MIETHKE

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SHARING EXPERTISE

WE UNDERSTAND.

NEUROSURGERY

M.scio®

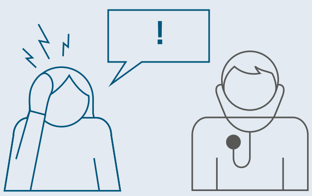
READING INNER VALUES.
FOR THE BIG PICTURE

CHALLENGES FOR SHUNT FUNCTION CONTROL

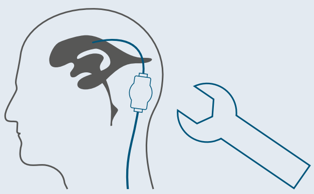
WHY MORE KNOWLEDGE ON SHUNT PERFORMANCE IS NEEDED

The mainstay of hydrocephalus treatment is the implantation of shunts. Advances in shunt technology, in particular adjustable and gravitational valves (1, 2), have improved patient outcomes. Finding the best possible patient-individual pressure setting and assessing shunt function can however be challenging and time-consuming.

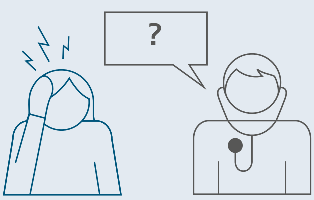
Unspecific symptoms



Multiple pressure adjustments

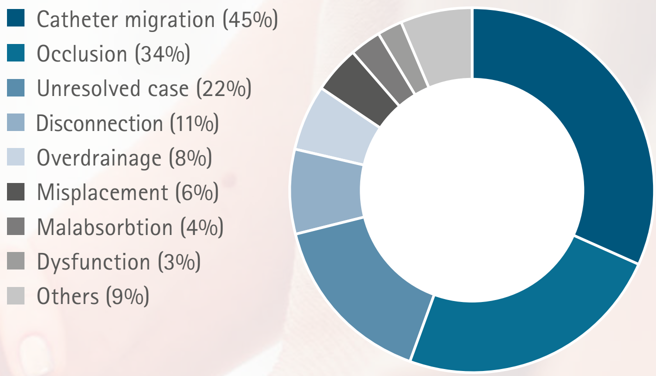


Cause of symptoms remains unclear



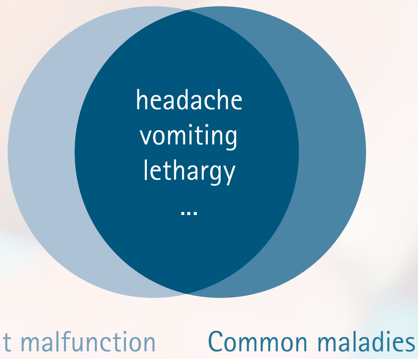
SHUNT FAILURE IS STILL COMMON

Failure rates of conventional shunts remain high (3) with complications affecting one in four patients (4).



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 (5, 6).



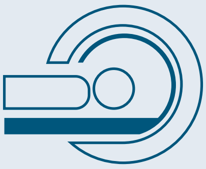
CHALLENGES FOR SHUNT FUNCTION CONTROL

ASSESSMENT OF SHUNT PERFORMANCE IS CHALLENGING ...

Currently available invasive and non-invasive methods such as the shunt tap or computed tomography (CT) cannot reliably assess shunt function (5-7).

Absence of changes in ventricular size

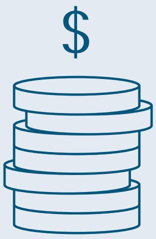
Low negative predictive values



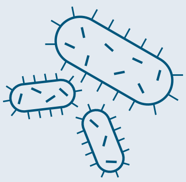
Evaluation of potential shunt malfunction

... AND NOT RISK-FREE

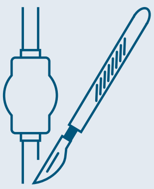
Invasive shunt assessment can increase the risk of infection, while non-invasive cranial CT has been shown to increase the risk for brain tumors (8).



High associated costs



Increased risk of infection



Unneccessary removal of shunt

» Surgical exploration is costly, puts the patient at risk, and is often shown to be unnecessary in hindsight (5).

M.scio® – NON-INVASIVE TELEMETRIC PRESSURE MEASUREMENT

STOP PLAYING THE GUESSING GAME!

