



**Australia:**  
LKB Instruments:  
Skudtek Scientific  
P.O.Box 892  
Mt.Waverley,  
VIC 3149 Australia  
T: +61 3 5996 1477  
F: +61 3 5996 1488  
www.LKB.com.au



**Japan:**  
Quantum Design Japan  
Ikebukuro Duplex B's 3F, 2-40-13  
Ikebukuro Toshima-ku,  
Tokyo 171-0014, Japan  
T: +81\*(0)\*3-5954-8573  
www.qd-japan.com



**India:**  
Biotron Healthcare P. Ltd.  
301 Coral Classic, 20th Road,  
Chem bur, Mumbai - 400 071  
T: +91 22 2528 7626  
F: +91 22 2528 1012  
www.biotronhealthcare.com



**Israel:**  
Eldan Electronic Instruments  
4 Baltimore Street,  
PO Box 7641  
Petach Tikva  
49170, Israel  
T: +972-3-9264484  
F: +972-3-9371161  
www.eldan.biz



**Europe:**  
**BioDot Ltd.**  
The Kingley Centre  
Downs Road, West Stoke  
Chichester, West Sussex  
PO18 9HJ, United Kingdom  
T: +44 1243 57 2044  
F: +44 1243 5757



**US Headquarters:**  
**BioDot Inc.**  
17781 Sky Park Circle  
Irvine, CA 92614  
T: +1.949.440.3685  
F: +1.949.440.3694  
www.biodot.com



**Singapore:**  
Research Biolabs Pte Ltd  
73 Ayer Rajah Crescent  
#04-05 Ayer Rajah Industrial Estate  
Singapore 139952  
T: +65 6777 5366  
F: +65 6778 5177  
www.researchbiolabs.com



**China:**  
Tower East Unit 7F 01  
No. 333 Chengdu North Rd  
China Merchants Plaza  
Jing An District  
Shanghai, China  
T: +8621.61524285  
www.biodot-china.com

**Korea:**  
Quantum Design Korea  
Hana Bldg., 4F, 414-15,  
Dogok-dong, Kangnam-gu  
Seoul 135-854  
Korea  
T: +82-2-2057-2710  
www.qdkorea.com

