





# Fact sheet update: Portable thermal ablation (TA) device and Loop Electrical Excision Procedure (LEEP) global price agreements

This pricing factsheet for thermal ablation devices from Liger and Wisap is an update to a previously published version in Feb 2024. 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)	WISAP (Unicef-SD route)
Product Name	<u>TC</u> <u>Thermocoagulator®</u> <u>- Liger Medical</u>	Ablation device,thermal,handheld, <u>model 1</u>	<u>C3 ECO4</u> Thermal Ablation	Ablation device,thermal,handheld,mo del 3
SRA Approval	FDA Cleared: Device Class 2, CE Marked, EU: Class lla		CE Marked, EU: Class lla	
Product Kit Configuration	<ul> <li>HTU-110 Thermocoagulator</li> <li>Thermocoagulator unit</li> <li>Two 12-volt, 3aH Li-Ion batteries</li> <li>Universal charger</li> <li>4 probes [Standard configuration 2 x 19 mm flat; 1 x 19 mm nipple; 1x 16 mm flat. Selection can be modified as requested]</li> <li>Instruction For Use (IFU)</li> <li>Hard carrying case</li> </ul>		<ul> <li>C3 ECO4 device <ul> <li>Thermocoagulator unit</li> <li>4 Thermo probes [Standard configuration 2 x 20mm flat, 1x20 mm nipple, 1x17 mm flat; Selection can be modified as requested]</li> <li>1x Li-lon battery pack with cable</li> <li>Instruction for use (IFU)</li> <li>Hard carrying case</li> </ul> </li> </ul>	
Price	USD 995.40/ unit	USD 995.40/unit	Contact supplier for pricing	EUR 933.80/ unit
Validity <sup>i</sup>	31 <sup>st</sup> Dec 2025	28 <sup>th</sup> Apr 2026	31 <sup>st</sup> Dec 2025	31 <sup>st</sup> Dec 2025
Warranty	2 years from date of shipment by Liger	2 years	2 years from date of shipment by Wisap	2 years
Incoterm	EXW	FCA	EXW	FCA
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	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
Handling fee	No	Yes	Yes	Yes
Minimum order quantity	None	None	5	5

Eligible countries	Specified eligible LMICs (see Appendix A)	<u>All low- and middle-</u> income countries (LMICs) as per the World Bank classification	Specified eligible LMICs (see Appendix A)	Global access with the exception of Indonesia, Guatemala, Honduras, Tanzania. Please contact Wisap directly at <u>info@wisap.de</u> for these 4 countries
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For further information, procurers are advised to consult the Frequently Asked Questions (FAQ) below.

### Table 2: Current price of LEEP device from Liger

Product Name SRA Approval	Liger (Direct to supplier route) ESU-110 Electrosurgical Generator - Liger Medical FDA Cleared ESU-110 LEEP unit • LEEP unit • 2 24V 3aH Li-Ion Batteries • 1 charger	
Product Kit Configuration	<ul> <li>3 hepa smoke filter</li> <li>Suction tubing and adapter</li> <li>Medium Speculum</li> <li>6 loop electrodes ( 2 of each size: 10x10mm, 20x15mm, 25x10mm)</li> <li>2 ball electrode (5mm)</li> <li>Grounding pad</li> <li>Instruction For Use (IFU)</li> <li>Carrying case</li> </ul>	
Price	USD 1,995/ unit	
Validity <sup>ii</sup>	31 <sup>st</sup> Dec 2025	
Warranty	2 years from date of shipment by Liger	
Incoterm	EXW	
Freight and insurance	Designated purchasers to make arrangements and cover costs	
Handling fee	No	
Minimum order quantity	None	
Eligible countries	Specified eligible LMICs (see Appendix A)	

### **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). Price, terms and conditions are only applicable to public sector buyers or 'designated purchasers' in LMICsThis 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 Nations organizations (or organization(s) or project(s) funded by these donors), NGOs<sup>1</sup> and academia<sup>2</sup>.

# 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: <u>sales@ligermedical.com</u>

#### Wisap: c3publicproc@wisap.de

Designated purchasers that want to adopt the Unicef-SD procurement route may follow the instructions at <u>Procurement services | UNICEF Supply Division</u> to initiate an order for the required product. The product-specific details are available at the following links:

Liger: <u>Ablation device, thermal, handheld, model 1</u>

Wisap: Ablation device, thermal, handheld, model 3

### 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 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<sup>3</sup> 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.

<sup>&</sup>lt;sup>1</sup> 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

<sup>&</sup>lt;sup>2</sup> 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

<sup>&</sup>lt;sup>3</sup> NGO- Non Governmental Organization, CSO- Civil Society Organization, FBO- Faith Based Organization

### 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.

**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: <a href="mailto:sales@ligermedical.com">sales@ligermedical.com</a>

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<sup>iii</sup>.

Liger: <a href="mailto:sales@ligermedical.com">sales@ligermedical.com</a>

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.

# 10. What can designated purchasers do if they're unable to access the pricing outlined here?

As a first step, designated purchasers should contact Liger/ Wisap using the contact details provided in FAQ 2. If still unable to access the pricing, buyers may reach out at <u>cxca.procurement@clintonhealthaccess.org</u> providing the requested quantity, brief background on communication with the suppliers, and the specific challenge faced in accessing the pricing.

### 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<sup>iv</sup> (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 350,000 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.<sup>v,vi, vii,viii,ix</sup> 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.

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

<sup>1</sup> For Wisap products in these countries, please contact at info@wisap.de. For Liger products, direct-to-supplier terms apply as usual.

<sup>2</sup> For Liger products in this country, please contact at <u>sales@ligermedical.com</u>. For Wisap products, direct-tosupplier terms apply as usual. <sup>iv</sup> 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.

<sup>v</sup> 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.

<sup>vi</sup> 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.

<sup>vii</sup> 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.

viii 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. <sup>ix</sup> 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

<sup>&</sup>lt;sup>iii</sup> WHO Guidance for post market surveillance and surveillance of medical devices