Technology of the GeneXpert® System

301-7932 Rev B.1 December 2020
US-IVD and CE-IVD. For *in vitro* diagnostic use

Agenda

Cepheid System Families

Technology of the GeneXpert® System

Technology of the Xpert® Cartridge

Connectivity

Power & Safety Requirements

Cartridge disposal

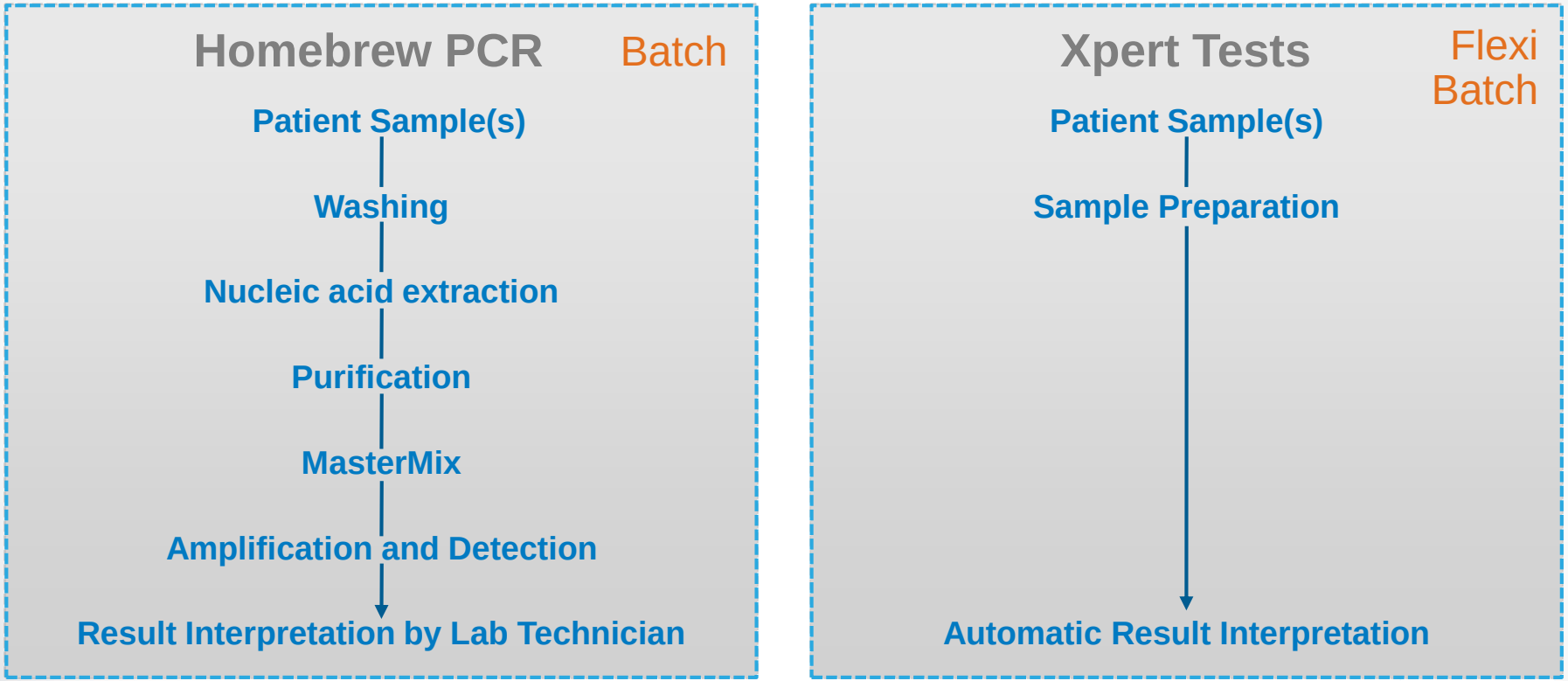
Learning Objectives

The General Objective of this Module Is to Give You an Understanding of the Technology of the GeneXpert® System

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

- Recognize and recall the different GeneXpert Systems
- Explain the technology of the GeneXpert 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

Polymerase Chain Reaction (PCR) Evolution



Cepheid Systems Family

History of Ongoing System Innovation

2000: SmartCycler

2006: GeneXpert System

2009: Infinity-48

2011: Infinity-80

2018: Xpress

2018: Edge

2020/21: **Omni

Information as of July 2020
* Not all systems available in all countries

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**Product in development. Not for use in diagnostic procedures. Not reviewed by any regulatory body.

