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.

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

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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

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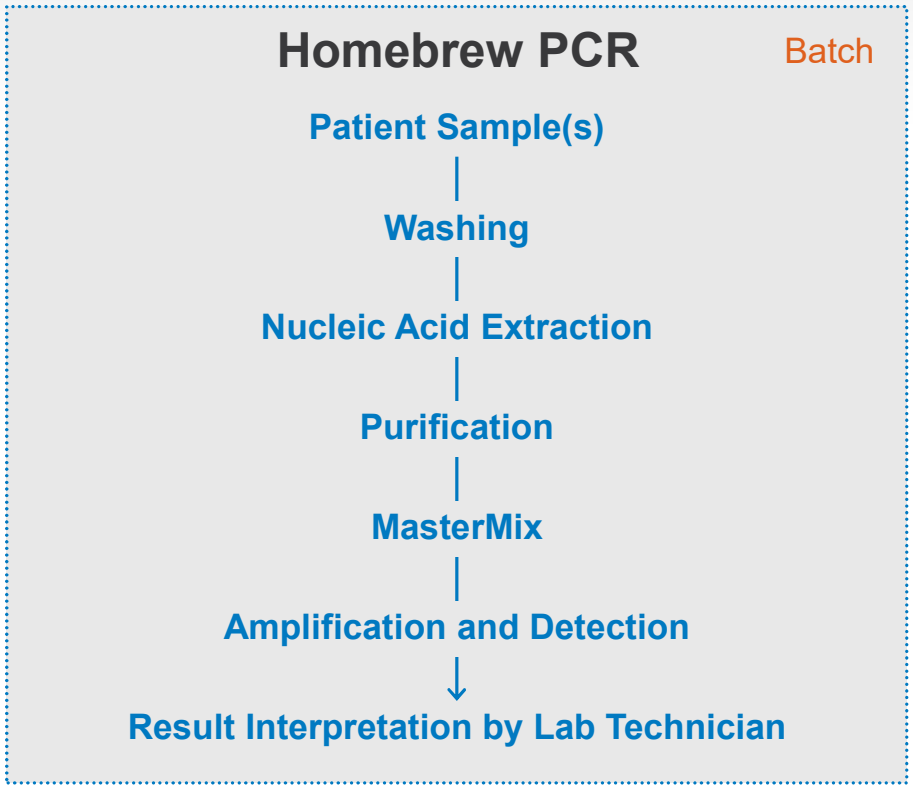
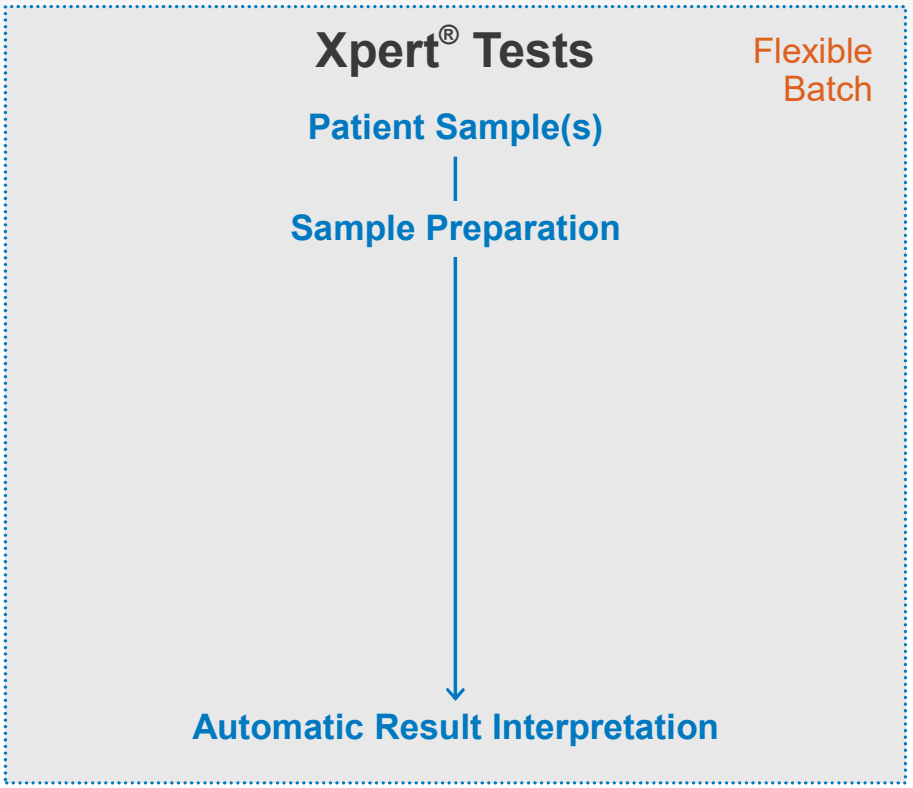
Polymerase Chain Reaction (PCR) Evolution





