



GeneXpert® Edge Technical Training

Cepheid Training Centre



CE IVD In Vitro Diagnostic Medical Device

302-0669 Rev. B May 2022

Training Agenda

- 1 Clinical utility
- 2 Hardware components overview
- 3 Technology of the System
- 4 Technology of the Cartridge
- 5 Installation
- 6 Q & A



Training Objectives

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

- Understand the expanding Cepheid[®] Systems family
- Understand the clinical utility of GeneXpert[®] Edge
- Understand the components that are delivered with the GeneXpert[®] Edge
- Properly install the GeneXpert[®] Edge system
- Understand how the technology works



Cepheid[®] Systems Family

Cepheid® System Families

- A growing instrument portfolio
- A wide range of application (infectious disease, virology, oncology, genetic disease, women's health, sexual health)

2000



SmartCycler® System
Integrated amplification
& detection

2006



GeneXpert® System
Integrated sample preparation,
amplification & detection.
Available in 2, 4 and 16-
module configurations

2009



**GeneXpert® Infinity-48
System**
Even greater
automation than GX,
and with up to 48
modules

2011



**GeneXpert® Infinity-
80 System**
With up to
80 modules

2018



GeneXpert® Edge*
Portable Single module
system with an external
battery.

* Footnote source space



Clinical Utility

GeneXpert® Edge Intended Use

- The GeneXpert® Edge system is an in vitro diagnostic device intended for use with Cepheid® Xpert® test kits. The GeneXpert® Edge system automates and integrates sample preparation, nucleic acid amplification, and detection of the target sequence in simple or complex samples using real-time Polymerase Chain Reaction (PCR). The system is designed for hands-off processing of patient samples (specimens) and provides both summarized and detailed test results data in tubular and graphic formats
- The GeneXpert® Edge System is intended to be used by laboratory professionals or specifically-trained healthcare **users in a Laboratory and near patient test setting** as specified in the Cepheid® Xpert® test instructions for use.
- Refer to assay-specific package insert for details on specific tests.



GeneXpert[®] Edge System Components

System Components

GeneXpert® Edge System

- Thermal and optical module
- Tablet/Computer with GeneXpert Edge Software
- Barcode scanner
- External small battery packs
- Laptop stand

Cartridge

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



Optional Extras : Epson® WorkForce WF-100 Printer (PN 800-0434)

Computer/Tablet (Lenovo[®])

- Computer/tablet with pre-installed software
- Touchscreen
- Folds down to be used as a tablet



* Footnote source space

© 2022 Cepheid.

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



Computer/Tablet (Lenovo® tablet) side view

Left-side view



1 Power connector	2 Ethernet connector
3 USB 3.0 connector	4 Media-card slot

Right-side view



1 Power button	2 Volume-control buttons
3 Audio connector	4 USB 3.0 connector
5 HDMI™ connector	6 Security-lock slot

* Footnote source space

Computer/Tablet (HP® ProBook x360 tablet)

- Computer/tablet with pre-installed software
- Touchscreen
- Folds down to be used as a tablet



Computer/Tablet (HP® ProBook x360) left side view

Overview
HP ProBook x360 11 G6 EE



- | | | | |
|----|---|-----|--|
| 1. | Webcam LED | 6. | World-facing Webcam LED (Optional) |
| 2. | 720p Webcam or optional HP Privacy Camera | 7. | Power Button |
| 3. | Microphone | 8. | Headphone / Microphone Combo Jack |
| 4. | ClickPad | 9. | USB 3.1 Gen 1 Port |
| 5. | World-facing 5 Megapixels Webcam (Optional) | 10. | Security Lock Slot (Nano lock sold separately) |

Computer/Tablet (HP® ProBook x360) right side view



1. Power Connector
2. Ethernet (RJ-45) Port
3. HDMI Port (Cable not included)

Right

4. USB 3.1 Gen 1 Port
5. USB Type-C™ (Data and Power in-out)

Laptop/Tablet Stand

- Dual Hinge Notebook Stand



Barcode scanner & Printer

- Code Barcode Scanner
 - Connect to USB port



- Epson® WorkForce WF-100 Printer (PN 800-0434)
 - Connect via USB or Wireless option



* Footnote source space

© 2022 Cepheid.

