MIETHKE

M.blue®

THE BALANCED WAY OF LIFE
INSPIRED BY YOU

EN Instructions for use |

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US This Instructions for Use is NOT intended for United States users. Please discard.
The Instructions for Use for United States users can be obtained by visiting our website at www.aesculapusa.com. If you wish to obtain a paper copy of the Instructions for Use, you may request one by contacting your local Aesculap representative or Aesculap's customer service at 1-800-282-9000. A paper copy will be provided to you upon request at no additional cost.

CONTENTS

1 PREFACE AND IMPORTANT INFORMATION

Preface

Thank you for purchasing the medical device *M.blue*. Please contact us if you have any questions about the contents of these instructions for use or the use of the product.
Your team at Christoph Miethke GmbH & Co. KG

Relevance of the instructions for use

WARNING

Improper handling and non-intended use of this product can cause risks and damages. Therefore, please read and closely follow these instructions for use. Always keep them to hand. Follow the safety instructions to avoid personal injury or material damage.

Scope

M.blue includes the following components:

- *M.blue*

Additional options:

- *Reservoirs* (including paediatric versions)
- *Prechambers* (including paediatric versions)
- *Burrhole Deflector* (including paediatric version)
- *Ventricular Catheter* with stylet
- *Peritoneal Catheter*

Basic UDI-DI

4041906653-MSHUNTS-0002CM

2 INFORMATION ON HANDLING THESE INSTRUCTIONS FOR USE

2.1 EXPLANATION OF THE WARNINGS

DANGER

Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

Indicates information considered important, but not hazard-related (e.g. messages relating to property damage).

The symbols for danger, warning and caution are yellow warning triangles with a black edge and a black exclamation mark.

2.2 DISPLAY CONVENTIONS

Display	Description
Italics	Indicates *product names*

2.3 OTHER ACCOMPANYING DOCUMENTS AND ADDITIONAL INFORMATION

These instructions for use as well as translations into additional languages can be found on our website:
https://www.miethke.com/downloads/
The delivery includes a Patient Implant Card (IC) with IC label containing product information. The respective healthcare facility must record the information about the patient, the implant as well as the doctor in charge on the IC, and the IC label must be attached. The Patient Implant Card is thus intended to make all of the important information available to the patient in a compact form. This website also contains information about the symbols used on the Patient Implant Card together with a description on how the Patient Implant Card is to be completed by the healthcare institution.
Patient labels containing information about the product are enclosed with the delivery. The patient labels provide the treating physician with all the product information in a compact form for the patient record. For individually purchased shunt components, the patient label must be added to the existing Implant Card.
Helpful information for patients, particularly concerning the symbols on the Implant Card and the labels, is available on this website:
https://www.miethke.com/ic/
If you still need additional information despite carefully reading the instructions for use and

the additional information, please contact us or your authorised distributor.

2.4 FEEDBACK ON THE INSTRUCTIONS FOR USE

Your opinion is important to us. Please let us know if you have any requests and criticisms about these instructions for use. We will analyse your feedback and take it into account for the next version of the instructions for use where appropriate.

2.5 COPYRIGHT, DISCLAIMER, WARRANTY AND OTHER INFORMATION

Christoph Miethke GmbH & Co. KG guarantees a faultless product that is free of material and manufacturing defects upon delivery.
No liability, guarantee or warranty for safety and functionality can be assumed if the product is modified in any way other than described in this document, if it is combined with products by another manufacturer or if it is used in any way other than for the intended purpose and the intended use.
Christoph Miethke GmbH & Co. KG points out that the reference to its trademark rights applies solely to jurisdictions in which it has trademark rights.

3 DESCRIPTION *M.blue*

3.1 MEDICAL PURPOSE

The product *M.blue* is intended for shunting of cerebrospinal fluid (CSF).

3.2 CLINICAL BENEFITS

The clinical benefit of the MIETHKE shunt component *M.blue* as part of a shunt system is improvement of symptoms in the hydrocephalus therapy.

