs and product measurement reports from your CT data. The bundle includes these software programs, each with a dongle license

- CALYPSO Metrotomography

660001-0602-315 660001-0602-000

- CALYPSO CNC
- CALYPSO Curve
- CALYPSO PCM
- CALYPSO STEP

Plus

- a portable security key
- a one year software maintenance agreement for each software license

METROTOM OS V3.0 software is required and must be purchased separately.

Metrotom VG StudioMax Software

StudioMax Cast & Mold Enhanced software bundle includes a dongle license for the

- Coordinate Measurement Module, for advanced surface determination.
- Nominal/Actual Compare Module, for directly comparing measured data with CAD models.
- Wall Thickness Analysis Module, for automatically localizing areas with insufficient or excessive wall thickness or gap width.
- Porosity/Inclusion Module, to locate pores, holes, and inclusions within castings and moldings and get detailed information about these defects
- Enhanced Porosity/Inclusion Module, so you can run your non-destructive 2D defect analysis

of castings directly on CT slice images.

- A one year software maintenance agreement (SMA) for all software. Second year SMA

available directly from Volume Graphics at www.volume graphics.com or 704-248-7736.

It's made for

- aluminum castings, mainly for the automotive industry;
- users who need non-destructive 2D defect analysis of castings directly on CT slice images according to P201/VW50097 or New P202/VW 50093 specifications

Pallet Fixturing Options

Pallet with magnetic mount for METROTOM 800

- pallet with 6 adhered, hardened stainless steel balls
- outside diameter 170 mm
- aluminum material, naturally anodized
- 3 pot magnets on reference diameter 32 mm
- crosshairs on upper side of pallet
- weight approx. 500 g

Training

METROTOM CALYPSO Training at Customer Location

- Learn to use CALYPSO to inspect parts that have been scanned on the METROTOM
- Four (4) days on-site. Maximum of three (3) participants
- · Pricing includes travel and expenses for ZEISS Trainer
- Prerequisite: METROTOM OS Class
- Training credits expire 90 days after machine installed (when applicable)



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669002-0300-002



626140-7210-010



611501-2627-020

METROTOM Operating System (MOS) Training at Customer Location

- Learn to safely operate the METROTOM, including how to fixture parts and set-up the METROTOM OS to scan parts
- · Hands-on class working with your parts
- Three (3) days on-site. Maximum of three (3) participants
- · Pricing includes travel and expenses for ZEISS Trainer
- · Prerequisite: None
- Training credits valid for 90 days from date of installation (when applicable)



611501-2627-040

METROTOM Calibration

First year maintenance program includes one visit at end of first year to

- Remove covers, secure machine cabling and provide a detailed cleaning and visual inspection of components
- Inspect mechanics for wear (replacement of parts not included)
- X-Ray system warm up check and lifetime check
- Check and adjust mechanical system
- Radiation safety test on the METROTOM with certificate
- Check of safety devices and cabinet
- Optimization of machine positioning and measuring system via electronic adjustments on reader heads and drives
- Calibration and adjustment of the X-ray system including detector
- Accuracy verification measurement using METROTOM Check Micro

Includes a calibration certificate indicating meet/not meet original factory specifications. Includes all labor, travel and expenses.

Metrotom Warranty

One Year Limited Warranty



000000-2196-866



Quoted Price (USD): \$520,909.00

(Plus all applicable state sales tax and shipping costs)

Note: We reserve the right to substitute components of equivalent or greater capability/value without notice.

Options

Description	sku	Price
Metrotom OS Virtual Horizontal Detector Add-on	661401-0300-302	\$7,500.00
Metrotom OS Material Mix Add-on VG StudioMax 3.0 Complete Software Bundle Pallet with magnetic mount for METROTOM 800	661401-0300-301 669002-0300-004 626140-7210-010	\$14,950.00 \$71,700.00 \$665.00

Proposal Validity and Delivery

Validity

This proposal is valid for 90 days from the proposal date. State and local taxes, where applicable, are not included. Prices may be higher if not ordered as a total system. To the best of our knowledge, the unit conforms to the safety requirements of the Occupational Safety and Health Act (OSHA), having been built to the standards of the VDE (Society of German Electrical Engineers) which coincides with the IEC (International Electrical Commission). All Zeiss CMMs manufactured in Minneapolis are subject to a 15-hour "dry cycle" factory runoff. Any other "dry cycle" runoff requirements must be negotiated prior to order. All terms and pricing are subject to creditworthiness.