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



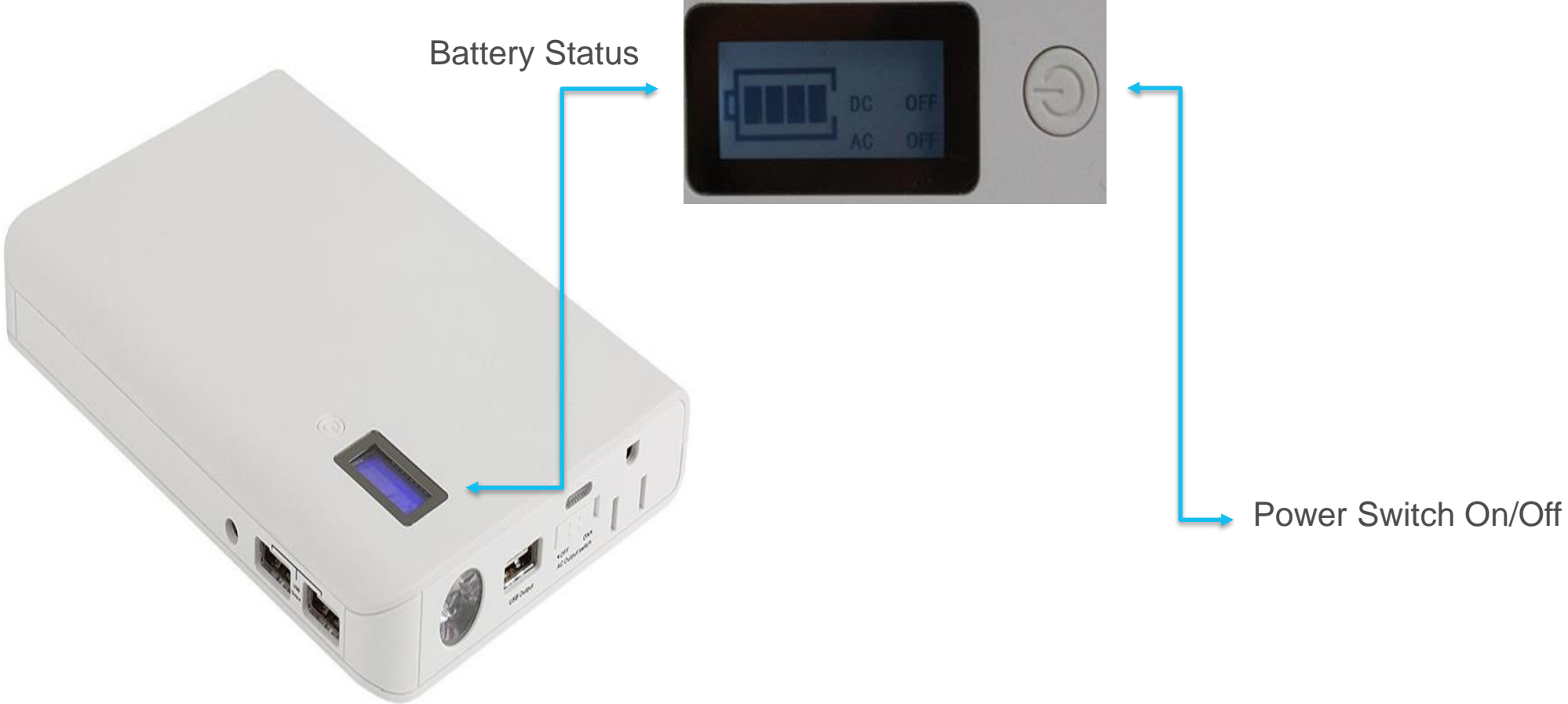
Accessories included with the system

- External DVD Drive
 - ADF upload
- USB to Ethernet Adapter
 - Network or LIS connection
- Universal Power Strip included

