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.