MIETHKE

B|BRAUN
SHARING EXPERTISE

WE UNDERSTAND.

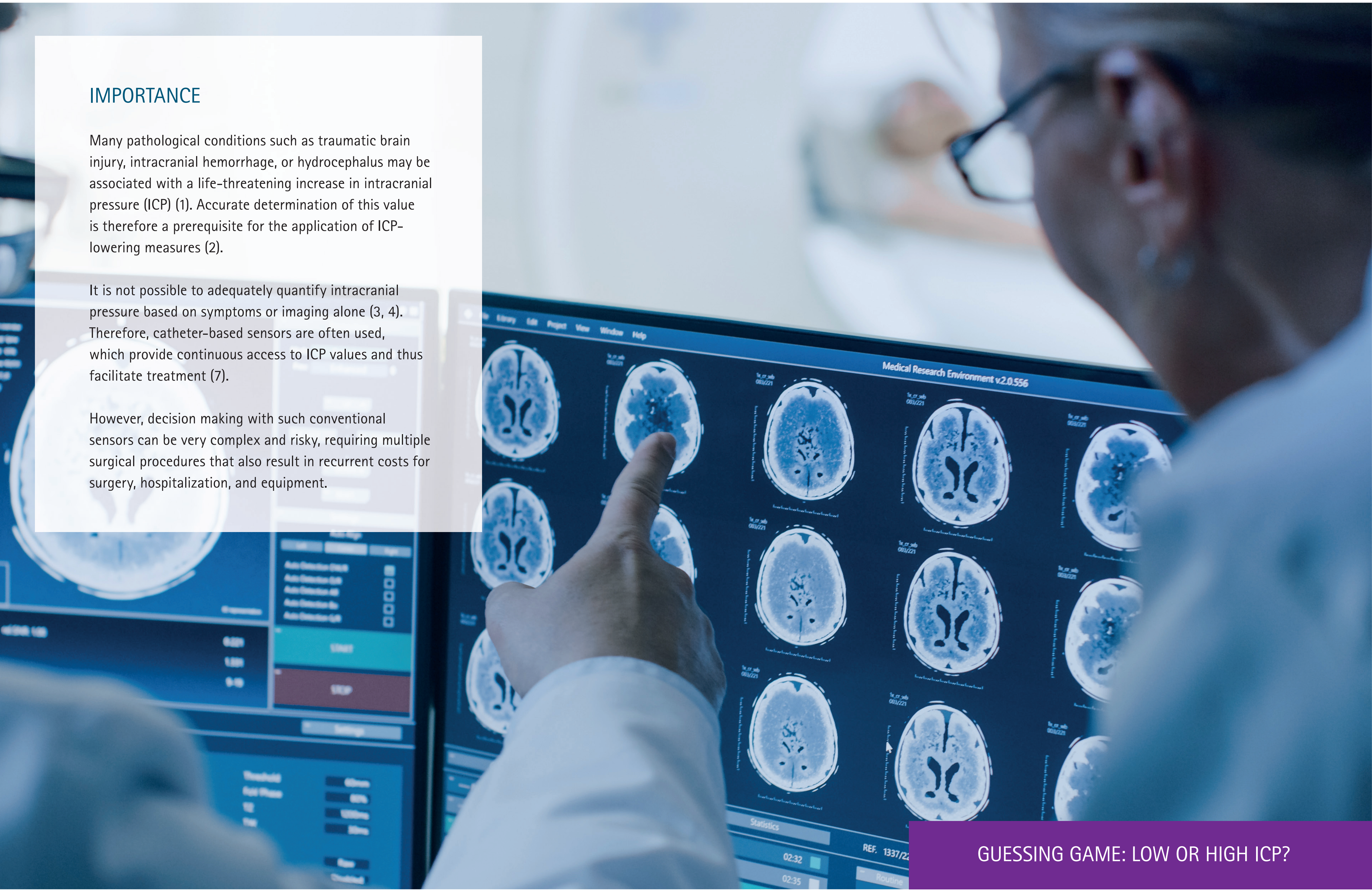
NEUROSURGERY

M.scio®

READING INNER VALUES
FOR THE BIG PICTURE

IMPORTANCE AND LIMITATIONS OF CONVENTIONAL ICP MONITORING

MIETHKE



IMPORTANCE

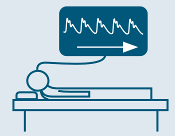
Many pathological conditions such as traumatic brain injury, intracranial hemorrhage, or hydrocephalus may be associated with a life-threatening increase in intracranial pressure (ICP) (1). Accurate determination of this value is therefore a prerequisite for the application of ICP-lowering measures (2).