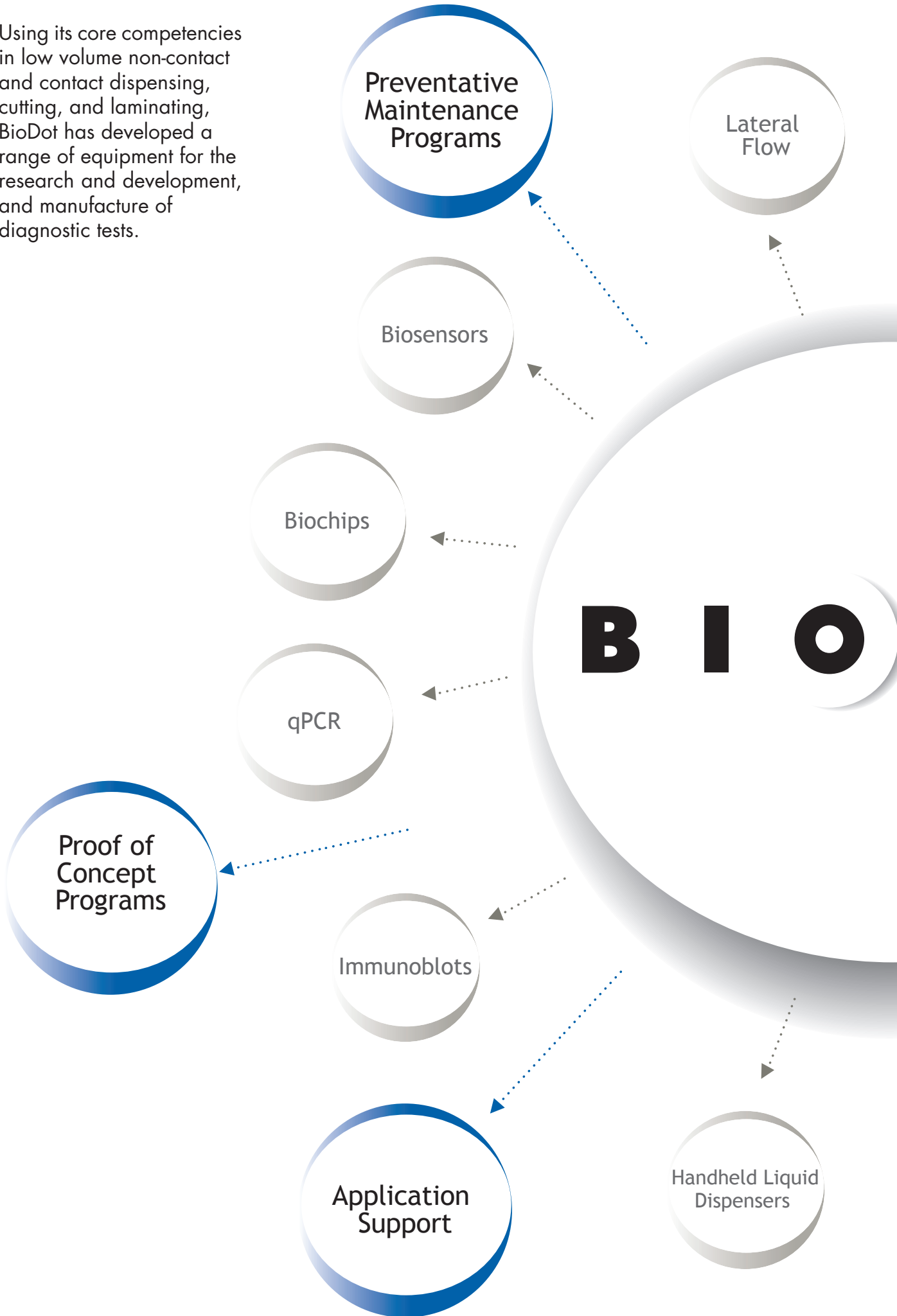
**Russia:**  
Eldan Electronic Instruments Co. Ltd.  
Адрес: Москва, Вадковский пер.,  
д.1, здание СТАНКИН, офис 913  
T: +8 (495) 589-49-45  
www.eldanruss.ru

**Thailand:**  
Heron Diagnostics  
131 Thailand Science Park  
INC 1, Suite 229  
Pahonyothin Rd., Klong 1, Klong Luang  
Pathumthani, 12110 Thailand  
T/F: +66 2564 7855