Prices quoted are valid for systems installed in North America only. Products and accessories included in this proposal may not be available in all countries.

Delivery

All Deliveries are subject to prior sales and U.S. government priority regulations. Instruments require air-ride equipment for transportation and insurance is not covered by Zeiss.

Estimated Delivery: As stated on price pages.

Delivery Terms: DDP, Port of Entry - Ship best way from port to customer dock at customer expense. (Pre-pay and add)*

Payment Terms USA/Canada: 30% due with purchase order, 60% due (net 30 days after delivery to freight carrier), 10% due upon installation not later than 45 days after delivery **

UCC1: A UCC1 security agreement will be filed with every machine order.

Transfer of Ownership: Upon delivery to freight carrier, North American Port of Entry.

- * Subject to INCOTERMS 2010
- **Any duties and/or taxes (if applicable) are the responsibility of the customer. Prior to shipping to Canada, a Conditional Sales Agreement (CSA) will be registered and must be signed by the customer.

Send Purchase Orders to:

Carl Zeiss Industrial Metrology, LLC Attn: Customer Care 6250 Sycamore Lane North Maple Grove, MN 55369 FAX (763) 533-0219

Send Remittance to:

Carl Zeiss Industrial Metrology 25065 Network Place Chicago, IL 60673-1250

Installation Supervision

Installation supervision includes:

- Direction of general labor/trades in the unpacking and delivery of machine to location
- Direction of general labor/trades in the assembly of machine
- Direction of general labor in hook up of required utilities
- Cable and level machine
- Perform electronic and mechanical adjustments as required to meet specification
- Run standard Zeiss accuracy and acceptance test in compliance with VDI/VDE 2617

Note: It is the customer's responsibility to provide all general labor, trades and rigging to insure initial machine setup and to insure that all environmental conditions for proper and correct machine installation and operation are met. This includes proper operational utilities as outlined in Zeiss machine specifications.

Software License

- 1. We accord you a non exclusive and non assignable right of use for the software programs, subsequent supplements and appertaining documentation relating to the internal operation of the subject of contract for which the programs have been delivered. You may only provide access to third persons after having received prior written consent from us. You shall not be entitled to perform any modifications or reengineering. Reproductions shall not be permitted with the exception of a backup copy.
- 2. We guarantee that the software delivered to you conforms to the performance scope defined in the operating manual, provided the software was installed on the system in question in accordance with our directives.
- 3. Only software defects which can be reproduced at any time shall be considered as defects. Our general warranty provisions shall apply as software defects liability guaranty. Defects can be rectified at our discretion by installing an improved software version or by providing information on how to eliminate or circumvent the effects of the defect.
- 4. In the event of claims resulting from any violation of the copyright, we shall ensure that you have the right to further utilize the software or we shall modify the software to the effect that no copyright violation exists. Should this not be possible at economically acceptable conditions, we shall take back the subject of contract excluding any further liability and shall reimburse the purchase price paid to us less an amount appropriate to the duration of use. This applies on condition that you inform us without delay in writing of any such claims, leaving all defensive measures and extrajudicial settlements up to us.
- 5. We reserve the right of terminating the right of use for good and sufficient cause, particularly in the event of violations of the afore mentioned liabilities or if you file for compulsory winding up or insolvency protection.

Terms and Conditions of Sale

Please Note: Terms on the Front (defined below) will supersede these general terms.

