An innovative solution to optimize ultrasound diagnostics by introducing a portable ultrasound device to the European medical market

Olga Paraska[1] Andriy Gorban[2] and Oleh Dynnyk[3]

[1] Khmelnytskyi National University, Khmelnytskyi 29016, Ukraine
[2] Petro Mohyla Black Sea National University, Mykolayiv, Ukraine
[3] Institute of elastography Medical center LLC, Kyiv, 03037, Ukraine
olgaparaska@gmail.com

Abstract. The article presents the peculiarities of the use of a successful Ukrainian startup HandyUsound in medical practice. HandyUsound is an innovative ultrasound complex, which, according to its characteristics (portability, lightweight, a possibility of autonomous power supply, intuitive touch control, newest innovative technologies (attenuation coefficient measurement – ACM, strain elastography – SE and more) similar to large ultrasound systems of the expert level, affordable price) has no analogues in the world markets of medical equipment. In particular, ACM allows solving the problem of screening and early diagnosis of such a challenge to the health care system as the fatty liver disease (FLD) pandemic. SE has become especially widely used in oncology for the purpose of differential diagnosis of malignant and benign tumors from the standpoint of evidence-based medicine. The COVID-19 pandemic prompted the integration of a ready-made standardized lung ultrasound (LUS) protocol into this hand held US device (HHUSD) according to WFUMB/EFSUMB Guidelines. In addition to the standard applications of expert US devices, this product has an advanced cardiovascular package with continuous wave, tissue and trans-cranial Doppler (CWD, TD, TCD). Intelligent acoustic adaptation allows the operator to automatically optimize B-mode and Doppler.

Keywords: portable ultrasound device, ultrasound diagnostics, HandyUsound, Ukrainian startup, innovation, fatty liver disease.

1 Introduction

Ultrasound diagnostics (USD), nowadays, is one of the most accessible and objective methods of examination of human internal organs and systems from the standpoint of evidence-based medicine. The high resolution of modern ultrasound devices, the non-invasiveness of the method (harmlessness) and the absence of radiation exposure created the prerequisites for the widespread use of ultrasound in almost all areas of medicine [1-3].

Ultrasound examinations have been used for about 60 years, and this field is rapidly progressing thanks to the development and implementation of new technologies. In

M. Petr et al. (eds.), *62nd International Conference of Machine Design Departments (ICMD 2022)*, Atlantis Highlights in Engineering 28,
https://doi.org/10.2991/978-94-6463-423-5_30

recent years, the following new US technologies have become widespread: elastography (study of the mechanical properties of tissues, in particular in oncology and liver cirrhosis, contrast enhancement of the US signal - contrast enhanced US (CEUS), technologies for attenuation coefficient measurement of US, backscattering, speed of sound (SoS), tissue doppler and intellectual acoustic adaptation to ultrasound scanning conditions, etc. These modern technologies are widely used to improve the informativeness of US diagnostics in almost all areas of medicine, mainly in expert devices of world brands. US diagnostics, as part of the field of radiology, is most often used in specialized wards of radiological services of medical institutions or by narrowly specialized specialists (obstetricians, gynecologists, cardiologists, urologists, etc.). At this stage of the development of medicine, ultrasound is one of the most effective methods of examining the human body [2, 3]. Its popularity is explained by reliability, simplicity, speed of obtaining results. Along with a number of advantages in the application of ultrasound diagnostic methods, there are certain complications, in particular [1-3]:

- innovative technologies on the market are offered by the majority of vendors in the top segment of high-value equipment, which inhibits their wide implementation in everyday medical practice;
- large dimensions and weight of ultrasound devices of expert level;
- difficulties in mastering modern ultrasound technologies by primary care doctors and middle medical staff.

The answer to these challenges was the emergence of the ultrasound segment directly for clinicians and even paramedics, which is gaining wide popularity. This approach of introducing ultrasound in the chain of primary medical care (PMD) and even at the stage of pre-medical medical care has acquired the established name [3] – Point-of-Care Ultrasound (POCUS). POCUS is based on the principle of providing ultrasound in the city where the need arises in the interests of the patient.