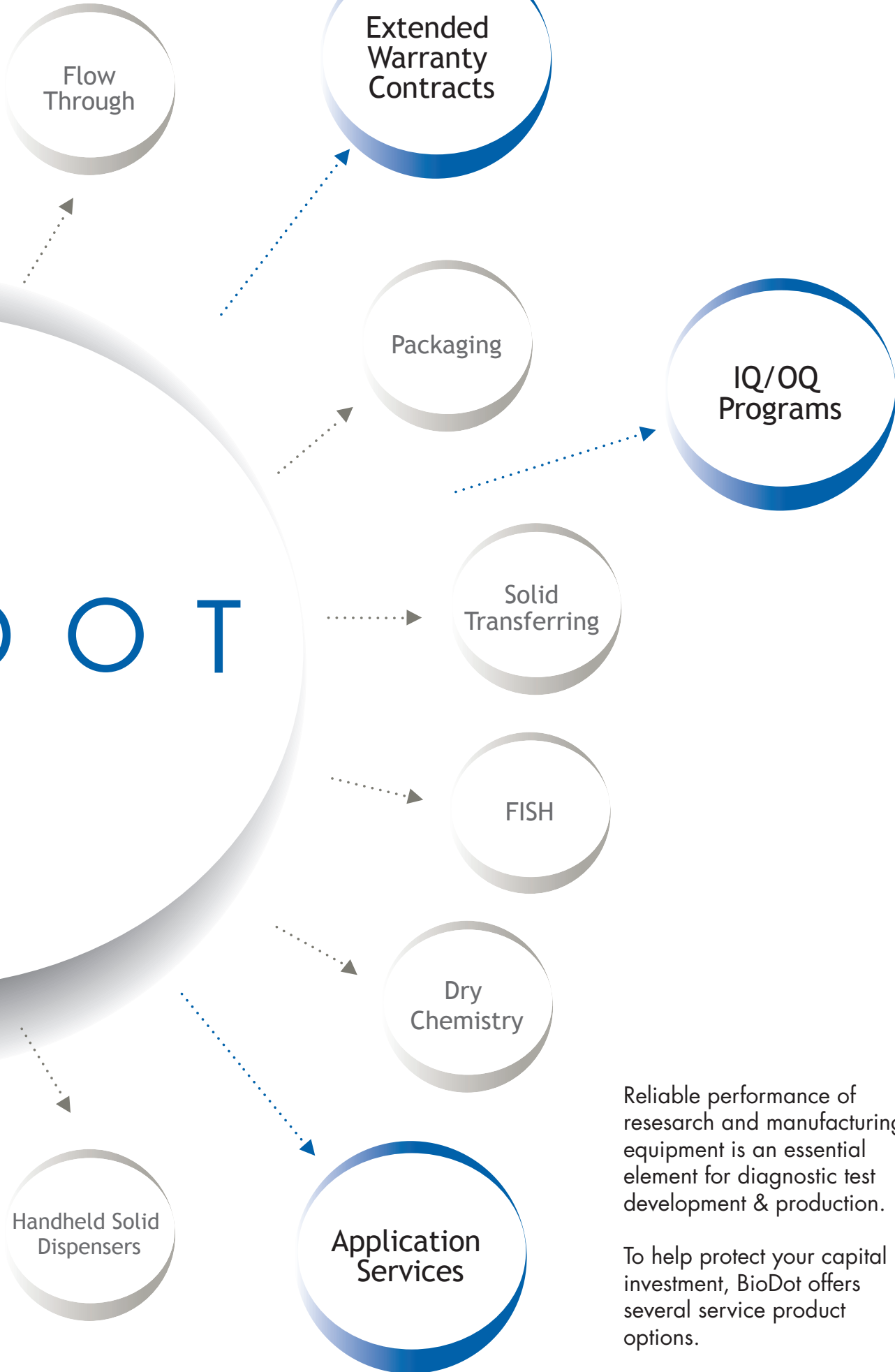
**Taiwan:**  
Prisma Biotech Corporation  
7F, No. 72, Song-Te Rd.,  
Xinyi District, Taipei City 110,  
Taiwan  
T: 886-2-27230886  
F: 886-2-27230876  
www.prismabiotech.com.tw



Using its core competencies in low volume non-contact and contact dispensing, cutting, and laminating, BioDot has developed a range of equipment for the research and development, and manufacture of diagnostic tests.



# DOT



**Application Services**

Reliable performance of research and manufacturing equipment is an essential element for diagnostic test development & production.

To help protect your capital investment, BioDot offers several service product options.

