Updated Feb 2024

Fact sheet update: Portable thermal ablation device global price agreements

This pricing factsheet for thermal ablation devices from Liger and Wisap is an update to a previously published version in July 2022. Please see Appendix for further background.

Table 1: Current price of TA products from Liger and Wisap and the associated terms and conditions:

	Liger (Direct to supplier route)	**Liger (Unicef-SD route)**	**WISAP (Direct to supplier route-only option[1])**
Product Name	HTU-110 Thermal Ablation	HTU-110 Thermal Ablation	C3 ECO4 Thermal Ablation
SRA Approval	FDA Cleared: Device Class 2, CE Marked, EU: Class lla		CE Marked, EU: Class lla
Product Kit Configuration	**HTU-110 Kit [A/ B / C Variants]** • Thermocoagulator unit, • Two 12-volt, 2aH Li-Ion batteries • Universal charger • 4 probes [selection out of 3 configurations - 16 mm flat, 19 mm flat, 19 mm nipple] • Instruction For Use (IFU) • Hard carrying case		**C3 ECO4** • Thermocoagualtor unit • 4 Thermo probes [2 x 20mm flat, 1x20 mm nipple, 1x17 mm flat] • 1x Li-Ion battery pack with cable • Hard carrying case • Instruction for use (IFU)
Price	**USD 925/ unit**	**USD 948.13/unit**	**Euro 870/ unit**
Validity[i]	**31st Dec 2024**	**31st Dec 2024**	**31st Dec 2024**
Warranty	**2 years from date of shipment by Liger**	**2 years**	**2 year from date of shipment by Wisap**
Incoterm	**EXW**	**FCA**	**EXW**
Freight and insurance	Designated purchasers to make arrangements and cover costs	UNICEF SD delivers on CIP (INCOTERMS 2020). Associated freight to nearest international airport in the receiving country, insurance & inspection costs will be included in addition to FCA price of the TA product	Designated purchasers to make arrangements and cover costs
Handling fee	No	Yes	Yes
Minimum order quantity	**5**	**None**	**10**
Eligible countries	Specified eligible LMICs (see Appendix A)	All low- and middle-income countries (LMICs) as per the World Bank classification	Specified eligible LMICs (see Appendix A)

For further information, procurers are advised to consult the Frequently Asked Questions (FAQ) below.

[1] Wisap products are only available by contacting the supplier directly.

Frequently Asked Questions

1. How can buyers procure Thermal Ablation devices and what are the associated terms and conditions?

Interested and eligible designated purchasers can exercise one of the two options to procure TA devices at the access prices: 1) place an order directly to supplier(s) – applicable for both Liger and Wisap, and 2) place an order via Unicef Supply Division (SD) – applicable only for Liger (Terms on Table 1). Price, terms and conditions are only applicable to public sector buyers in LMICs. This includes the ministries of health and their parastatal procurement agencies and international donors such as The Global Fund to Fight AIDS, Tuberculosis and Malaria, President's Emergency Plan for AIDS Relief (PEPFAR), United States Agency for International Development (USAID), United Nations organizations (or organization(s) or project(s) funded by these donors), NGOs[2] and academia[3].

2. How can countries and designated purchasers access the pricing agreements and initiate procurement?

Designated purchasers may approach suppliers directly using the contact details provided below.

Liger: sales@ligermedical.com

Wisap: c3publicproc@wisap.de

The TA product from Liger is also available for procurement through UNICEF Supply Catalogue. Link to specific product pages are as follows: HTU-110 Thermal Ablation (Liger). Designated purchasers may follow the instructions at Procurement services | UNICEF Supply Division to initiate an order for the required product.

3. What is "designated purchaser" and what documentation requirements are required to access the listed price?

Designated purchasers includes the ministries of health and their parastatal procurement agencies and international donors such as The Global Fund to Fight AIDS, Tuberculosis and Malaria, President's Emergency Plan for AIDS Relief (PEPFAR), United States Agency for International Development (USAID), United Nations organizations (or organization(s) or project(s) funded by these donors), NGOs and academia.

The suppliers may conduct a quick due delligence to check for the buyers' eligibility as a 'designated purchaser' – for example, for NGOs, CSOs, FBOs[4] and academia organizations, this might involve supplying documentation to prove they have received funding from international agencies listed above. In case of purchases from Wisap, designated purchasers will need to provide details in 'C3ECO4 public procucrement order form' that will be shared by Wisap when contacted.