1. DEFINITIONS.

- "Agreement" refers to these terms, the quote/acknowledgment/invoice.
- "Buyer" refers to the person (natural or legal) listed on the Front purchasing the Product(s), including such person's heirs, executors, administrators, successors by merger or consolidation, or assigns.
- "Components" refers to parts, spare parts, retrofits, retrofit parts.
- "Front" refers to the parts of this Agreement specifying the Products, the Buyer, and specific payment and/or shipment terms. "Parties" refers to Buyer and Zeiss.
- "Product(s)" refers to the Systems, components, parts, accessories and services to be sold by Zeiss to Buyer as stated on the Front.
- "System(s)" refers to the complete, functioning measuring system as configured and sold hereunder.
- "Zeiss" refers to Carl Zeiss Industrial Metrology, LLC.
- 2. ORDER OF PRECEDENCE. This Agreement is the sole expression of the understanding between the Buyer and Zeiss regarding the Product(s), and will supersede any additional or differing terms stated in any Buyer's purchase order or other communication. Zeiss's acceptance of Buyer's purchase order is limited to these terms and is conditioned on Buyer's acceptance of these terms. Neither Zeiss's performance nor delivery of Product(s) will be construed as Zeiss's acceptance of Buyer's terms or conditions.

3. PRICE & PAYMENTS.

- A. Prices (i) do not include any additional fittings or adjustments, and (ii) are net F.C.A. Zeiss's shipping point, exclusive of delivery and installation charges including, but not limited to rigging, or transit insurance. Buyer is responsible for any tax, fee, levy, assessment, exaction, imposition or other charge imposed by any local, state or federal government levied upon the production, sale, use, import, export, ownership or shipment of the Products, except for taxes on Zeiss's net income.

 B. Payment. Buyer will pay for the Product(s) within thirty (30) days from shipment. No deductions or offsets are permitted. Amounts past due are subject to a service charge at the maximum rate of interest then-permitted by law until paid. Buyer will pay all of Zeiss's costs and expenses incurred in the collection of past due amounts, including reasonable collection agency or attorney's fees, court filing fees and other costs and disbursements.
- 4. RETURN POLICY. Zeiss will not accept any Product returns, unless it has given its written consent in the form of a Return Authorization (RA). Contact your Zeiss Customer Care Representative to obtain an RA. A restocking fee of twenty percent (20%) will be charged for all Product returns. Buyer is responsible for the risk of loss, shipping and handling fees for returned Product. Unless Zeiss agrees otherwise, returned Product(s) must be in new condition and in the original packaging. Certain electronic parts (e.g. printed circuit boards) are not returnable.
- 5. CANCELLATION POLICY. If Buyer cancels this Agreement, Zeiss will charge Buyer a 20% cancellation fee. If Buyer and Zeiss agree to cancel part of this Agreement, Zeiss may adjust the price of the remaining Product(s) being purchased and discounts offered on the original order may not be available.

6. SHIPMENT, SHIPPING DATE.

- A. Shipment. All shipments are made F.C.A Zeiss's shipping points. Zeiss will select the carrier. Zeiss may provide substitute Product provided they are of equal or better performance criteria. Zeiss may provide partial shipments.
- B. Shipping Date. Shipping dates are estimated delivery dates, and not a material term of this Agreement. Zeiss will make all reasonable efforts to meet the delivery date.
- 7. TITLE, RISK OF LOSS, CLAIMS FOR DAMAGE IN TRANSIT.
- A. Title. Title to the Product(s) passes to the Buyer upon Zeiss's delivery to the designated carrier.
- B. Risk of Loss. Zeiss's responsibility ends upon delivery of the Products to the carrier, or such other shipping point as designated by Zeiss. Buyer assumes all risk of loss for the Products after Zeiss delivers the Product(s) to the carrier for shipment to Buyer, and Buyer's sole recourse for any loss of or damage to the Products shall be against the carrier.
- C. Claims for Damage in Transit. Buyer will carefully examine the Product(s) immediately upon delivery and before signing any receipt. Buyer must note on the shipping receipt any visible damage to the Product and send notice of such damage to Zeiss within five (5) days of receipt of delivery. Buyer's signature on a receipt without notation of damage or Buyer's failure to send notice to Zeiss of damage or shortage within such five (5) day period shall constitute conclusive evidence of Buyer's receipt of the Product(s) in satisfactory condition.
- 8. FAILURE TO TAKE DELIVERY; DELAYED DELIVERY. If Zeiss is ready to ship, or has shipped, Product(s) to Buyer pursuant to this Agreement, and Buyer fails to take delivery or notifies Zeiss that delivery will be rejected. Zeiss may elect to

treat such failure or notice as Buyer's repudiation of this Agreement and may recover from Buyer Zeiss's costs of manufacture, customization, preparation, shipping and storage of the Product(s), in addition to all other rights and remedies available in law or equity. If Buyer requests a delay in delivery of more than thirty (30) days, Zeiss may, at its discretion, charge Buyer a holding charge of 2% of the net sales price per month.

