



Addendum

Power Express In Vitro Diagnostic Regulation Requirements

For *In Vitro* Diagnostic Use



C72994AA
March 2021



Beckman Coulter, Inc.
250 S. Kraemer Blvd.
Brea, CA 92821 U.S.A.



Addendum**Power Express In Vitro Diagnostic Regulation Requirements**

PN C72994AA (March 2021)

© 2021 Beckman Coulter, Inc.
All Rights Reserved.

Trademarks

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

All other trademarks are the property of their respective owners.

Find us on the World Wide Web at:

www.beckmancoulter.com



Beckman Coulter Ireland Inc.
Lismeehan, O'Callaghan's Mills,
Co. Clare, Ireland
Phone: +353-65-683-1100
FAX: +353-65-683-1122

Rx Only
Original Instructions

Contents

	Introduction, v
CHAPTER 1:	General System Operation IFU, 1-1
	Warranty and Service, 1-1
	Notice to Users, 1-2
	Electromagnetic Wave and Noise Precautions, 1-2
	For the Russian Market Only, 1-3
	Introduction, 1-3
	Intended Purpose, 1-3
	Optional Modules, 1-4
	Installation, 1-4
	Optional Modules, 1-4
	Minimum Software Requirement, 1-5
	Regulatory Agency Approvals, 1-5
	System Consumables, 1-5
	Training and Education Resources, 1-6
CHAPTER 2:	Inlets and Outlets Modules IFU, 2-1
	Warranty and Service, 2-1
	Notice to Users, 2-2
	Electromagnetic Wave and Noise Precautions, 2-2
	For the Russian Market Only, 2-3
	Intended Purpose, 2-3
	Training and Education Resources, 2-4
CHAPTER 3:	Centrifuge Module IFU, 3-1
	Warranty and Service, 3-1
	Notice to Users, 3-2
	Electromagnetic Wave and Noise Precautions, 3-2
	For the Russian Market Only, 3-3
	Intended Purpose, 3-3
	Training and Education Resources, 3-4
CHAPTER 4:	Decapper and Recapper Modules IFU, 4-1
	Warranty and Service, 4-1
	Notice to Users, 4-2
	Electromagnetic Wave and Noise Precautions, 4-2
	For the Russian Market Only, 4-3
	Intended Purpose, 4-3
	Training and Education Resources, 4-4

Contents

CHAPTER 5:	Aliquot Module IFU, 5-1 Warranty and Service, 5-1 Notice to Users, 5-2 Electromagnetic Wave and Noise Precautions, 5-2 For the Russian Market Only, 5-3 Intended Purpose, 5-3 Training and Education Resources, 5-4
CHAPTER 6:	Rack Builder Modules IFU, 6-1 Warranty and Service, 6-1 Notice to Users, 6-2 Electromagnetic Wave and Noise Precautions, 6-2 For the Russian Market Only, 6-3 Intended Purpose, 6-3 Training and Education Resources, 6-4
CHAPTER 7:	Direct Track Sampling Modules IFU, 7-1 Warranty and Service, 7-1 Notice to Users, 7-2 Electromagnetic Wave and Noise Precautions, 7-2 For the Russian Market Only, 7-3 Intended Purpose, 7-3 Training and Education Resources, 7-4
CHAPTER 8:	Storage Modules IFU, 8-1 Warranty and Service, 8-1 Notice to Users, 8-2 Electromagnetic Wave and Noise Precautions, 8-2 For the Russian Market Only, 8-3 Intended Purpose, 8-3 Training and Education Resources, 8-4
CHAPTER 9:	Cennexus IFU, 9-1 Warranty and Service, 9-1 Notice to Users, 9-2 Electromagnetic Wave and Noise Precautions, 9-2 For the Russian Market Only, 9-3 Intended Purpose, 9-3 Minimum Software Requirement, 9-4 Training and Education Resources, 9-4

Introduction

This addendum is a separate document containing additions to the software version 5.0 of the Power Express Instructions for Use Document Set required by In Vitro Diagnostic Regulation (IVDR).

This addendum contains the following chapters:

- [Chapter 1: General System Operation IFU](#)
- [Chapter 2: Inlets and Outlets Modules IFU](#)
- [Chapter 3: Centrifuge Module IFU](#)
- [Chapter 4: Decapper and Recapper Modules IFU](#)
- [Chapter 5: Aliquot Module IFU](#)
- [Chapter 6: Rack Builder Modules IFU](#)
- [Chapter 7: Direct Track Sampling Modules IFU](#)
- [Chapter 8: Storage Modules IFU](#)
- [Chapter 9: Cennexus IFU](#)

Introduction

Warranty and Service

**Note**

This section replaces the *Warranty and Service* section.