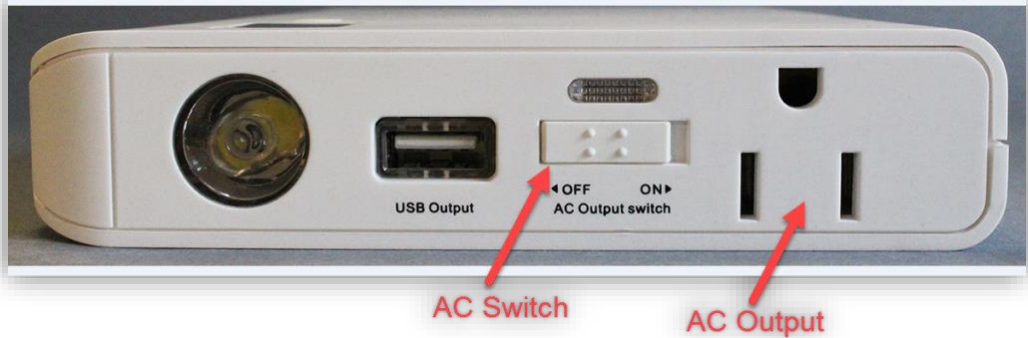


GeneXpert® Edge System – External Battery

- Small Battery



Small Battery (side views)





