Specification

For the procurement of equipment for the provision of medical services using telemedicine for rural communities (**30 items**)- 2 for Kherson region, 14 for Ivano-Frankivsk region and 14 for Zakarpattya region.

Strengthening the Community Resilience in Kherson oblast (SCR-II) Project

Background Information

UNDP and the Government of Ukraine have partnered in implementing the reforms in many different areas for the achievement of SDGs. Over the last two decades UNDP built long-lasting partnerships with national, regional and local authorities throughout the country, non-governmental development actors and local communities. Through a permanent local presence in each Ukrainian oblast and the quality of its partnerships, UNDP has been able to introduce and promote best practices of sustainable development at regional and local levels. Under its Sustainable Local Development Programme, UNDP helps to advance regional and local sustainable development.

At the same time, Ukraine, like all other countries in the world, faces the negative impact of the COVID-19 pandemic. This outbreak coincided with the change of government in the country, exacerbated by the insufficient progress of reforms, weakened health system, ageing population, macroeconomic decline and the protracted armed conflict in eastern Ukraine. The COVID-19 pandemic severely affected all the regions and local communities in Ukraine, in particular putting additional strains on the local budgets and exacerbating the results of long-term underinvestment in the public health system. In addition, administrative services are suspended or only partially provided due to the lack of local capacity, both institutional and human resources, to operate under these critical circumstances.

UNDP is already helping countries to advance inclusive and integrated crisis management by supporting governments around the globe to maintain core functions, and to plan, coordinate, communicate and finance their responses to COVID-19. UNDP has defined a structured approach and strategy for high-impact programmatic interventions to support both national and sub-national governments to prepare, respond and recover from COVID-19.

The Project purpose is to support regional and local authorities in assessing and addressing the socio-economic impact of COVID-19 .

Expected outcomes: Improved capacity of regional and local authorities of target oblasts to plan and implement crisis response and post-crisis recovery measures and secure progress towards SDGs.

Delivery Terms:

INCOTERMS-2020 DDP, Kherson city, Ivano-Frankivsk city and Uzhgorod city of Ukraine.

Address of delivery:

# of sets	Address of delivery
2	Kherson, # 47 Ushakova avenue, off 141
14	76004, Ivano-Frankivsk, #21 Hrushevskoho street, off 600
14	Zakarpattya region (14 territorial communities)- the exact addresses will be communicated later

Latest expected delivery date:

Items should be delivered and installed no later than **28 February 2022**. Shorter delivery terms will be an advantage.

Additional requirements:

- The price of the goods must include the cost of installation and delivery of all goods to the above mentioned address;
- The warranty period for the equipment should be not less than 12 months after installation;
- Equipment must have official warranty service centres in Ukraine;
- Supplier/s must provide after-sale services.

Quality assurance and acceptance:

Joint quality assurance team of UNDP (2 UNDP Coordinators at Kherson and Ivano-Frankivsk regions) and representatives of the ATCs at Kherson region, Ivano-Frankivsk and Zakarpattya regions of Ukraine should accept the installed equipment. Acceptance acts to be signed by both UNDP and Supplier upon quality assurance team confirmation.

Requirements to the organization/company

- Duly registered company/organization
- At least 3 years of experience in the supply of similar products
- Full acceptance of UNDP General Terms and Conditions
- At least 2 positive references from previous clients in the past 2 years.

Payment terms

- Upon delivery, installation and acceptance of items by UNDP team;
- Delivery in several stages may be considered in terms of established deadline upon confirmation by UNDP, payments linked to delivered goods cost.

Technical Specification

System for selective control of physiological parameters, for home use (equipment for the provision of medical services using telemedicine)

Goods delivery quantity - 30 sets of equipment for the provision of medical services using telemedicine;

General medical and technical requirements:

1. The equipment must be new, not used before, of the model produced not earlier than 2019, and not used as a demonstration sample (please provide a ***warranty letter).***

2. The equipment has to be put into operation in accordance with the legislation on the technical regulation and conformity assessment and in the manner prescribed by law.

