# Fact sheet: Portable thermal ablation device global price agreements

This factsheet has been amended on 6th July 2022 with the following corrections:

(i) On page 2, the price terms and conditions for NGOs and academia are accessible via the Unicef-SD route only, and not via direct to supplier route;
(ii) On page 3, the minimum order quantity listed in Table 1 direct to supplier route has been updated from 'none' to '5 units' for Liger

# Fact sheet: Portable thermal ablation device global price agreements

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. The new agreements with two manufacturers, Liger Medical and Wisap Medical Technologies GmbH, will secure reduced costs of the high-quality treatment devices relative to current market prices. 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[i] (UNICEF), have engaged with manufacturers and concluded global price agreements to scale up the use of portable TA devices in low- and middle-income countries.

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 low- and middle-income countries 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 – about 80 percent of lesions 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 low- and middle-income countries 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.[ii,iii, iv,v,vi] 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 low-and middle-income countries 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 pave 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.

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

# Frequently Asked Questions

## What is the cost of the Thermal Ablation devices and 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), 2) place an order via Unicef Supply Division (SD). The terms associated with these two procurement channels are summarized in the Tables 1 and 2 respectively.

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, NGOs[1] and academia[2].

**Table 1:** Cost of the products and the associated **terms and conditions under direct-to-supplier orders:**

| | **Liger** | **WISAP** |
|---|---|---|
| **Product Name** | HTU-110<br>Thermal Ablation | C3 THERMO-COAGULATOR<br>Thermal Ablation |
| **SRA Approval** | FDA Cleared: Device Class 2<br>CE Marked, EU: Class lla | CE Marked, EU: Class lla |
| **Product Kit Configuration** | **HTU-110 Kit [ A/ B / C Variants]**<br>• Thermocoagulator unit,<br>• Two 12-volt, 2aH Li-Ion batteries<br>• Universal charger<br>• 4 probes [ selection out of 3 configurations - 16 mm flat, 19 mm flat, 19 mm nipple]<br>• Instruction For Use (IFU)<br>• Hard carrying case | **C3 Thermo-Coagulator Kit**<br>**Option A**<br>• Handle<br>• Thermos probes 2 x 20mm flat shaped<br>• Battery pack with cable<br>• Sliders 2 x 20 mm<br>• Carrying case<br>**Option B**<br>Power supply unit in addition to all the components for Option A |
| **Price** | **USD 925/ unit** | **Option A Euro 904/unit**<br>**Option B Euro 938/unit** |
| **Validity[vii]** | **31st Dec 2023** | **14th March 2023** |
| **Warranty** | **2 Years** | |
| **Incoterm** | **EXW** | |

[1] **Price, terms and conditions for NGOs are accessible via UNICEF SD and not via the direct to supplier route. Additional costs for freight, insurance etc. need to be incurred as explained in the third FAQ**

[2] **Price, terms and conditions for academia are accessible via UNICEF SD and not via the direct to supplier route. Additional costs for freight, insurance etc. need to be incurred as explained in the third FAQ**

| | | |
|---|---|---|
| **Freight and insurance** | Designated purchasers to make arrangements and cover costs | |
| **Minimum order quantity** | **5** | **5** |
| **Eligible countries** | Specified eligible LMICs (see Appendix A) | |

**Table 2:** Cost of the products and the associated **terms and conditions applicable for Unicef SD procurement:**

| | **Liger** | **WISAP** |
|---|---|---|
| **Product Name** | HTU-110<br>Thermal Ablation | C3 THERMO-COAGULATOR<br>Thermal Ablation |
| **SRA Approval** | FDA Cleared: Device Class 2<br>CE Marked, EU: Class lla | CE Marked, EU: Class lla |
| **Product Kit Configuration** | **HTU-110 Kit [ A/ B / C Variants]**<br>• Thermo-coagulator unit,<br>• Two 12-volt, 2aH Li-Ion batteries<br>• Universal charger<br>• 4 probes [ selection out of 3 configurations - 16 mm flat, 19 mm flat, 19 mm nipple]<br>• Instruction For Use (IFU)<br>• Hard carrying case | **C3 Thermo-Coagulator Kit**<br>• Handle<br>• Thermos probes 2 x 20mm flat shaped<br>• Battery pack with cable<br>• Sliders 2 x 20 mm<br>• Carrying case<br>• Power supply unit |
| **Price** | **USD 948.13/unit** | **Euro 938/unit** |
| **Validity**[viii] | **April 2023** | **April 2023** |
| **Warranty** | **2 Years** | |
| **Incoterm** | **FCA** | |
| **Freight and insurance** | UNICEF SD delivers on CIP (INCOTERMS 2020) basis. Associated freight to the nearest international airport in the receiving country, insurance and inspection costs will be included in addition to FCA price of the TA product | |
| **Minimum order quantity** | **None** | **5 units** |
| **Eligible countries** | All low- and middle-income countries (LMICs) as per the World Bank classification | |

## 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 products from both suppliers are also available for procurement through UNICEF Supply Catalogue. Links to specific product pages are as follows:

HTU-110 Thermal Ablation (Liger)

C3 THERMO-COAGULATOR Thermal Ablation (WISAP)

Designated purchasers may follow the instructions at Procurement services | UNICEF Supply Division to initiate an order for the required product.

## What additional costs should a designated purchaser expect to incur?

**Direct to supplier orders:** Unit prices are based on Ex-Works INCOTERMS. Designated purchasers need to make arrangements and cover for handling fee, shipment, insurance etc. as applicable.

**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.

## 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.

## 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.

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

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

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

[i] UNICEF tender which was launched in 2021 resulted into long-term awards and contractually-binding obligations with two Thermal Ablation manufacturers.

[ii] 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.

[iii] 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.

[iv] 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.

[v] 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.

[vi] 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

[vii] This is the date until which the specified terms and conditions are valid. After the dates shown, the deal terms may change. Please note that the validity dates differ between the UNICEF SD procurement channel and the direct-to-supplier channel.

[viii] This is the date until which the specified terms and conditions are valid. After the dates shown, the deal terms may change. Please note that the validity dates differ between the UNICEF SD procurement channel and the direct-to-supplier channel.