The Technology

The GeneXpert[®] Edge System

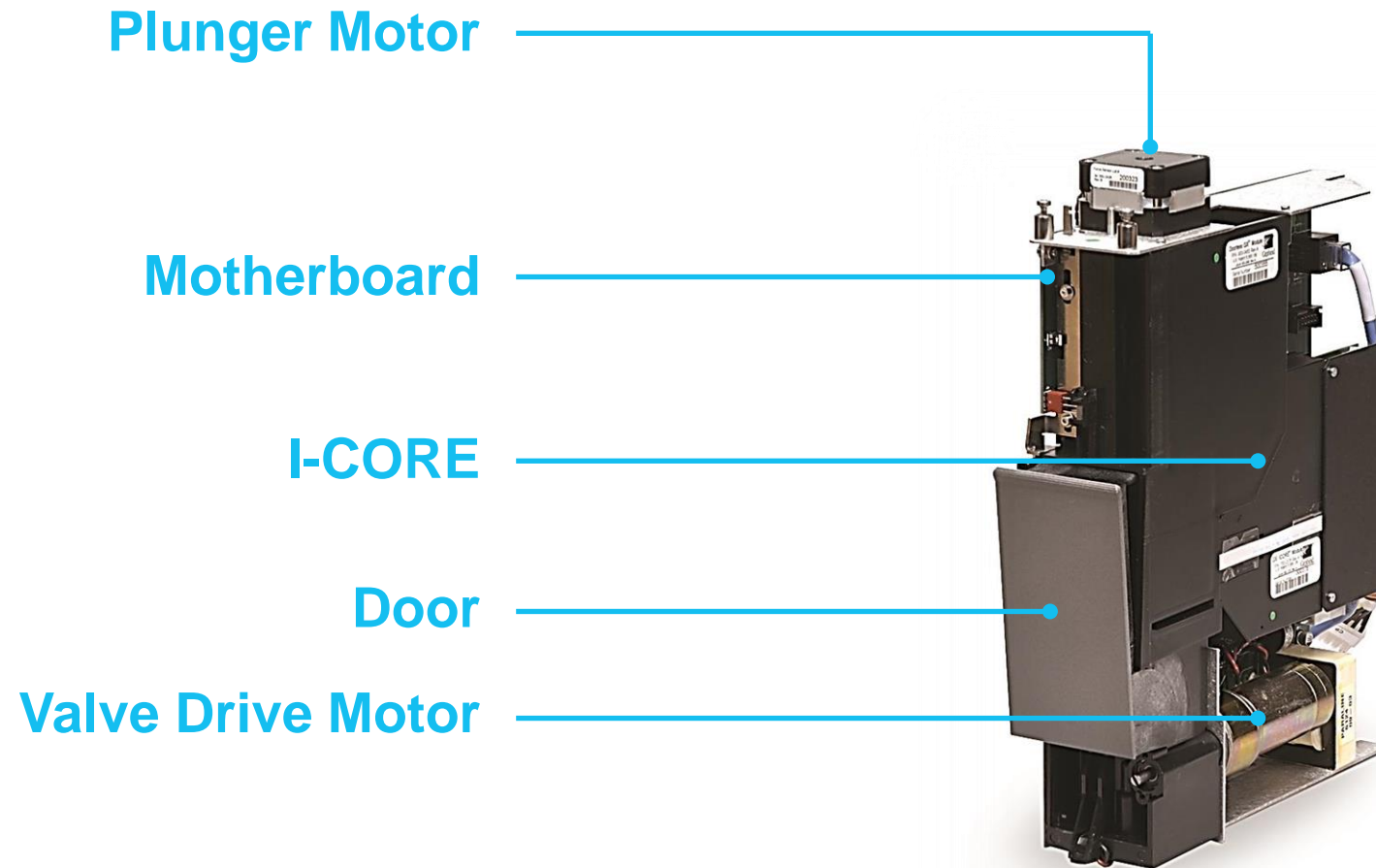
GeneXpert[®] Edge Technology

- 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



GeneXpert[®] Edge Module



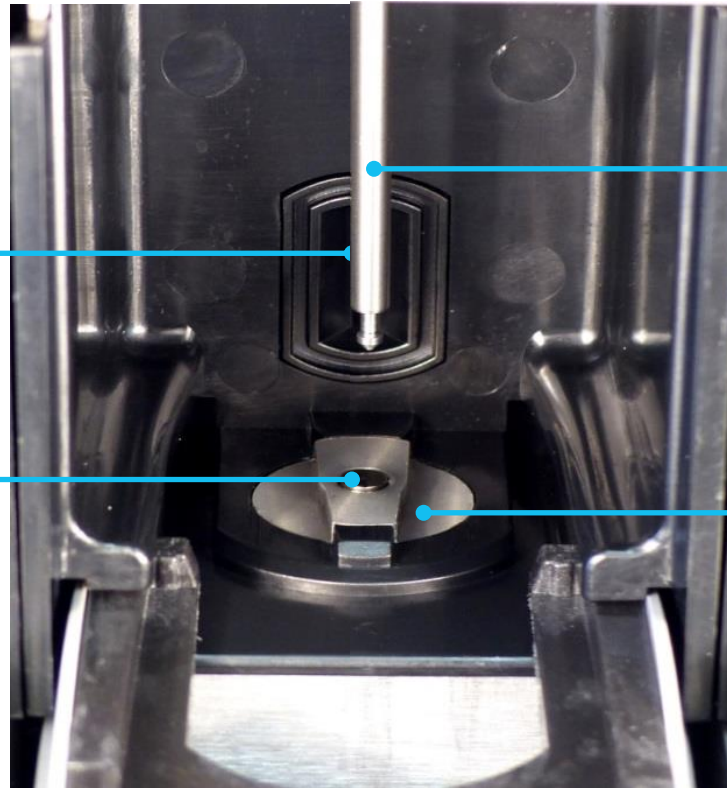
Cartridge Bay

Module Slot

PCR amplification & detection

Ultrasonic Horn

Lyses the sample (if applicable)



