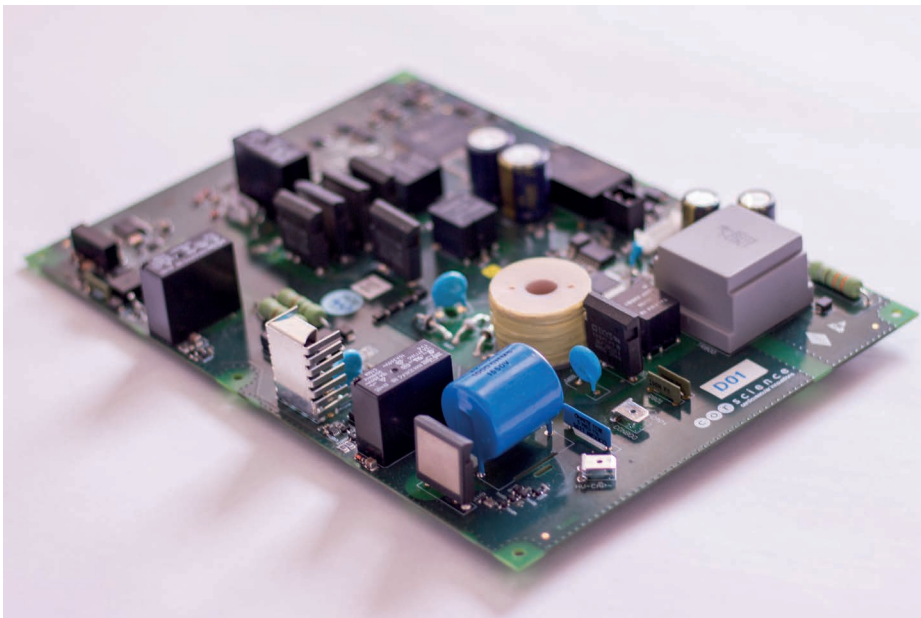


BDM75 – The modern biphasic defibrillation module for professional and public access devices

With the Biphasic Defibrillation Module 75 (BDM75), Corscience is bringing a state-of-the-art and compact yet affordable OEM defibrillation module to the market, for integration into professional defibrillators and automatic external defibrillators (AEDs). The module combines, as its key functions, ECG recording and analysis as well as the generation and delivery of current pulses for defibrillation, cardioversion and cardiac muscle stimulation. This opens up numerous therapy options, ranging from the treatment of life-threatening arrhythmias, in patients requiring resuscitation, by means of intracorporeal or transthoracic defibrillation through to synchronised delivery of cardioversion shocks for the treatment of atrial fibrillation. One important therapeutic advantage compared to conventional defibrillation modules is the pacemaker function offered by the BDM75, which allows the treatment of bradycardias and conduction disorders by means of transthoracic cardiac stimulation. In order to cover the wide range of therapies and the associated application scenarios, the BDM75 meets the requirements of the emergency services and hospitals and also use by lay persons in public spaces.

cardiac damage and high energy efficiency, which is advantageous from both a medical and a technical perspective. The shock energy can be set to between 0.5 J and 300 J, using the host system into which the BDM75 is integrated. Depending on the particular type of use, the current pulses can be applied via adhesive or contact electrodes (paddles), which are stuck or pressed onto the chest. With an open thorax, it is also possible to perform treatment on the exposed heart using spoon electrodes. In this case, the BDM75 limits the maximum energy to 50 J in order to prevent tissue damage. The electrode configuration is defined by the host system.

Delivery of the defibrillation pulses is current-controlled in the BDM75, meaning that a virtually constant flow of current is guaranteed in each of the two shock phases. In order to ensure effective therapy with different patient impedances, the BDM75 calculates the current required in each case, based on the specified shock energy. This means that the right amount of energy is applied to each patient, while simultaneously minimising the risk of injury to the cardiac muscle.



Biphasic defibrillation module BDM75

The defibrillation pulse from the BDM75 is characterised by its biphasic form and time-restricted quality. This guarantees a high level of treatment feasibility, a low re-fibrillation risk, minimised my-

In order to meet the requirements of both professional defibrillators and AEDs, the BDM75 supports both manual and automatic shock delivery. The ECG analysis can be performed on an ECG signal provided by the host system. Alternatively, the BDM75 allows direct recording and analysis of a 1-channel ECG signal via the defibrillation electrodes. It is important to stress here that the patient interface on the BDM75 is designed to be defibrillator-protected in order to avoid reducing the effect of external defibrillation shocks, while also protecting the device electronics from damage.