2.1. **With the purpose of confirming the procurement subject compliance with regulatory and technical documentation and technical and qualitative properties, the bidder shall provide the following information within the scope of the bid**:

- With the purpose of confirming the goods introduction into circulation in accordance with the legislation on the technical regulation and conformity assessment and in the manner prescribed by law, the bidder shall provide:

a) a declaration copy or a copy of the documents confirming the possibility of putting into circulation and/or into operation (usage) of the medical device based on results of the conformity assessment procedure in accordance with the requirements of the technical regulations, **or,**

b) a warranty letter confirming that a declaration copy or a copy of documents will be provided at the time of goods delivery, which confirms the possibility of putting into circulation and/or operation (usage) of the medical device based on results of the conformity assessment procedure in accordance with the requirements of the technical regulations at the time of goods delivery, **or**

c) if the bidder offers medical devices that have undergone state registration, are registered in the State Register of Medical Equipment and Medical Devices and approved for use in the territory of Ukraine and were put into circulation before the date of mandatory application of technical regulations, then it is allowed to offer such devices until the end their shelf life and not more than five years from the date of putting them into circulation, without undergoing the conformity assessment procedure and without marking with the national conformity sign, **or**

d) if the Technical Regulations for Medical Devices do not apply to the offered equipment, the bidder shall provide a ***written explanation*** stating the reasons for skipping a conformity assessment procedure in accordance with the requirements of the Technical Regulations for Medical Devices.

- Copies of instructions for use or technical passports and brochures.

- Documents confirming the availability of the Cloud Service and related software, or authorization to use them in its economic activity (dealer or license agreements, etc., with enclosing documents confirming this).

- Documents confirming that the bidder is a manufacturer of the equipment or a

manufacturer's dealer or supplier (a contract with the manufacturer, or a power of attorney from the manufacturer, or a dealer's certificate etc., or an authorization/warranty letter from the manufacturer or an authorized representative (or dealer) warranting that the bidder has the possibility to deliver goods, which are the subject of procurement, in the amount and within the time specified in the tender documents and the bidder's offer with enclosing the relevant authorization documents, which attest the status of the dealer or the authorized representative).

3. Warranty period for the equipment – not less than 12 months.

4. Mandatory availability of technical personnel in Ukraine, who is trained and certified by the manufacturer for installation, warranty and post-warranty equipment maintenance (***please provide a copy of the engineer's certificate***).

5. Equipment connection to the Cloud Service and equipment delivery should be carried out at the expense of the supplier.

6. The equipment shall jointly form a single complex and perform the following functions, a set of equipment for the provision of medical services using telemedicine:

- Electrocardiographic examination
- Blood pressure measurement
- Heart rate measurement
- Blood oxygenation measurement
- Body temperature measurement
- Spirometery
- General examination of the patient with the possibility of obtaining digital images
- Auscultation internal sounds of the body
- Function of measuring glucose and cholesterol levels.

7. The equipment must have a digital interface for inputting the examination data received from a patient.

8. The weight of one set of equipment shall not exceed 6 kg.

9. Each set shall have a durable transport suitcase.

10. The subject of procurement shall meet the following medical and technical specifications (**please provide information on the following**):

Medical and technical specification of a set of equipment for the provision of medical services using telemedicine	**Compliance with the requirements (Yes / No) Indicator**	**Reference to an item (a page) in the instructions for use or other authorized technical documentation of the goods manufacturer, or other authorized documents.**
I. General requirements		
The portable telemedicine diagnostic tool kit shall provide diagnostics of the patient's functions (receiving, storing and transmitting information about the physiological measurements of the patient's body)		
The portable telemedicine diagnostic tool kit shall contain specialized applications and form a software and hardware appliance (SHA).		
SHA shall ensure the receipt and transmission of diagnostic		

