



Visiomed Group SA [®]

« A new vision of your health »

PRESS RELEASE

The FDA grants VisioCheck® the 510 (k) certification as well as its registration, authorizing the marketing in the United-States of the world's first mobile connected telemedicine station under 300g

Paris, December 27, 2018

VISIOMED GROUP is proud to announce that its mobile and connected teleconsultation station BW-X07HD "Handheld VitalSigns Monitoring System", called VisioCheck® and developed by BewellConnect®, obtained the 510 (k) certificate and is now registered by the US Food and Drug Administration (FDA).

FDA Registration: A key step in accelerating the commercial roll-out!

To date, the BW-X07HD VisioCheck® is the first and only ultra-portable, 2G, 3G, 4G and WiFi-connected, telemedicine station in the world with less than 300 grams to obtain medical certification in Europe by the CE and in the United States by the FDA.

After Receiving the European Marketing Authorization (CE0197 Marking According to the 93 / 42EEC Directive) in July 2017, the FDA now authorizes VisioCheck's BW-X07HD marketing on the whole territory of the United States of America.

This innovative, ultra-portable Class IIa certified medical device makes it possible to establish a secure connection between healthcare professionals and patients to easily carry out an HD videoconferencing teleconsultation. It provides vital signs measurement and transmits the encrypted data (pulse, blood pressure, body temperature, oxygen saturation (SpO2), electrocardiogram (ECG), etc.) in real time through 2G, 3G, 4G and WIFI networks, to health professionals all over the world.

In addition, the BW-X07HD VisioCheck® backs up secure and encrypted data on authorized HDS servers through the various local ministries of health.

Accessing the American market, a major milestone

This FDA registration of BW-X07HD VisioCheck® was the last step before its marketing in the US. It comes at a time when telemedicine will undergo a new acceleration thanks to the implementation on January 1st, 2019 of new reimbursement codes for remote monitoring of patients. Visiocheck fits perfectly into these new healthcare pathways in the United States by providing healthcare professionals with the mobile technology needed to optimize their actions.

BW-X07HD VisioCheck® has already been qualified and validated by the services of Janz Corporation and can now be integrated into their commercial offering under the distribution agreement signed in March 2018 with the distributor of medical devices, equipment and health services for the US Government.

The distributor Janz Corporation had identified the technology and performance of VisioCheck® as innovative and revolutionary, particularly suited to mobile medical teams.

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With VisioCheck® and its ultra-portability, collecting, transmitting in WiFi, 2G, 3G, 4G and real-time monitoring of vital data remotely to an advanced medical post can be valuable and decisive in the field operations of the armed forces.

Janz Corporation has the status of Service-Disabled Veteran-Owned Small Business (SCVOSB) which gives it privileged access to US government orders. Today, Janz Corporation equips the federal agencies (FBI), the US Forces (US Army, US Air Force, US Navy), the Government (Ministry of Veterans Affairs) and the main public services (Schools, Hospitals) as well as the NATO member countries.

"By being a US Army Veteran and Medical Device Specialist, we offer our partners privileged access to US government orders, whether from the Department of Defense, Department of Veterans Affairs or federal agencies all over the country. We have identified BewellConnect's strong innovation capability and are very pleased to be able to bring its breakthrough solutions in the field of connected health to our customers. We are looking forward to adding VisioCheck® to our catalog as we see the tremendous potential for this all-in-one device with no equivalent in the market." Said Rick FINSTERBUSCH, CEO of Janz Corporation at the signing of the distribution agreement in March 2018 with BewellConnect.

A concentrate of the latest BewellConnect® innovations

BW-X07HD VisioCheck® includes several medical devices that are necessary and essential for measuring the vital physiological constants of patients:

- a blood pressure humeral cuff;
- a non-contact body thermometer equipped with MSFT® ThermoFlash® automatic calibration technology;
- an electrocardiogram (5 electrodes, 7 leads);
- a pulse oximeter (SpO2)
- A glucose meter.

A stethoscope, an otoscope, a dermato-scope are being integrated and will very soon complement and enhance the features of the BW-X07HD VisioCheck®.

All data collected via the BW-X07HD VisioCheck® can be transferred either to a doctor or to a telemedicine / remote monitoring and coordination platform available 24 / 7.

BW-X07HD VisioCheck® also features an HD camera, a high-brightness FlashLED, and a 16 million color touch screen. The BW-X07HD VisioCheck® is the ideal, ultra-portable and scalable Connected Smart Device that facilitates and simplifies the deployment and practice of telemedicine via videoconferencing between healthcare professionals or between patients and healthcare professionals all over the world and under all circumstances.

BW-X07HD VisioCheck®, the versatile telemedicine tool for all healthcare professionals worldwide.