It is not possible to adequately quantify intracranial pressure based on symptoms or imaging alone (3, 4). Therefore, catheter-based sensors are often used, which provide continuous access to ICP values and thus facilitate treatment (7).

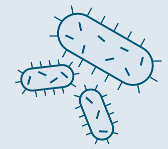
However, decision making with such conventional sensors can be very complex and risky, requiring multiple surgical procedures that also result in recurrent costs for surgery, hospitalization, and equipment.

GUESSING GAME: LOW OR HIGH ICP?

LIMITATIONS

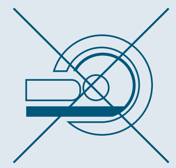


Physical connection to patient required (9)



Increased risk of infection (4, 6, 7)

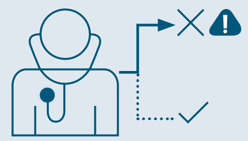
Malfunctions (12)



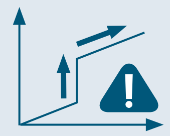
Unsuitable for MRI (10)

time-consuming preperation and calibration needed (11)

Unsuitable for long-term monitoring (4, 8)



Incorrect treatment decisions (14)



Baseline shifts (> 10–20 mmHg) and drifts (5, 13, 14)

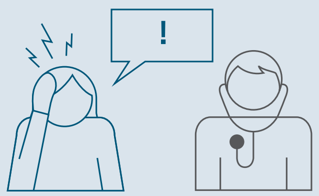
IMPORTANCE AND LIMITATIONS OF SHUNT-BASED ICP MANAGEMENT

WHY MORE KNOWLEDGE ON SHUNT PERFORMANCE IS NEEDED

Management of ICP in hydrocephalus patients often involves implantation of a shunt. Advances in shunt technology, particularly adjustable and gravitational valves, have significantly improved patient outcomes (15, 16).

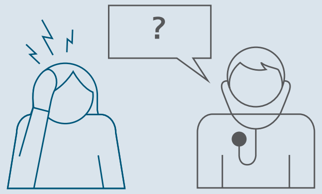
However, finding the best possible patient specific pressure setting and verifying shunt function can be difficult and time consuming.

Unspecific symptoms



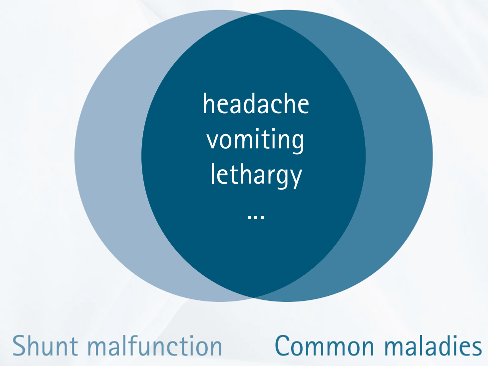
Multiple pressure adjustments

Cause of symptoms remains unclear



WHEN DECISION MAKING TURNS INTO A GUESSING GAME

Symptom-based decision making is challenging, due to the overlap of symptoms of shunt malfunction and common maladies such as lethargy, headaches, and vomiting (17, 18).



IMPORTANCE AND LIMITATIONS OF SHUNT-BASED ICP MANAGEMENT

MIETHKE

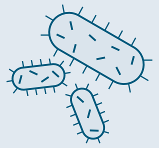
SHUNT ASSESSMENT IS CHALLENGING, EXPENSIVE AND NOT RISK-FREE

Currently available invasive and non-invasive methods such as shunt tap or computed tomography (CT) cannot reliably assess shunt function (17, 18, 21).

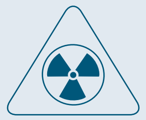
Absence in ventricular size

Low negative predictive values

Surgical exploration of shunt function puts the patient at risk, is costly and is often shown to be unnecessary in hindsight (18). In addition, cranial CT has been shown to increase the risk for brain tumors (22).