3.3 INDICATIONS

The following indications apply to *M.blue*:

- Treatment of hydrocephalus

3.4 CONTRAINDICATIONS

The following contraindications apply to *M.blue*:

- Infections in the implantation area
- Pathological concentrations levels (e.g. of blood components and/or protein) within the cerebrospinal fluid
- Intolerance to materials of the shunt system

3.5 INTENDED PATIENT GROUPS

- Patients who are treated with a CSF shunt system on account of their clinical picture

3.6 INTENDED USERS

In order to avoid risks due to false diagnoses, incorrect treatments and delays, the product must only be used by users with the following qualifications:

- Medical professionals, e. g. neurosurgeons
- Knowledge of mode of operation and intended use of the product
- Successful participation in product training

3.7 INTENDED USE ENVIRONMENT

Professional Healthcare Facilities

- Implantation under sterile operating theatre conditions

3.8 TECHNICAL DESCRIPTION

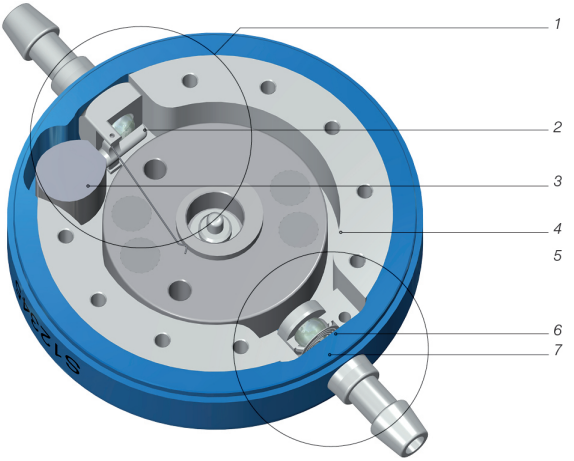


Fig. 1: M.blue cross section

1. **Adjustable gravitational unit**
2. Sapphire ball
3. Tantalum weight
4. Rotor
5. **Differential pressure unit**
6. Sapphire ball
7. Micro-coil spring

The *M.blue* is a valve made of titanium. It consists of an adjustable gravitational unit and a differential pressure unit (Fig. 1).
The adjustable gravitational unit (1) in the proximal part of the valve contains a tantalum weight (3), which holds a sapphire ball in the ball seat via a lever (2). Depending on the patient's body position, the influence of the tantalum weight on the sapphire ball changes, which also affects the valve opening pressure. Via a rotor (4), the pretension of the torsion spring connected to the lever can be adjusted through the skin after surgery. This way, the impact of the tantalum weight on the sapphire ball can be influenced and, consequently, the valve opening pressure can be adjusted.
In the distal part of the valve, a micro-coil spring (7) controls the opening pressure of the differential pressure unit (5). A sapphire ball (6) ensures precise opening and closing of the ball-cone unit.

3.9 OPERATING PRINCIPLE OF THE VALVE

The *M.blue* is a posture-dependent hydrocephalus valve. The opening pressure of the *M.blue* is composed of the opening pressures of the adjustable gravitational unit and the differential pressure unit.

Horizontal body position

In the horizontal position, the gravitational unit is always open and does not present any resistance.
The opening pressure of the *M.blue* in the horizontal position is thus determined by the differential pressure unit. The basic operating principle of the differential pressure unit is shown in Fig. 2 a) and b).

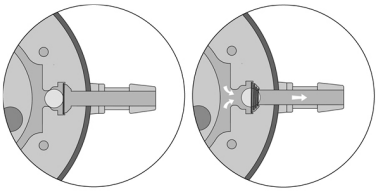


Fig. 2: Functional principle of the differential pressure unit
a) closed b) open

In Fig. 2 a), the valve is closed; hence, shunting is not possible.
If the patient's intraventricular pressure (IVP) exceeds the spring force of the micro-coil spring, which otherwise keeps the differential pressure unit closed, the sealing ball moves out of the cone, leaving a gap for CSF shunting (Fig. 2 b).