Plunger Rod

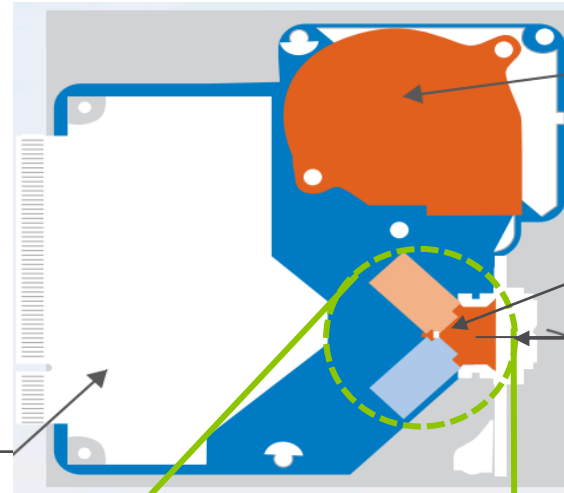
Allows transfer of sample and reagents into the different cartridge chambers

Valve Drive

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

The I-CORE[®] Module

Building Block of the GeneXpert[®] Edge System



Fan

Heater

Rapid, precise temperature control

Inserts into the I-CORE



Cartridge

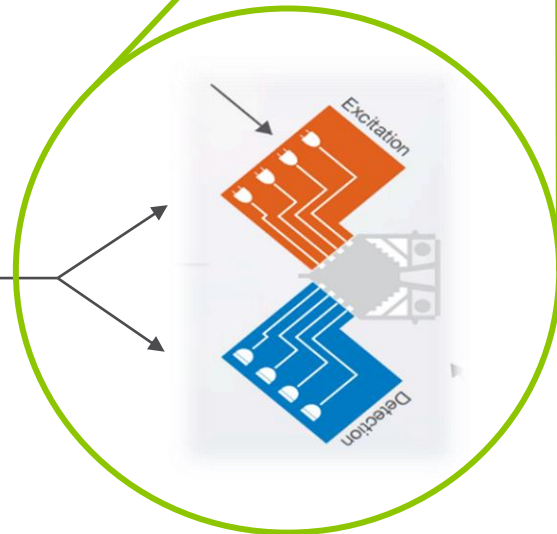
Sample preparation

Circuitry

Passes optical information to the computer for analysis and display

Optical Blocks

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





The Technology

Xpert[®] Test Cartridge

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

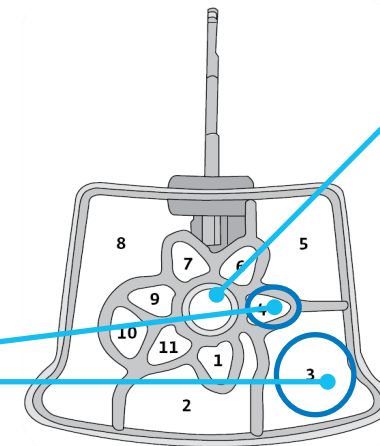
- Some chambers are used for sample processing
- Some chambers are for reagents