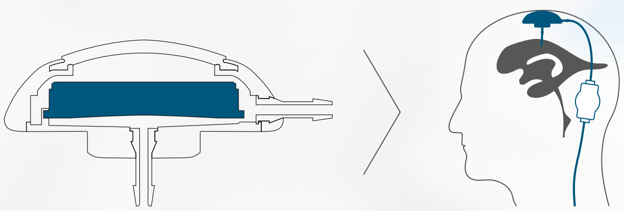
For shunt-treated hydrocephalic patients, measuring the intracranial pressure (ICP) can provide the necessary information to steer the course of treatment in the right direction (2).

M.scio® – THE PERMANENT SOLUTION FOR PRESSURE MEASUREMENT

Hermetic encapsulation in titanium, a zero-point drift of less than 1 mmHg/year (14), the possibility of validating shunt functionality via the shape of the recorded pressure pulse, and classification as MRI-conditional make *M.scio®* the first pressure sensor approved for permanent implantation.

Telemetric pressure sensor

Integration into shunt system

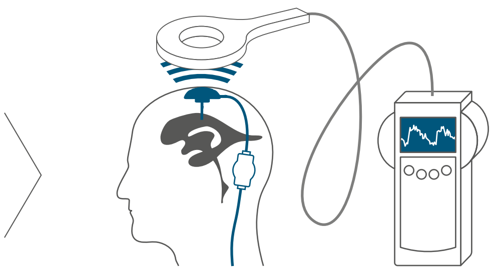


M.scio® – NON-INVASIVE AND EASY-TO-USE

With the means of the Reader Unit Set, *M.scio*® provides straightforward, non-invasive and easy-to-use real-time measurements of the pressure inside of a shunt system (11). Thanks to the high sampling frequency of up to 44 Hz clinically relevant oscillations such as pulse and breathing can be resolved and intracranial compliance can be interpreted (10).

Measuring the ICP can provide additional information on the individual pressure situation and on shunt function (2). We believe that reliable and durable sensors with accurate and telemetric readout of the pressure can provide neurosurgeons and patients with valuable insight helping to reduce time-consuming follow-up investigations, avoid unnecessary shunt revisions and improve patient outcomes.

Non-invasive real-time measurement



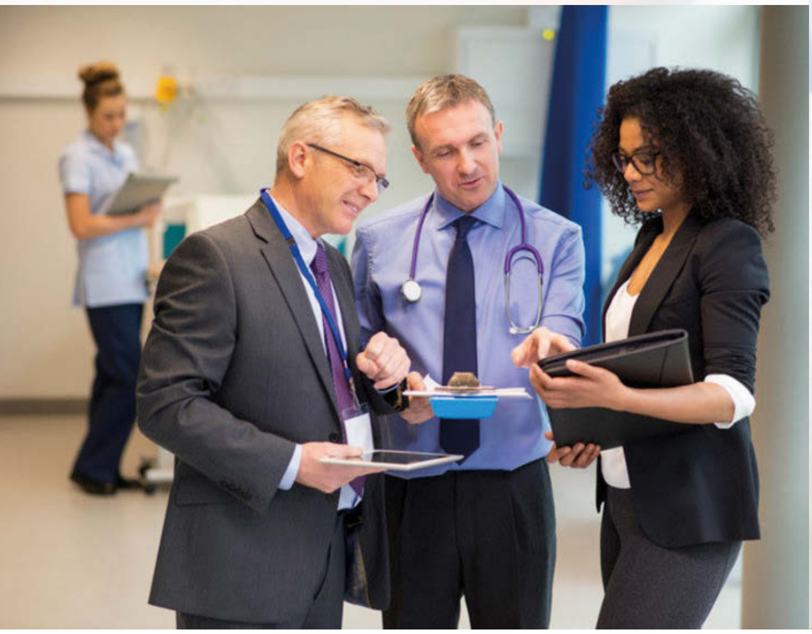
M.scio® – NON-INVASIVE TELEMETRIC PRESSURE MEASUREMENT

M.scio®– IMPROVES PATIENT OUTCOMES AND OPTIMIZES PATIENT MANAGEMENT

Valve adjustments following telemetric read-out of the pressure via the *M.scio*® improve outcomes in most patients (1) and knowledge of the pressure can help to avoid unnecessary hospitalizations, investigations, and radiation exposure (9). In addition, the easily accessible measurement can ease the mind of the patient and relatives (10).

70%

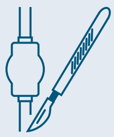
of patients reported improvement of clinical symptoms after valve adjustements based on *M.scio*® readout (1).