information for telemedicine consultations		
SHA shall provide the possibility to be used both in the healthcare facility and at the patient's home		
SHA shall provide both online and offline operation modes with automatic data downloading after re-establishing the internet connection.		
Examinations can be performed by junior medical staff, a physician assistant or a family doctor.		
SHA shall measure the physiological parameters of the patient during the examination		
SHA equipment shall have a self-contained power supply (batteries or accumulators) or power supply option from a USB port		
II. SHA Functions		
1. ECG recording		
Requirements for ECG recording and displaying:		
ECG registration - 12 channels, availability.		
Manual ECG recording mode, availability.		
Heart rate mode, availability		
ECG lead system: standard and amplified (I, II, III, aVR, aVL, aVF and V1, V2, V3, V4, V5, V6), availability		
ECG displaying on the monitor of the main SHA module, availability		
Simultaneous ECG channels displaying on the monitor, not less than 12 leads (I, II, III, aVR, aVL, aVF and V1, V2, V3, V4, V5, V6), availability		
Sensitivity, 5, 10, 25, 50, 100 mm/mV		
ECG viewing before recording, availability		
ECG recording time, not less than 10 s, availability		
Heart rate measurement, availability		
Inbuilt printer is mandatory with speed options: 12,5 mm/s, 25 mm/s, 50 mm/s		
Function of preliminary atuomatical interpretation of the patient's ECG is mandatory.		
2. Blood pressure measurement		
Blood pressure measurement, availability		
Measurement method - oscillometric, compliance		
Measurement modes compatibility: adults, children		
Pressure measuring range, at least: • Systolic: 60 to 230 mm Hg • Diastolic: 40 to 130 mm Hg		
Absolute error range when measuring pressure, not more than ±3 mm Hg.		
Leakage testing function, availability.		
Irregular rhythm fault resistant.		
3 sizes of patient cuffs S, M and L availability.		
3. Heart rate measurement		
The range for heart rate measurement is not less than 25 to 250 beats per minute, compliance		

Finger pulse oximeter, compliance		
Error not more than: ± 2 beats per minute or 2 units		
Use for - adults, children, compatibility.		
Interoperability with SHA workstation for transmission of measurement data via wired or wireless interfaces, availability		
4. Non-invasive measurement of the oxygenation level of capillary blood		
Measurement of capillary blood oxygenation, availability		
Finger pulse oximeter, compliance		
The range for blood oxygenation measurement is not less than 35 ~ 100%		
Error, not more than: ± 2% (at the range of 80% ~ 100%).		
Use for - adults, children, compatibility.		
Interoperability with SHA workstation for transmission of measurement data via wired or wireless interfaces, availability		
5. Non-contact temperature measurement (thermometry)		
Body temperature measurement by non-contact method, availability.		
Measurement modes: body / object temperature, availability.		
Colour display of normal (green light) and elevated (red light) temperature, preferred availability.		
Measuring range, not less than 34-42 ℃		
Resolution, not less than 0.1 ℃		
Error at the range of 35 - 42 ℃, not more than ± 0.2 ℃		
Auto power-off, availability		
Interoperability with SHA for measurement data transfer via USB or Bluetooth or manually, availability		
6. Pulmonary function test (spirometry)		
Requirements for basic parameters:		
Maximum volume: not less than 10 lts.		
Flow range: not less than 0 l/s ~ 16 l/s		
Volume accuracy: not less than ± 3% or 0.05 lts (whichever is greater)		
Flow accuracy: not less than ± 5% or 0.2 lts/s (whichever is greater)		
Examined parameters:		
Forced vital lung capacity, FVC, l, availability		
Peak expiratory flow rate, PEF, l/s, availability		
Forced exhalation volume for 1 second, FEV1, l, availability		
FEV1%: the ratio of FEV1 and FVC,%, availability		
Parameters graphs drawing based on examination results, availability		
Other requirements for the device:		
Function graphs display, availability.		
Data processing: saving, deleting, downloading and viewing, possibility.		
Interoperability with SHA workstation for transmission of measurement data via wired or wireless interfaces, availability		

