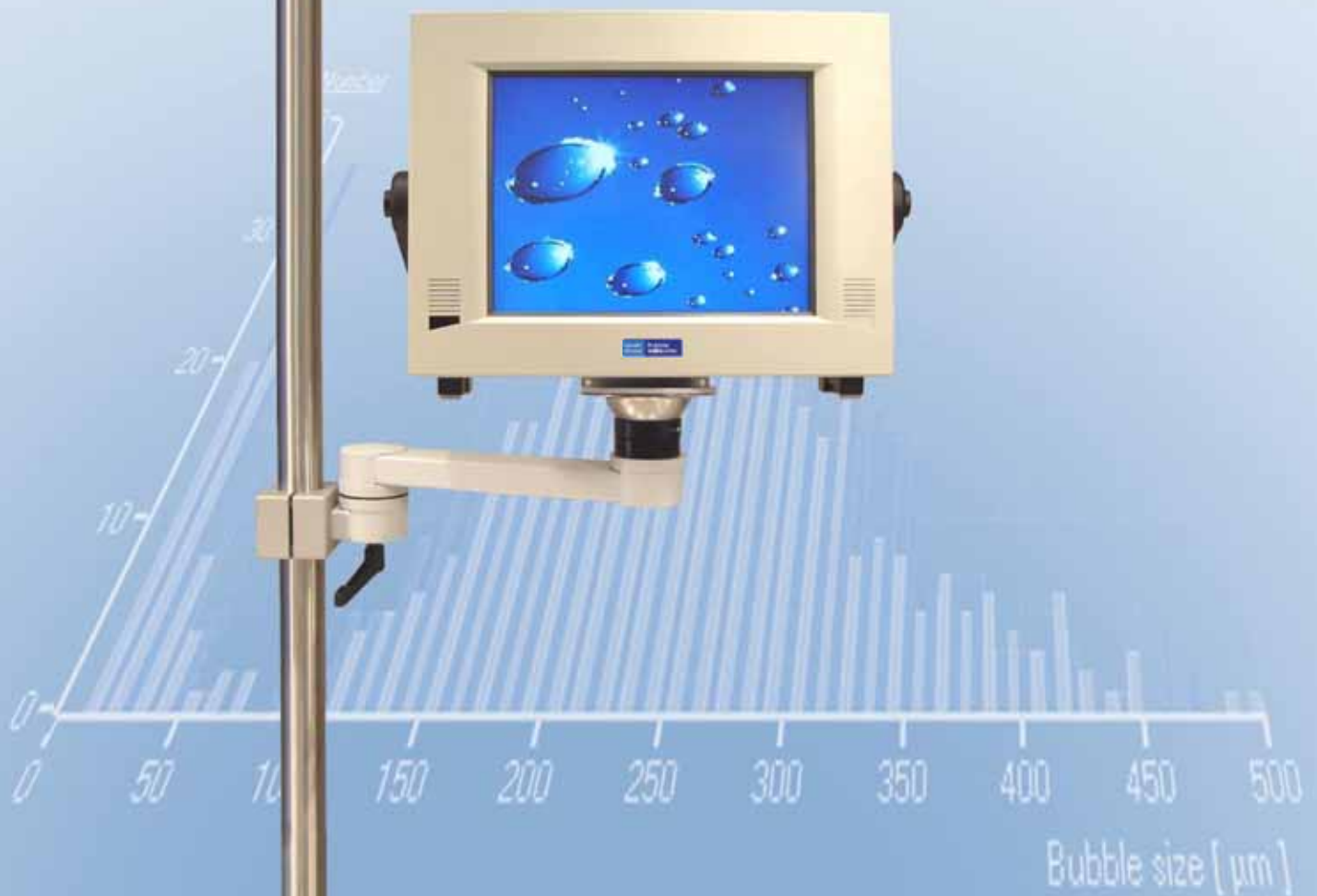


GAS EMBOLISM MANAGEMENT WITH

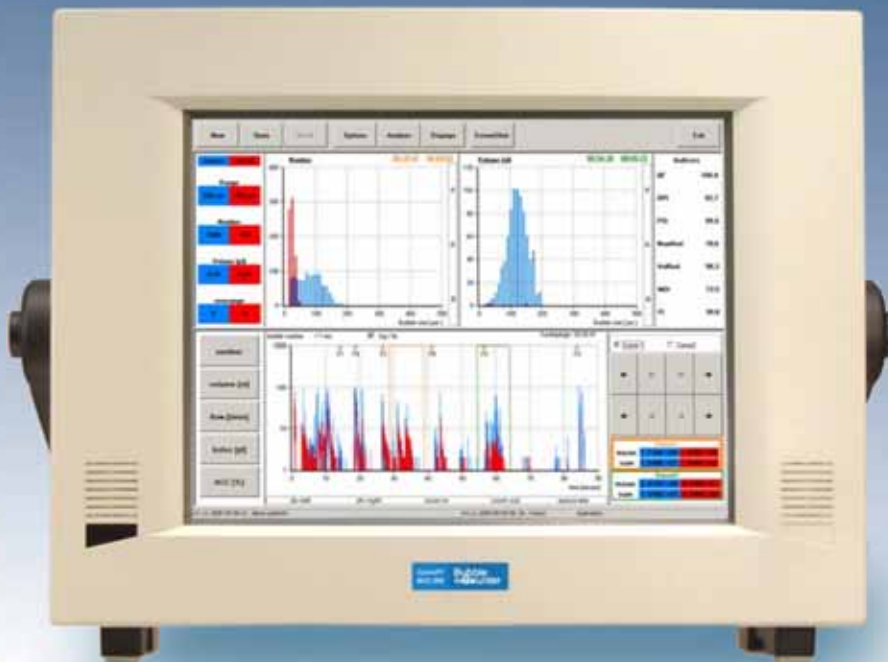
BCC 200

FOR THE SAKE OF PATIENTS

BUBBLE COUNTER FOR CLINICAL
MONITORING OF MICRO BUBBLES



HIGHER SAFETY IN HEART SURGERY BY MONITORING OF GAS EMBOLISM DURING PERFUSION



- An innovative system for analysis of micro bubbles und high gas volumes (bolus)
- Reduced risk of post-operative neurological deficiencies
- Patient safety improvement by targeted surgical team training using BCC200
- Easy operation through TFT display with integrated touch screen control
- Offline embolism activity analysis to supplement perfusion report



Why is gas embolism management of great importance for the patient?

The application of extracorporeal circulation (ECC) during heart surgical interventions is often connected with a considerable neurophysiologic risk [Roach G.W. et al.; N. Engl. J. Med. 1996; 335:1857-63]; [Walzer T. et al.; J. Neurol. Neurosurg. Psychiatry 1997; 6: 644-48]. And micro bubbles play a decisive role in ECC. It could be shown that transcranially detected micro-embolism in medial cerebral artery is closely connected to micro bubble concentration in ECC and such may be jointly responsible for post-operative neurophysiologic deficiencies [Borger M.A. et al.; J. Thorac. Cardiovasc. Surg. 2001; 4: 743-49]. Hence, in ECC precise monitoring of micro bubbles formation and spreading is indispensable to prevent such from occurring in patients and reduce patient risks.

How does gas embolism management function during perfusion?

With the BCC200, a certified measuring system that enables micro bubbles formation and spreading analysis is available for clinical use. The venous and arterial side of ECC or the input and output of individual components can be monitored by two independent sensors. This procedure does not only detect and count micro bubbles but also determines their size and volume and displays the data in a histogram. The chronological sequence of size and volume are determined as well as the entire gas volume calculated for both sensors. Design and course of ECC can be fundamentally improved by evaluation of differential measurement at individual

components and at the total system. This way, for example, it was shown that an additional sealing around the venous cannula highly reduces gaseous contamination [Perthel et.al.; Perfusion 2005; 20: 329-333].

Do mini-systems pose a higher embolism risk?