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter and at the expense of the customer.

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, contact Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

For Russian Market Only

1. The manufacturer guarantees the conformity of manufactured products to requirements of normative and technical documentation. Safety and quality of products are guaranteed throughout the entire shelf life.
2. The manufacturer is responsible for product defects, except for defects that have arisen because of violation of the rules of use, transportation, and storage preconditions, or a third party, or force majeure.
3. The manufacturer will replace the product at its own expense:
 - If technical and functional (consumer properties) do not comply with the regulatory and technical documentation.
 - If these disadvantages are caused by latent defect in materials or workmanship by the product manufacturer.

For product quality, contact the representative of the manufacturer in the Russian Federation.

Notice to Users



Note

This section is added to the *Alerts for Warning, Caution, Important, Note, and Tip* section.

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact your Beckman Coulter Representative.

Electromagnetic Wave and Noise Precautions



Note

The following replaces the Caution in the *Electromagnetic Wave and Noise Precautions* section.

Electromagnetic Compatibility



Caution

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

For the Russian Market Only



Note

This section is added to the *Introduction* section.

Contraindications: N/A

Possible Side Effect: N/A

Introduction



Note

The following is added to the *Introduction* section in Chapter 2.

Refer to your Beckman Coulter Representative for more information regarding your installation and verification. Third-party instrument installation, setup, testing, and support are the sole responsibility of the third-party representative of the vendor. For questions related to the instrument, contact the representative of the instrument vendor.

Intended Purpose



Note

This section is added to the *Introduction* section.

Power Express is an automated sample handing system that routes sample tubes to connected analyzers for in vitro diagnostic testing. Power Express is intended to optimize workflow and minimizes errors in hospital and clinical laboratories. This product is intended for laboratory professional use.

Detailed considerations:

- Specification of the analyte or marker to be determined: N/A. Power Express does not measure specific analytes or markers.
- Function screen/monitor/diagnose, or aid in diagnosis, prognosis and prediction: N/A. Power Express does not screen, monitor, diagnose, or aid in the diagnosis, prognosis and prediction of any disease. The function of the connected analyzers in that regard are not limited by Power Express.
- Disorder, condition to that is intended to be detected, defined, or differentiated: N/A. Power Express does not detect, define, or differentiate any disorders or conditions. Power Express delivers samples to various connected analytical instruments that perform sample analysis.
- Automation: Power Express is an automation system that sorts, routes, and presents sample tubes to analyzers for analysis using a track system. Power Express can connect to various analytical instruments.

General System Operation IFU

Optional Modules

- Qualitative, semi-qualitative, or quantitative: N/A. Power Express does not measure specific analytes or markers and therefore does not have a testing method. Power Express delivers samples to connected analytical instruments that perform sample analysis.
- Type of specimen: Power Express performs pre-analytical and post-analytical sample processing for connected analyzers. Refer to connected analyzer IFUs for supported sample types.
- Testing population: N/A. Power Express does not analyze specific analytes or markers and therefore is not relevant to testing population.
- For companion diagnostics, the target population and the associated medicinal products – if applicable: N/A. Power Express does not analyze specific analytes or markers and therefore it does not have any companion diagnostics, target populations or associated medicinal products.

Optional Modules



Note

The following Note is added to *System Description > Hardware > Optional Modules* in Chapter 1.

Note: Refer to the Published Specifications for connection configuration limitations. All modules and analyzer connections must be validated and installed by Beckman Coulter. Contact your Beckman Coulter Representative for support.

Installation



Note

This section is added to the *System Specifications* section.

- Before installing the system, refer to the System Specifications for the installation requirements.
- A Beckman Coulter Field Service Engineer must be present when the analyzer is removed from the shipping crate.
- A qualified Beckman Coulter Field Service Engineer must install the system. If the analyzer must be relocated, contact Beckman Coulter Customer Support.

A Beckman Coulter Field Service Engineer performs the applicable system verification for your Power Express system.

Optional Modules

The following Note is added to the *Optional Modules* section.

 **Note**

Refer to the Published Specifications for connection configuration limitations. All modules and analyzer connections must be validated and installed by Beckman Coulter. Contact your Beckman Coulter Representative for support.

Minimum Software Requirement

 **Note**

This section is added after the *Power Requirements* section.

Software usage environment: Use only on the PC included with this product.

Note: All software installation and upgrades must be performed by Beckman Coulter. Contact your Beckman Coulter Representative for support.


Regulatory Agency Approvals

 **Note**

The following bullet item is added to the *Regulatory Agency Approvals* section.

- The service life of the Power Express system is a minimum of 10 years. For disposal of the system, contact a Beckman Coulter Representative.