# BioServe Programs

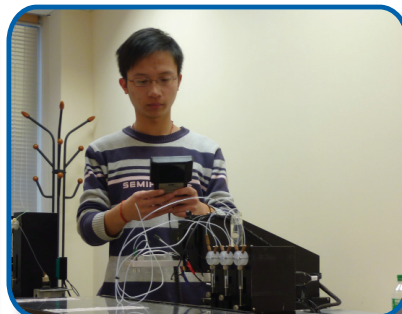
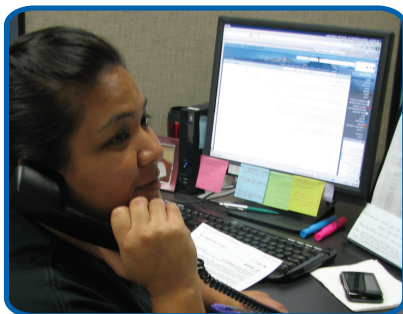
BioDot Technical Support is an integrated team of experienced individuals working towards a common goal: providing customers with high-performance systems, efficient installation, and superior technical support.

BioDot views service as a critical element of our product offering. Good service simplifies operations in either a research and development laboratory or manufacturing environment. We believe that when supplying equipment to the diagnostic manufacturing community, providing sound service and support is as important as offering quality products.

BioDot has developed several programs for maintaining the integrity of our systems and minimizing downtime. Our BioServe program at the minimum level offers preventative maintenance for a single instrument, a complete laboratory, or an entire facility. In addition to the annual preventative maintenance, BioDot offers on going support and training through our “hands on” workshop programs and our site visits.

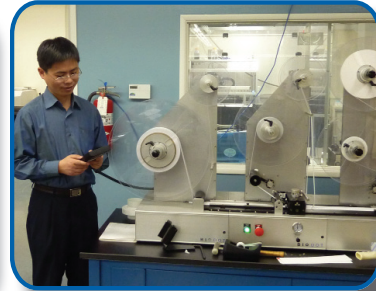
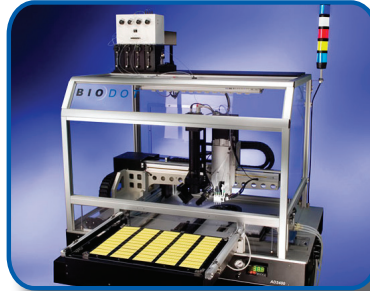
Recognizing the importance of regulatory guidelines, BioDot has implemented Installation Qualification and Operation Qualification procedures. BioDot’s Installation Qualification (IQ) and Operational Qualification (OQ) service ensures your instrumentation and software is installed correctly and functions according to BioDot’s specifications. It also confirms that all functionality operates as intended by BioDot. IQ documentation is supplied in a standard checklist format, and it includes all items delivered and installed. The results of the IQ/OQ are fully documented and include analysis data and statistical analyses.

All BioDot equipment can be covered under these programs.



# Preventative Maintenance Program

Scheduled Preventive Maintenance (PM) calls increase system reliability and performance. Thorough PM procedures include cleaning, inspecting, adjustments and calibration to published factory specifications. Minor problems are corrected to prevent catastrophic failures that jeopardize valuable materials and productivity.



## DELIVERABLES

- One annual preventative maintenance visit at a mutually agreed upon date and time arranged between commencement date and expiration date of the contract.
- BioDot systems covered by the plan will be fully cleaned, serviced and re-calibrated where necessary. parts contained in the systems's PM kit will be replaced. Worn or faulty parts not included in the PM kit will be replaced only with customer consent.
- At the conclusion of the PM, a certificate stating the PM has been completed by a BioDot service representative will be provided.
- Software upgrades and any additional training as part of the PMI visit

An IQ/OQ service can be performed on the system to verify performance against specified accuracy and precision criteria. At the conclusion of IQ/OQ, the customer will receive a signed Certificate of Verification and supporting test data sheets. Contact your local representative for more details.

# Extended Warranty Program

Extended Warranty provides continued service support for your system. Budgeting is simplified as service costs are fixed for the duration of the agreement. Order processing is minimized.

## DELIVERABLES

- The Extended Warranty Service Plan covers all service parts replacement on your BioDot system for a period of one year using BioDot's depot repair facility.
- Parts can be sent to a customer for replacement only when a BioDot service representative has determined that a part is faulty and needs to be replaced.
- If service parts are sent to a customer, the failed service parts must be returned to BioDot for inspection.
- Parts sent to a customer that have not been used for a repair must be returned to BioDot.