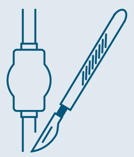


Increased risk of infection (18)

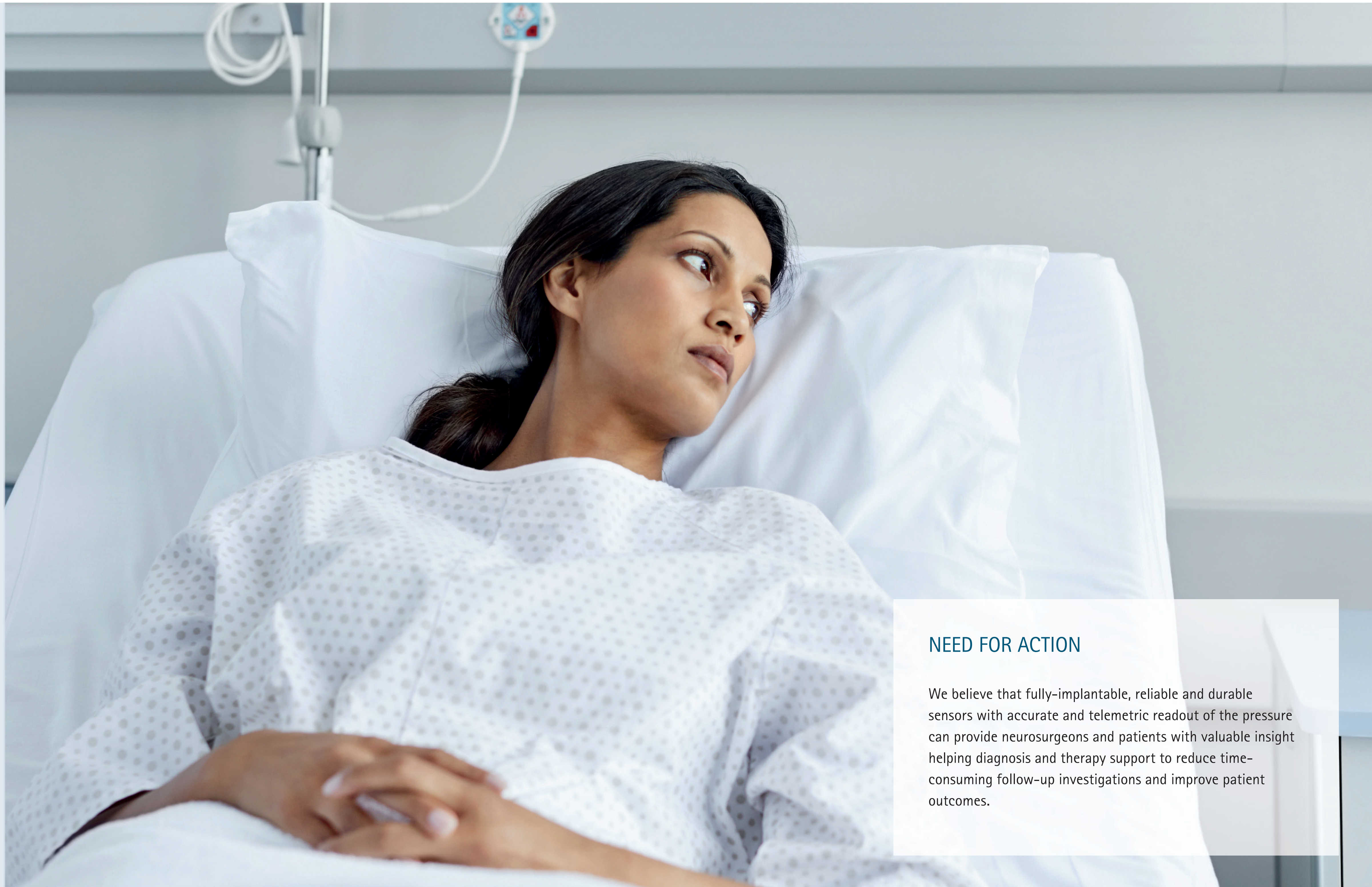


Risk of brain tumors (22)

High associated costs (18)



Unneccessary removal of shunt (18)



NEED FOR ACTION

We believe that fully-implantable, reliable and durable sensors with accurate and telemetric readout of the pressure can provide neurosurgeons and patients with valuable insight helping diagnosis and therapy support to reduce time-consuming follow-up investigations and improve patient outcomes.