System Consumables

 **Note**

The following two table rows are updated in the *System Consumables* section. The updated text is in **Bold** type.

Description	Part Number
Universal Caps for Universal Recapper (V3.0 and later), 500/bag. Not reusable.	B95367
Caps for Recapper, 500/bag. Not reusable.	A17638

Training and Education Resources



Note

This section is added to the *Related Documents* section.

To confirm that trainees in your lab are proficient in basic system operations, go to the Beckman Coulter Training and Education website (www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm) to find resources on product training.

Inlets and Outlets Modules IFU

Warranty and Service



Note

This section replaces the *Warranty and Service* section.

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter and at the expense of the customer.

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, contact Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

For Russian Market Only

1. The manufacturer guarantees the conformity of manufactured products to requirements of normative and technical documentation. Safety and quality of products are guaranteed throughout the entire shelf life.
2. The manufacturer is responsible for product defects, except for defects that have arisen because of violation of the rules of use, transportation, and storage preconditions, or a third party, or force majeure.
3. The manufacturer will replace the product at its own expense:
 - If technical and functional (consumer properties) do not comply with the regulatory and technical documentation.
 - If these disadvantages are caused by latent defect in materials or workmanship by the product manufacturer.

For product quality, contact the representative of the manufacturer in the Russian Federation.

Notice to Users



Note

This section is added to the *Alerts for Warning, Caution, Important, Note, and Tip* section.

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact your Beckman Coulter Representative.

Electromagnetic Wave and Noise Precautions



Note

The following replaces the Caution in the *Electromagnetic Wave and Noise Precautions* section.

Electromagnetic Compatibility



Caution

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

For the Russian Market Only

 **Note**

This section is added to the *Introduction* section.

Contraindications: N/A

Possible Side Effect: N/A

Intended Purpose

 **Note**

This section is added to the *Introduction* section.

Power Express is an automated sample handing system that routes sample tubes to connected analyzers for in vitro diagnostic testing. Power Express is intended to optimize workflow and minimizes errors in hospital and clinical laboratories. This product is intended for laboratory professional use.

Detailed considerations:

- Specification of the analyte or marker to be determined: N/A. Power Express does not measure specific analytes or markers.
- Function screen/monitor/diagnose, or aid in diagnosis, prognosis and prediction: N/A. Power Express does not screen, monitor, diagnose, or aid in the diagnosis, prognosis and prediction of any disease. The function of the connected analyzers in that regard are not limited by Power Express.
- Disorder, condition to that is intended to be detected, defined, or differentiated: N/A. Power Express does not detect, define, or differentiate any disorders or conditions. Power Express delivers samples to various connected analytical instruments that perform sample analysis.
- Automation: Power Express is an automation system that sorts, routes, and presents sample tubes to analyzers for analysis using a track system. Power Express can connect to various analytical instruments.
- Qualitative, semi-qualitative, or quantitative: N/A. Power Express does not measure specific analytes or markers and therefore does not have a testing method. Power Express delivers samples to connected analytical instruments that perform sample analysis.
- Type of specimen: Power Express performs pre-analytical and post-analytical sample processing for connected analyzers. Refer to connected analyzer IFUs for supported sample types.
- Testing population: N/A. Power Express does not analyze specific analytes or markers and therefore is not relevant to testing population.
- For companion diagnostics, the target population and the associated medicinal products – if applicable: N/A. Power Express does not analyze specific analytes or markers and therefore it does not have any companion diagnostics, target populations or associated medicinal products.

Training and Education Resources



Note

This section is added to the *Related Documents* section.

To confirm that trainees in your lab are proficient in basic system operations, go to the Beckman Coulter Training and Education website (www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm) to find resources on product training.

Warranty and Service



Note

This section replaces the *Warranty and Service* section.

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter and at the expense of the customer.

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, contact Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

For Russian Market Only

1. The manufacturer guarantees the conformity of manufactured products to requirements of normative and technical documentation. Safety and quality of products are guaranteed throughout the entire shelf life.
2. The manufacturer is responsible for product defects, except for defects that have arisen because of violation of the rules of use, transportation, and storage preconditions, or a third party, or force majeure.
3. The manufacturer will replace the product at its own expense:
 - If technical and functional (consumer properties) do not comply with the regulatory and technical documentation.
 - If these disadvantages are caused by latent defect in materials or workmanship by the product manufacturer.

For product quality, contact the representative of the manufacturer in the Russian Federation.

Notice to Users



Note

This section is added to the *Alerts for Warning, Caution, Important, Note, and Tip* section.

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact your Beckman Coulter Representative.

Electromagnetic Wave and Noise Precautions



Note

The following replaces the Caution in the *Electromagnetic Wave and Noise Precautions* section.