M.scio® – HIGHLY RESOURCE-EFFICIENT

The *M.scio*® saves time by avoiding unnecessary diagnostic procedures and revisions, surgery time for valve implantation is not significantly prolonged (11). As a consequence, the *M.scio*® is also highly cost-efficient. Already 12 months after implantation the return on investment is positive (12) and hospital cost can be reduced by 50% compared to traditional clinical practice (10, 13).

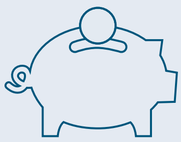
Avoids unnecessary inpatient stays (10, 13)



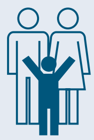
Avoids unnecessary revisions (15)

Avoids unnecessary radiation exposure (15)

Avoids unnecessary diagnostic procedures (10, 12, 15)



Reduces hospital cost by up to 50% (10, 13)

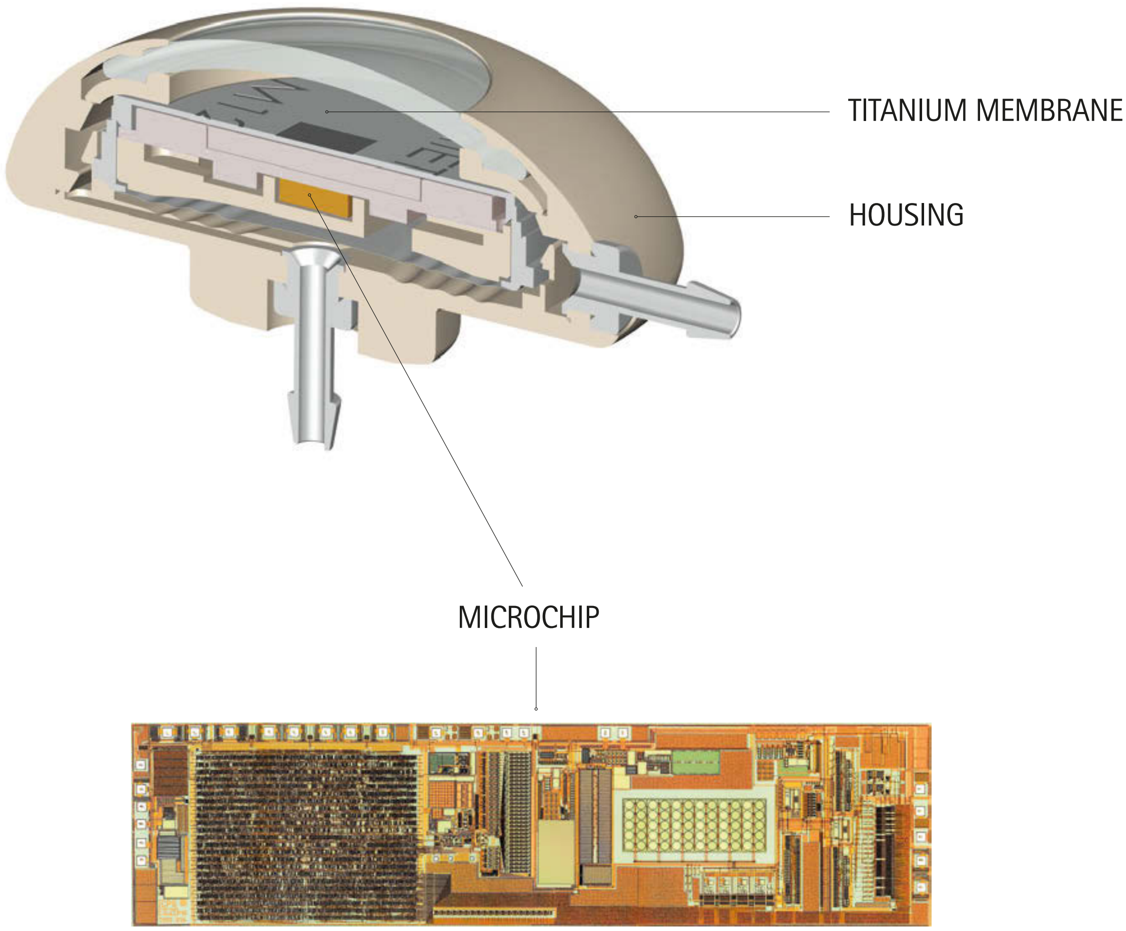


Eases the mind of patients and relatives (10)

M.scio® IMPLANTS

FEATURES

- Theranostic system for optimized patient management.
- Reduction of shunt revisions.
- Improved patient outcome through detailed pressure curves.
- High sampling rate of up to 44 Hz.
- Stable long-term implant with long life time.
- Reliable measured values thanks to minimum drift of < 1 cmH_2O/year.
- Small implant in four variants for individual treatment requirements.
- Puncturability of the membrane* enables verification of the pressure values *(versions dome).
- Simple telemetric pressure measurement in real time.
- MRI-compatible up to 3 Tesla.



