



GeneXpert® System with Touchscreen GX II – GX IV Technology Training

Speaker's Name
Date

For Use with GeneXpert® Systems with Touchscreen

302-8142 Rev. A February 2022

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

1 © 2022 Cepheid.



Training Agenda

- 1 Cepheid Family of Systems
- 2 Technology of the GeneXpert® System
- 3 Technology of the Xpert® Cartridge
- 4 Connectivity
- 5 Power and Safety Requirements
- 6 Cartridge Disposal



CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Training Objectives

➔ The general objective of this module is to give you an understanding of the GeneXpert® system.

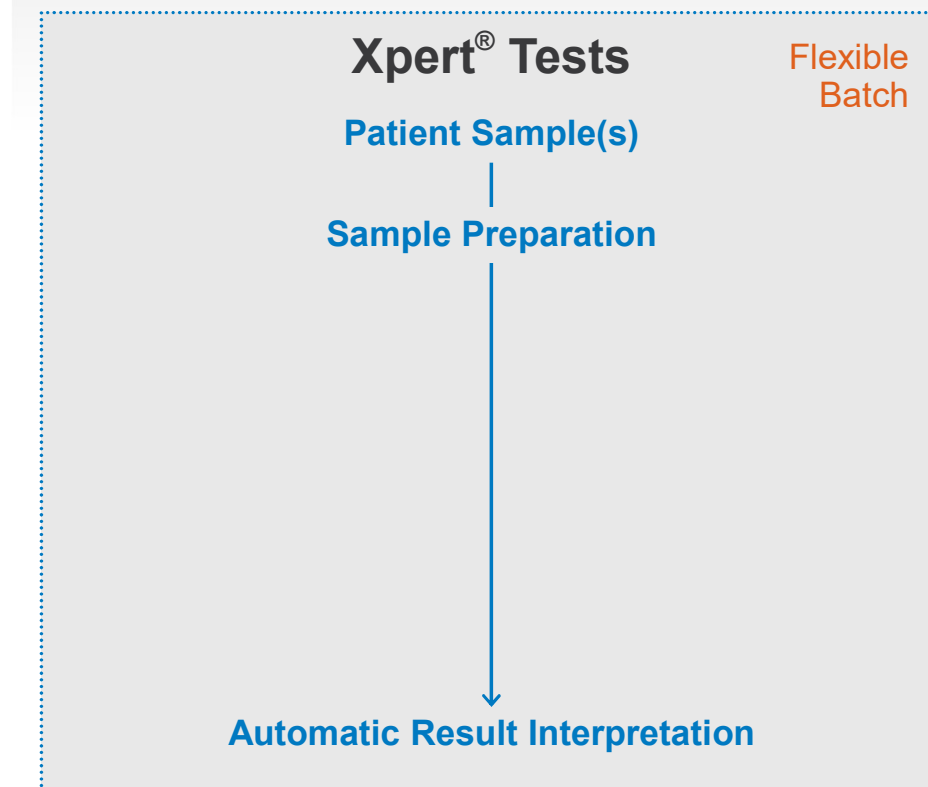
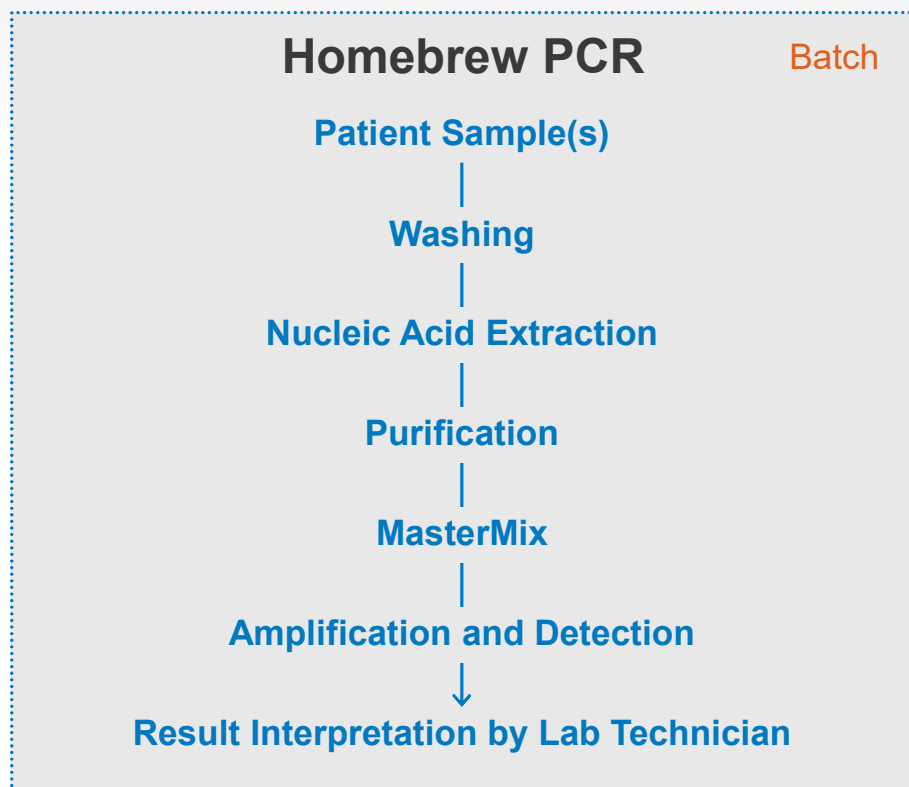
At the end of the training, users will be able to:

