

XPERT OMNI FACTSHEET



MSF concerns on suitability for context

This “factsheet” provides information regarding running costs, service support, connectivity options, operational concerns, and impact expectations to countries interested in implementing GeneXpert Omni, Cepheid’s single-module point-of-care device. **NOTE: MSF has major concerns on the suitability of this tool for remote settings within low-to-middle income countries.** Omni is not yet available or undergone WHO review; however, the device is undergoing country-level field performance evaluations with FIND. Information below was acquired from discussions with Cepheid.

Price increase

\$5315

New price quote

Formerly \$2895 upon initial announcement in 2015.
Launch delayed (2019)

Includes:

- 1 GeneXpert Omni unit with stand
- 1 smart phone with stand
- 1 USB power adapter
- 1 external battery pack
- 1 security cable lock for the Omni device only



Omni-specific cartridge

Omni requires cartridges with an NFC (near field communication) chip, as there will be no barcode scanner. Thus, a special cartridge is required.

- An Omni cartridge surcharge of approximately \$1.50 will be added (9.98 +1.50) to pay for peripheral-level services and to cover the cost of the NFC chip.
- Omni cartridge will work in all GeneXperts, but at the added cost noted above.
- Traditional GeneXpert cartridges will NOT work in Xpert Omni as they lack an NFC chip.
- Internal assay is the same for both cartridges.



Connectivity considerations



- Cepheid’s proprietary C360 connectivity platform is mandatory for software updates and service support to ensure device functionality. Cloud-based connectivity option only (no in-country server options).
- An offline option will be available. Offline units will need to be transported periodically to areas with connectivity in order to upload data, download software updates, or add new assays.
- Use of third party connectivity solutions (e.g. GxAlert, DataToCare, etc.) via *OmniConnect* is predicted to be available at launch. *OmniConnect* will also allow data to flow to Laboratory Information Management Systems (LIMS).
- Patient information will be transferred to Cepheid’s C360 cloud-based server with identifiers encrypted.
- Transferring patient information can be “opt-in” for those interested in leveraging C360 for epidemiological purposes.
- Cost for C360 is initially free, but Cepheid reserves the right to charge in the future. Running cost estimated at \$500-\$600 per unit per year with Vodafone network. Network running costs are NOT supported by Cepheid.
- C360 User Agreement was revised to identify data fields that are/are not transferred or visible/not visible to end user.
- Cepheid requires a user agreement to be signed to authorize storage of data, use of data for providing remote technical and to monitor unit functionality.

Service & maintenance

- In addition to remote support, peripheral on-site support will be provided with in-country networks of peripheral service providers. Services include maintenance, on-site repairs, training, and troubleshooting.
- A surcharge of approximately \$1.50 will be incurred per cartridge to support this model.
- In addition, a warranty is offered to cover costs of parts and repairs. Warranty provision upon initial purchase is 3 years.
- After the initial 3 year warranty period, a 2 year warranty extension is offered at \$940 per unit. If the extension is bought at the initial purchase (totaling 5 years service) the costs reduced to \$780 per unit.



Feasible use in remote settings

- No data has been made public yet on the device regarding operational performance or feasibility of use in remote settings. Factors such as dust, temperature, ruggedness, and overall durability remain unknown.
- Options for battery recharging also remains unclear in remote settings. Reported battery life is 12 hrs.