Electromagnetic Compatibility



Caution

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

For the Russian Market Only



This section is added to the *Introduction* section.

Contraindications: N/A

Possible Side Effect: N/A

Intended Purpose



This section is added to the *Introduction* section.

Power Express is an automated sample handing system that routes sample tubes to connected analyzers for in vitro diagnostic testing. Power Express is intended to optimize workflow and minimizes errors in hospital and clinical laboratories. This product is intended for laboratory professional use.

Detailed considerations:

- Specification of the analyte or marker to be determined: N/A. Power Express does not measure specific analytes or markers.
- Function screen/monitor/diagnose, or aid in diagnosis, prognosis and prediction: N/A. Power Express does not screen, monitor, diagnose, or aid in the diagnosis, prognosis and prediction of any disease. The function of the connected analyzers in that regard are not limited by Power Express.
- Disorder, condition to that is intended to be detected, defined, or differentiated: N/A. Power Express does not detect, define, or differentiate any disorders or conditions. Power Express delivers samples to various connected analytical instruments that perform sample analysis.
- Automation: Power Express is an automation system that sorts, routes, and presents sample tubes to analyzers for analysis using a track system. Power Express can connect to various analytical instruments.
- Qualitative, semi-qualitative, or quantitative: N/A. Power Express does not measure specific analytes or markers and therefore does not have a testing method. Power Express delivers samples to connected analytical instruments that perform sample analysis.
- Type of specimen: Power Express performs pre-analytical and post-analytical sample processing for connected analyzers. Refer to connected analyzer IFUs for supported sample types.
- Testing population: N/A. Power Express does not analyze specific analytes or markers and therefore is not relevant to testing population.
- For companion diagnostics, the target population and the associated medicinal products – if applicable: N/A. Power Express does not analyze specific analytes or markers and therefore it does not have any companion diagnostics, target populations or associated medicinal products.

Training and Education Resources



Note

This section is added to the *Related Documents* section.

To confirm that trainees in your lab are proficient in basic system operations, go to the Beckman Coulter Training and Education website (www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm) to find resources on product training.

Decapper and Recapper Modules IFU

Warranty and Service



Note

This section replaces the *Warranty and Service* section.

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter and at the expense of the customer.

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, contact Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

For Russian Market Only

1. The manufacturer guarantees the conformity of manufactured products to requirements of normative and technical documentation. Safety and quality of products are guaranteed throughout the entire shelf life.
2. The manufacturer is responsible for product defects, except for defects that have arisen because of violation of the rules of use, transportation, and storage preconditions, or a third party, or force majeure.
3. The manufacturer will replace the product at its own expense:
 - If technical and functional (consumer properties) do not comply with the regulatory and technical documentation.
 - If these disadvantages are caused by latent defect in materials or workmanship by the product manufacturer.

For product quality, contact the representative of the manufacturer in the Russian Federation.

Notice to Users



Note

This section is added to the *Alerts for Warning, Caution, Important, Note, and Tip* section.

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact your Beckman Coulter Representative.

Electromagnetic Wave and Noise Precautions



Note

The following replaces the Caution in the *Electromagnetic Wave and Noise Precautions* section.

Electromagnetic Compatibility



Caution

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

For the Russian Market Only



Note

This section is added to the *Introduction* section.

Contraindications: N/A

Possible Side Effect: N/A

Intended Purpose



Note

This section is added to the *Introduction* section.

Power Express is an automated sample handing system that routes sample tubes to connected analyzers for in vitro diagnostic testing. Power Express is intended to optimize workflow and minimizes errors in hospital and clinical laboratories. This product is intended for laboratory professional use.

Detailed considerations:

- Specification of the analyte or marker to be determined: N/A. Power Express does not measure specific analytes or markers.
- Function screen/monitor/diagnose, or aid in diagnosis, prognosis and prediction: N/A. Power Express does not screen, monitor, diagnose, or aid in the diagnosis, prognosis and prediction of any disease. The function of the connected analyzers in that regard are not limited by Power Express.
- Disorder, condition to that is intended to be detected, defined, or differentiated: N/A. Power Express does not detect, define, or differentiate any disorders or conditions. Power Express delivers samples to various connected analytical instruments that perform sample analysis.
- Automation: Power Express is an automation system that sorts, routes, and presents sample tubes to analyzers for analysis using a track system. Power Express can connect to various analytical instruments.
- Qualitative, semi-qualitative, or quantitative: N/A. Power Express does not measure specific analytes or markers and therefore does not have a testing method. Power Express delivers samples to connected analytical instruments that perform sample analysis.
- Type of specimen: Power Express performs pre-analytical and post-analytical sample processing for connected analyzers. Refer to connected analyzer IFUs for supported sample types.
- Testing population: N/A. Power Express does not analyze specific analytes or markers and therefore is not relevant to testing population.
- For companion diagnostics, the target population and the associated medicinal products – if applicable: N/A. Power Express does not analyze specific analytes or markers and therefore it does not have any companion diagnostics, target populations or associated medicinal products.