- Recognize and recall the different GeneXpert® systems
- Explain the technology of the GeneXpert® system and how the cartridge works
- Summarize the basics of GeneXpert® connectivity
- Recognize the GeneXpert® system power requirement needs
- Recall basic safety precautions
- Explain the general disposal requirements of test cartridges



CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Polymerase Chain Reaction (PCR) Evolution



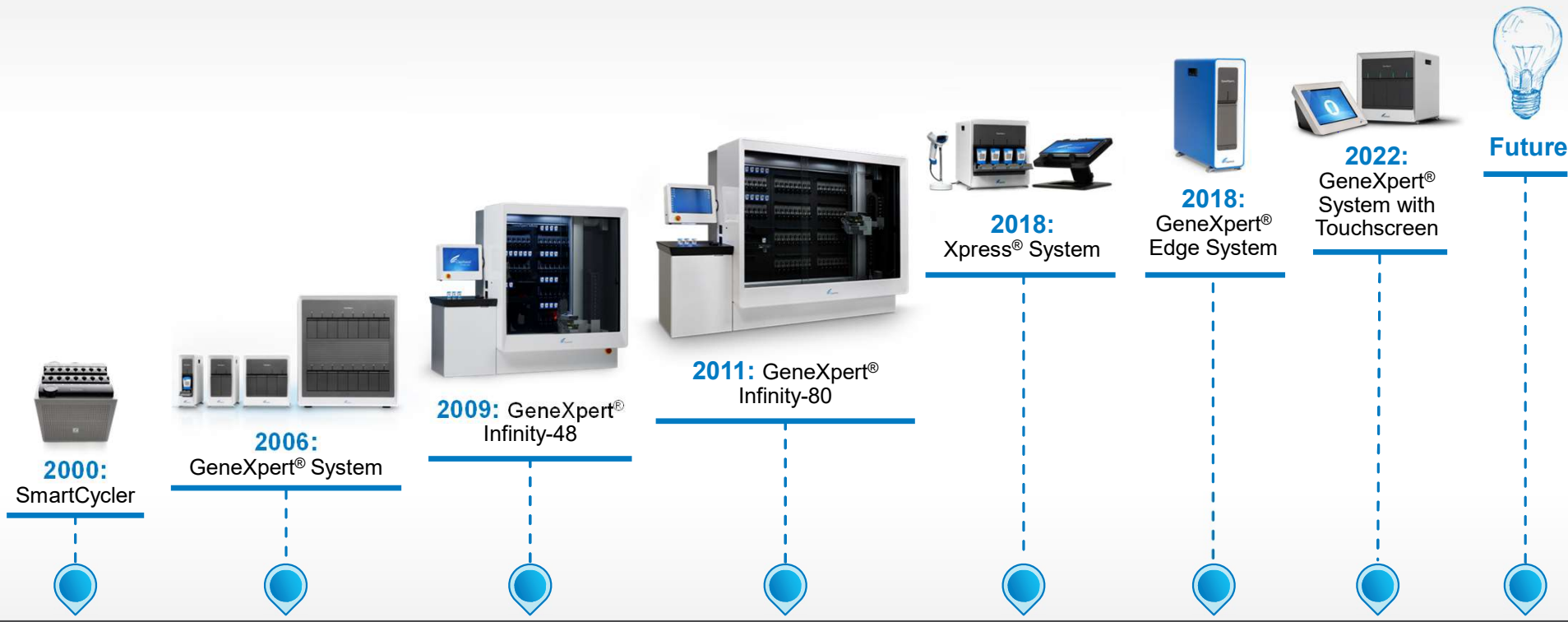
CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.