The segment of the market of manufacturers of ultrasound equipment that allows the implementation of the POCUS principle is gaining strength, namely portability, light weight, basic ultrasound functions that do not require a long learning period, standardized protocols for performing the procedure (e.g., FAST-, FATE-, BLUE -, LUS-protocols, etc.). Today, the budget of portable ultrasound devices already makes up a third of the entire global budget of US systems [3, 4].

The use of a hand held US device (HHUSD) for FMA in accordance with the WFUMB/EFSUMB Guidelines has become especially relevant during the COVID-19 pandemic [1-3]. The role of POCUS at the stages of providing medical care was fundamentally revised. The main points of ultrasound application have been:

- medical sorting at the stage of evacuation of a patient and in a reception department of a COVID-hospital, determination of the need for immediate referral to a CT scan of the lungs and to the ICU;
- assessment of the course of COVID in units (aggravation, complications, recovery, relapse);
- US support of rehabilitation from post-Covid syndrome.

A special moment of overcoming the COVID-19 pandemic was the introduction of US diagnostics into practice of family doctors and general practitioners, namely the hand held US device (HHUSD) [4].
Chronic non-communicable diseases (NCDs) have become another challenge to the health care system, which, according to the WHO, are the causes of premature disability and reduced quality of life, severe disabling complications and mortality. There is even a term – Years of life lost from mortality (YLL) [1, 5].
One of these challenges is fatty liver disease – alcoholic and non-alcoholic – ALD and NAFLD. They are often combined as liver steatosis. It has been proven that only NAFLD covers a third of the adult population of the planet and has acquired the characteristics of a pandemic. Steatosis often has a hidden course. Clinical manifestations have their debut already at the stage of complications. In particular, NAFLD is an independent predictor of cardiovascular disasters (strokes and heart attacks), metabolic syndrome and type 2 diabetes, fibrosis and cirrhosis of the liver, the development of chronic kidney disease and oncology (hepatocellular carcinoma, colorectal cancer).
There are no specific clinical and biochemical tests for liver steatosis. The insidiousness of steatosis requires the development of the concept of its US screening.
Therefore, modern ultrasound examinations require narrow-profile specialists and are expensive, which limits the availability of the diagnostics for broad segments of the population [8, 9].
The aim of this study is to provide accessibility of the nowadays medical technologies and make the process of ultrasound diagnostics more efficient and ergonomic. HandyUsound portable ultrasound system has an intuitive touch control system. HandyUsound is an innovative portable ultrasound system that has a wide range of features at an affordable price [6].

2 Materials and Methods

Ultrasound research today is one of the main fields of research based on medical imaging. US research is a combination of various physical methods of acoustic probing of biological tissues - biological acoustics. The basic and main method of US visualization is a B-mode. It is based on the reading by a special sensor of ultrasonic waves, which are reflected differently from the boundaries between body tissues. A special mathematical apparatus forms a generator signal and processes the information received at the reception and displays it in the form of a graphic raster image of a set of pixels of different brightness in a 512x512 screen matrix. US research is based on receiving echo signals from structures with different acoustic densities.
Different tissues of the body (muscles, blood, liver, etc.) have different densities, so the emission of ultrasound in them is also different. The ultrasound method is based on this difference, using the physical properties of ultrasound as waves. The ultrasound image can be formed in the two- and three-dimensional space of Cartesian coordinates (2D or 3D). Scanning a 3D image in real-time makes it possible to obtain a 4D sequence.

Analyzing the delay time of the ultrasound waves that covered the path from emission to reflection from the tissues and returning to the sensor, and the amplitude of the signals, the computer determines the position of each pixel of the ultrasound image on the monitor screen in the system of coordinate axes. Based on data on the position and brightness of each image pixel, an image (echogram) of the boundaries of various tissues is constructed, giving the pixels certain coordinates and brightness on a gray scale (256 degrees). The topography, shape, size and structure of organs and tissues can be determined on echograms, which is the basis for determining the presence or absence of pathology. Modern ultrasound sensors have a wide range of radiation frequencies. Each frequency carries its own additional information about the acoustic properties of tissues.

In order to avoid interference between the emitted US waves and the waves returning to the sensor, the generator works in pulse mode (pulse repetition frequency – PRF approximately 1000-1500 per 1s). The charge of pulses alternates with the reception period. The emission mode lasts only 0.1% of the cycle time, and the reception mode lasts 99.9%. This is one of the factors that determine the safety of USS research.