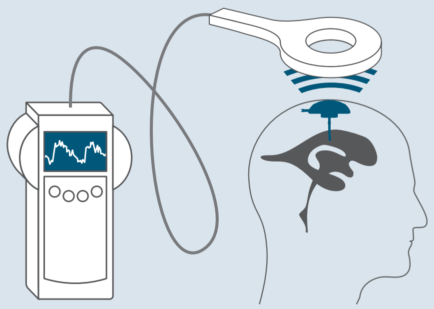
M.scio® – NON-INVASIVE TELEMETRIC PRESSURE MEASUREMENT

MIETHKE

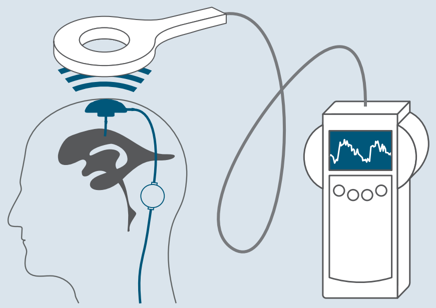
PERMANENT SOLUTION FOR ICP MEASUREMENT

M.scio® is the first ICP sensor approved for permanent implantation.

With the means of the Reader Unit Set, *M.scio*® provides straightforward, non-invasive and easy-to-use real-time ICP measurements (23). No calibration, zeroing or complex setup is required before implantation and measurements.



Single device for diagnosis ...



... in connection with shunt for therapy support

DETAILED

Display of detailed pressure curves and resolution of clinically relevant ICP morphologies due to high sampling rate of 44 Hz (16, 25)

RELIABLE

Stable long-term implant with high lifetime and reliable readings due to low drift of < 2mmHg / 4 years (24)

MULTIFUNCTIONAL

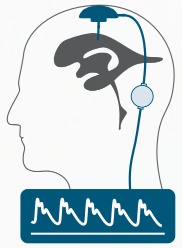
Multifunctional use for diagnosis and therapy support (25, 29)

M.scio® – NON-INVASIVE TELEMETRIC PRESSURE MEASUREMENT

MIETHKE

STOP PLAYING THE GUESSING GAME!

M.scio® is a useful tool to verify shunt function (16). In addition, the easily accessible measurement can ease the mind of the patient and relatives (25).

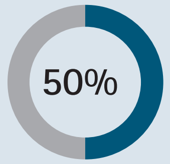


Validating shunt functio-nality via the shape of the recorded ICP signal

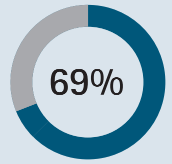
Eases the mind of patients and relatives.

HIGHLY RESOURCE EFFICIENT

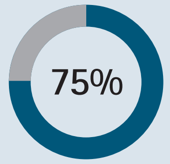
The *M.scio*® saves time by avoiding unnecessary hospitalizations, investigations, radiation exposure and revisions (16, 25-27). Surgery time for valve implantation is not significantly prolonged (23). As a consequence, the *M.scio*® is also highly cost-efficient compared to traditional clinical practice (26). Clinical studies have shown a potential of...



Reduction in acute presentations to hospital (26)



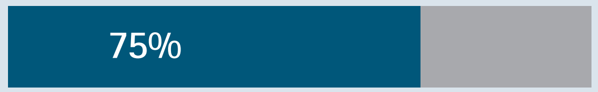
Cost saving per patient compared to non M.scio® supported therapy (26)



Reduction in CT Scans (26)

Reduction of number of unnecessary Revisions (16, 25-27)