Training and Education Resources



Note

This section is added to the *Related Documents* section.

To confirm that trainees in your lab are proficient in basic system operations, go to the Beckman Coulter Training and Education website (www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm) to find resources on product training.

Warranty and Service



Note

This section replaces the *Warranty and Service* section.

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter and at the expense of the customer.

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, contact Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

For Russian Market Only

1. The manufacturer guarantees the conformity of manufactured products to requirements of normative and technical documentation. Safety and quality of products are guaranteed throughout the entire shelf life.
2. The manufacturer is responsible for product defects, except for defects that have arisen because of violation of the rules of use, transportation, and storage preconditions, or a third party, or force majeure.
3. The manufacturer will replace the product at its own expense:
 - If technical and functional (consumer properties) do not comply with the regulatory and technical documentation.
 - If these disadvantages are caused by latent defect in materials or workmanship by the product manufacturer.

For product quality, contact the representative of the manufacturer in the Russian Federation.

Notice to Users



Note

This section is added to the *Alerts for Warning, Caution, Important, Note, and Tip* section.

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact your Beckman Coulter Representative.

Electromagnetic Wave and Noise Precautions



Note

The following replaces the Caution in the *Electromagnetic Wave and Noise Precautions* section.

Electromagnetic Compatibility



Caution

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

For the Russian Market Only



Note

This section is added to the *Introduction* section.

Contraindications: N/A

Possible Side Effect: N/A

Intended Purpose



Note

This section is added to the *Introduction* section.

Power Express is an automated sample handing system that routes sample tubes to connected analyzers for in vitro diagnostic testing. Power Express is intended to optimize workflow and minimizes errors in hospital and clinical laboratories. This product is intended for laboratory professional use.

Detailed considerations:

- Specification of the analyte or marker to be determined: N/A. Power Express does not measure specific analytes or markers.
- Function screen/monitor/diagnose, or aid in diagnosis, prognosis and prediction: N/A. Power Express does not screen, monitor, diagnose, or aid in the diagnosis, prognosis and prediction of any disease. The function of the connected analyzers in that regard are not limited by Power Express.
- Disorder, condition to that is intended to be detected, defined, or differentiated: N/A. Power Express does not detect, define, or differentiate any disorders or conditions. Power Express delivers samples to various connected analytical instruments that perform sample analysis.
- Automation: Power Express is an automation system that sorts, routes, and presents sample tubes to analyzers for analysis using a track system. Power Express can connect to various analytical instruments.
- Qualitative, semi-qualitative, or quantitative: N/A. Power Express does not measure specific analytes or markers and therefore does not have a testing method. Power Express delivers samples to connected analytical instruments that perform sample analysis.
- Type of specimen: Power Express performs pre-analytical and post-analytical sample processing for connected analyzers. Refer to connected analyzer IFUs for supported sample types.
- Testing population: N/A. Power Express does not analyze specific analytes or markers and therefore is not relevant to testing population.
- For companion diagnostics, the target population and the associated medicinal products – if applicable: N/A. Power Express does not analyze specific analytes or markers and therefore it does not have any companion diagnostics, target populations or associated medicinal products.

Training and Education Resources



Note

This section is added to the *Related Documents* section.

To confirm that trainees in your lab are proficient in basic system operations, go to the Beckman Coulter Training and Education website (www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm) to find resources on product training.

Warranty and Service



Note

This section replaces the *Warranty and Service* section.

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter and at the expense of the customer.

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, contact Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

For Russian Market Only

1. The manufacturer guarantees the conformity of manufactured products to requirements of normative and technical documentation. Safety and quality of products are guaranteed throughout the entire shelf life.
2. The manufacturer is responsible for product defects, except for defects that have arisen because of violation of the rules of use, transportation, and storage preconditions, or a third party, or force majeure.
3. The manufacturer will replace the product at its own expense:
 - If technical and functional (consumer properties) do not comply with the regulatory and technical documentation.
 - If these disadvantages are caused by latent defect in materials or workmanship by the product manufacturer.

For product quality, contact the representative of the manufacturer in the Russian Federation.

Notice to Users



Note

This section is added to the *Alerts for Warning, Caution, Important, Note, and Tip* section.

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact your Beckman Coulter Representative.

Electromagnetic Wave and Noise Precautions



Note

The following replaces the Caution in the *Electromagnetic Wave and Noise Precautions* section.