M.scio® is available in two different designs, "dome" or "flat" housing. In addition to pressure measurement, the "dome" design offers the same features as any other Aesculap-MIETHKE reservoir.

The reservoir membrane permits:
· the pressure measurement in the shunt system
· the injection of medication
· fluid removal
· valve inspections.

The measuring cell with integrated microchip is protected from possible penetration by a titanium membrane.

Every *M.scio*® is calibrated. The calibration data are stored on an associated SD card that is included with the device.

M.scio® READER UNIT SET

The *M.scio*® Reader Unit Set is used to read and display the pressure using telemetric methods. The measured data are automatically stored on an SD card for later analysis.

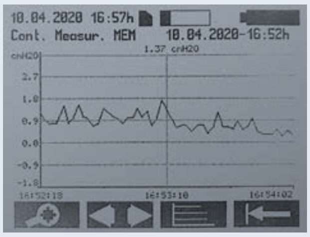
MIETHKE

MEASUREMENT MODES

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. For a later detailed analysis, the data and curves can be accessed again with the Reader Unit Set and evaluated for further processing on the computer, e.g. in EXCEL or ***ICP****icture*.

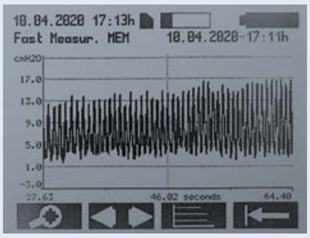
SINGLE MEASUREMENT

The single measurement is a static measurement of the current pressure value and is displayed as a digital value averaged from 8 to 10 measurements. The unit of measurement can be selected in the settings.



CONTINUOUS MEASUREMENT

In continuous measurement, the measured values are displayed sequentially as individual measurements in a curve over a configured measurement interval.



FAST MEASUREMENT

The fast measurement is a sequence of non-averaged individual measured values at the maximum measurement rate available (44 Hz = 44 measurements per second) that can be shown sequentially as a curve.

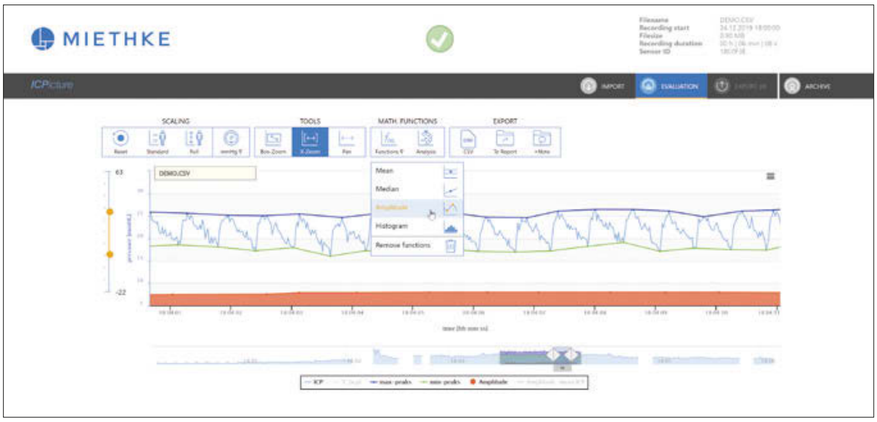
44 Hz

Resolves pulse wave morphology and identifies
clinically relevant oscillations (in fast measurement mode)