Monitoring of air contamination is indispensable especially upon use of new, minimised systems, because de-airing effect is extremely limited by virtue of lacking reservoir. Use and benefit of new respectively additional components (e.g. venous bubble traps) can be objectively assessed and, thus, may result in cost savings.

Is BCC200 capable of avoiding gas embolism?

BCC200 records bubble concentration with high resolution per time unit during entire surgery, so that higher bubble activities can be always assigned to respective surgery sections and individual activities of surgeon, anaesthetist and cardiac technicians. The surgery team, thus, is always able to respond to severe air contaminations, optimise course of surgery and therefore reduce the risk of gas embolism and neurophysiologic disorders.

Uninterrupted monitoring...

The continuous advance in perfusion technology - especially bypass systems miniaturisation - is very demanding for safety functions. In this connection, BCC200 outperforms by far conventional bubble detection systems through its precision and flexibility. BCC200 monitors simultaneously the venous and arterial ECC line by use of advanced technologies. They detect smallest gas embolisms (5µm micro bubbles) that occur typically in arterial line subsequently to filter just as precisely as big gas activities (bolus) in venous line.

In addition, BCC200 is able to transform each embolism event into an acoustic signal for the determination of micro bubbles in size and volume. This makes available an alarm function that clearly reduces the embolism risk by early detection of gas contamination.



BCC200 with support arm used at HLM



Sensor (3/8") in venous ECC line

... at all HLM systems

BCC200 can be integrated into all heart-lung-machines without problems. Monitoring at standard and mini-systems and in children's cardiac surgery will be enabled by broad choice of probes. All embolism events are automatically logged during surgery and can be subsequently evaluated directly at the device. For this purpose, BCC200 can be extended to a convenient PC workstation in few steps. The measure dates analysis allows a detailed assessment of all embolism-relevant surgery activities. The course of events can be considerably optimised this way for the benefit of patient safety. Targeted measurements of individual ECC components result in further improvement of perfusion systems and setup.



BCC200 front view with accessories

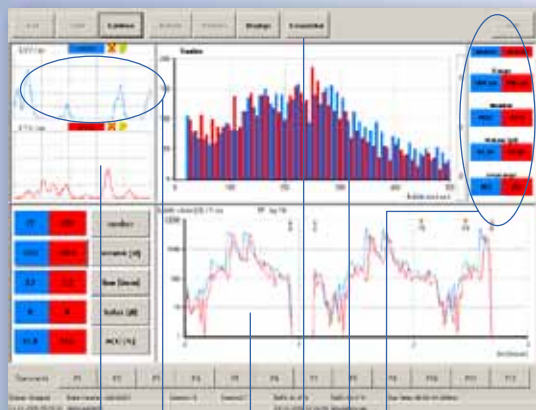
The gas embolism management by means of BCC200 represents the safest way to careful patient treatment and embolism-poor perfusion!



BCC200 side view with handle and connection sockets

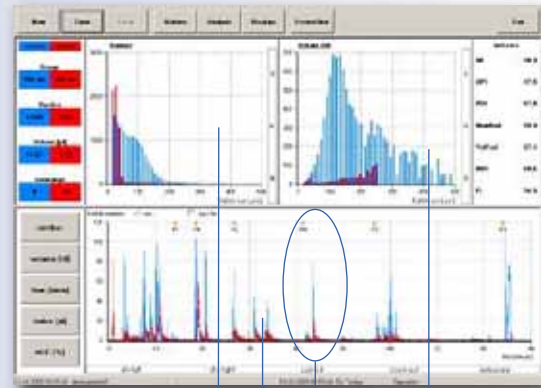
Stay in control at any time

Cardiac technician has to pay full attention to optimal perfusion of patient during ECC. Thus, BCC200 has a clearly structured menu interface that enables immediate recognition of all relevant display and control functions. Thus, cardiac technician has full control over embolism activities in venous and arterial line at any time. Acoustic alarm functions can additionally warn about risky gas embolisms. This enables the surgery team to respond in a timely manner and considerably reduce cerebral gas embolism risks.