On site service can be provided and addressed on an individual basis. Ask your local representative for more information.

An IQ/OQ service can be performed on the system to verify performance against specified accuracy and precision criteria. At the conclusion of IQ/OQ, the customer will receive a signed Certificate of Verification and supporting test data sheets. Contact your local representative for more details.



# BioServe Total Program

BioDot Total provides full service support for your system by combining Extended Warranty with a pre-scheduled Preventative Maintenance (PM). Budgeting is simplified as service costs are fixed for the duration of the agreement, order processing is minimized and scheduled PM calls increase system reliability and performance.



## DELIVERABLES

- The Bioserve Total Service Plan covers all service part replacements, depot repair labor, and one (1) onsite PM service of your BioDot machine for a period of one year.
- One annual preventative maintenance visit at a mutually agreed upon date and time arranged between commencement date and expiration date of the service plan.
- During PM, BioDot systems covered by the plan will be fully cleaned, serviced and re-calibrated where necessary. Parts contained in the machine's PM kit will be replaced. Worn or faulty parts found during the inspection will be replaced at no additional charge
- At the conclusion of the PM, a certificate stating the PM has been completed by a BioDot service representative will be provided.
- Software upgrades and any additional training as part of the PMI visit

On site service can be provided and addressed on an individual basis. Ask your local representative for more information.

An IQ/OQ service can be performed on the system to verify performance against specified accuracy and precision criteria. At the conclusion of IQ/OQ, the customer will receive a signed Certificate of Verification and supporting test data sheets. Contact your local representative for more details.

# Installation & Operational Qualification Programs



BioDot's Installation Qualification (IQ) and Operational Qualification (OQ) service ensures your instrumentation and software is installed correctly and functions according to BioDot's specifications. It also confirms that all functionality operates as intended by BioDot.

IQ documentation is supplied in a standard checklist format, and it includes all items delivered and installed. The results of the IQ/OQ are fully documented and include analysis data and statistical analyses.

IQ/OQ is performed on-site at your facility by a certified BioDot service engineer, specially trained to validate BioDot instrumentation.

## Installation Qualification (IQ)

This qualification is performed on site and during the time of installation. It documents the key aspects of the installation and verifies compliance with BioDot's specifications and safety parameters. In order to qualify for an IQ Certificate, this procedure must be performed by a certified BioDot service engineer. This IQ procedure includes the following protocols:

- Verifying installation location meets BioDot requirements before the instrument is installed
  - Location meets floor space requirements
  - Power requirements are met
  - Gas supply requirements are met
  - Environmental operating conditions are met
- Unpacking of instrument to check for damage and cross-checking contents with packing list
- Documenting the computer hardware/operating system
- Checking the installation of the software and its basic accessibility
- Installing the instrument and options per BioDot's installation procedure
- Verifying all connections to peripheral units and that communication is operational
- Documenting the instrumentation controlled by the software
- Checking basic communication with the instrument
- Recording all firmware versions and BioDot serial numbers
- Tagging the instrument with IQ sticker
- Recording the calibration dates for equipment used during IQ
- All manuals, relevant outputs from the instrument, and certificates of conformity are gathered and placed in IQ/OQ binder for transfer to end user



# Operational Qualification (OQ)

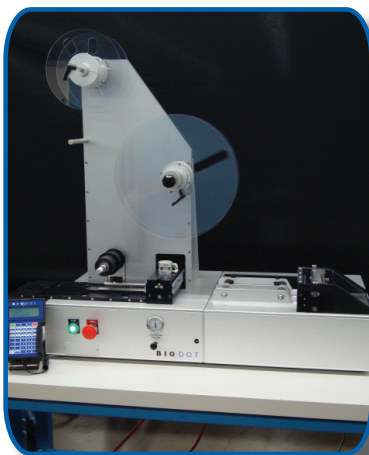
Operational qualification is performed subsequent to installation, after major maintenance or modification of the instrument, or can be based on a customer-specified quality schedule. It documents that the instrument performs consistently throughout the BioDot-specified operating ranges.