Electromagnetic Compatibility



Caution

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

For the Russian Market Only



Note

This section is added to the *Introduction* section.

Contraindications: N/A

Possible Side Effect: N/A

Intended Purpose



Note

This section is added to the *Introduction* section.

Power Express is an automated sample handing system that routes sample tubes to connected analyzers for in vitro diagnostic testing. Power Express is intended to optimize workflow and minimizes errors in hospital and clinical laboratories. This product is intended for laboratory professional use.

Detailed considerations:

- Specification of the analyte or marker to be determined: N/A. Power Express does not measure specific analytes or markers.
- Function screen/monitor/diagnose, or aid in diagnosis, prognosis and prediction: N/A. Power Express does not screen, monitor, diagnose, or aid in the diagnosis, prognosis and prediction of any disease. The function of the connected analyzers in that regard are not limited by Power Express.
- Disorder, condition to that is intended to be detected, defined, or differentiated: N/A. Power Express does not detect, define, or differentiate any disorders or conditions. Power Express delivers samples to various connected analytical instruments that perform sample analysis.
- Automation: Power Express is an automation system that sorts, routes, and presents sample tubes to analyzers for analysis using a track system. Power Express can connect to various analytical instruments.
- Qualitative, semi-qualitative, or quantitative: N/A. Power Express does not measure specific analytes or markers and therefore does not have a testing method. Power Express delivers samples to connected analytical instruments that perform sample analysis.
- Type of specimen: Power Express performs pre-analytical and post-analytical sample processing for connected analyzers. Refer to connected analyzer IFUs for supported sample types.
- Testing population: N/A. Power Express does not analyze specific analytes or markers and therefore is not relevant to testing population.
- For companion diagnostics, the target population and the associated medicinal products – if applicable: N/A. Power Express does not analyze specific analytes or markers and therefore it does not have any companion diagnostics, target populations or associated medicinal products.

Training and Education Resources



Note

This section is added to the *Related Documents* section.

To confirm that trainees in your lab are proficient in basic system operations, go to the Beckman Coulter Training and Education website (www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm) to find resources on product training.

Direct Track Sampling Modules IFU

Warranty and Service



Note

This section replaces the *Warranty and Service* section.

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter and at the expense of the customer.

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, contact Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

For Russian Market Only

1. The manufacturer guarantees the conformity of manufactured products to requirements of normative and technical documentation. Safety and quality of products are guaranteed throughout the entire shelf life.
2. The manufacturer is responsible for product defects, except for defects that have arisen because of violation of the rules of use, transportation, and storage preconditions, or a third party, or force majeure.
3. The manufacturer will replace the product at its own expense:
 - If technical and functional (consumer properties) do not comply with the regulatory and technical documentation.
 - If these disadvantages are caused by latent defect in materials or workmanship by the product manufacturer.

For product quality, contact the representative of the manufacturer in the Russian Federation.

Notice to Users



Note

This section is added to the *Alerts for Warning, Caution, Important, Note, and Tip* section.

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact your Beckman Coulter Representative.

Electromagnetic Wave and Noise Precautions



Note

The following replaces the Caution in the *Electromagnetic Wave and Noise Precautions* section.

Electromagnetic Compatibility



Caution

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

For the Russian Market Only



Note

This section is added to the *Introduction* section.

Contraindications: N/A

Possible Side Effect: N/A

Intended Purpose



Note

This section is added to the *Introduction* section.

Power Express is an automated sample handing system that routes sample tubes to connected analyzers for in vitro diagnostic testing. Power Express is intended to optimize workflow and minimizes errors in hospital and clinical laboratories. This product is intended for laboratory professional use.

Detailed considerations:

- Specification of the analyte or marker to be determined: N/A. Power Express does not measure specific analytes or markers.
- Function screen/monitor/diagnose, or aid in diagnosis, prognosis and prediction: N/A. Power Express does not screen, monitor, diagnose, or aid in the diagnosis, prognosis and prediction of any disease. The function of the connected analyzers in that regard are not limited by Power Express.
- Disorder, condition to that is intended to be detected, defined, or differentiated: N/A. Power Express does not detect, define, or differentiate any disorders or conditions. Power Express delivers samples to various connected analytical instruments that perform sample analysis.
- Automation: Power Express is an automation system that sorts, routes, and presents sample tubes to analyzers for analysis using a track system. Power Express can connect to various analytical instruments.
- Qualitative, semi-qualitative, or quantitative: N/A. Power Express does not measure specific analytes or markers and therefore does not have a testing method. Power Express delivers samples to connected analytical instruments that perform sample analysis.
- Type of specimen: Power Express performs pre-analytical and post-analytical sample processing for connected analyzers. Refer to connected analyzer IFUs for supported sample types.
- Testing population: N/A. Power Express does not analyze specific analytes or markers and therefore is not relevant to testing population.
- For companion diagnostics, the target population and the associated medicinal products – if applicable: N/A. Power Express does not analyze specific analytes or markers and therefore it does not have any companion diagnostics, target populations or associated medicinal products.