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The Package

GeneXpert® System*

- Thermal and optical module(s)
- Computer System and GeneXpert Dx Software
- Barcode scanner

Cartridge

- Self-Contained
- Disposable
- Assay Definition Protocol (ADF)

Recommended Accessories

- UPS
- Surge protector

Optional Accessories

- Batteries/Power generator
- Printer

** FDA cleared*

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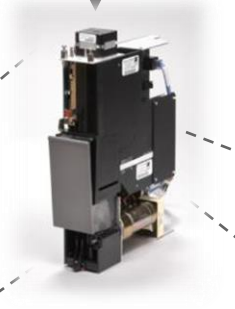
The Technology

The GeneXpert® System

Proven Technology

I-CORE®

GeneXpert Module



2000
SmartCycler System

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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

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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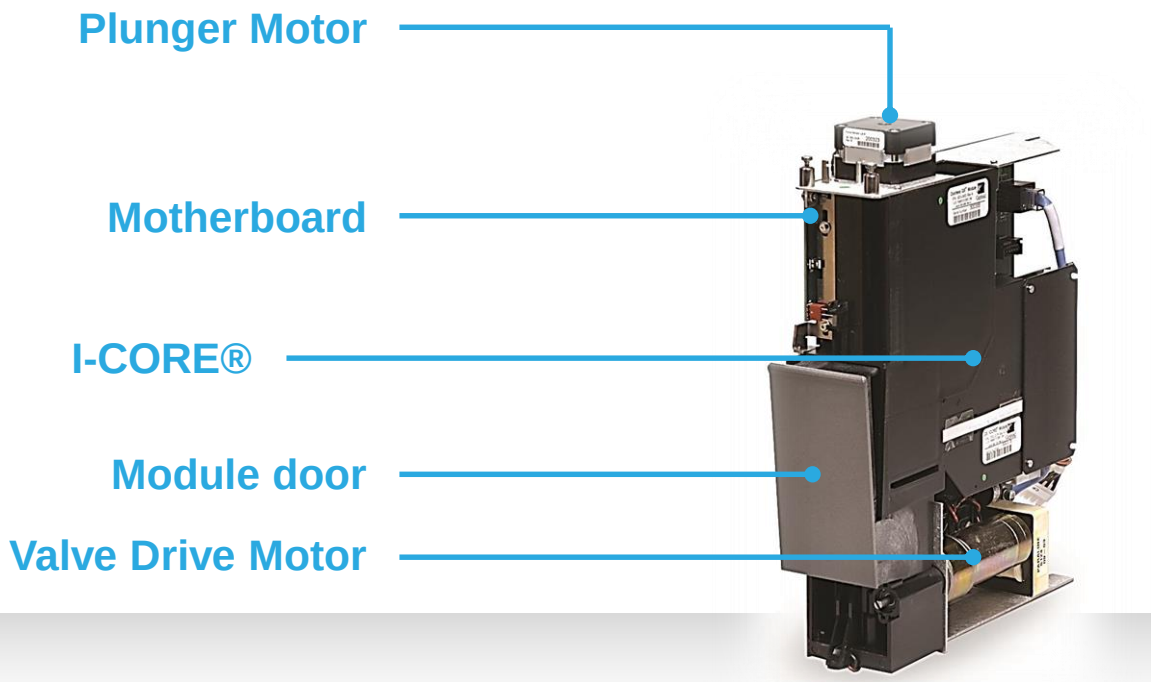
GeneXpert® Module