In order to qualify for an OQ Certificate, this procedure is to be performed by a certified BioDot service engineer.



OQ validation is performed on the instrument as a system. BioDot's specified protocols are used to show that the accuracy and precision of the system meet our required specifications. These protocols include the following:

- Testing of configuration menus and instrument control
- Instrument-specific protocols verifying the analytical parameters defined by BioDot
  - Accuracy
  - Precision
- Tagging the instrument with OQ sticker
- Recording the calibration dates for equipment used during OQ
- All relevant outputs from the instrument are gathered and placed in IQ/OQ binder for transfer to the end user



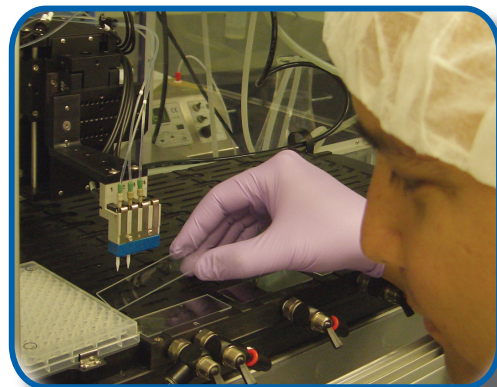
At the end of the IQ and OQ you are supplied with complete documentation contained in an IQ/OQ binder, including installation checklist, operational checklist, validation data, pass/fail documentation, manuals, relevant outputs from the instrument, certificates of conformity, and copies of the protocols used during the qualification procedures. At the completion of the OQ the BioDot service engineer will provide instrument familiarization training and review the operation and maintenance, confirming the end user's ability to properly operate the instrument.

# Application Support and Services

BioDot recognizes that its customers have a wide range of applications, each of which may require technical support for adapting the BioDot equipment and technology to their unique needs. In order to serve these customer need, BioDot has established application laboratories in North America, Europe and China. The application laboratories are staffed with qualified application specialists and equipped with a full range of demonstration equipment. The equipment includes dispensing technologies with environmental control, vision systems, as well as cutting and slitting technologies and lamination and assembly technologies.