GUIDANCE FOR HYDROCEPHALUS MANAGEMENT



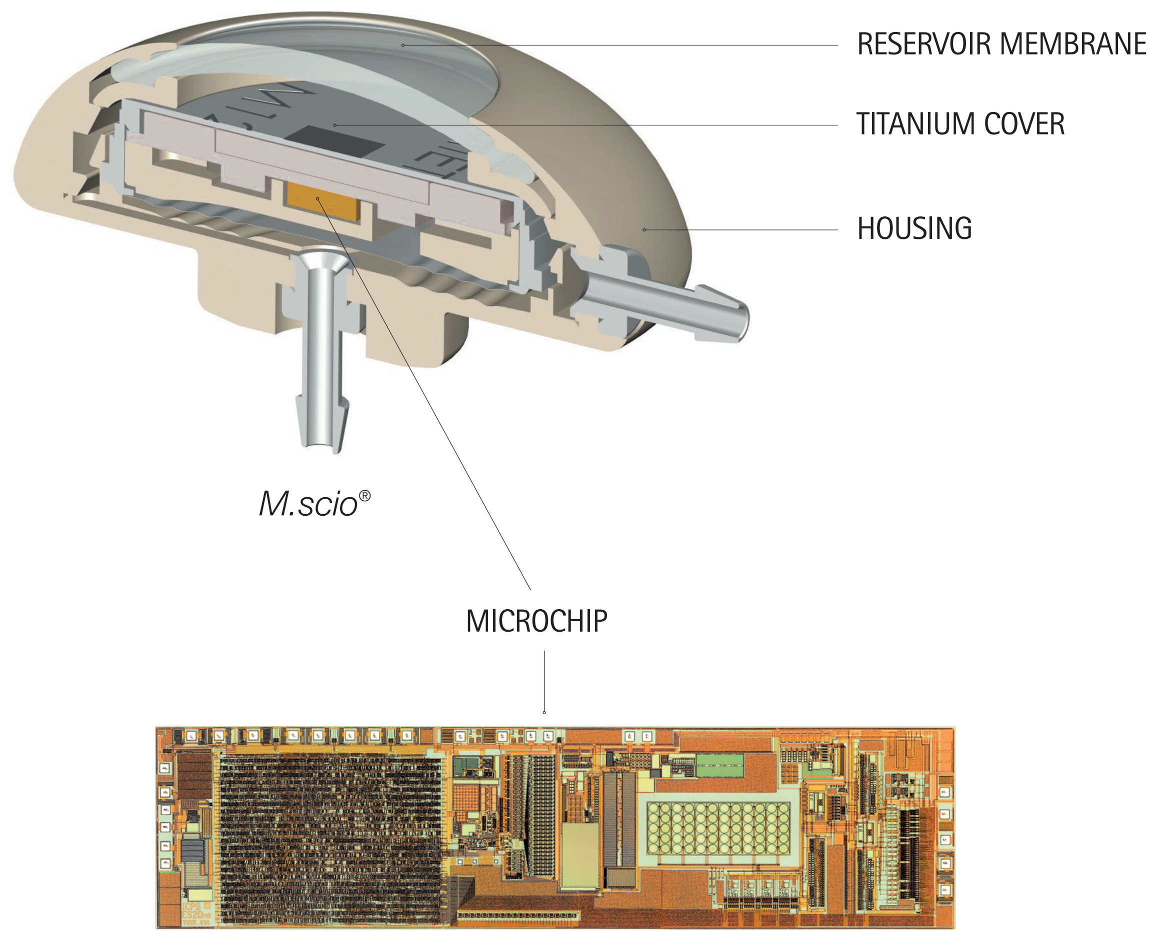
Up to 75% of patients reported improvement of clinical symptoms after valve adjustments based on *M.scio*® readout (16, 26).

M.scio® IMPLANTS

M.scio® is available in four different designs, with either "dome" or "flat" housing. Both "dome" variants fulfill the characteristics of a conventional reservoir. The measuring cell with integrated microchip is protected from possible penetration by a titanium cover.

The reservoir membrane permits:

- CSF removal for therapeutic pressure reduction and diagnostic analyses
- Administration of fluids
- Verification of pressure values



Each *M.scio*® is calibrated. The calibration data is stored on an associated SD card that is included in the delivery of the *M.scio*®

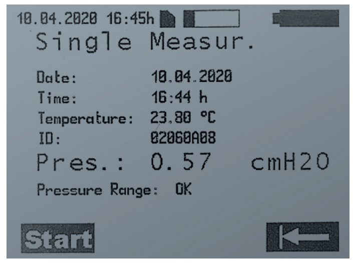
M.scio® READER UNIT SET

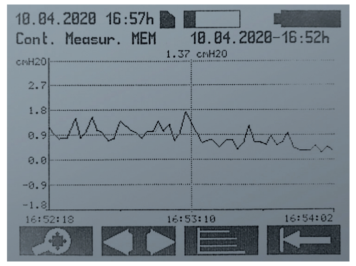
The measured values of the *M.scio*® can be read out by the treating physician using the Reader Unit Set.