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

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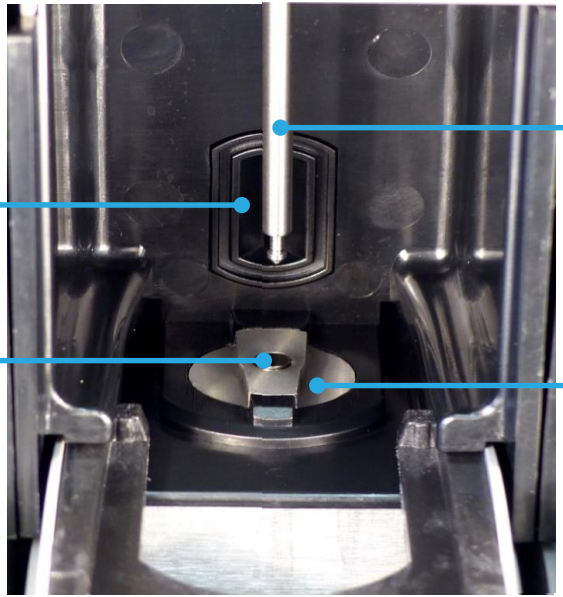
Cartridge Bay

I-CORE® Slit

PCR amplification & 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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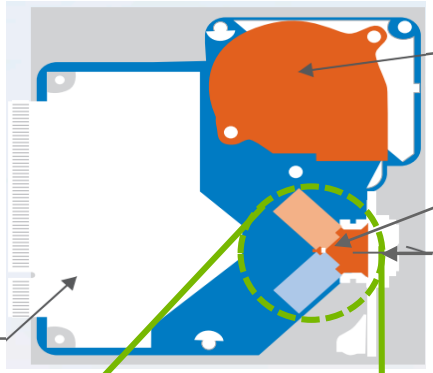
The I-CORE® Module

Building Block of the GeneXpert® System



Fan

Heater

Rapid, precise temperature control

Inserts into the I-CORE®

Cartridge

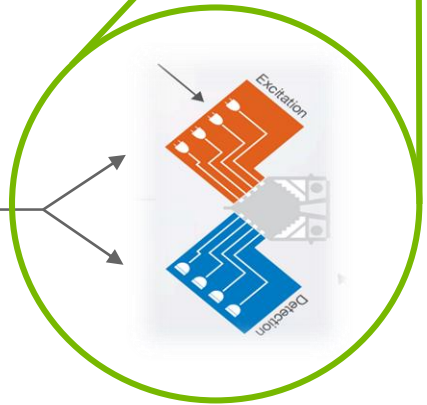
Sample preparation

Circuitry

Passes optical information to the computer for analysis and display

Optical Blocks

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



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The Technology

Xpert Test Cartridge

Xpert® Cartridge

- Self-contained cartridge
- Avoids cross-contamination

Cartridge Lid

Processing Chambers

Holds the sample, reagents, processed sample and waste solutions

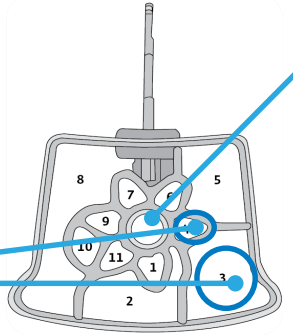
PCR Reaction Tube

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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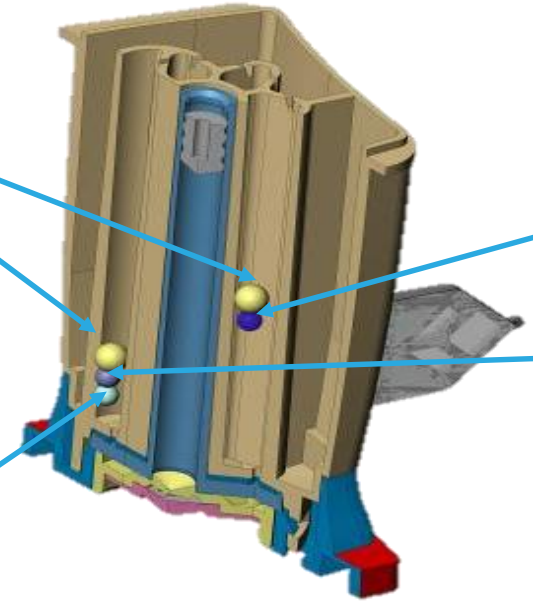
Internal View of the Cartridge