Vertical body position

As the patient sits or stands up, the Gravitational Unit closes the discharge channel in the proximal part of the valve (Fig. 3 a). Thus, the opening pressure of the *M.blue* is increased in the upright position, because now the weight of the tantalum weight (opening pressure of the Gravitational Unit) must be overcome in addition to the opening pressure of the differential pressure unit. Shunting is only possible again when the sum of IVP and hydrostatic suction is greater than the opening pressure of both units (Fig. 3 b). For individual adaptation of the opening pressure to the patient, a valve opening pressure between 0 and 40 cmH_2O can be selected for the adjustable Gravitational Unit.

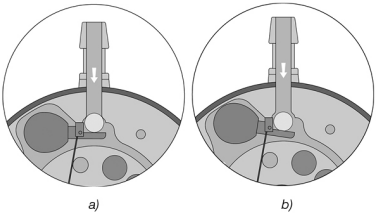


Fig. 3: Gravitational unit in the vertical body position
a) closed b) open

CAUTION

During physical activity associated with shock (e.g. jogging), the opening pressure of the *M.blue* may decrease temporarily according to laboratory results. Fundamentally, though, functionality remains the same. At the end of physical activity, the opening pressure returns to its original level and remains stable.

3.10 SELECTION OF THE APPROPRIATE PRESSURE SETTING

Recommended pressure settings for the *M.blue* are available at:
https://www.miethke.com/downloads/
This is a non-binding recommendation for the treating physician. The physician decides on each case independently, individually and autonomously in accordance with his/her diagnosis.
The adjustable Gravitational Unit of the *M.blue* is set to a pressure level of 20 cmH_2O upon delivery.
By changing the pressure level, this pre-set opening pressure can be changed to a different pressure prior to implantation.

Horizontal body position

The opening pressure in the horizontal body position is determined by the pressure level of the differential pressure unit.
In this case, the pressure level should be set in accordance with the patient's clinical picture, indication and age. The standard settings for the horizontal position are 5 to 10 cmH_2O.

Vertical body position

The opening pressure of the *M.blue* for the vertical body position is calculated from the sum of the pressure levels of the differential pressure unit and the Gravitational Unit.
Patient height, activity level and potentially increased abdominal pressure (obesity) should be taken into account in selecting the opening pressure level for the gravitational unit.

3.11 PRESSURE-FLOW CHARACTERISTICS

A flow rate of 5 to 50 ml/h causes the following pressure-flow characteristics. The pressure level at the reference flow rate of 20 ml/h is highlighted in bold. The reference flow rate is highlighted by a dotted line (····). Note that test-

ing the product may provide different results depending on the test setup.
The valve design allows continuously variable adjustment (shown by double arrows: ⟷) between the illustrated pressure values to find the individual pressure setting for each patient. The combination with catheters (inner diameter > 1 mm) does not fundamentally affect the pressure-flow characteristics.

Horizontal body position

The opening pressure in the horizontal body position is determined by the selected pressure level of the differential pressure unit. The pressure flow characteristics of the *M.blue* differential pressure unit are shown below for pressure levels of 0, 5, 10 and 15 cmH_2O in the horizontal body position:

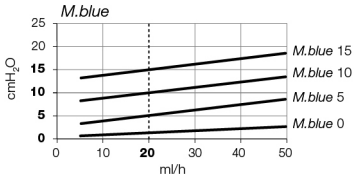


Fig. 4: M.blue 0, 5, 10, 15 horizontal; pressure (cmH_2O), flow rate (ml/h); tolerance: ±3 cmH_2O

Vertical body position

In the vertical body position, the *M.blue* opening pressure is composed of the pressure levels of the differential pressure unit and the continuously variable Gravitational Unit. Below are examples of the pressure-flow characteristics of *M.blue* 0, 5, 10, 15 for gravitational unit pressure level settings (0, 20 and 40 cmH_2O) in the vertical body position; pressure (cmH_2O), flow rate (ml/h):