BW-X07HD VisioCheck® is an ultra-portable telemedicine station that facilitates all uses of telemedicine, in both liberal and hospital medicine, pharmacists, paramedics and other industries and services to the person, whether in terms of:

- ✓ tele-expertise among health professionals,
- ✓ Teleconsultation between patients and health professionals,
- ✓ Remote surveillance between patients and medical platforms.

Thanks to the BW-X07HD VisioCheck® and all its connected medical devices for monitoring and coordination of care, VISIOMED GROUP is positioned at the forefront as one of the players offering one of the most innovative all in one solution.

Telemedicine, a \$ 93.45 billion global market * at your fingertips

The telemedicine market is constantly evolving and could reach \$ 93.45 billion in 2026 * (source Market & Research 2017). Many customers in different industries around the world have shown a strong interest in the VisioCheck® solution. The potential market is huge, and the commercial procedures will be accelerated by being directed to:

- Point of Care and pharmacies
- Hospitals
- Aircraft manufacturers
- Nursing homes
- Merchant and commercial marine
- Emergency relief
- Offshore platforms
- Nurses and other paramedics
- Ambulances
- Doctors

According to the study conducted by Market & Research

The global market will grow by 17.7% between 2017 and 2026. The global telemedicine market was worth \$ 21.56 billion in 2017 and is expected to reach \$ 93.45 billion by 2026, with annual growth of 17.7% over the forecast period. Among the main factors influencing market growth are the increasing prevalence of chronic diseases, favorable government initiatives, telecommunication growth in BRIC countries, increasing reimbursement of health insurance for telehealth services, and areas of medical desertification. However, privacy and security issues and high infrastructure costs hamper the market.

In addition, the growing acceptance of the 4G and 5G frequency bands offers enormous opportunities for market players.

(According to the study conducted by Market & Research 2017 - Telemedicine - Global Market to Grow CAGR of 17.7% during the 2017-2026 period).*

BW-X07HD VisioCheck® ultra-portable version, equipped with all its accessories, medical devices and software solutions is offered either for sale at the recommended public price of € 3,990 excluding taxes and monthly access to services for a cost of € 49 HT to 79 € HT according to the options desired by the user, or only by monthly subscription ranging from 199 € HT to 249 € HT depending on the options chosen.

BW-X07HD VisioCheck® in mobile teleconsultation station version (pharmacies type), equipped with all its accessories, its medical diagnostic devices, a telescopic medical trolley, a 27-inch touch screen, a micro-PC, a webcam, a headset, etc ... and its software teleconsultation solutions is offered for sale at the recommended public rate of 32.000 € HT.

This rate also includes unlimited access for 48 months to the teleconsultation platform available 24/7.

To help pharmacists to purchase the equipment, VISIOMED also offers an ultra-flexible financial leasing solution through its partner ASTERA Groupe Coopératif. The pharmacist can therefore purchase this equipment flexibly for a monthly rent of 750 € HT or for a daily cost of about 25 € HT.

VisioCheck® BW-X07HD already leading teleconsultation in pharmacies

Since the launch of its offer in October 2018 and more than 250 teleconsultations, VISIOMED has already claimed its leading position in pharmacies. In addition, VISIOMED recorded a significant rise in support of requests from pharmacists interested in equipping the turnkey solution of its VisioCheck® teleconsultation station. VISIOMED indicates that it has taken the necessary measures to respond to this strong demand, by stocking more than 950 BW-X07HD VisioCheck®, that are available today.

About VISIOMED GROUP

Founded in 2007 by Eric SEBBAN, VISIOMED GROUP develops and markets innovative health products and services focused on the uses of prevention and well-being, medical self-diagnosis and support for the chronically ill. Its mission: to put innovation at the service of the health of all, starting from the needs of each one.

VISIOMED GROUP is the inventor of ThermoFlash®, the first non-contact infrared medical thermometer that has been adopted worldwide. In 2014, VISIOMED GROUP became the first medical electronics laboratory to penetrate the high-potential Internet of Things (IoT) market by launching a unique range of digital healthcare products under the BewellConnect® brand.

Today, BewellConnect® focuses all of VISIOMED GROUP's eHealth know-how for the general public as well as for the healthcare community through certified connected medical devices, a medical interpretation platform and advanced telemedicine solutions. Based in Paris and Boston, VISIOMED GROUP relies on a team of 115 employees. The Group achieved a turnover of € 10 million in 2017. Its products are distributed in 35 countries. Winner of the Pass French Tech 2016/2017 and member of the FrenchTech, VISIOMED GROUP is qualified «innovative company» by Bpifrance and listed on Euronext Growth (ALVMG). Its solutions have been recognized with numerous awards. In 2016, the company won the ScaleUpAwards organized by KPMG and CroissancePlus. More information on www.visiomed-group.com and www.bewell-connect.com



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