Retaining Balls

Sample Preparation Control Bead

Internal Controls, excipients…

Enzyme Reagent Bead

Taq polymerase, dNTPs, excipients…

Target-specific Reagent Bead

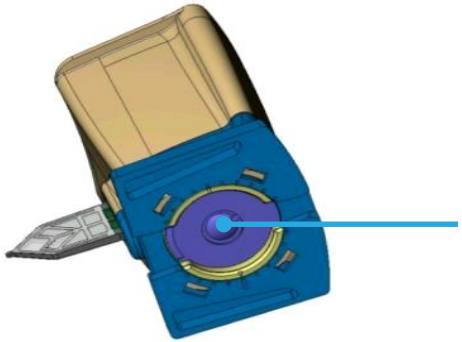
Primers, probes

(Liquid Reagents not shown)

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

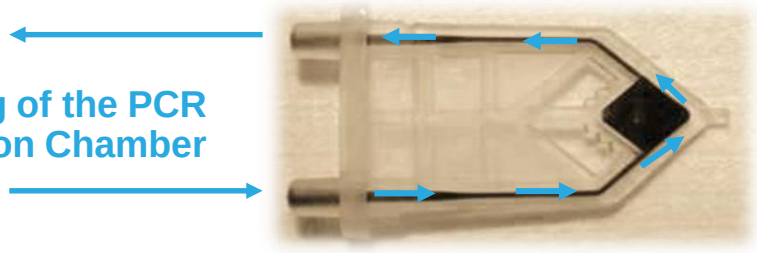


Bottom View of the Rotary Valve

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

Laboratory Information System (LIS) Compatibility

Result availability

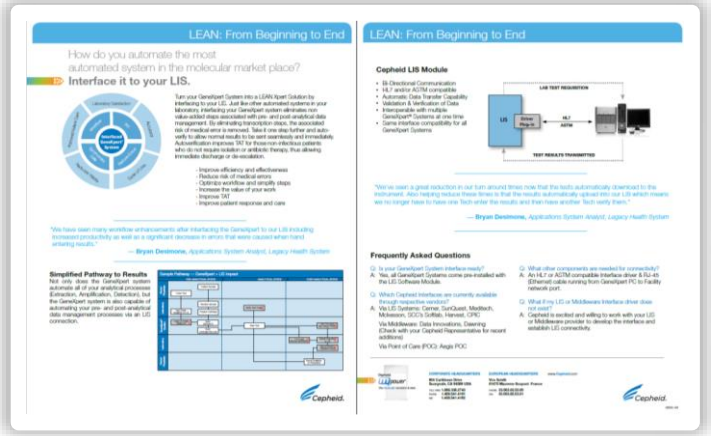
- Improve Turn Around Time (TAT)
- Improve efficiency and effectiveness