4. What additional costs should a designated purchaser expect to incur?

Order via UNICEF: UNICEF arranges for freight, insurance and inspection and delivers on CIP (INCOTERMS 2020) terms. Associated freight to the nearest international airport in the receiving country, Unicef handling fee, insurance and inspection costs will be included in addition to FCA price of the TA products.

[2] Price, terms and conditions for NGOs are accessible via UNICEF-SD under the terms explained in Table 1. Terms are not *guaranteed* if NGOs purchase directly from the suppliers

[3] Price, terms and conditions for academia are accessible via UNICEF-SD under the terms explained in Table 1. Terms are not *guaranteed* if academia purchase directly purchase from the suppliers

[4] NGO- Non Governmental Organization, CSO- Civil Society Organization, FBO- Faith Based Organization

Direct to supplier orders: Unit prices are based on Ex-Works INCOTERMS. Designated purchasers need to make arrangements and cover for shipment, handling fee (only for Wisap; no handling fee for Liger), insurance etc. as applicable.

5. What happens if the device malfunctions or needs repair? What are the maintenance charges?

The devices are maintenance-free and are covered by a two year warranty. Instructions for use will be provided by the suppliers, including handling and cleaning. If the device is deemed to be defective due to production during the warranty period, the devices will be replaced at no cost to the designated purchasers.

6. How will the complaints or request for spare parts including probes, batteries etc., replacement due to defects be addressed?

The buyers may contact the suppliers directly at the following email addresses to get after sales support including ordering new spare parts or asking for a replacement device in the event of a device breakdown withing the warranty period:

Liger: sales@ligermedical.com

Wisap: c3publicproc@wisap.de

7. How do I report adverse events from the use of the equipment?

In the event of an adverse event during a procedure, please contact the suppliers at the following email address and a formal processes will be initiated for you to report the incident. Also please inform your national regulatory authority (NRA), if applicable in your country context and in line with WHO guidance[ii].

Liger: sales@ligermedical.com

Wisap: c3publicproc@wisap.de

8. What are the implications of this agreement for ensuring a healthy market place for other manufacturers of portable TA devices?

Unitaid is maintaining a multi-pronged engagement strategy to ensure a healthy market for all manufacturers that wish to develop and commercialize portable TA devices. They are continually scanning the supplier landscape and will welcome discussions with potential new entrants.

9. What is the difference between TA vs cryotherapy?

Both TA and cryotherapy are ablative treatments for cervical lesions, where the cells of the transformation zone of the cervix are destroyed, thereby removing their cancerous potential. Cryotherapy employs gas to effect controlled freezing of cells, while TA employs heat to remove those cells. Both ablative approaches remove problematic cells and allow new, healthy cells to replace them. Aside from the temperatures used to achieve ablation, the two techniques differ also in terms of consumables and time required to conduct the treatment; TA can be done both without the gas supply required by cryotherapy and in a shorter time.

Appendix: Background

The global push to eliminate cervical cancer received a boost with global access prices for thermal ablation (TA) devices, which are a critical tool in the global efforts to screen and treat women for cervical precancer. Unitaid backed volume guarantee agreements with two manufacturers of TA devices Liger Medical and Wisap Medical Technologies GmbH, that helped secure reduced prices of the high-quality treatment devices, has spurred advancement of access to treatment for pre-cancerous cervical lesions, thus preventing the disease from progressing to invasive cancer. This is part of Unitaid's commitment to support World Health Organization's (WHO) Global Strategy to Accelerate the Elimination of Cervical Cancer – the first time the world has ever committed to eliminating a cancer.

Through an innovative grant from Unitaid to prevent deaths from cervical cancer by catalyzing the use of optimal screening and treatment devices, the Clinton Health Access Initiative (CHAI) and the United Nations Children's Fund[iii] (UNICEF), engaged with manufacturers to conclude access pricing commitments that has led to the substantial scale up and use of >6,000 portable TA devices across 28 low-and middle-income countries (LMICs). This intervention has helped stabilize the market for TA devices and created a steady demand among both public and private sector purchasers. Both manufacturers are also engaged in improvement and expansion of their product offering and remain committed to making their products available and accessible in LMICs.

Cervical cancer is the fourth most common cancer in women, affecting over half a million and killing more than 300,000 each year. Nine out of ten women who die from cervical cancer are from LMICs and women living with HIV are six times more likely to develop cervical cancer.