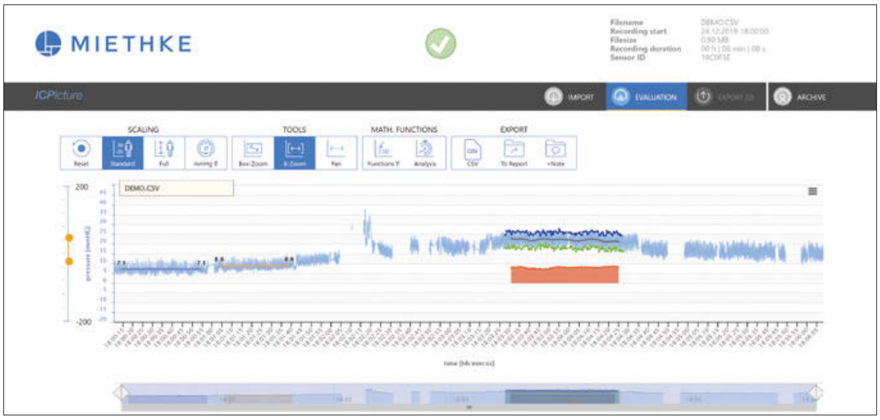
SOFTWARE TOOL

ICP*icture*

Thanks to the research tool ***ICP****icture*, comprehensive data analyses of the measured pressure curves are possible. The data can be easily inserted by drag&drop directly from the SD card or computer. After the analysis, the evaluations are stored clearly arranged in the archive for later review. The evaluations made can also be exported or printed out as a comprehensive PDF protocol. For more information please contact your local B. Braun sales representative.



Extensive analysis tools are available to evaluate the data



The analysis of the data can be applied to the entire measurement data or to individual user-defined sections

Data analyses stored in the archive can be individually compiled for further processing

- Reader Unit Set

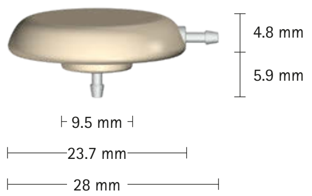
Art. no.	Product
FV907X	Reader Unit Set

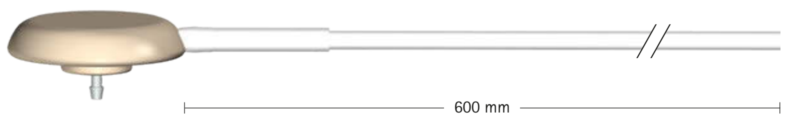
- SD card

Art. no.	Product
FV906X	SD card for Reader Unit (substitute)

M.scio®

- *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)

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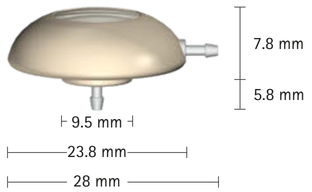
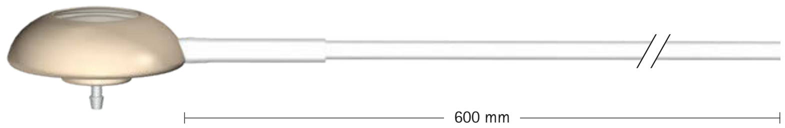
- *M.scio*®, dome-angled





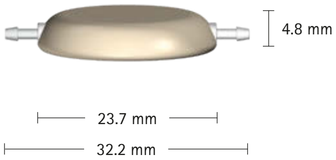
Connector: do = 1.9 mm
preferably to be used with
Catheter: di = 1.2 mm, do = 2.5 mm

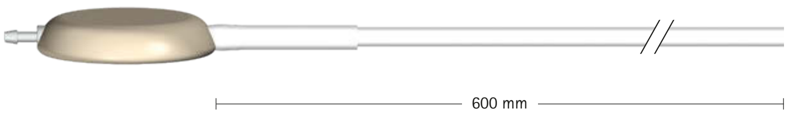
M.scio®

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®

- *M.scio*®, flat-inline



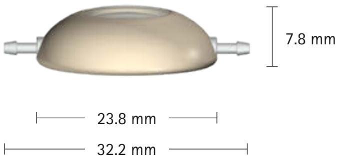


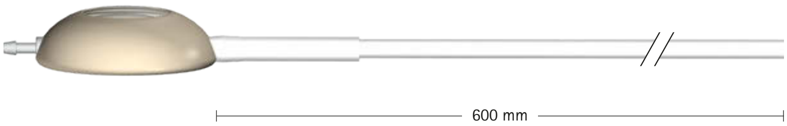
Connector: do = 1.9 mm
preferably to be used with
Catheter: di = 1.2 mm, do = 2.5 mm

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)

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(14) Miethke In-House bench-test

(15) Customer survey

OUR SHUNT SYSTEMS – YOUR CHOICE

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

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NEUROSURGERY

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MIETHKE GRAVITATIONAL VALVES

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