Training and Education Resources



Note

This section is added to the *Related Documents* section.

To confirm that trainees in your lab are proficient in basic system operations, go to the Beckman Coulter Training and Education website (www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm) to find resources on product training.

Warranty and Service



Note

This section replaces the *Warranty and Service* section.

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter and at the expense of the customer.

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, contact Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

For Russian Market Only

1. The manufacturer guarantees the conformity of manufactured products to requirements of normative and technical documentation. Safety and quality of products are guaranteed throughout the entire shelf life.
2. The manufacturer is responsible for product defects, except for defects that have arisen because of violation of the rules of use, transportation, and storage preconditions, or a third party, or force majeure.
3. The manufacturer will replace the product at its own expense:
 - If technical and functional (consumer properties) do not comply with the regulatory and technical documentation.
 - If these disadvantages are caused by latent defect in materials or workmanship by the product manufacturer.

For product quality, contact the representative of the manufacturer in the Russian Federation.

Notice to Users



Note

This section is added to the *Alerts for Warning, Caution, Important, Note, and Tip* section.

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact your Beckman Coulter Representative.

Electromagnetic Wave and Noise Precautions



Note

The following replaces the Caution in the *Electromagnetic Wave and Noise Precautions* section.

Electromagnetic Compatibility



Caution

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

For the Russian Market Only



Note

This section is added to the *Introduction* section.

Contraindications: N/A

Possible Side Effect: N/A

Intended Purpose



Note

This section is added to the *Introduction* section.

Power Express is an automated sample handing system that routes sample tubes to connected analyzers for in vitro diagnostic testing. Power Express is intended to optimize workflow and minimizes errors in hospital and clinical laboratories. This product is intended for laboratory professional use.

Detailed considerations:

- Specification of the analyte or marker to be determined: N/A. Power Express does not measure specific analytes or markers.
- Function screen/monitor/diagnose, or aid in diagnosis, prognosis and prediction: N/A. Power Express does not screen, monitor, diagnose, or aid in the diagnosis, prognosis and prediction of any disease. The function of the connected analyzers in that regard are not limited by Power Express.
- Disorder, condition to that is intended to be detected, defined, or differentiated: N/A. Power Express does not detect, define, or differentiate any disorders or conditions. Power Express delivers samples to various connected analytical instruments that perform sample analysis.
- Automation: Power Express is an automation system that sorts, routes, and presents sample tubes to analyzers for analysis using a track system. Power Express can connect to various analytical instruments.
- Qualitative, semi-qualitative, or quantitative: N/A. Power Express does not measure specific analytes or markers and therefore does not have a testing method. Power Express delivers samples to connected analytical instruments that perform sample analysis.
- Type of specimen: Power Express performs pre-analytical and post-analytical sample processing for connected analyzers. Refer to connected analyzer IFUs for supported sample types.
- Testing population: N/A. Power Express does not analyze specific analytes or markers and therefore is not relevant to testing population.
- For companion diagnostics, the target population and the associated medicinal products – if applicable: N/A. Power Express does not analyze specific analytes or markers and therefore it does not have any companion diagnostics, target populations or associated medicinal products.

Training and Education Resources



Note

This section is added to the *Related Documents* section.

To confirm that trainees in your lab are proficient in basic system operations, go to the Beckman Coulter Training and Education website (www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm) to find resources on product training.

Warranty and Service



Note

This section replaces the *Warranty and Service* section.

The system is covered by and subject to the provisions of the warranty included in your contractual agreement for the system or its reagents.

The customer is responsible for routine preventive maintenance procedures. Repairs arising from the failure to perform these maintenance procedures at the indicated time intervals are made at the discretion of Beckman Coulter and at the expense of the customer.

If any problems occur in the system during the warranty period, contact your Beckman Coulter Representative. Provide the serial number or system ID number and a complete description of the problem.

Telephone Service: USA and Canada

For United States and Canada customers, contact Beckman Coulter Customer Support toll-free at (800) 854-3633. Beckman Coulter Customer Support is available 24 hours a day to customers in the continental United States, Alaska, Hawaii, and Canada.

Telephone Service: International

For international customers, contact your local Beckman Coulter Customer Support.