To effectively prevent cervical cancer, screening needs to be tied to prompt treatment for precancerous lesions – the majority of which are treatable with cryotherapy or TA. While cryotherapy treatment can be effective, it is dependent on a steady supply of medical gas which can be disrupted in LMICs due to stock-outs and significant operating costs.

TA has comparable effectiveness to cryotherapy for the treatment of precancerous lesions, and the procedure is safe, with minimal side effects and adverse events, and no measurable impact on fertility.[iv,v, vi,vii,viii] Portable TA devices are considerably easier to use and manage than traditional cryotherapy machines, since they do not rely on medical gas. As a result, many LMICs have already started using these TA devices albeit on a small scale.

By improving access to affordable, high-quality treatment for precancerous lesions, the agreements paved the way for widespread scale-up of these lifesaving devices and build on Unitaid's growing investment in the management of HIV co-infections. The new generation of tools complements other cervical cancer control approaches, such as HPV vaccination, contributing to the WHO's targets for the elimination of cervical cancer.

Appendix A: List of eligible countries (applicable for direct-to-supplier orders)

Afghanistan
Albania
Algeria
Angola
Argentina
Armenia
Azerbaijan
Bahamas
Bangladesh
Barbados
Belarus
Belize
Benin
Bhutan
Bolivia
Bosnia & Herzegovina
Botswana
Brazil
Bulgaria
Burkina Faso
Burundi
Cabo Verde
Cambodia
Cameroon
Cape Verde
Central African Republic
Chad
Chile
China
Colombia
Comoros
Congo, Rep.
Costa Rica
Côte d'Ivoire
Croatia
Cuba
Democratic Republic of the Congo
Djibouti
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Eswatini
Ethiopia
Fiji
Gabon
Gambia
Georgia
Ghana
Guatemala[1]
Guinea
Guinea-Bissau
Guyana
Haiti
Honduras[1]
India[1]
Indonesia
Iran (Islamic Republic) [1]
Iraq
Jamaica
Jordan
Kazakhstan
Kenya
Kiribati
Korea (Democratic Peoples Republic) [1]
Kosovo
Kyrgyz Republic
Kyrgyzstan
Lao (Peoples Democratic Republic)
Lesotho
Liberia
Madagascar
Malawi
Malaysia[1]
Maldives
Mali
Mauritania
Mauritius
Mexico
Micronesia,Fed States
Moldova
Mongolia
Montenegro
Morocco
Mozambique
Myanmar
Namibia
Nepal
Nicaragua
Niger
Nigeria
North Macedonia
Pakistan
Palestine
Panama
Papua New Guinea
Paraguay
Peru[2]
Philippines
Romania[1]
Russian Federation
Rwanda
Sao Tome & Principe
Senegal
Serbia
Sierra Leone
Solomon Islands
Somalia
South Africa[1]
South Sudan
Sri Lanka
Sudan
Suriname
Syrian Arab Republic
Tajikistan
Tanzania
Timor-Leste
Togo
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Uganda
Ukraine
Uruguay
Uzbekistan[1]
Vanuatu
Vanuatu
West Bank and Gaza
Yemen
Zambia
Zanzibar
Zimbabwe

[1] Countries eligible only for Liger prices.
[2] Countries eligible only for Wisap prices.

[ii] WHO Guidance for post market surveillance and surveillance of medical devices

[iii] UNICEF launched a tender in 2021 resulting into long-term awards and contractually-binding obligations with two Thermal Ablation manufacturers. A new tender is foreseen to be launched in late 2024.

[iv] Dolman et al., Meta-analysis of the efficacy of cold coagulation as a treatment method for cervical intraepithelial neoplasia: a systematic review. BJOG 2014; 121:929-942.

[v] Nessa et al., Efficacy, Safety, and Acceptability of Thermal Coagulation to Treat Cervical Intraepithelial Neoplasia: Pooled Data from Bangladesh, Brazil and India. J Clin Gynecol Obstet. 2017;6(3-4):58-64.

[vi] Campbell et al., Use of thermo-coagulation as an alternative treatment modality in a "screen-and-treat" programme of cervical screening in rural Malawi. Int. J. Cancer: 2016.

[vii] Pinder et al., Thermal ablation versus cryotherapy or loop excision to treat women positive for cervical precancer on visual inspection with acetic acid test: pilot phase of a randomised controlled trial.www.thelancet.com/Oncology: November 2019.

[viii] WHO technical guidance and specifications of medical devices for screening and treatment of precancerous lesions in the prevention of cervical cancer. https://www.who.int/medical_devices/publications/en/: 2020