Eliminate manual data entry

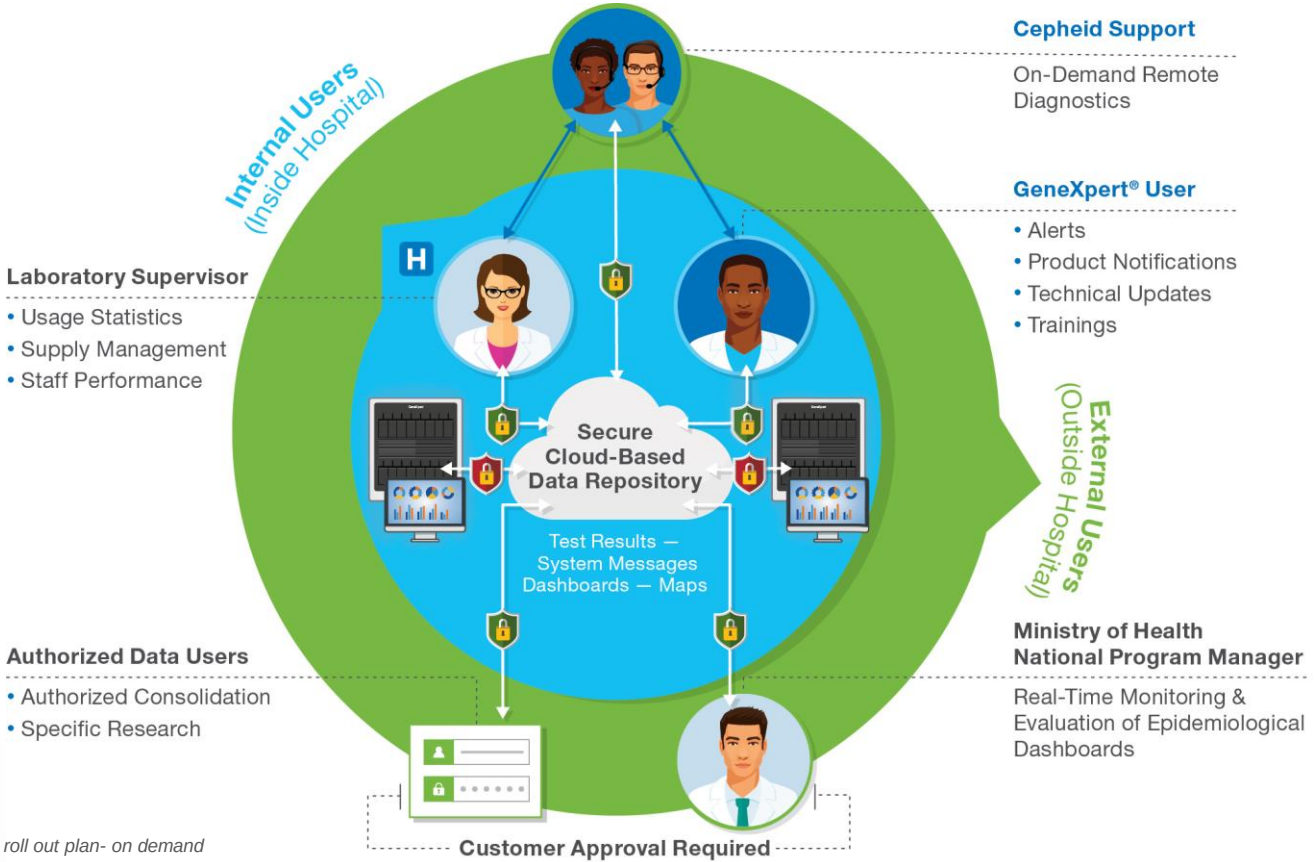
- Reduce risk of data entry errors
- Optimize workflow and simplify steps

Improve patient response and care

- Instant access to actionable results



Cepheid C360 Connectivity*



  ** Progressive roll out plan- on demand*

Power and Safety Requirements

System Power Consumption Requirements

- Power Supply: Auto Rating
- GeneXpert Energy Consumption information

System Size	On Power Mode Consumption (W)	Annual Energy Consumption (KWh)	Standby Power Consumption
GX-1	61	263	58
GX-II	85	372	71
GX-IV	100	489	83
GX-XVI	270	1168	170
Infinity-48	2426	5840	1248
Infinity-80	2426	5840	1248

- Computer Energy Consumption information
  - Laptop 350 kW
  - Desktop 350 kW

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.

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

Technical Assistance

- Before contacting Cepheid Technical Support, collect the following information:
  - Product name
  - Lot number
  - Serial number of the System
  - Error messages (if any)
  - Software version and, if applicable, Computer Service Tag number

- Log your complaint online using the following link ***http://www.cepheid.com/us/support :***

Create a Support Case


Thank You.
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