Acoustic power and radiation time in B-mode do not violate ALARA principles and B-mode has practically no contraindications and is not time-consuming.

Frequencies from 1 to 25 mHz are mainly used in USR. Although there are already systems with 75 and 100 MHz for ultrasound of the skin. Today, B-mode has developed towards second and inverse harmonic image analysis. In particular, visualization of resonance harmonics of micro-bubbles of ultrasound contrasts in vessels and tissues of the body, which provides extremely important diagnostic information for the differential diagnosis of tumors.

The last direction of ultrasound research has acquired the name – contrast enhancement US (CEUS).

Another family of ultrasound studies is the Doppler. The method provides visualization of the movement of blood and other fluids, as well as body tissues. It is based on the physical principle of the frequency shift of US waves during their interaction with moving objects. The Doppler frequency shift can be coded on a color scale and a motion map can be visualized in the screen matrix. This allows mapping the presence and direction of blood movement in the heart and blood vessels. Modern tissue doppler technology provides mapping of the movement of the myocardium and valves. 2D and 3D reconstructions provide an idea of the angioarchitectonics of organs and tumors. The spectral doppler curve allows the measurement of quantitative parameters of movement speed in meters per second and an idea of the direction of the movement.

In the last decade, the integration of the family of elastography methods (strain elastography – SE and share wave elastography – SWE) into conventional ultrasound diagnostic devices has become revolutionary. In general, as a section of solid body physics, ultrasound elastography provides qualitative and quantitative information about the mechanical properties of body tissues, their ability to deformations in kPa. SE has found significant application in oncology. Most malignant neoplasms present a higher stiffness than benign ones. SWE allowed primarily to assess the development of liver fibrosis and cirrhosis in viral hepatitis and fatty liver disease [7, 8].

The basis of the US steatometry method is the fundamental property of ultrasound waves to attenuate and dissipate energy in the medium when they travel a certain distance. The set of these acoustic phenomena is called attenuation. The attenuation is proportional to the wavelength. Attenuation coefficient measurement (ACM) allows quantitative staging of the stage of hepatic steatosis or another synonym – fatty liver disease (FLD). The unit of ACM is dB/cm or dB/cm/MHz. Today, there is an aim and an opportunity to introduce the screening of liver steatosis by the innovative method of ultrasound steatometry for measurement of the attenuation coefficient (ACM) [9-15].

3 Results and Discussion

The portable (5 kg) HandyUsound device combines the leading expert modes of US research:

1) high resolution real-time B-mode with a wide range of broadband sensors;
2) almost all types of doppler known today;
3) compression elastography in the Natural and Active Strain;
4) ACM for staging and screening of fatty liver disease. The latter is unique for portable US devices.

For the first time, the Ukrainian startup HandyUsound and a model of a portable ultrasound diagnostics complex was presented on 5 March 2020 in Prague at the Bio-Spot conference [16]. From 2020 to 2022, the startup team continued intensive work on improving innovative technologies and combining them in one device. The pre-series ultrasound diagnostics prototype of the HandyUsound complex at the stage of Minimum Viable Product (MVP) was presented on 13-17 July 2022 in Vienna at the European Congress of Radiologists (ESR 2022) [17], where it was recognized by European opinions-leaders in ultrasound diagnostics. The unique technological solutions developed and used in the HandyUsound were presented on 13-15 September 2022 at The 62nd International Conference of Machine Design Departments (ICMD 2022, Liberec, Czech Republic) [18], where its innovativeness was confirmed. Currently, the registration and organization of production of the HandyUsound portable ultrasound system in the EU is underway. The areas of application a portable ultrasound device HandyUsound: general practice – family medicine, emergency aid, gastroenterology, gynecology, urology, dermatology, endocrinology, cardiology.

Main technical characteristics of HandyUsound are:

The device supports broadband sensors with 192 elements (Support for 192-element probes).