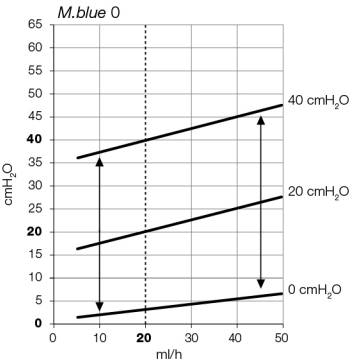


Fig. 5: M.blue 0 vertical; tolerance: ±8 cmH_2O

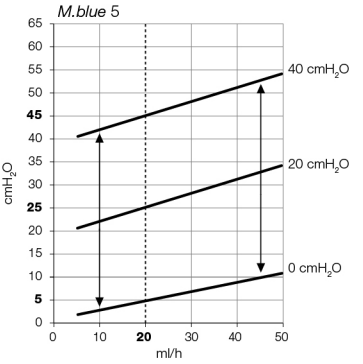


Fig. 6: M.blue 5 vertical; tolerance: +5/-12 cmH_2O

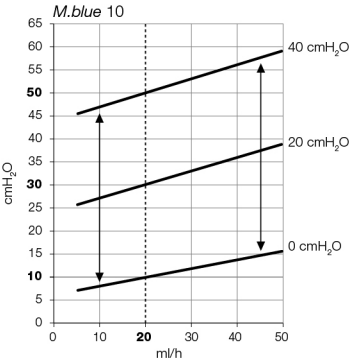


Fig. 7: M.blue 10 vertical; tolerance: +5/-14 cmH_2O

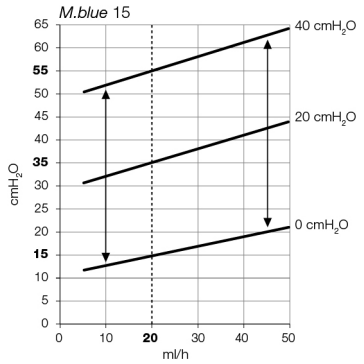


Fig. 8: M.blue 15 vertical; tolerance: +5/-15 cmH_2O

3.12 PRESSURE LEVEL IDENTIFICATION IN X-RAY IMAGES

M.blue gravitational unit

The selected pressure level of the *M.blue* gravitational unit should always be monitored using the *M.blue plus Compass*, but it can also be checked using X-ray (Fig. 9).

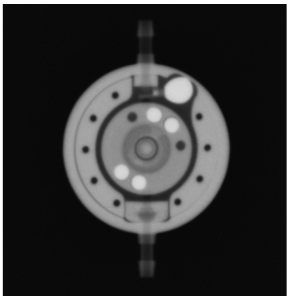


Fig. 9: X-ray image (adjustable gravitational unit pre-set to 20 cmH_2O; differential pressure unit: 0 cmH_2O)

The rotor setting is decisive in this case. The four magnets in the rotor appear in the X-ray image as white dots and are located opposite each other in pairs. On one side of the rotor, two additional burr holes (right and left next to the magnet pairs) serve as orientation. They appear as black dots in the X-ray image. This side can be described as the rear side of the rotor. The two front magnets are on the opposite side.
The space between these two magnets can be considered as the apex of the triangle. The pressure level can be read off using the orientation of this intermediate space (Fig. 10). The apex of the triangle can take up any position except the space marked as a the non-adjustable range in Fig. 10. This means that the opening pressure of the *M.blue* can be infinitely variably adjusted from 0 up to 40 cmH_2O. To prevent reading the pressure level in reverse, the top view of the valve shows an obvious recess in the housing ring with the tantalum weight to the right of the inlet connector (Fig. 9).