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Cepheid Family of Systems

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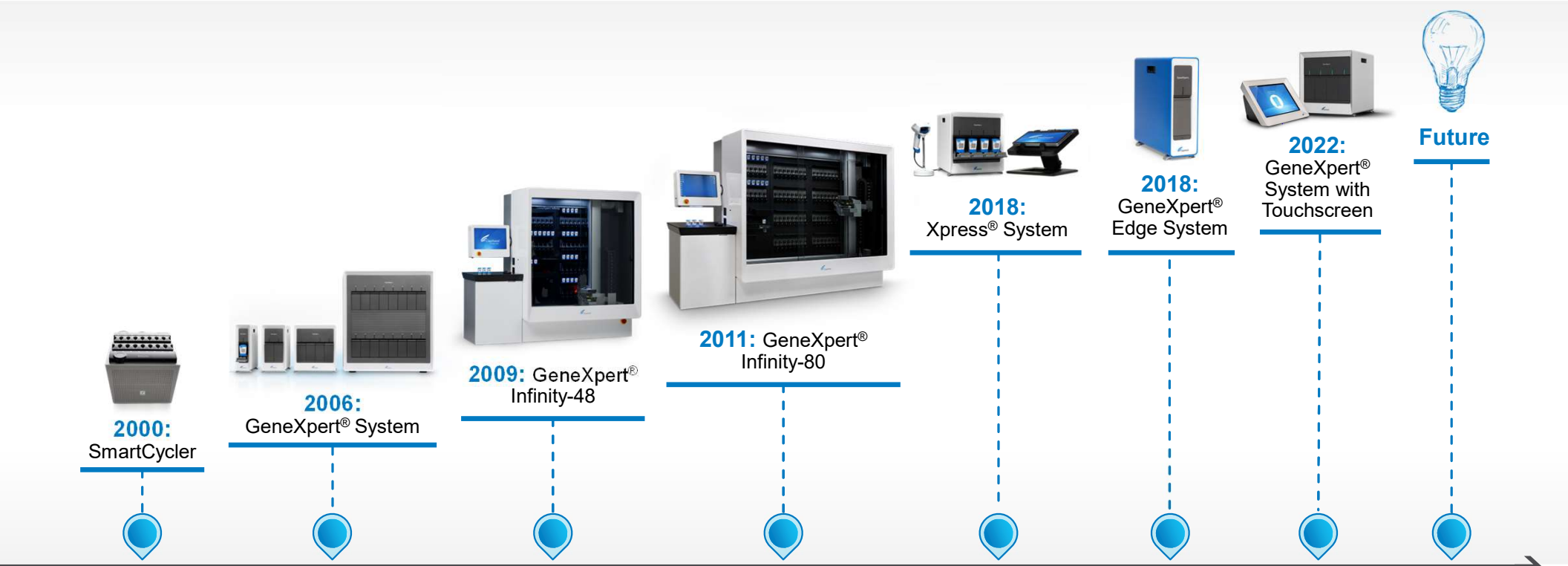
History of Ongoing System Innovation



*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

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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

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The Technology

The GeneXpert® System

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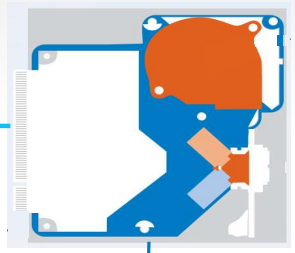
Proven Technology



I-CORE® module

GeneXpert® module

2000	2006	2009	2011	2018	2022
SmartCycler System	GeneXpert® System	GeneXpert® Infinity-48 System	GeneXpert® Infinity-80 System	GeneXpert® Edge System	GeneXpert® System with Touchscreen

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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