Cepheid Family of Systems

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

History of Ongoing System Innovation



*Not all systems available in all countries. ** Product in development. Not for use in diagnostic procedures. Not reviewed by any regulatory body.
Information as of July 2020

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

The Package

GeneXpert® System with Touchscreen

- Thermal and optical module(s)
- Touchscreen unit with integrated LED barcode scanner
- Simplified and intuitive Cepheid OS software
- USB Wi-Fi dongle for ethernet connection
- Padlock for instrument security



Cartridge

- Self-contained
- Disposable
- Assay Definition File



Recommended Accessories

- UPS
- Surge protector

Optional Accessories

- Power generator
- Printer

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

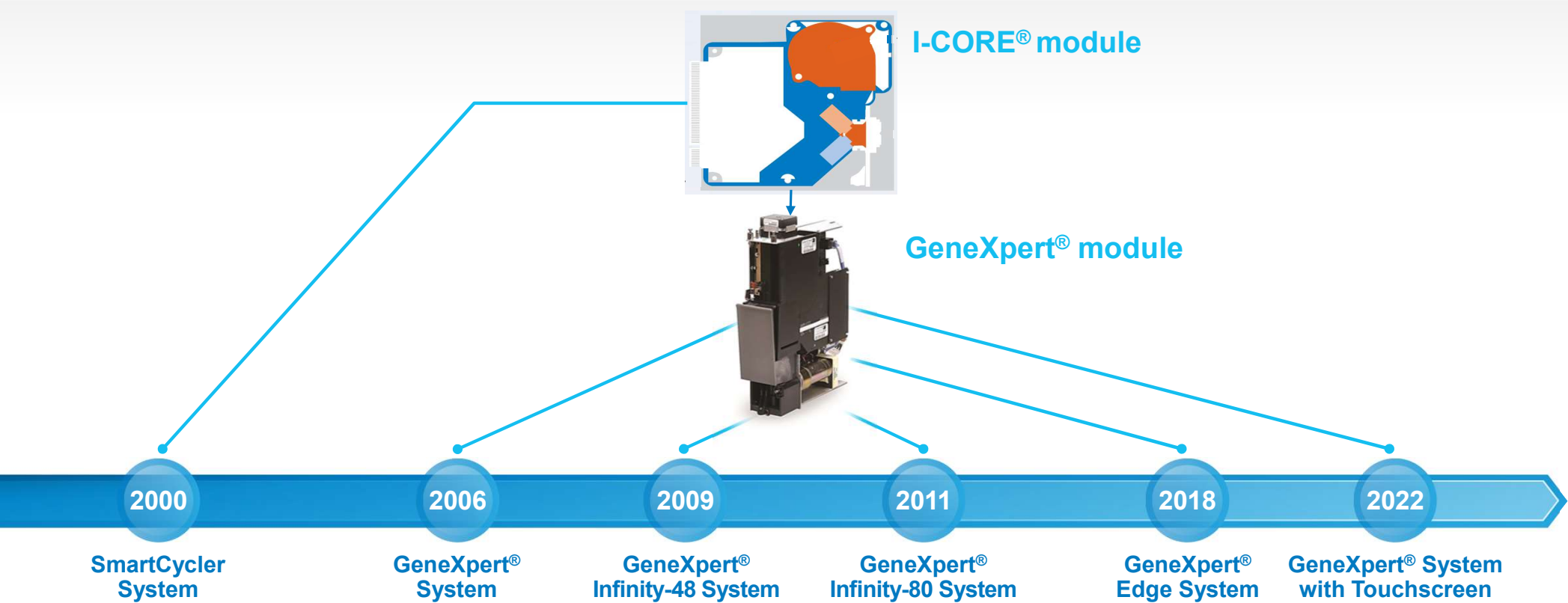


The Technology

The GeneXpert® System

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Proven Technology



CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

*Not all systems available in all countries.



GeneXpert® Technology

Integrated and closed system

- No direct contact between instrument and sample to eliminate carry-over
- The sample is enclosed in the cartridge
- Integrated ultrasonic horn for cell lysis (when applicable)

Fluid transfer: Micro fluidics-based reconstitution, and automated filling

- Advanced micro fluidics technologies to enable complex sample preparation processing protocols
- Software-driven motors for valve movement and integral hydraulic drives