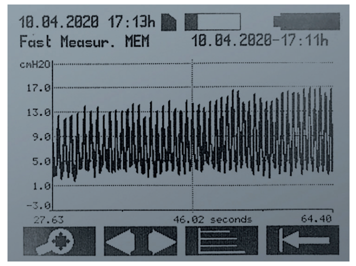
The pressure values are shown on the display in real time and automatically saved with date and time on an SD card.

The data and curves can be accessed again with the Reader Unit Set.

MEASUREMENT MODES







SINGLE MEASUREMENT

With the single measurement, the pressure value measured at a point is displayed as an single measured value. The measuring unit of the pressure value can be selected in the settings.

CONTINUOUS MEASUREMENT

During the continuous measurement, sequential single measurements are performed and the recorded measured values are displayed as a curve. The interval between the single measurements can be adjusted in the settings in the range from 1 to 300 seconds.

FAST MEASUREMENT

With the fast measurement, sequential single measurements are recorded at a high sampling rate (44 measurements per second) and displayed as a curve.

https://www.miethke-journal.com/en/icp

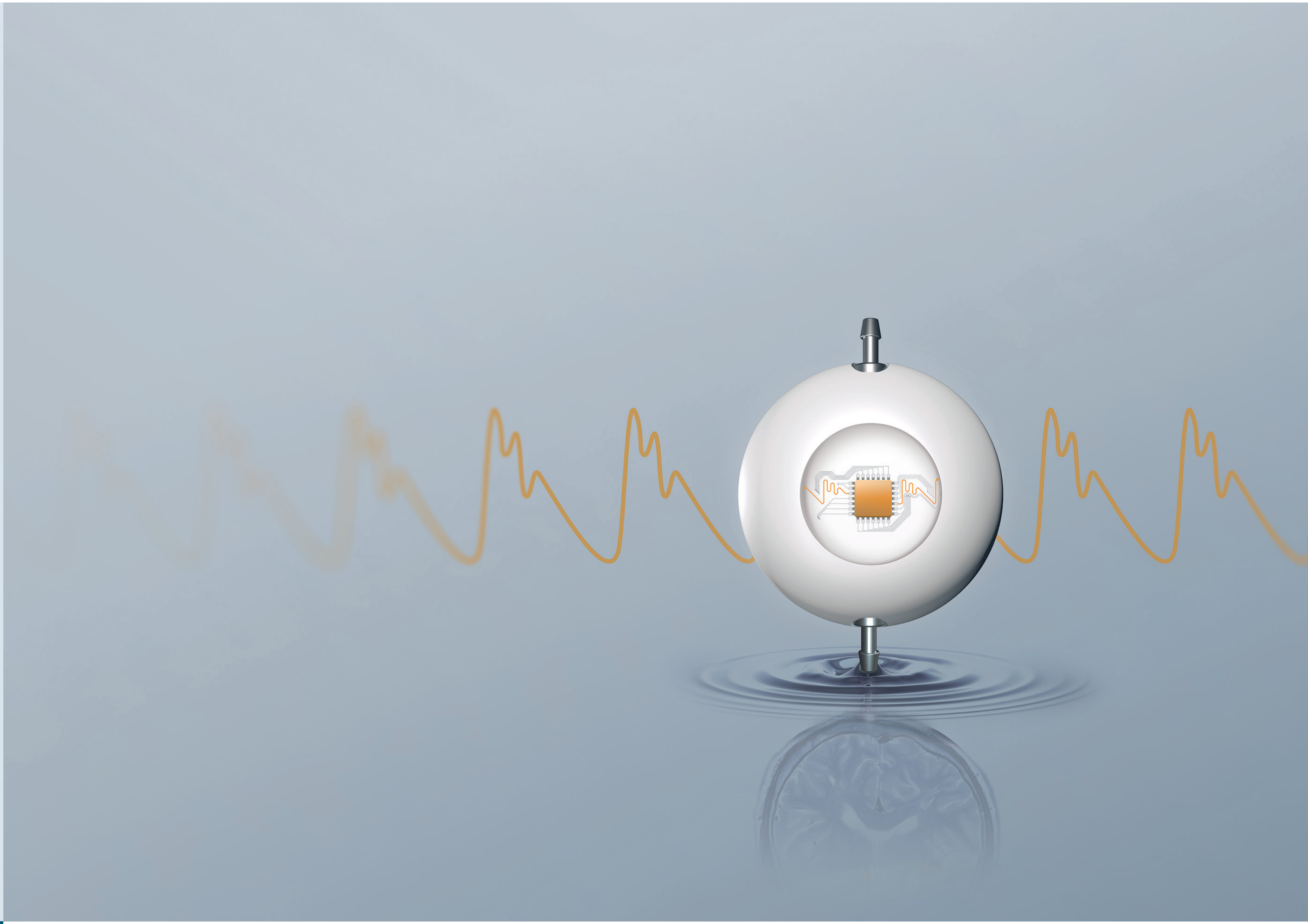
The fast measurement mode enables the identification of individual pulse waves and the clear determination of the pulse wave morphology of the ICP curve (25). Such morphologies contain unique information about the cerebrospinal system, and they are useful for the study of intracranial pathologies (28).