Cartridge Lid

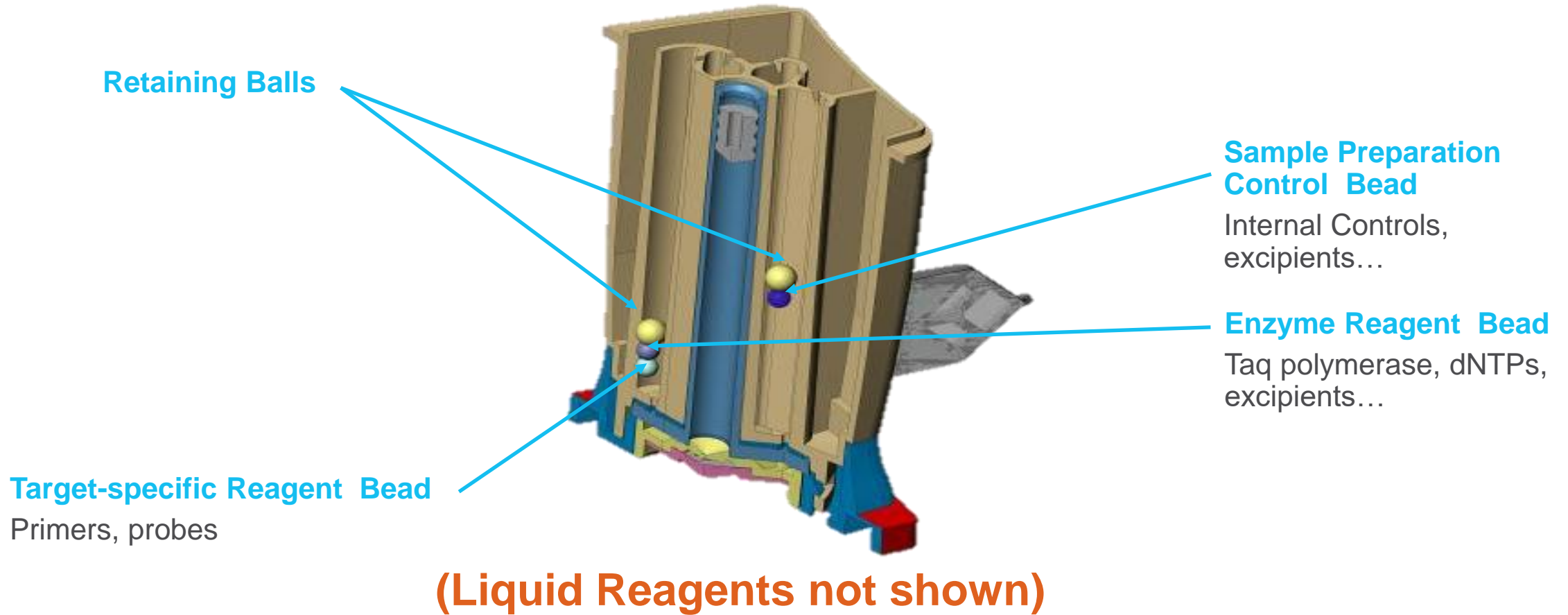
PCR Reaction Tube

Enables rapid thermal cycling and optical excitation/detection



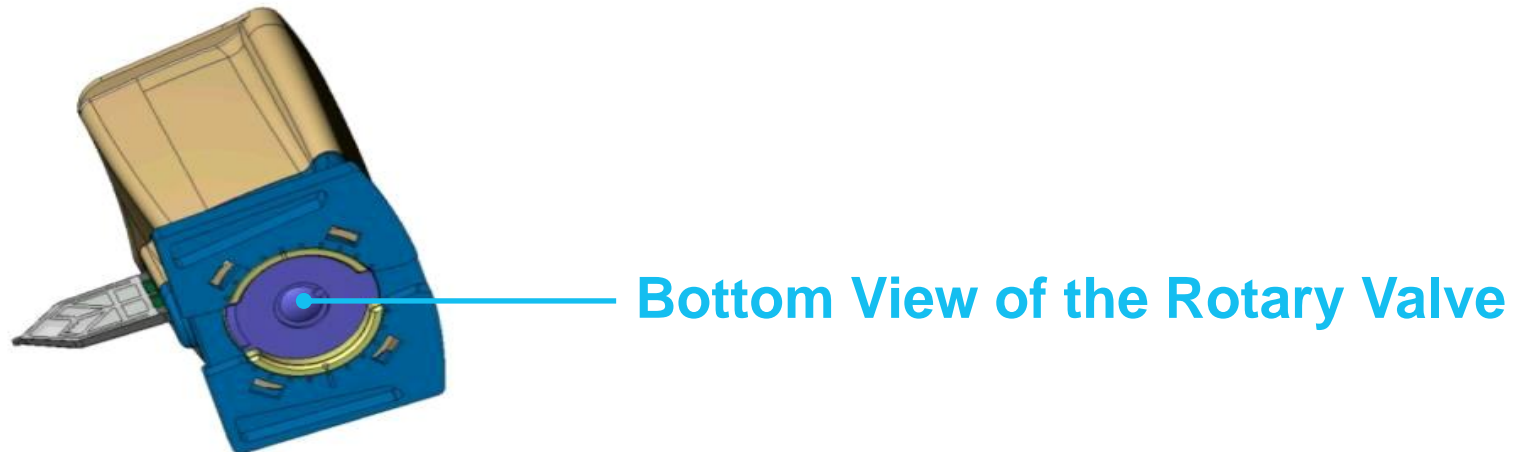
Dedicated for the Plunger

Internal View of the Cartridge



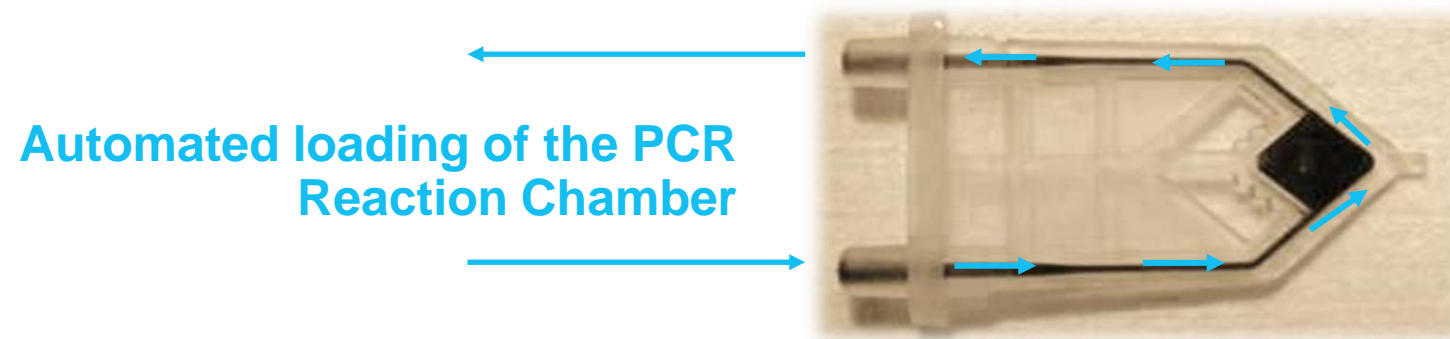
Cartridge Bottom View

- 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



PCR Reaction Chamber

- Fluid transfer in the PCR Reaction Tube
 - Do not touch the PCR reaction tube
 - Wear gloves whenever you prepare a cartridge





GeneXpert[®] Edge Installation

Easy Installation of Your GeneXpert® Edge

GeneXpert® Edge: Installation



1. Unpack the system
2. Plug in barcode scanner, instrument and tablet PC.
3. Turn on instrument and tablet PC
4. Perform setup functions
5. Available in English ONLY

Your GeneXpert® Edge is ready for use

Installation assistance


- Getting started guide provides a step-by-step process for installation

Getting Started Guide

GeneXpert® Edge System

BEFORE YOU BEGIN
Read these instructions completely and carefully.

INSTALLATION
GeneXpert Edge System Components



UNPACKING THE GeneXpert Edge SYSTEM
Carefully remove all boxes from the large shipping box.
Remove each of the components from their individual packaging.

NOTE
Be sure to save all packaging material.

CHARGING THE BATTERIES

1. Charge the battery fully before use. Do not start a test with 2 bars or less of charge on the small battery **7**, or 50% power or less on the optional large battery. Connect the battery cord **8** to the DC In power port on the battery. Connect the other end to the power strip **9** and connect to local power to charge. Do not attempt to charge the battery while running a test. Loss of test will occur.
2. Charge the computer battery fully before use. Do not start a test with 50% or less of charge on the computer. Connect the computer

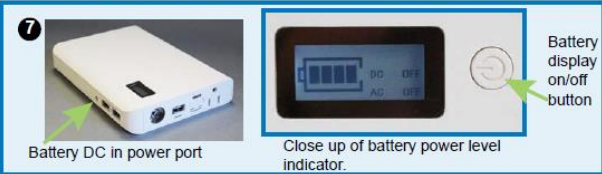


Figure 3. Small Battery Connections



Q&A



Thank You

www.cepheid.com