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Automated Xpert® Protocol

1 Sample is added to the cartridge

2 The cartridge is loaded into the instrument

3 Nucleic acids are purified

4 Purified nucleic acids mix with the PCR reagents

5 Simultaneous amplification and detection occurs

6 Results are ready to view

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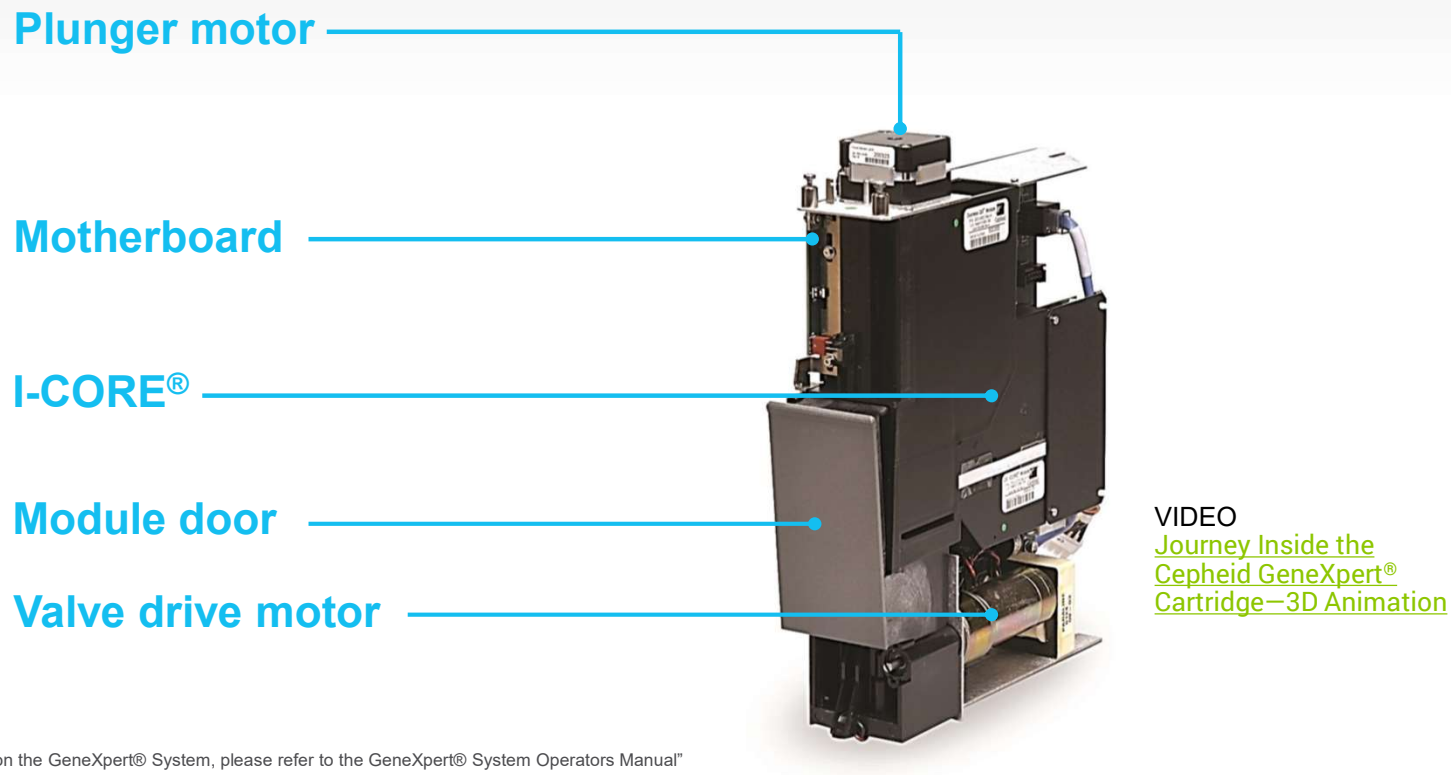
GeneXpert® Module