Scan modes and programs:

1st group of modes combines B-mode, its variants (M-mode) and the combination with real-time Doppler mode Duplex mode and Triplex mode. Important features of B-mode: Digital beam formation; Frequency range from 1 to 15.0 MHz; Scanning depth 28 cm; Magnifying the image of the region of interest, 16x Zoom; digital expansion of the scanning aperture – Trapezoidal scan,

Angle of inclination at trapezoidal scanning: ± 10 degrees. Tissue harmonics and inversion harmonics.

Intellectual adaptation of scanning modes to the patient's individual acoustics – Automatic image optimization with one button (B-mode and Doppler).
2nd group combines various Doppler modes: Pulse-wave (PW) Doppler (Pulse-wave Doppler pulse repetition frequency: 4.5 – 12 kHz, Maximum registered speed: 5.0 m/sec, Minimum control volume: 0.5 mm); Color Doppler (CD – 2D image mode with color flow rate mapping mode). Color Doppler pulse repetition frequency: 0.55 – 9.86 kHz, Simultaneous display of B-mode and color Doppler in real-time, Maximum frequency: 95 frames/sec.
Two more types of Doppler: PD (Two-dimensional image mode with color mapping of energy, energy and direction) and TD. Tissue Doppler mode (color mapping, spectrum, M-mode).
Available combinations of modes:
B/B. Display mode of two B-images
B / CD (PD, DF, TD). Display mode of two B-images (black and white and color mapping) in real time.
B / M Display mode of B-image and one-dimensional M-image with time scan
M.A. Anatomical M-mode
4B. Display mode of four B-images
Unique expert capabilities:
WTrack (E-AS). Mode of vascular wall elasticity assessment.
CE. Compression elastography mode (Active & Natural Strain)
AC, Attenuation coefficient measurement mode
Display and image processing modes:
Automatic measurement of hemodynamic parameters (Doppler autotracing)
Automatic measurement of the thickness of the intima-media complex
Re-study with saved settings
Flow profile research (flow volume)
Vector scan in B-mode
Synthetic aperture scanning in B-mode
Multi-view composite image (MCI) in B-mode
Color mapping of pulsating blood flow
Real-time visualization filter.
Measurement and calculation of diagnostic parameters for all areas of research.
Types of probes:
Convex
Phased
Linear
Microconvex
Cavitation (rectal, vaginal)
Measurements and calculations:
Ability to perform standard measurements and calculations (obstetrics and gynecology, cardiology, angiology; abdominal, renal and prostate; small parts).
Ability to perform measurements on images stored in the archive (work with RAW DATA)
Availability of calculations for compression elastography (Strain Ratio).

Ready-to-print attenuation measurement protocol and hepato-renal index (liver steatosis).

Presence of Pancreatic-Lienal Index (PII) calculations (pancreatic steatosis).

Ready-to-print lungs examination protocol for COVID-19.

Archiving and data transmission system: movie loop in B-mode: 2700 frames, DICOM).

Cloud service.

Network service.

So according to its characteristics, the HandyUsound complex can become a basic tool for the implementation of the modern European trend "Perform of ultrasound examinations by general practitioners" [17], which aims at making diagnostics more accessible to the general population.

Conclusion

Implementation of the innovative portable ultrasound diagnostic complex HandyUsound into the practice of public health in Ukraine and EU countries will significantly simplify and spread the detection of diseases in the early stages, which, in turn, will have a positive effect on personal health indicators and population health indicators individual regions as a whole.

The use in Ukraine and the EU countries of the developed innovative technology, the tool of which is the portable ultrasonic diagnostic complex HandyUsound, is possible only on the condition of developing educational and methodological materials for future users of the technology and corresponding technological documentation, which is used for passing certification procedures and organizing the industrial production of ultrasonic diagnostic complex.

The implementation into the family general practitioners' practice of the availability and prevalence of ultrasound diagnostics will enable the early detection of serious diseases, which in its turn will increase the efficiency and reduce the costs of further treatment. It will also make this diagnosis available to potential users of medical care (screening studies of contingents, preventive examinations of contingents).

Acknowledgements Authors of the paper would like to express special thanks for the support by the Project "Modular platform for autonomous chassis of specialized electric vehicles for freight and equipment transportation", Reg. No. CZ.02.1.01/0.0/0.0/16_025/0007293.