- 9. ACCEPTANCE. Buyer's acceptance of the Products will occur on the earlier of (a) delivery to Buyer, if installation by Zeiss is not included in the purchase price; or (b) certification by Zeiss, in such form as Zeiss shall prescribe, that the Products have been installed and meet Zeiss's specifications, if installation by Zeiss is included in the purchase price; or (c) Buyer's use of the Product(s). If Buyer engages in a third-party financing relationship, the terms of such agreement will specifically include a provision that incorporates the terms of this Agreement, including a provision that unequivocally obligates Buyer to provide the third-party financing entity with a certification of acceptance in accord with the terms of this paragraph.
- 10. FORCE MAJEURE. Zeiss will make every reasonable effort to complete shipment, but shall not be liable for any loss or damage for delay in delivery, or any other failure to perform due to causes beyond its reasonable control including but not limited to, accident (in manufacture or otherwise) fire, storm, flood, earthquake, explosion, accident, acts of a public enemy, war, rebellion, insurrection, sabotage, epidemic, quarantine restrictions, labor disputes, labor or material shortages, embargo, failure or delays in transportation, unavailability of components or parts for machinery used for manufacture of its Product(s), acts of God, acts of the Federal Government or any agency thereof, acts of any state or local government or any agency thereof, and judicial action. Should a delay occur, Zeiss may reasonably extend delivery or production schedules or, at its option, cancel the order in whole or part without any liability other than to return any unearned deposit or prepayment. Zeiss may also make partial shipments to Buyer and invoice accordingly, and Buyer shall be obligated to pay for such partial shipments when invoiced.
- 11. FINANCIAL INSTABILITY & SECURITY INTEREST. Buyer warrants that it has established a budget, and has approved financing. Buyer warrants that it is able to: (i) pay its debts as they become due, (ii) is in fact now paying its debts in the ordinary course of business, and (iii) is not insolvent within the meaning of the Federal Bankruptcy Act. Buyer fully understands that Zeiss is relying upon these representations in extending credit under this Agreement. Zeiss may, at any time(s), suspend shipment or cancel its obligations hereunder, require cash payments, payment in advance, satisfactory security for future deliveries, or other adequate assurances of performance satisfactory to Zeiss, when in Zeiss's sole and commercially reasonable opinion, such measures are warranted because of Buyer's financial condition or other grounds for insecurity regarding Buyer's ability to perform under this Agreement. Under this Agreement, until the Products are paid for in full, Buyer gives Zeiss a security interest in the Products, all monies received for the Products, or in any chattel paper regarding the Products (e.g.: lease agreements).
- 12. LIMITED WARRANTY. Duration of Warranty: The effectiveness of this Warranty will be for (a) Systems: the earlier of (i) one (1) year from installation by Zeiss or Zeiss's authorized installer or (ii) eighteen (18) months from the shipment date; (b) Components: six (6) months from the date of installation if installed by Zeiss; (c) Labor: thirty (30) days from the completion of the work ((a), (b) and (c) referred to collectively or individually, as applicable, as the "Warranty Period"). What Is Covered: All parts will be free from defects in material and workmanship. Labor will be performed in a workman-like manner. What Zeiss Will Do: Zeiss will, at its sole option, repair or replace any parts it reasonably determines to have failed due to defects in material or workmanship during the Warranty Period.