For automatic shock delivery, the BDM75 provides an analysis algorithm that checks the ECG signal for the presence of ventricular fibrillation or ventricular tachycardia. As soon as a shockable ECG rhythm is detected, this is signalled to the host system.

During the analysis, the BDM75 can differentiate between two patient groups (children and adults), as specified by the host system, in order to take the respective characteristics into account in the ECG signal. The analysis algorithm is therefore able to achieve a sensitivity of over 94% and a specificity of over 98%.

The BDM75 provides an internal QRS detection algorithm in order to deliver cardioversion shocks that can be synchronised with the QRS complex. Alternatively, the host system can trigger the cardioversion shock by means of an external trigger signal without using the BDM75's detection algorithm.

The pacemaker pulses for transthoracic cardiac stimulation are characterised in the BDM75 by their monophasic and rectangular form. The pulse width is 20ms. The current strength can be adjusted to between 0 mA and 200 mA in 5 mA steps, and is designed for a maximum patient impedance of 1000 ohms. The pulse rate can be adjusted to between 30 and 180 pulses per minute. The BDM75 delivers a pacemaker pulse each time the host system sends the relevant command to the module. This means that the required pacemaker modes can be implemented on the host system as needed.

In addition to the signal processing (VF/VT analysis, QRS detection) required for shock delivery, the BDM75 also provides algorithms for ECG analysis. These cover the detection of asystole (cardiac arrest), calculation of the heart rate in a range of between 30 and 300 beats per minute, measurement of patient impedance and detection of whether the electrodes are correctly connected. Correct connection of the electrodes is essential for successful defibrillation. The additional parameters are usually displayed by the host system on a graphic interface as part of the standard monitoring of vital signs.

The BDM75 is characterised by its very compact design and light weight of approx. 600 g, making it particularly suitable for integration in portable defibrillators. With its dimensions of 170 x 242 x 40 mm, the whole module is not much bigger than an A5 sheet of paper. In order to reliably withstand the adverse conditions of use in the emergency services, the module was developed for a wide temperature range of between -20°C and 70°C, at a relative humidity of up to 95%. The BDM75 can be used in an air-pressure range of between 540 hPa and 1060 hPa, making it suitable both for high altitudes and for areas considerably below sea level. The module is designed for a service life of 10 years, or a minimum of 10,000 shocks, in order to cover the long service life of AEDs, while also meeting the high demands of professional defibrillators in the emergency services and hospital market.

One key objective in the development of the BDM75 was simple and efficient integration of the module into professional defibrillators and AEDs. In addition to the power supply, the host system therefore only needs to provide a few input and output pins (GPIOs) and one UART interface. The BDM75 can be operated with input voltages of between 10 V and 17 V, and has a maximum input current of 10 A. For battery-operated defibrillators, the module offers a low-current mode with only approx. 3 A of current during charging. Communication between the module and the host system is via the UART interface, at a symbol rate of 230,400 bauds. The BDM75 enables simple firmware updates, meaning that the module can be updated via the host system at a later date, as required.

In order to ensure a smooth approval process for the professional defibrillator or AED following integration of the BDM75, the module already meets the requirements of the relevant standards. These relate to the safety of medical electrical equipment (EN 60601-1) and its electromagnetic compatibility (EN 60601-1-2) in general, and specifically the safety of defibrillators (EN 60601-2-4).

When selecting a suitable defibrillation module, commercial aspects are always a priority as well as technical considerations. In order to meet the particular requirements of business customers in this area, Corscience offers flexible licensing models and comprehensive support for the BDM75. More information about the module and the topics of defibrillation, ECG algorithms and cardiovascular technologies can be found on the Corscience website (www.corscience.de). The Corscience team will be happy to answer your questions over the telephone on +49 (0) 9131 – 977986 0.

Corscience is the trusted development service provider for international medical technology companies, providing innovative solutions for human medicine and offering comprehensive engineering services, module and licence solutions, approvals and production & logistics. This range of services makes Corscience a “one-stop company” for medical devices and systems for use in clinical, pre-clinical and homecare settings, as well as for clinical studies. With over 15 years' experience in the development of defibrillators, Corscience is an industry leader in the field of electrostimulation and in the specialist areas of monitoring, ventilation, gas analysis and mobile health.



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