M.scio® FEATURES

MIETHKE

- Innovative, easy-to-use telemetric ICP sensor (16, 23)
- For diagnosis and therapy support (16, 29)
- Improvement of clinical symptoms (16, 26)
- Reduction of treatment costs (26)
- Optimized patient management (25, 26, 30)
- Increased sense of security (25)
- Stable long-term implant (24, 27)
- Display of detailed pressure curves (25)
- High sampling rate (44 Hz) (16)
- Puncturability of the silicone membrane* (25, 29)
- Reliable long-term readings (24)
- MR conditional up to 3 Tesla (31)
- Four implant variants

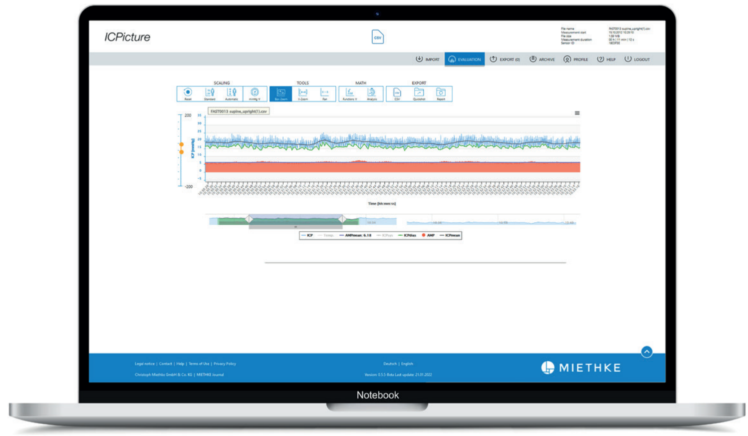
* M.scio dome variants only



ICPicture LOGIN

icpicture.miethke.com

SOFTWARE TOOL FOR THE EVALUATION AND DOCUMENTATION OF ICP DATA

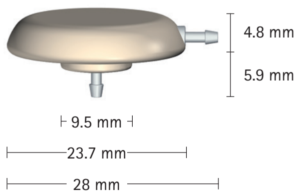


- Research tool to support new diagnostic and therapeutic approaches with intracranial pressure data
- Browser-based software without installation requirement for high flexibility and easy access
- Simple visualization, evaluation, documentation, and organization of intracranial pressure curves specifically for research purposes
- Time savings through intuitive handling and automated evaluations
- Comprehensive options for a systematic organization of patient-specific data and evaluations to identify trends
- Creation of detailed, individualized reports in PDF format for documentation purposes, publications, and professional exchange
- Data export in CSV format for further evaluations

"I use the MIETHKE *M.scio*® in complex HC patients who had multiple revisions and in IIH. We have started analysing the recording on the *ICPicture* software over the last few months and we are excited with the potential it offers. We now understand a bit better the waveforms, mean ICPs and amplitudes etc and I believe that this new technology will help us understand CSF hydrodynamics better and base clinical decisions on them."