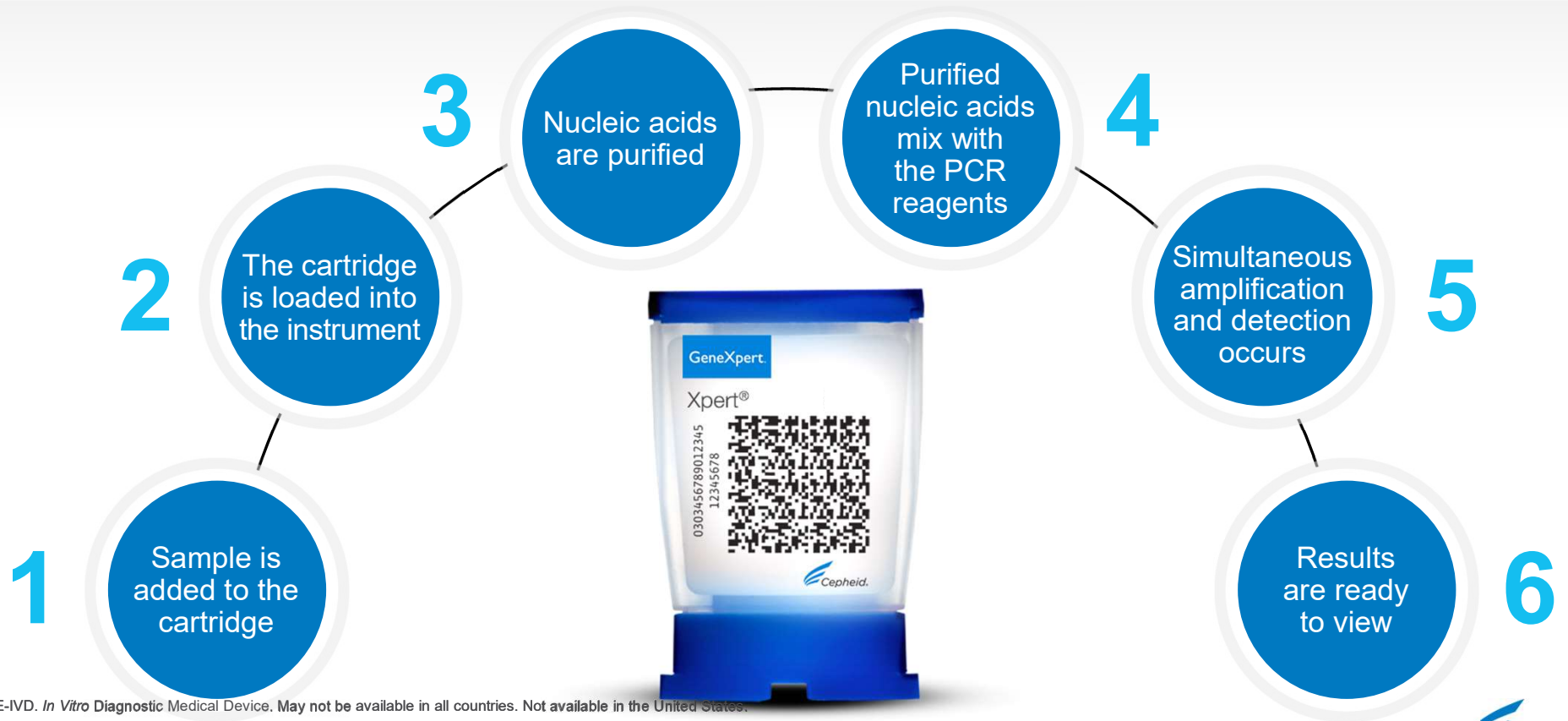
Multiple integrated controls to validate every step

Automated protocol, data reduction, and results interpretation



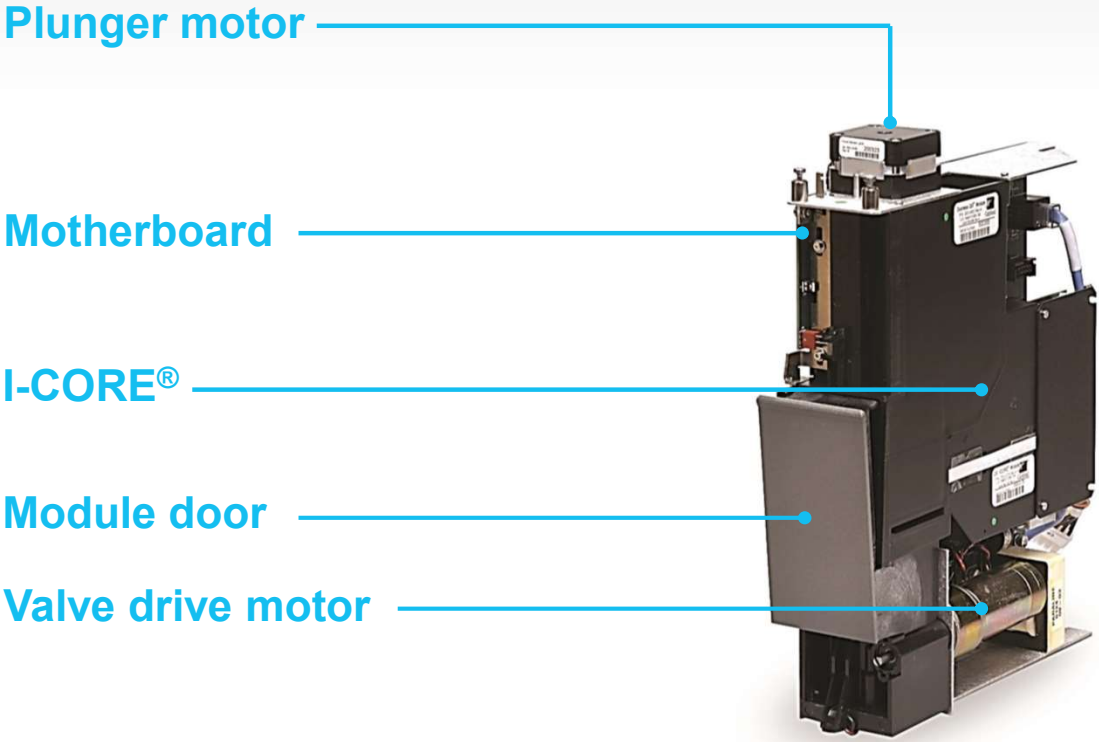
CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Automated Xpert® Protocol



CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

GeneXpert® Module



VIDEO
[Journey Inside the
Cepheid GeneXpert®
Cartridge—3D Animation](#)

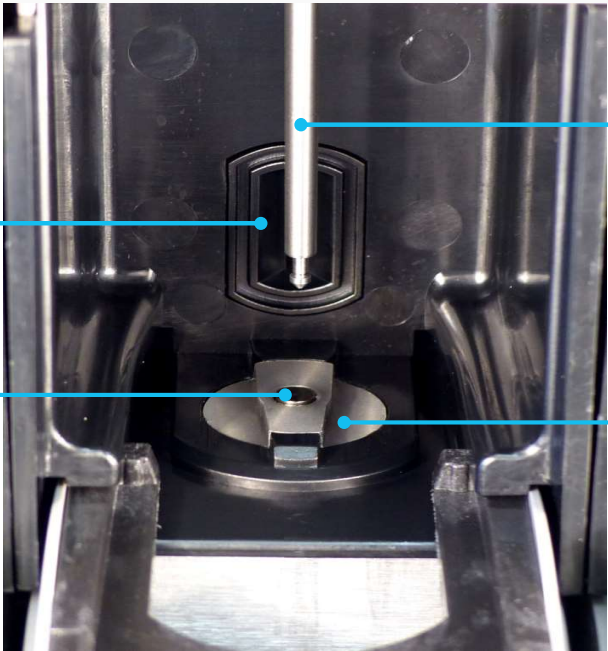
"For complete details on the GeneXpert® System, please refer to the GeneXpert® System Operators Manual"
CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.



Cartridge Bay

I-CORE® slit
PCR amplification
and detection

Ultrasonic horn
Lyses the sample
(if applicable)



Plunger rod
Facilitates movement of
sample and reagents into
different chambers

Valve drive
Rotates the cartridge valve
body to allow access to the
different cartridge chambers

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

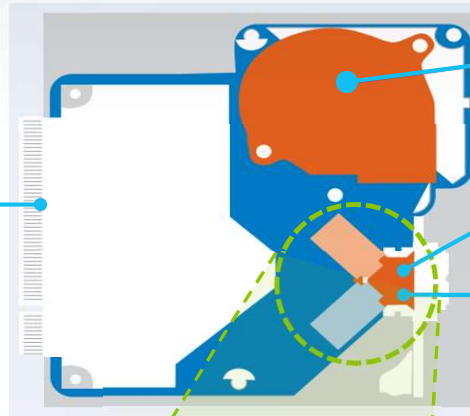


The I-CORE® Module

Building Block of the GeneXpert® System

Circuitry

Passes optical information to the computer for analysis and display



Fan (Cooler)

Heater

Rapid, precise temperature control

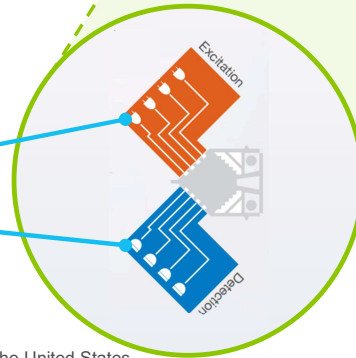
Inserts into the I-CORE® module



Cartridge
Sample preparation

Optical Blocks

Optical analysis, detect, and quantify up to 10 different DNA targets simultaneously



CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.