7. General examination of the patient with the possibility of obtaining digital images using a digital camera		
General examination of the patient with the possibility of obtaining digital images (e.g., limbs, body parts, etc.), compliance.		
Camera with a function that allows viewing a patient and any signs/symptoms of the patient's disease (e.g., skin lesions, rashes, wounds, etc.), availability		
Photo recording, availability		
Video recording, availability		
Camera type: built-in or external with connection to the main SHA module or tablet PC or PC, compliance		
Connection interface - USB and/or Wi-Fi (for external camera), possibility		
8. Auscultation internal sounds of the body		
The portable stethoscope should be intended for auscultation of the sounds leaving heart, vessels, lungs, bronchial tubes, intestines and other bodies.		
Frequency range: not less than 50 ~ 800 Hz		
Data processing: saving, deleting, downloading and viewing, possibility.		
Connection interface - USB		
9. Function of measuring glucose and cholesterol levels		
Intended for quantitative determination of the following blood parameters:		
Glucose, general cholesterol		
Triglycerides		
High density lipoproteins		
The range of glucose measurement: not less than 0,6-33,3 mmol / l		
The range of general cholesterol measurement: not less than 2.59-11.64 mmol / l		
The range of triglycerides measurement: not less than 0.51-7.34 mmol / l		
The range of high density lipoproteins measurement: not less than 0.65-2.46 mmol / l		
Measurement time not more than:		
5 sec. for Glucose		
3 min. for Lipids		
III. main SHA module		
main SHA module provides:		
– Measurement of patients' vital signs, availability		
– Online transmission of received data, availability		
– Specialized software, availability		
– ECG recording, availability		
– Blood pressure measurement, availability		

– Measurement of capillary blood oxygenation, availability		
– Obtaining all measured parameters of patient functions from SHA standard and external diagnostic devices (ECG, blood pressure, pulse rate, blood oxygen saturation, temperature, spirometry data, dermatoscopy data, etc.), availability.		
– Connection of standard and external diagnostic devices (spirometer, dermatoscope, etc.) via USB or Bluetooth or Wi-Fi, availability		
– Connect external USB or Wi-Fi imaging devices (digital cameras, scanning systems such as dermatoscopes), availability.		
– Display of all measured examination data (ECG, blood pressure, pulse rate, blood oxygenation, body temperature, respiratory function, dermatoscopy, images from a common digital examination camera) on the monitor of the main SHA module, availability.		
– Photographing the patient or the necessary parts of the body, etc., availability.		
– Audio recording, availability		
Main SHA module specifications (tablet, laptop etc.):		
- Color touch LCD display, availability		
- Display size, at least 10 inches		
- At least 4GB of RAM		
- At least 16GB of internal memory		
- Android or Windows or iPad OS operating system		
- Support for Wi-Fi, Bluetooth, 3G, availability		
IV. Software requirements for the main SHA module		
The availability of the operating system that ensures SHA operation.		
Support for Bluetooth interfacing protocol, compliance.		
Creating a patient's examination record, availability		
A unique number shall be assigned to each examination, availability		
Patient data input: o Patient (any identifier) o Date of birth or number of full years or months if the patient is less than 1 year old o Height (in centimetres) o Weight (in kilograms) o Sex		
Selection of a sort or a type of measurements for a patient to be performed, by type of device, availability		
Measurement results storage in the local information storage of the SHA software, availability.		

Examination information storage in the local storage of the main module (examination number, patient data, examination results)		
Examination and measurements results storage in the local storage of the main SHA module until they are transferred to the cloud storage		
SHA authorization in the cloud storage of examination information for further interoperation.		
Transfer of information from the local information storage of the main SHA module to the cloud storage		
Transfer of information to the local storage on the main SHA module is performed after each saving of the examination results or by the operator command, provided that the SHA is connected to the Internet		
Printing a paper form based on the results of the examination with the possibility of adding a doctor's opinion after printing the form		
Requirements for the transfer of examination information to the data storage		
The software and hardware appliance shall ensure the transfer of the obtained examination data to the cloud storage.		
The examination data shall be transmitted using the following Internet communication methods: Wi-Fi, or 3G / LTE, LAN, USB or other connectivity.		
SHA shall ensure the data transfer (indicating the unique study number) to the cloud storage only when the authorization from the cloud storage is confirmed.		
V. Availability of informational and technical support for SHA		
Provision with equipment instructions for use (operation manuals) (prefferebale in Ukrainian, English is exceptable)		
Informational and technical support (a warranty) for not less than 12 months		
Requirements for a cloud storage:		
Ensuring SHA authorization		
Blocking the data transfer to the data storage in case of unsuccessful SHA authorization		
Data storage capacity for 100 thousand patients for at least 36 months since delivery of the SHA in the cloud storage, availability		
Possibility for doctors and patients to access examinations and measurements results through a web browser after their authorization		
Possibility for a cloud service to interact with medical information systems or a telemedicine network.		
Possibility to transfer the examination results to the medical information system or electronic medical card.		

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