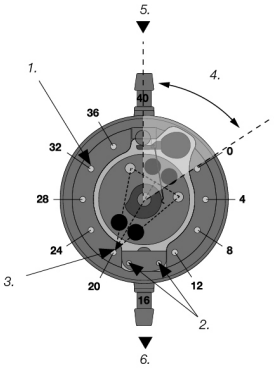


Fig. 10: Schematic representation of rotor in an X-ray image
1. Coding holes for the adjustable gravitational unit
2. Coding holes for the differential pressure unit
3. Triangle apex, 4. Non-adjustable range
5. proximal, 6. distal

Differential pressure unit of the *M.blue*

The pressure level of the pre-set *M.blue* differential pressure unit can be recognised in the X-ray image by the encoding (Fig. 11). The following pressure levels are possible for the differential pressure unit:

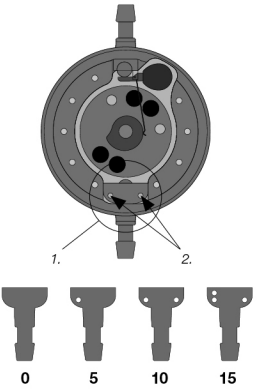


Fig. 11: Pressure level encodings of the differential pressure unit (1.) with coding holes (2.)

3.13 APPLICATION OF THE *M.blue plus Instruments*

WARNING

Because of the magnets inside the *M.blue plus Instruments*, *M.blue plus Instruments* must not be used in the vicinity of active implants that are influenced by magnetism, such as cardiac pacemakers. When adjusting with the *M.blue plus Instruments*, the safety distance specified by the manufacturer of the active implant should be observed.

CAUTION

- **The *M.blue plus Instruments* must not be taken into a MRI facility as this may pose a safety risk to the patient and/or the user.**
- **Only *M.blue plus Instruments* approved for that purpose must be used to determine, change and monitor the opening pressure of the gravitational unit of the *M.blue*.**

NOTICE

The *M.blue plus Adjustment Ring* emits a magnetic field. Metallic objects and magnetic storage media should be placed at a sufficient safety distance.

The *M.blue plus Instruments* may only be used by trained specialists.
The selected pressure level of the *M.blue* can be determined, adjusted and monitored using the *M.blue plus Instruments*.

The *M.blue plus Compass* (Fig. 12) is used for localising and reading the adjustable gravitational unit of the *M.blue*.

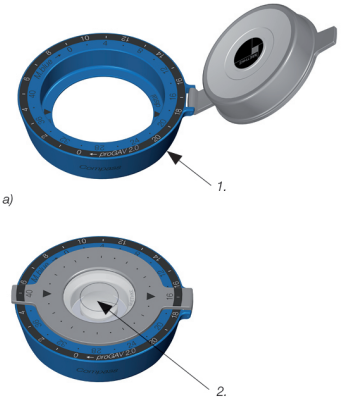


Fig. 12: M.blue plus Compass
a) open, 1. scale ring
b) closed, 2. float gauge compass

The *M.blue plus Adjustment Ring* (Fig. 13) is used to set the opening pressure of the gravitational unit of the *M.blue* from 0 to 40 cmH_2O.

Fig. 13: M.blue plus Adjustment Ring

The opening pressure of the adjustable gravitational unit of the *M.blue* can be changed before or after implantation. It is pre-set by the manufacturer to 20 cmH_2O.

In order to set the opening pressures, the following steps must be performed:

1. Localisation

CAUTION

- **The *M.blue plus Compass* reacts sensitively to external magnetic fields. In order to rule out unwanted interactions, the *M.blue plus Adjustment Ring* should not be placed in the immediate vicinity of the *M.blue plus Compass* when determining the opening pressure. We recommend a minimum distance of 30 cm.**

CAUTION

- **Swelling of the skin may make adjustment difficult for a few days after surgery. If the valve setting cannot be checked conclusively using the *M.blue plus Compass*, we recommend checking it with an imaging method.**
- **The *M.blue plus Compass* should be placed as centrally as possible over the valve, as the determined opening pressure may otherwise be incorrect.**
- **Possible air pockets in the *M.blue plus Compass* do not affect the compass function.**

When the *M.blue plus Compass* is opened, a circular cut-out becomes visible, which is used to localise the valve in the patient's head as centrally as possible using the index finger (Fig. 14).