The Technology

Xpert[®] Test Cartridge

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Xpert® Cartridge

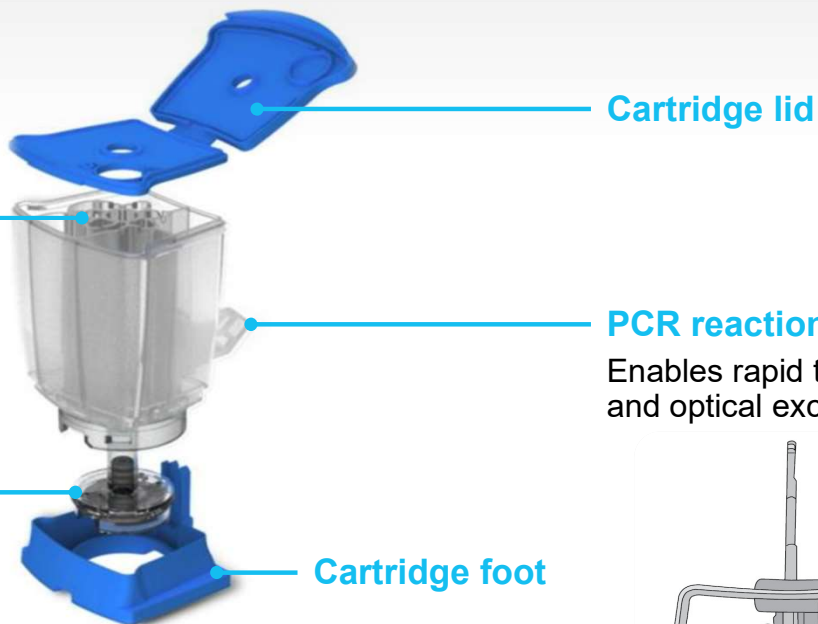
- Self-contained cartridge
- Avoids cross-contamination

Processing chambers

Holds the sample, reagents, processed sample, and waste solutions

Valve body

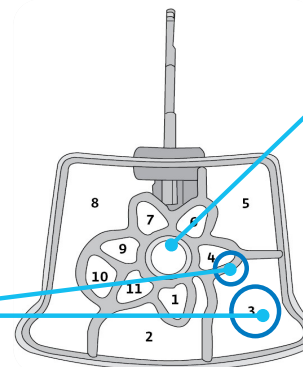
Rotates and allows fluid to move to different chambers and to the reaction tube



PCR reaction tube

Enables rapid thermal cycling and optical excitation/detection

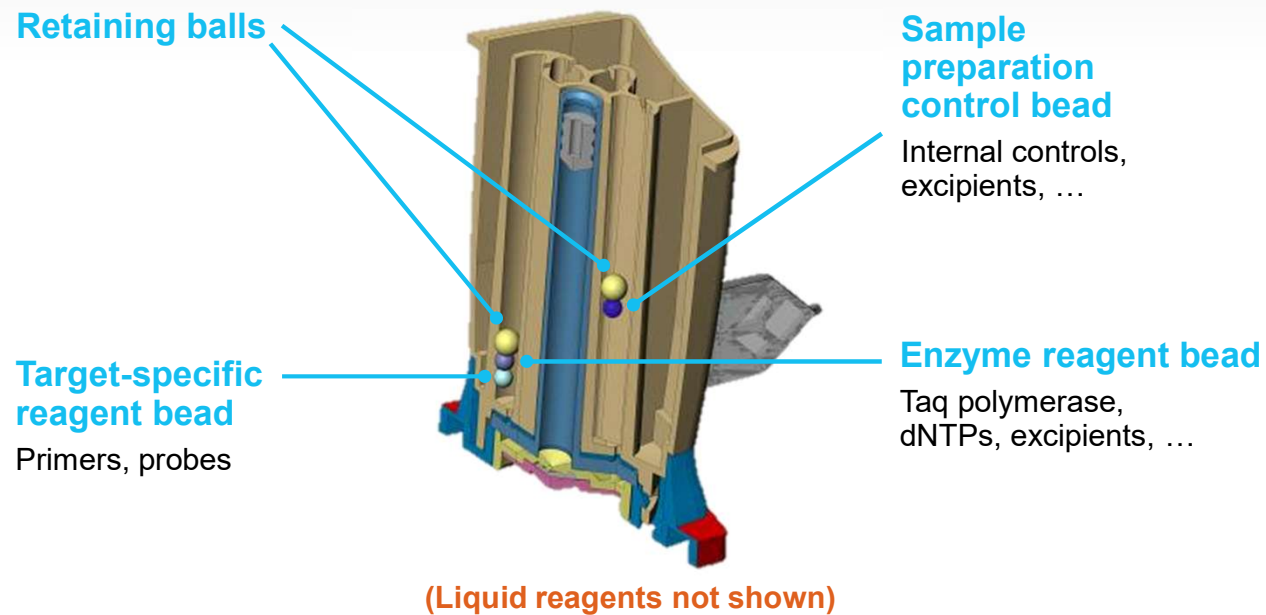
Dedicated for the plunger



- Some chambers are used for sample processing
- Some chambers are for reagents

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Internal View of the Cartridge