M.D. Georgios Tsermoulas

- *M.scio*®, flat-angled

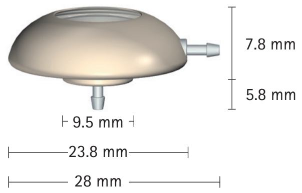


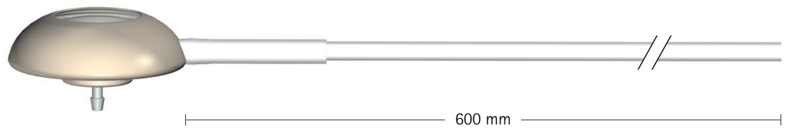
Connector: do = 1.9 mm
preferably to be used with
Catheter: di = 1.2 mm, do = 2.5 mm

M.scio®

Art. no.	Product
FV913X	*M.scio*®, flat-angled (incl. SD card)
FV914X	*M.scio*®, flat-angled with 60 cm distal catheter (incl. SD card)

- *M.scio*®, dome-angled



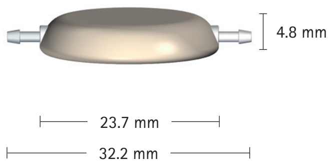


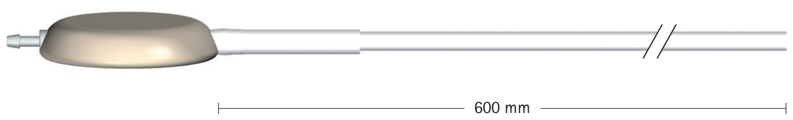
Connector: do = 1.9 mm
preferably to be used with
Catheter: di = 1.2 mm, do = 2.5 mm

M.scio®

Art. no.	Product
FV915X	*M.scio*®, dome-angled (incl. SD card)
FV916X	*M.scio*®, dome-angled with 60 cm distal catheter (incl. SD card)

- *M.scio*®, flat-inline



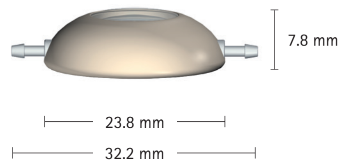


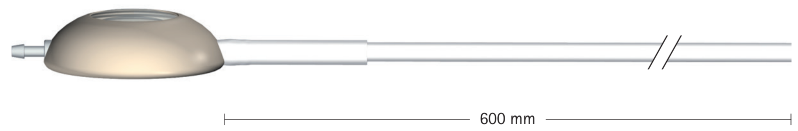
Connector: do = 1.9 mm
preferably to be used with
Catheter: di = 1.2 mm, do = 2.5 mm

M.scio®

Art. no.	Product
FV922X	*M.scio*®, flat-inline (incl. SD card)
FV923X	*M.scio*®, flat-inline with 60 cm distal catheter (incl. SD card)

- *M.scio*®, dome-inline





Connector: do = 1.9 mm
preferably to be used with
Catheter: di = 1.2 mm, do = 2.5 mm

M.scio®

Art. no.	Product
FV924X	*M.scio*®, dome-inline (incl. SD card)
FV925X	*M.scio*®, dome-inline with 60 cm distal catheter (incl. SD card)

ACCESSORIES

- *Reader Unit Set*

Art. no.	Product
FV907X	*Reader Unit Set*

- SD card

Art. no.	Product
FV906X	SD card (substitute)

- Power supply

Art. no.	Product
FV907200	Power supply FV907X (substitute)

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SHARING EXPERTISE

OUR SHUNT SYSTEMS – YOUR CHOICE

		Description	Indication: LP	Indication: NPH	Indication: Pediatric HC	Indication: Adult HC	Patient: Bedridden	Patient: Active	Feature: 3-Tesla MR Conditional	Feature: Gravitational unit	Feature: Adjustable
M.blue®		Adjustable gravitational valve with integrated differential pressure unit		✓	✓	✓	✓	✓	✓	✓	✓
M.blue® plus		Adjustable differential pressure valve with adjustable gravitational unit		✓	✓	✓	✓	✓	✓	✓	✓
proGAV® 2.0		Adjustable differential pressure valve with gravitational unit		✓	✓	✓		✓	✓	✓	✓
GAV® 2.0		Gravitational valve for the treatment of hydrocephalus	✓	✓	✓	✓		✓	✓	✓	
SHUNT-ASSISTANT® 2.0		Gravitational unit for integration into shunt systems in order to avoid excess drainage	✓	✓	✓	✓		✓	✓	✓	
miniNAV®		Differential pressure valve, specifically for premature babies and newborns or bedridden or non-mobile patients			✓	✓	✓	*	✓		
Accessories											

NEUROCHIRURGIE

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MIETHKE GRAVITATIONAL VALVES

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