Fig. 14: Localising the valve

The direction markings show the flow direction.

2. Verification procedure

In order to determine the selected pressure level, the *M.blue plus Compass* is then closed again. The float gauge should now be centred by moving the instrument within the designated circular marking (Fig. 15). Once the float gauge is centred, the current setting of the opening pressure the gravitational unit (*M.blue*) can be read from the line marking on the float gauge (Fig. 15).

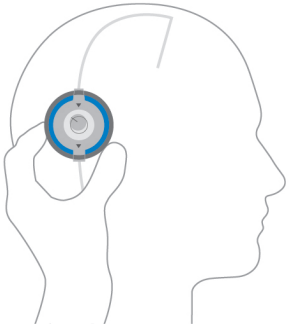


Fig. 15: Determining the pressure setting with the M.blue plus Compass

There are two scales on the scale ring (Fig. 16). The blue adjustment range from 0 to 40 cmH_2O on the inner scale applies to the opening pressure of the gravitational unit of the *M.blue*.

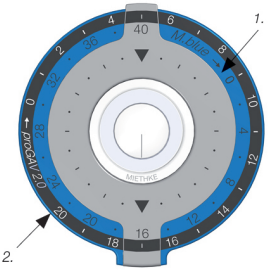


Fig. 16: Scale ring of the M.blue plus Compass
1. Inner: Scale for the M.blue gravitational unit from 0 to 40 cmH_2O (the opening pressure of the M.blue gravitational unit in the illustrated example is 16 cmH_2O)
2. Outer: Scale for the proGAV 2.0 differential pressure unit from 0 to 20 cmH_2O (the opening pressure of the proGAV 2.0 differential pressure unit in the illustrated example is 17 cmH_2O)

3. Adjustment process

CAUTION

When adjusting the gravitational unit of the *M.blue*, care must be taken to change the opening pressure by a maximum of 16 cmH_2O per adjustment process; otherwise, errors can result.
Example: The opening pressure is to be changed from 6 to 36 cmH_2O. The correct method is an adjustment in two stages: an initial adjustment from 6 to 22 cmH_2O and subsequently from 22 to 36 cmH_2O.

3a. Adjustment using the *M.blue plus Adjustment Ring*

In order to adjust the opening pressure, the *M.blue plus Compass* is opened, but without changing the position of the scale ring. The *M.blue plus Adjustment Ring* is now inserted into the scale ring in such a manner that the line marking points to the desired value on the scale of the scale ring (Fig. 17).

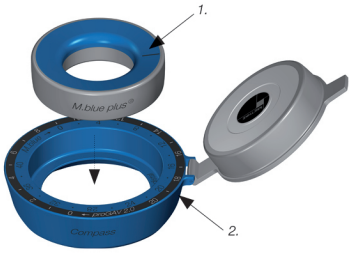


Fig. 17: Inserting the M.blue plus Adjustment Ring
1. M.blue plus Adjustment Ring, 2. scale ring

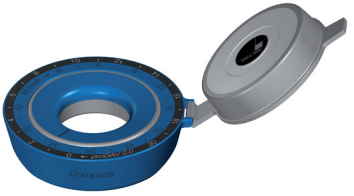


Fig. 18: setting the M.blue gravitational unit to 32 cmH_2O.

By applying slight pressure with the index finger to the valve diaphragm located in the centre of the *M.blue plus Adjustment Ring* and under the skin, the rotor brake is released and the opening pressure of the gravitational unit is changed to the desired value (Fig. 19).