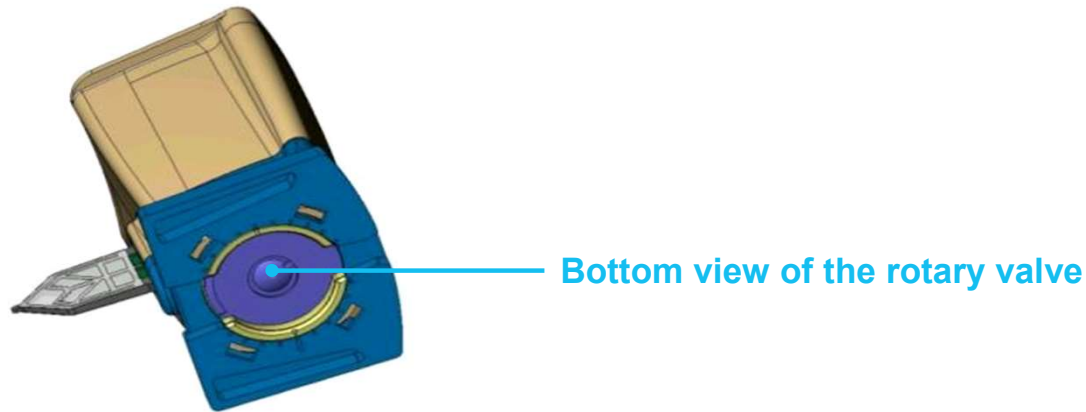


CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Cartridge Bottom View

Rotary valve is pre-aligned to fit with the valve in the module

- Do not rotate the rotary valve
- Alignment required to lock the module door and start the process

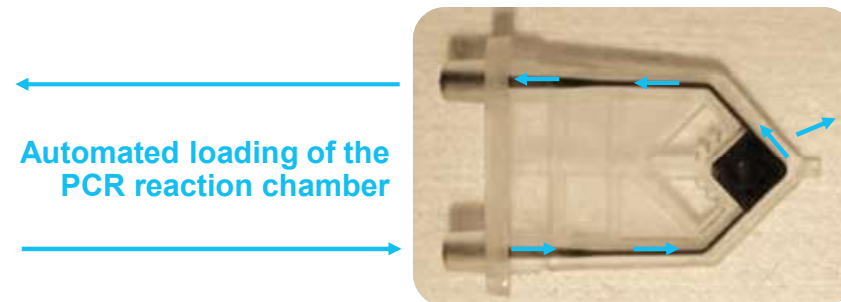


CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

PCR Reaction Chamber

Fluid transfer in the PCR reaction tube

- Do not touch the PCR reaction tube
- Wear gloves whenever you prepare a cartridge





Connectivity

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Laboratory Information System (LIS) Compatibility

Result availability

- Improve turnaround time (TAT)
- Improve efficiency and effectiveness

Eliminate manual data entry

- Reduce risk and data entry errors
- Optimize workflow and simplify steps

Improve patient response and care

- Instant access to actionable results

LEAN: From Beginning to End

How do you automate the most automated system in the molecular market place?
Interface it to your LIS.

Turn your GeniePort System into a LEAN Open Solution by interfacing to your LIS. Just like other automated systems in your laboratory, interfacing your GeniePort system eliminates non value-added steps associated with pre- and post-analytical data management. By streamlining transcription steps, the associated risk of medical error is removed. This is one step further and automatically allows normal results to be sent seamlessly and irrevocably. Advise patients TAT for those non-infectious patients who do not require isolation or antibiotic therapy, thus allowing immediate discharge or de-isolation.

- Improve efficiency and effectiveness
- Reduce risk of medical errors
- Define workflow and simplify steps
- Increase the value of your work
- Improve TAT
- Improve patient response and care

"We have seen many workflow enhancements after interfacing the GeniePort to our LIS including increased productivity as well as a significant decrease in errors that were caused when hand entering results."
— Bryan Desimone, Applications System Analyst, Legacy Health System

Simplified Pathway to Results
Not only does the GeniePort system automate all of your analytical processes (Extraction, Amplification, Detection) but the GeniePort system is also capable of automating your pre- and post-analytical data management processes via an LIS connection.