VIDEO
Journey Inside the Cepheid GeneXpert® Cartridge—3D Animation

"For complete details on the GeneXpert® System, please refer to the GeneXpert® System Operators Manual"
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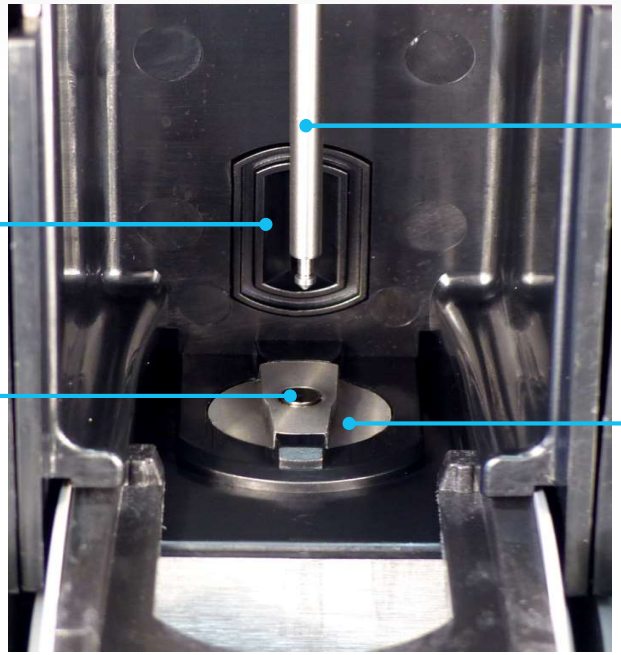
Cartridge Bay



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

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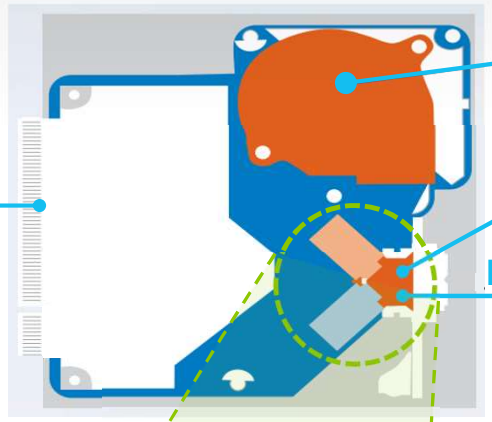
The I-CORE® Module

Building Block of the GeneXpert® System



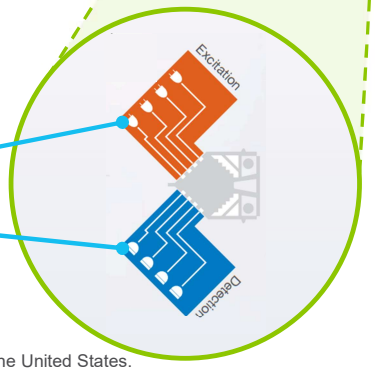
Fan (Cooler)

Heater
Rapid, precise temperature control

Circuitry
Passes optical information to the computer for analysis and display

Inserts into the I-CORE® module

Cartridge
Sample preparation



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

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The Technology

Xpert® Test Cartridge

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Xpert® Cartridge

- Self-contained cartridge
- Avoids cross-contamination

Cartridge lid

Processing chambers

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

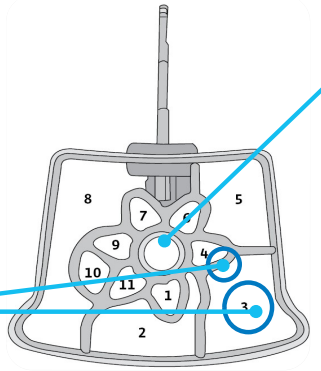
PCR reaction tube

Enables rapid thermal cycling and optical excitation/detection

Valve body

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

Cartridge foot



Dedicated for the plunger

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

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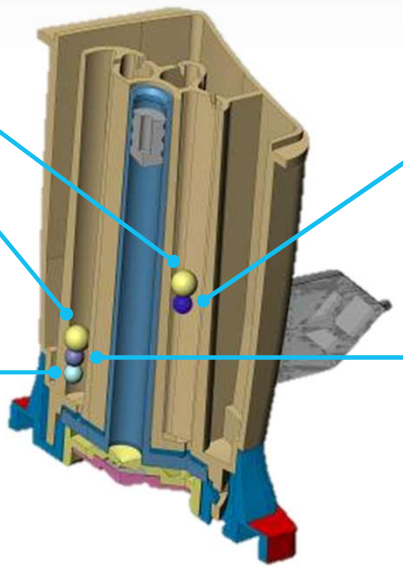
Internal View of the Cartridge



(Liquid reagents not shown)