What is Not Covered: Warranty does not cover high-wear, consumable items (e.g.: styli, air filters, items in the Zeiss Styli & Accessory Product Catalog) nor the servicing/replacement of other manufacturer's equipment or accessories. These items, and any third-party supplied items (software or hardware) will be covered by their manufacturer's warranty and arrangements for service or replacement must be made through that manufacturer. This Warranty does not cover failure that has resulted from improper third party services, improper or unreasonable use or maintenance, accident, or environmental conditions outside of those prescribed in the Product specifications or industry standards, improper packaging or shipment, electrical failure, or unauthorized tampering, alteration or modification. On-site planned or preventive maintenance activities are not included as a part of this Warranty. Software. This Warranty does not apply to Software, which is warranted separately. Exclusive Warranty: THE PROVISIONS OF THIS LIMITED WARRANTY ARE IN LIEU OF ANY OTHER WARRANTY, WHETHER EXPRESSED OR IMPLIED, WRITTEN OR ORAL, INCLUDING ANY WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. Exclusive Remedy: Zeiss's obligation to repair, replace or refund is the only remedy available under this Warranty or for any claim of any kind arising from this Agreement or the Products. ZEISS WILL NOT BE LIABLE UNDER ANY THEORY OF LAW (e.g.: CONTRACT OR TORT) TO BUYER OR ANY OTHER PERSON FOR ANY PUNITIVE, SPECIAL INCIDENTAL OR CONSEQUENTIAL DAMAGES WITH RESPECT TO ZEISS'S OBLIGATIONS HEREUNDER, SUCH AS, BUT NOT LIMITED TO, DAMAGE TO, LOSS OF, OR LOSS OF THE USE OF OTHER PROPERTY OR EQUIPMENT, LOSS OF PROFITS OR REVENUES OR CLAIMS OF BUYER OR BUYER'S CUSTOMERS, FOR LOSSES OF ANY KIND. Some jurisdictions do not allow limitations on exclusion of or limitation of remedies so the foregoing limitations and exclusions may not apply.

13. PATENT INDEMNITY. Zeiss will defend or settle any claim, suit or proceeding brought against Buyer based on allegations that the Product(s) infringe on a third party patent, provided that: Zeiss is notified timely of such claim, suit or proceeding; Buyer renders all reasonable cooperation to Zeiss; Buyer gives Zeiss the sole authority to defend or settle the same. If the Product(s) are held to infringe on any patent and the use of the Product(s) is enjoined, Zeiss will have the option, at its discretion (i) to procure Buyer the right to use the Product(s) or (ii) to modify the Product(s) so that they no longer infringe or (iii) refund Buyer the depreciated value of the Product(s) and accept the return thereof. This indemnity will not apply to changes made by Zeiss at Buyer's instruction or by Buyer, or by the use of third party items in conjunction with the Product(s) (unless sold or directed by Zeiss). Zeiss's total liability to Buyer will not exceed the depreciated value of the Product(s).

- 14. NOTICES. All notices, consents, requests, instructions, approvals and other communications hereunder shall be in writing and given by personal delivery, or by certified mail, return receipt requested, or by express delivery service to the address of Buyer or Zeiss as shown on the Front or to such other address as any party hereto may, from time to time, designate in writing. Notices shall be deemed to be effective on the date personally delivered, or five (5) days after deposited in the United States mail as certified mail, or one day after deposited with an express delivery service, as the case may be.
- 15. APPLICABLE LAW, DISPUTES, JURISDICTION AND VENUE. This Agreement is governed by and construed under the laws of the New York State applicable to contracts made and to be performed wholly within New York State. The Parties will negotiate in good faith to resolve any dispute arising between them, and those negotiations will be considered as settlement discussions and not subject to discovery. The Parties agree to submit to the personal jurisdiction of the federal courts of Westchester County, New York, and to have their disputes resolved by a trial without a jury.
- 16. ENTIRE AGREEMENT. This Agreement is the complete and exclusive statement of the understanding between the Parties, and the Parties enter into this Agreement solely upon the terms expressly stated herein without relying on any other expressions, verbal or written. This Agreement can only be modified in a writing signed by the Parties.
- 17. NO WAIVER. The failure or delay to enforce any part of this Agreement will not constitute a waiver of the right to enforce such term or condition in the future.
- 18. SEVERABILITY. If a court of competent jurisdiction deems any of the provisions in this Agreement to be invalid, illegal or unenforceable ("Invalid") in any respect, the remainder of the Agreement will remain valid and the Parties will work in good faith to amend such Invalid provision in a manner that lawfully accomplishes the original intent of the Invalid provision. If removing or amending the Invalid provision has a material adverse effect on either party, then either party may terminate this Agreement without further obligation or liability.
- 19. ASSIGNMENT. Neither Zeiss nor Buyer may assign or transfer their rights or obligations under this Agreement, except that Zeiss may, without the Buyer's consent, assign its rights and obligations to its parent, subsidiaries or affiliates.
- 20. EXPORT / RE-EXPORT. The Product(s) may be subject to United States Export Administration Regulations and diversion contrary to U.S. law is prohibited. All transactions are conditioned on compliance with all applicable export control laws and regulations and all other applicable laws and treaties, including without limitation the Foreign Corrupt Practices Act, of the U.S.A., international treaty and/or the Buyer's country. Buyer agrees that it shall not, except as permitted by those laws, regulations or treaties, make any disposition, either by transshipment, re-export, diversion or otherwise, of Products in whole or in part. Buyer warrants that it will not export or re-export any Products with knowledge that they will be used in the design, development, production, or use of chemical, biological, nuclear, or ballistic weapons, or in a facility engaged in such activities, unless Buyer has obtained all required permits and approvals. Buyer further warrants that it will not export or re-export, directly or indirectly, any Products to embargoed countries or sell Products to companies or individuals listed on the Denied Persons List published by the Department of Commerce. All obligations in this paragraph survive any termination of site access, and discharge of any other contract obligations.