Actual signal
Bubble peaks
Time course
Cumulative data
Bubble histogram
Menu / Control

Optimisation for the sake of the patient



Analyses of details
Time course
Selected area
Histogram of bubbles

Distinctly high gas contaminations are caused during course of ECC by several activities of surgeon, anaesthetist and cardiac technician (e.g. EEC start, medication, cardioplegia, cannulation, volume management, aorta clamp). BCC200 monitors the bubble activities during entire ECC and calculates the exact individual and total volumes. The data analysis enables the surgery team to optimise courses of action and, thus, realise an embolism-poor perfusion.

Objective assessment of performance parameters

The heart-lung-machine consists of multitude components whose individual behaviour concerning creation or protection of gas embolisms are difficult to assess. BCC200 provides specific measurement routines that allow an objective efficiency analysis of individual HLM elements. This enables a targeted setups adjustment to the respective perfusion requirements.

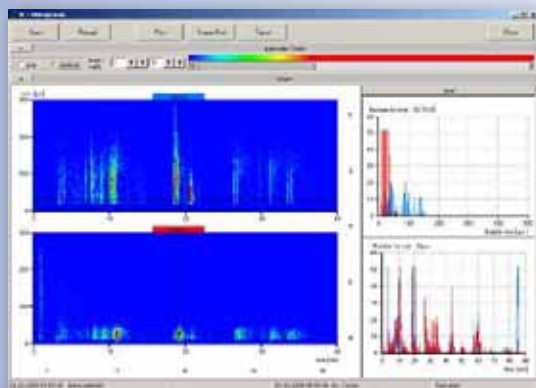
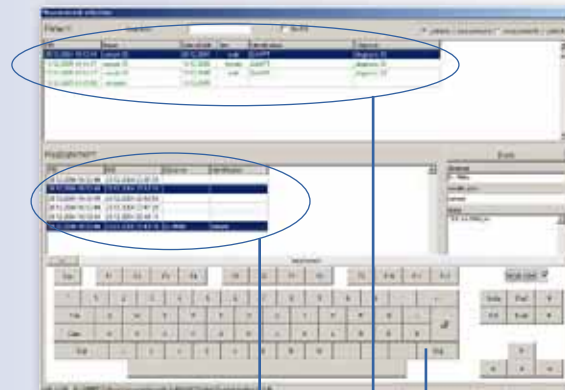


Figure of movement and size variation of a short gas contamination (bolus) from venous to arterial ECC side

Advanced data communication

The measuring data documentation forms an essential part of perfusion report. For this reason, BCC200 offers a program package that equally supports data evaluation and documentation. Additionally, the data can be exported to all standard programs (e.g. Excel) or for external archiving.



Data of measurement
Data of patients
Onscreen keyboard

SAFETY

- Uninterrupted ECC monitoring by venous and arterial probe
- Exact determination of smallest embolisms and high gas volumes
- Early detection of gas contamination through alarm functions
- Noticeable reduction of gas embolisms through courses of activity optimization
- Increase of patient safety by advanced embolism management
- Reduction of neurological deficits risk and exogenous Psychoses

APPLICATIONS

- Unproblematic integration into all heart-lung-machines
- Probes for all standard tube available
- Special probes (e.g. for cardioplegia tubes) available on request
- Monitoring of standard ECC and mini-bypass
- Embolism management in children's cardiac surgery

TECHNOLOGY

- Continuous monitoring up to several hours
- Exact measurement of smallest embolisms (5 μ m - 500 μ m)
- Simultaneous detection of macro-bubbles (bolus up to 10ml volume)
- Flow speed of 0.2 - 10 l/min
- Individual alarm functions
- Acoustic embolism signal

DESIGN

- Ergonomic design for convenient handling
- Automated measurement data collection
- Touch screen control
- Offline analysis directly at measuring device
- Convenient documentation in desktop mode
- Comprehensible analysis software
- Integrated data management system
- Easy data transfer (Excel, ASCII)