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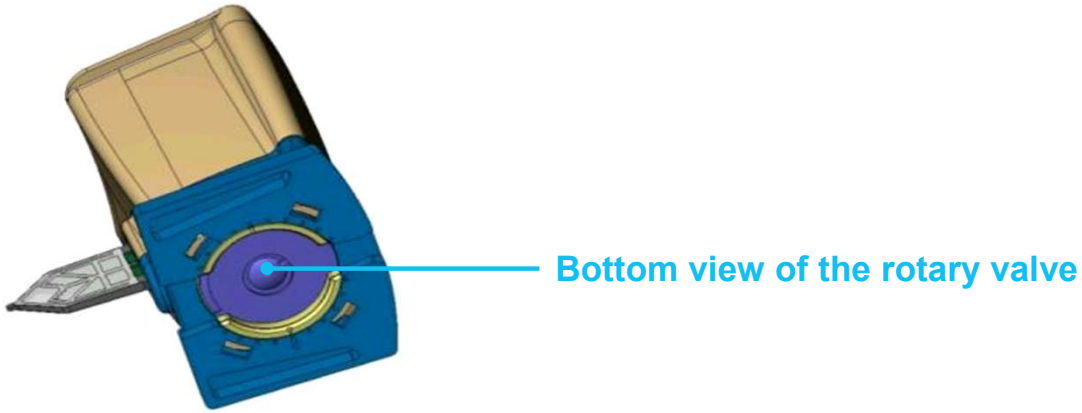
Cartridge Bottom View

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



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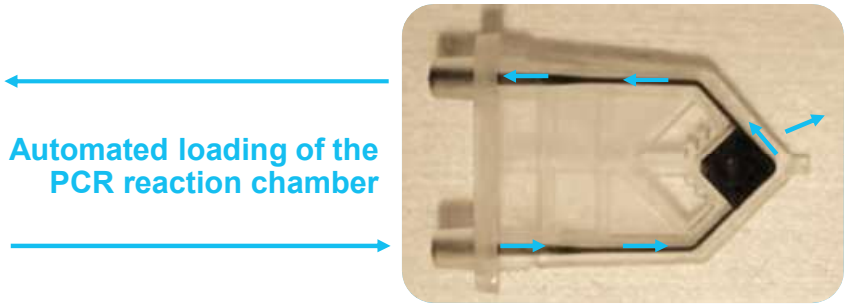
PCR Reaction Chamber

Fluid transfer in the PCR reaction tube

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



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Connectivity

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Laboratory Information System (LIS) Compatibility

Result availability

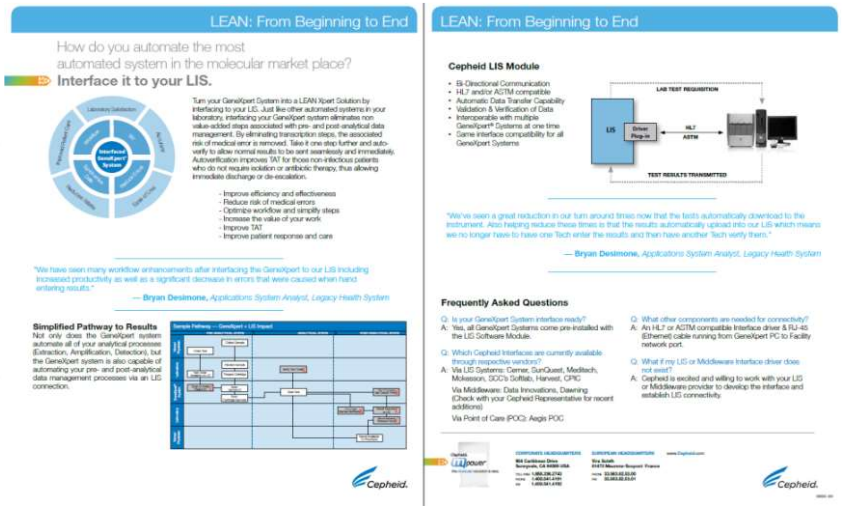
- Improve turnaround time (TAT)
- Improve efficiency and effectiveness

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



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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

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Power and Safety Requirements

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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

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Cartridge Disposal

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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.

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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.

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Technical Assistance

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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

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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
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South Africa	+ 27 861 22 76 35	support@cepheideurope.com
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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

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Thank You

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