LEAN: From Beginning to End

Cepheid LIS Module

- Bi-Directional Communication
- HL7 and ASTM compatible
- Automatic Data Transfer Capability
- Validation & Verification of Data
- Interoperable with multiple GeniePort Systems at one time
- Same interface compatibility for all GeniePort Systems

"We've seen a great reduction in our turn around times now that the tests automatically download to the instrument. Also helping reduce time is that the results automatically upload into our LIS which means we no longer have to have one Tech enter the results and then have another Tech verify them."
— Bryan Desimone, Applications System Analyst, Legacy Health System

Frequently Asked Questions

Q: Is your GeniePort System interface ready?
A: Yes, all GeniePort Systems come pre-installed with the LIS Software Module.

Q: Which Cepheid interfaces are currently available through respective vendors?
A: Via LIS Systems: Corner, StarQuest, Meditech, Mission, (CC)S, Sunlit, Harvest, CPC
Via Middleware: Data Innovations, Dwaning
(Check with your Cepheid Representative for recent additions)
Via Point of Care (POC): Aegis POC

Q: What other components are needed for connectivity?
A: An HL7 or ASTM compatible Interface driver & I/O-45 Ethernet cable running from GeniePort PC to Facility network port.

Q: What if my LIS or Middleware interface driver does not exist?
A: Cepheid is excited and willing to work with your LIS or Middleware provider to develop the interface and establish LIS connectivity.

Cepheid C360 Connectivity

Web Portal

Dashboard which aggregates data stream from GeneXpert® Systems

Instrument Monitoring

Real-time audit of the systems and enhanced support



Included in the GX Solution

No additional costs to use C360

Two Prerequisites

Internet connection and Signed Agreement



Real-Time Actionable Data

Relevant information, easier to scale-up and extrapolate

Clinical Surveillance

Infectious diseases monitoring with easy trends and mapping



Improved Connectivity and Support

Maximize instrument uptime & ease access to impactful data. Server located in Germany.

Living Solution

Constant enhancements to ensure maximum security level and more actionable insights

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.



Power and Safety Requirements

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

System Power Consumption Requirements

Power Supply: Auto Rating

- GeneXpert[®] System Energy Consumption information

System Size	On Power Mode Consumption (W)	Annual Energy Consumption (KWh)	Standby Power Consumption
GX-II	85	372	71
GX-IV	100	489	83

- Computer Energy Consumption information
 - Touchscreen unit 149kW

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.





Cartridge Disposal

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Safety Precautions

Injury may result if the instrument is not lifted properly.



It is possible for you or the system to be exposed to biological hazards.



The GeneXpert[®] instrument's enclosure is designed to protect operators from electrical shock hazards.



CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.



Disposal

Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring standard precautions.

Follow your institution's environmental waste procedures for proper disposal.

.....

These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures.

.....

If national or regional regulations do not provide clear direction on proper disposal, the biological specimens and used cartridges should be disposed of per WHO (World Health Organization) medical waste handling and disposal guidelines.



CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.



Technical Assistance

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Technical Assistance

Before contacting Cepheid Technical Support, collect the following GeneXpert® information:

Person in charge (name)	X
Phone number	X
Serial number of your GeneXpert® System (on back panel)	X
E-mail address	X
Address, City, Country	X
Touchscreen Unit Tag Number	X
Installation date of the System	xx/xx/xxxx
Description of the issue (software messages/codes)	X
Assay(s) used	X

 **When contacting Cepheid, please prepare this information in advance: www.cepheid.com/support**

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

Technical Assistance

Log your case online using the following link: <http://www.cepheid.com/en/support>

→ Create a Support Case

- Contact local technical support

Region	Telephone	Email
US	+ 1 888 838 3222	techsupport@cepheid.com
Australia and New Zealand	+ 1800 130 821 + 0800 001 028	techsupportANZ@cepheid.com
Brazil and Latin America	+ 55 11 3524 8373	latamsupport@cepheid.com
China	+ 86 021 5406 5387	techsupportchina@cepheid.com
France	+ 33 563 825 319	support@cepheideurope.com
Germany	+ 49 69 710 480 480	support@cepheideurope.com
Spain	+ 34 919 90 67 62	support@cepheideurope.com
Portugal	+ 351 800 913 174	support@cepheideurope.com
India, Bangladesh, Bhutan, Nepal, and Sri Lanka	+ 91 11 48353010	techsupportindia@cepheid.com
Italy	+ 39 800 902 567	support@cepheideurope.com
South Africa	+ 27 861 22 76 35	support@cepheideurope.com
United Kingdom	+ 44 3303 332 533	support@cepheideurope.com
Othe European, Middle East, and African countries	+ 33 563 825 319 + 971 4 253 3218	support@cepheideurope.com
Other countries not listed	+ 1 408 400 8495	techsupport@cepheid.com

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.



Thank You

www.Cepheid.com

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

31 © 2022 Cepheid.