For Russian Market Only

1. The manufacturer guarantees the conformity of manufactured products to requirements of normative and technical documentation. Safety and quality of products are guaranteed throughout the entire shelf life.
2. The manufacturer is responsible for product defects, except for defects that have arisen because of violation of the rules of use, transportation, and storage preconditions, or a third party, or force majeure.
3. The manufacturer will replace the product at its own expense:
 - If technical and functional (consumer properties) do not comply with the regulatory and technical documentation.
 - If these disadvantages are caused by latent defect in materials or workmanship by the product manufacturer.

For product quality, contact the representative of the manufacturer in the Russian Federation.

Notice to Users



Note

This section is added to the *Alerts for Warning, Caution, Important, Note, and Tip* section.

In the unlikely event that a serious incident occurs with this product, we will notify the user and the administrative authorities of the country in writing.

If you discover a serious incident, contact your Beckman Coulter Representative.

Electromagnetic Wave and Noise Precautions



Note

The following replaces the Caution in the *Electromagnetic Wave and Noise Precautions* section.

Electromagnetic Compatibility



Caution

This device complies with the emissions and immunity requirements as specified in the EN/IEC 61326 series of Product Family Standards for a "basic electromagnetic environment." Such equipment is supplied directly at low voltage from public mains network. This equipment is not intended for residential use.

This device generates, uses, and can radiate unintentional radio-frequency (RF) energy. If this device is not installed and operated correctly, this RF energy can cause interference with other equipment. It is the responsibility of the end user to be sure that a compatible electromagnetic environment for the device can be maintained so that the device operates as intended.

In addition, other equipment can radiate RF energy to which this device is sensitive. If one suspects interference between this device and other equipment, Beckman Coulter recommends the following actions to correct the interference:

- Evaluate the electromagnetic environment before installation and operation of this device.
- Do not operate this device close to sources of strong electromagnetic radiation (for example: unshielded intentional RF sources), as these can interfere with proper operation. Examples of unshielded intentional radiators are handheld radio transmitters, cordless phones, and cellular phones.
- Do not place this device near medical electrical equipment that can be susceptible to malfunctions caused by close-proximity to electromagnetic fields.
- This device has been designed and tested to CISPR 11, Class A emission limits. In a domestic environment, this device can cause radio interference, in which case, you need to take measures to mitigate the interference.

For the Russian Market Only



Note

This section is added to the *Introduction* section.

Contraindications: N/A

Possible Side Effect: N/A

Intended Purpose



Note

This section is added to the *Introduction* section.

Power Express is an automated sample handing system that routes sample tubes to connected analyzers for in vitro diagnostic testing. Power Express is intended to optimize workflow and minimizes errors in hospital and clinical laboratories. This product is intended for laboratory professional use.

Detailed considerations:

- Specification of the analyte or marker to be determined: N/A. Power Express does not measure specific analytes or markers.
- Function screen/monitor/diagnose, or aid in diagnosis, prognosis and prediction: N/A. Power Express does not screen, monitor, diagnose, or aid in the diagnosis, prognosis and prediction of any disease. The function of the connected analyzers in that regard are not limited by Power Express.
- Disorder, condition to that is intended to be detected, defined, or differentiated: N/A. Power Express does not detect, define, or differentiate any disorders or conditions. Power Express delivers samples to various connected analytical instruments that perform sample analysis.
- Automation: Power Express is an automation system that sorts, routes, and presents sample tubes to analyzers for analysis using a track system. Power Express can connect to various analytical instruments.
- Qualitative, semi-qualitative, or quantitative: N/A. Power Express does not measure specific analytes or markers and therefore does not have a testing method. Power Express delivers samples to connected analytical instruments that perform sample analysis.
- Type of specimen: Power Express performs pre-analytical and post-analytical sample processing for connected analyzers. Refer to connected analyzer IFUs for supported sample types.
- Testing population: N/A. Power Express does not analyze specific analytes or markers and therefore is not relevant to testing population.
- For companion diagnostics, the target population and the associated medicinal products – if applicable: N/A. Power Express does not analyze specific analytes or markers and therefore it does not have any companion diagnostics, target populations or associated medicinal products.

Minimum Software Requirement



Note

This section is added after the *Power Requirements* section.

Software usage environment: Use only on the PC included with this product.

Note: All software installation and upgrades must be performed by Beckman Coulter. Contact your Beckman Coulter Representative for support.

Training and Education Resources



Note

This section is added to the *Related Documents* section.

To confirm that trainees in your lab are proficient in basic system operations, go to the Beckman Coulter Training and Education website (www.beckmancoulter.com/wsrportal/wsr/support/training-education/index.htm) to find resources on product training.

www.beckmancoulter.com



© 2021 Beckman Coulter, Inc.
All Rights Reserved.