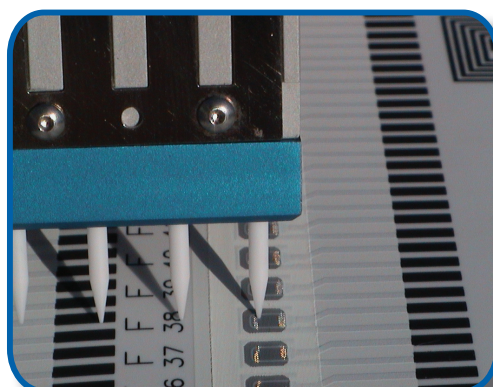
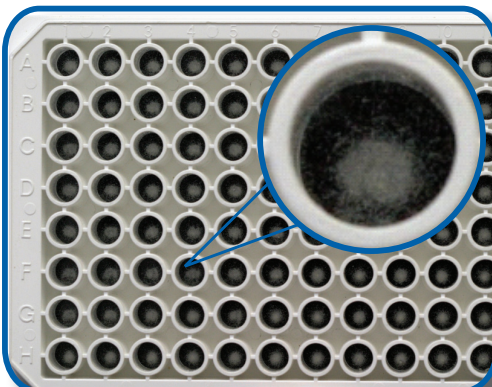
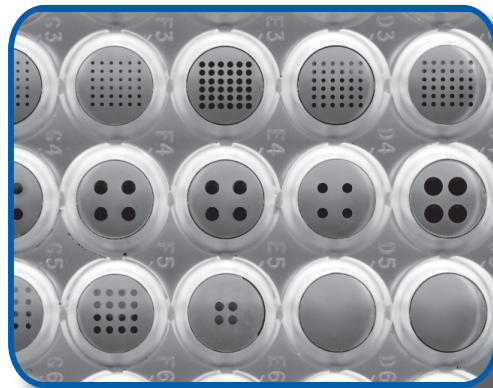
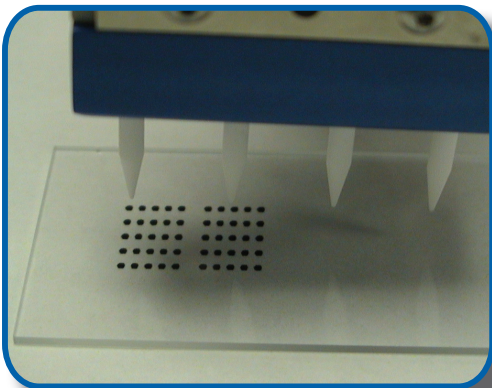
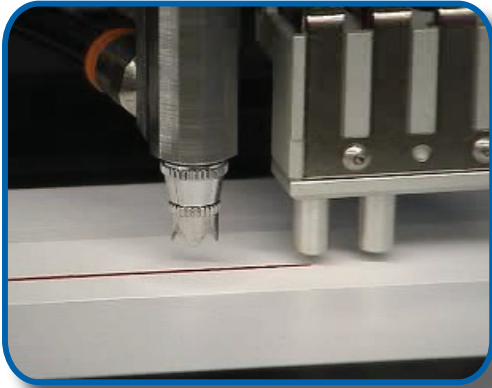
## Our Technical Support includes:

- Demonstration equipment using standard reagents and materials. This support category can also include limited work with the customer's reagents and substrates but is not intended for development of a customer application.
- Training: This type of support is to assist the customer in the use of the equipment in terms of programming and operating parameters.
- Product/Process Development: This program is designed to work with customer requirements and to optimize processes associated with the BioDot equipment to assist the customer in his development efforts.
- Technology transfer to manufacture: In this type of program BioDot will work with the customre to develop and implement scale up processes suitable for manufacturing. In addition BioDot engineering team can also provide new engineering designs for high throughput manufacturing equipment. These designs would integrate the BioDot process technology that was used for the initial product and process development in order to maintain continuity between R&D and manufacturing. This equipment can be implemented by BioDot or in conjunction with an equipment integrator using BioDot technology.



# Proof of Concept Programs

BioDot recognizes that in many applications, it is important to make an assessment prior to making a capital investment. Using our applications laboratories in either North America, Europe, or China, and our application team of Scientists, we give you an opportunity to do just that. Application studies can be designed with a simple dispensing test or a more detailed study analyzing parameters that could effect results.



# BioServe Summary

	BioServe PM	Extended Warranty	BioServe Total	IQ/ OQ
Service/Repair Parts		✓	✓	
Software Support		✓	✓	
Software Upgrades		✓	✓	
Consumable Parts Replaced Annually <small>*to be purchase separately</small>	✓		✓	
Phone Support	✓	✓	✓	
Annual Onsite Visit	✓		✓	
Discounted Parts	✓	✓	✓	✓
IQ/OQ Documents				✓



**BioDot Inc: +1.949.440.3685**

**BioDot Ltd: +44 1243 57 2044**  
**support@biodot.com**

**BioDot China: +86 21 61524285 16**

To help our dedicated staff provide you with the appropriate information, have the serial number of the product in question prior to contacting BioDot.

If the warranty has already expired, an onsite assessment may be necessary prior to initiating a BioServe Program.

These programs do not include:

- Damages caused by unauthorized service agents
- Consumable components
- Modifications which are made to the instrumentation
- Use of unauthorized parts or components
- System misuse, abuse, inappropriate power supply or acts of God
- Products with undetermined serial numbers