ZEISS METROTOM SpecificationsVersion: October 2016



System description

Operating mode	Stop and go mode, measurement in the image
Measuring principle	Measuring the attenuation of X-ray radiation through matter and volume reconstruction of local attenuation values using cone-beam reconstruction method
Sensor technology	Flat-panel detector
Software	Operating software: ZEISS METROTOM OS
Applications	Dimensional measurements and material analysis

Radiation generation and sensor technolgy

ZEISS METROTOM			800/130 kV	800/225 kV	1500/225 kV
Micro-focus tube	Max. tube voltage	in kV	130	225	225
	Max. tube current	in µA	300	3000	3000
	Max. target performance	in W	39	500	500
	Min. focal spot size	in mm	0,005	0,007	0,007
Flat-panel detector	Number of pixels 1)		1536 x 1920	1024 x 1024	2048 x 2048
	Pixel size	in µm	127 x 127	200 x 200	200 x 200

Resolution (ISO 15708) 2)

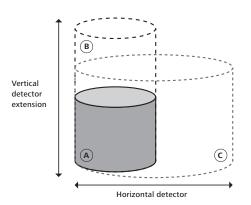
		800/130 kV	800/225 kV	1500/225 kV
Maximum spatial resolution at 10 % modulation transfer	in µm	3.5 (143 lp/mm ³⁾)	6.0 (83 lp/mm ³⁾)	4.0 (125 lp/mm ³⁾)

Accuracy (MPE complies with VDI/VDE 2630 sheet 1.3) ⁴⁾

			800/130 kV	800/225 kV	1500/225 kV
Sphere center point error	SD (TS)	in µm	2.9+L/100	4.0+L/100	4.5+L/50
Probing error	PS (TS)	in µm	3	3	3
	PF (TS)	in µm	4	4	4
Length measurement error 5)	E (TS)	in µm	6.9+L/100	8+L/100	9+L/50

Measuring range

			800/130 kV		800/225 kV	1500/225 kV
A) in the image without image field extansion			Portrait (Standard)	Landscape		
	Max. Diameter	in mm	150	170	170	305
	Max. Height	in mm	170	115	150	260
B) with max. vertical image field extension	Max. Diameter	in mm	150	170	170	305
	Max. Height	in mm	360	360	405	655
C) with max. vertical and horizontal image field extension [optional]	Max. Diameter	in mm	275	300	300 ⁶⁾	570 ⁶⁾
	Max. Height	in mm	360	360	390	550



- (A) Imaging volume without image field extension
- **B** With maximal vertical image field extension
- $\overline{(c)}$ With maximal vertical and horizontal image field extension [optional]

Travel path

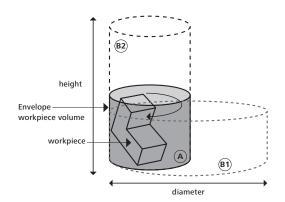
······································				
		800/130 kV	800/225 kV	1500/225 kV
X axis	in mm	700	700	1033
Y axis	in mm	270	270	300
Z axis	in mm	270	270	395

- 90 % active pixels.
 Factory inspection prior to delivery
 Ip/mm = line pairs per millimeter
 The given accuracies are valid for for operating condition stop and go and measurement in the image without image field extension.
- 1) 2) 3) 4) 5) 6)
- Measuring length L in mm.