References

1. WFUMB (World Federation for Ultrasound in Medicine and Biology) Course Book. Editors: Nurnberg, D., Chammas, M.C., Gilja, O.H., Sporea, I., Sirli, R. 1st.ed., Mirton, Timisoara (2022).
2. Todsen, T., Ewertsen, C., Jenssen, C. et al.: EFSUMB Training Recommendations for the Practice of Medical Ultrasound in Europe. Ultrasound Int Open (2022); 8: E29–E34. DOI. 10.1055/a-1922-6778.

3. Jarman, R.D., McDermott C., Colclough, A. et al.: EFSUMB Clinical Practice Guidelines for Point-of-Care Ultrasound: Part One (Common, Heart and Pulmonary Applications). Long version. Ultraschall in Med. Thieme. (2022). DOI: 10.1055/a-1882-5615.
4. Nielsen, M.B., Cantisani, V., Sidhu, P.S. et al.: The Use of Handheld Ultrasound Devices – An EFSUMB Position Paper. Ultraschall in Med No 40, 30–39. 2019. DOI https://doi.org/10.1055/a-0783-2303.
5. Global Burden of Disease, http://www.who.int/healthinfo/global_burden_disease/en/.
6. HandyUsound Homepage, https://handyusound.com/.
7. Boursier, J., Castera, L., Cazzagon, N. et all.: EASL Clinical Practice Guidelines on non-invasive tests for evaluation of liver disease severity and prognosis – 2021. Hepatology 75(3), 659–689 (2021). DOI: 10.1016/j.jhep.2021.05.025.
8. Barr, R.G., Wilson, S.R., Rubens, D., Garcia-Tsao G., Ferraioli, G.: Update to the Society of Radiologists in Ultrasound Liver Elastography Consensus Statement. Radiology 296, 263–274 (2020).
9. Francque, S.M., Marchesini, G., Kautz, A. et al.: Non-alcoholic fatty liver disease: A patient guideline. EASL. JHEP Reports 3(5), 1–39 (2021). DOI: https://doi.org/10.1016/j.jhepr.2021.100322 .
10. Sasso, M., Tengher-Barna, I., Ziol, M. et al.: Novel controlled attenuation parameter for noninvasive assessment of steatosis using Fibroscan®: validation in chronic hepatitis.: C. J Viral Hepat 19(4), 244–253 (2012). DOI: 10.1111/j.1365-2893.2011.01534.x.PMID:22404722.
11. Screening and Treating Non-Alcoholic Fatty Liver Disease. Scientific Resource Center under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. HHSA 290-2017-00003C).
12. Dietrich, C.G., Rau, M., Geier, A.: Screening for nonalcoholic fatty liver disease-when, who and how? Review. World J Gastroenterol 27(35), 5803–5821 (2021). DOI: 10.3748/wjg.v27.i35.5803. PMID: 34629804.
13. Karen Alavi S., Ayatollahi, M. R., Jamali, J., Petru, M.: On the applicability of digital image correlation method in extracting the higher order terms in stress field around blunt notches. Theoretical and Applied Fracture Mechanics. 121(1), 103436 (2022). DOI: https://doi.org/10.1016/j.tafmec.2022.103436.
14. EASL-EASD-EASO Clinical Practice Guidelines for the management of non-alcoholic fatty liver disease. J Hepatol. 64(6), 1388–402 (2016). DOI: 10.1016/j.jhep.2015.11.004.
15. Ferraioli, G., Berzigotti, A., Barr, R., et al.: Quantification of liver fat content with Ultrasound: A WFUMB Position Paper. Ultrasound in Med. & Biol., 47(10), 2803–2820 (2021). DOI.org/10.1016/j.ultrasmedbio.2021.06.002.
16. Gorban, A. Tech-transfer conference BioSpot 2020, Prague, Czech Republic, pp 29. https://biospot.eu/conferences/.
17. European Congress of Radiologists ECR 2022 Homepage, https://www.myesr.org/congress.
18. Paraska, O., Gorban, A., Dynnyk, O.: An innovative solution to optimize ultrasound diagnostics by introducing a portable ultrasound device HandyUsound. The 62nd International Conference of Machine Design Departments ICMD 2022, Liberec, Czech Republic, https://2022.icmd.cz/.