 Warning: Restriction of mover travel ranges. Danger of collision. Manual and careful operation of the system necessary.

Workpiece size 1)

			800/130 kV	800/225 kV	1500/225 kV	
Max. workpiece weight		in kg	5	5	50	
A) Max. workpiece size (without limitation	Diameter	in mm	300	550	430	
of travel range in Y and Z axis)	Height	in mm	360	550	800	
Max. fittable workpiece size with in part significant restriction of travel and measurement range						
B1) optimized for max. diameter	Diameter	in mm	400	650	700	
	Height	in mm	255	550	750	
B2) optimized for max. height	Diameter	in mm	300	550	430	
	Height	in mm	620	800	1100	



- $\begin{tabular}{ll} \bf A & {\it Max. workpiece size (without limitation of travel range)} \end{tabular}$ in Y and Z axis)
- **B1** Max. fittable workpiece size optimized for maximum diameter (with in part significant restriction of travel and measurement range)
- $\begin{tabular}{ll} \begin{tabular}{ll} \beg$

Technical features

	800/130 kV	800/225 kV	1500/225 kV
Positioning system	Design: welded steel design with 3 linear axes	Design: welded steel design with 3 linear axes	Design: welded steel design with 3 linear axes
Length measuring system	Electro-optical reflected light system, photoelectric, resolution 0.2 µm	Electro-optical reflected light system, photoelectric, resolution 0.2 µm	Electro-optical reflected light system, photoelectric, resolution 0.1 µm
Protective enclosure	The ZEISS METROTOM 800 satisfies the conditions of Annex 2, Point 3 of the German X-Ray Regulation; it thus meets the requirements of a full protection device.	The ZEISS METROTOM 800 satisfies the conditions of Annex 2, Point 3 of the German X-Ray Regulation; it thus meets the requirements of a full protection device.	The ZEISS METROTOM 1500 satisfies the conditions of Annex 2, Point 3 of the German X-Ray Regulation; it thus meets the requirements of a full protection device.
Clamping device	Changer pallet on rotary table with 170 mm diameter	Changer pallet on rotary table with 170 mm diameter	Changer pallet on rotary table with 300 mm diameter

Environmental requirements 2)

		800/130 kV	800/225 kV	1500/225 kV	
Relative humidity		40 % to 70 %	40 % to 70 %	40 % to 70 %	
Measuring reference temperature		+18°C to +22°C	+18°C to +22°C	+18°C to +22°C	
	per day	2.0 K/d	2.0 K/d	2.0 K/d	
	per hour	1.0 K/h	1.0 K/h	1.0 K/h	
	spatial	1.0 K/m	1.0 K/m	1.0 K/m	

Requirements for operational readiness

	800/130 kV	800/225 kV	1500/225 kV
Relative humidity	40 % to 70 %	40 % to 70 %	40 % to 70 %
Ambient temperature	+15°C to +35°C	+15°C to +35°C	+15°C to +35°C
Power rating	1/N/PE 100/110/120/125/230/240 V~ (±10%); 50-60 Hz. Power consumption: max. 2500 VA, including computer technology Medium power consumption 1 kWh	3/N/PE/400/230~(±10%), 50-60 Hz. Medium power consumption 15000 VA / 1.5 - 2.5 kWh (Power consumption depends on integrated components) Fuse C25A	3/N/PE/400/230~(±10%), 50-60 Hz. Medium power consumption 15000 VA / 1.5 - 2.5 kWh (Power consumption depends on integrated components) Fuse C25A

- 1) The theoretical max. workpiece size is given. Given values describe the envelop cylinder when part is rotated. Sample holders are not yet considered and might reduce the given values.

 2) Necessary to achieve the specified accuracy.



ZEISS products and packaging returned to us are disposed of in accordance with applicable legal Disposal

Certification/accreditation

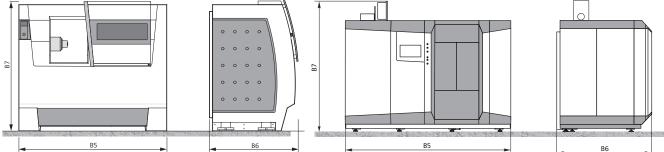
Quality management system	ISO 9001:2008, VDA 6, Parts 4, 2. Version 2005	
Environmental management system	ISO 14001:2004	
Occupational health & safety management systems	BS OHSAS 18001:2007	
Accredited	ISO / IEC 17025:2005	

ZEISS METROTOM	Dimensions in mm			Weight in kg
sizes	Overall machine dimensions			
	Width	Length	Height	
	B6	B5	B7	
800/130 kV	1310	2190	1960	5700
800/225 kV	1900	3330	2600	3550
1500/225 kV	1950	4150	2650	7400

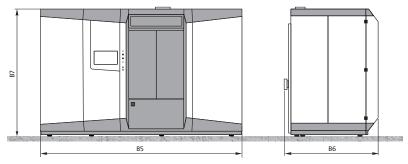
ZEISS METROTOM 800/130 kV



ZEISS METROTOM 800/225 kV



ZEISS METROTOM 1500/225 kV



Note: the given dimensions and weights are approximate values. Subject to change.

Actual appearance of specific sizes may vary from illustration. Dimensioning based on DIN 4000-167:2009.

Carl Zeiss

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Industrielle Messtechnik GmbH

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STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H. Commissioner



Dannel P. Malloy Governor Nancy Wyman Lt. Governor

Office of Health Care Access

April 19, 2017

Eric Hasel Quality Engineer/Project Engineer Advance Mold and Manufacturing, Inc. 71 Utopia Road Manchester, CT 06042

RE:

Certificate of Need Determination Report Number 17-32162-DTR

Acquisition of a Computed Tomography Scanner

Dear Mr. Hasel:

On April 17, 2017, the Office of Health Care Access ("OHCA") received your Certificate of Need ("CON") Determination request on behalf of Advance Mold and Manufacturing, Inc. ("Petitioner") with respect to the acquisition of a computed tomography scanner.

The Petitioner is an injection mold manufacturing company and custom injection molder. The Petitioner serves the medical industry almost exclusively, producing injection molded plastic components and offering ancillary assembly operations. The Petitioner seeks to purchase a Zeiss Metrotom 800-130 computed tomography scanner ("CT Scanner"). The CT Scanner will be used to measure and analyze complex plastic parts which would otherwise require the sectioning and destruction of the subject parts. The Petitioner does not intend to use the CT Scanner for any type of scientific research.

Pursuant to Conn. Gen. Stat. § 19a-638(a)(10), a certificate of need is required for the "[t]he acquisition of computed tomography scanners, ... by any person, physician, provider, short-term acute care general hospital or children's hospital, except (A) as provided for in subdivision (22) of subsection (b) of this section, ..." Conn. Gen. Stat. § 19a-638(b)(22) provides an exception for CT Scanners that will be used "... exclusively for scientific research that is not conducted on humans." The Petitioner will use the CT Scanner for a purpose other than that outlined in Conn. Gen. Stat. § 19a-638(b)(22). Therefore, the exception does not apply in this instance. Consequently, a CON is required for the Petitioner's proposal.

Sincerely.

Kimberly R. Martone Director of Operations Cc: Rose McLellan



Phone: (860) 418-7001 • Fax: (860) 418-7053 410 Capitol Avenue, MS#13HCA Hartford, Connecticut 06134-0308 www.ct.gov/dph Affirmative Action/Equal Opportunity Employer

Olejarz, Barbara

From: Microsoft Outlook
To: Eric.hasel@flex.com

Sent: Wednesday, April 19, 2017 2:20 PM

Subject: Relayed: Determination

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

Eric.hasel@flex.com (Eric.hasel@flex.com)

Subject: Determination