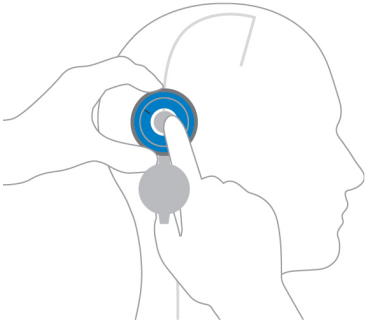


Fig. 19: Adjustment using the M.blue plus Adjustment Ring

The gravitational unit of the *M.blue* is equipped with a feedback mechanism.
Due to the valve housing design, targeted pressure on the valve produces an audible acoustic signal (a clicking sound) and/or palpable resistance as soon as the rotor brake has been released. The valve thus shows both acoustically and haptically when the pressure is sufficient for uncoupling. Once this pressure has been released, the rotor is once again adjustment-proof. Although the click caused by releasing the rotor brake is easily audible before implantation, it may be considerably reduced after implantation and the filling of the valve depending on its position and the condition of the implant surroundings. Normally, however, it should be audible to the patient or by using a stethoscope.

3b. Adjustment using the *M.blue plus Adjustment Assistant*

Alternatively, the *M.blue plus Adjustment Assistant* can be used to adjust the opening pressure. To do this, insert the *M.blue plus Adjustment Assistant* into the *M.blue plus Adjustment Ring* aligned to the desired value and press it with your index finger (Fig. 20).

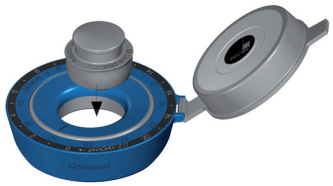


Fig. 20: M.blue plus Adjustment Assistant

4. Checking after adjustment

After adjusting the valve opening pressure, it is recommended to check the set pressure level. To do this, proceed as in Points 1 and 2. Should the measured value not correspond with the required pressure level, the adjustment process should be repeated. To do this, start again at Point 3.

5. Check and adjustment using the *M.blue Checkmate*

The *M.blue Checkmate* (Fig. 21) is supplied sterile and can be re-sterilised. The *M.blue Checkmate* can be used to change and check the pressure level before and during valve implantation directly at the *M.blue*. To determine the pressure level, the *M.blue Checkmate* is placed centrally onto the *M.blue*. The *M.blue Checkmate* automatically aligns itself over the valve. The pressure level can be read from the direction of the proximal catheter (leading towards the valve). If the pressure level is to be adjusted, the *M.blue Checkmate* is placed centrally onto the *M.blue*. When doing so, the required pressure level must point towards the proximal catheter (leading towards the valve). By slightly pressing the *M.blue Checkmate* onto the valve, the rotor brake in the *M.blue* is released and the pressure level set.

Fig. 21: M.blue Checkmate, colour: blue
Pressure levels: 0 to 40 cmH_2O

3.14 SYSTEM COMPONENTS

Combination with shunt components

The *M.blue* can be safely combined with our range of implantable shunt components. We recommend using the Christoph Miethke GmbH & Co. KG products in combination with *M.blue*.

Reservoirs

The use of shunt systems with a reservoir makes it possible to puncture the reservoir and check the shunt function.
Any punction of the reservoir should be performed perpendicular to the reservoir surface with a sharp cannula of max. Ø 0.9 mm. The silicone membrane can be punctured 30 times without any restrictions. A stable titanium base prevents the base from being pierced.
An integrated check valve in the *SPRUNG RESERVOIR* and the *CONTROL RESERVOIR* pumps the cerebrospinal fluid towards the valve, thus making it possible to check the distal part of the shunting system (reservoir difficult to squeeze out) as well as the *Ventricular Catheter* (reservoir fills very slowly after squeezing out). The volume per pump cycle is approx. 0.2 ml for the normal reservoirs und approx. 0.1 ml for the paediatric reservoirs with check valve.
During pumping, access to the *Ventricular Catheter* is closed. The use of a reservoir does not change the opening pressure of the shunt system.

⚠ **CAUTION**

Frequent pumping of the Reservoir can result in excessive shunting and thus lead to pressure conditions outside the normal physiological range. The patient should be properly informed about this risk.

Burrhole Deflector

Because of the tight fit on the *Ventricular Catheter*, the *Burrhole Deflector* makes it possible to choose the length of catheter penetrating into the skull prior to implantation. The *Ventricular Catheter* is deflected at a right angle in the burr hole (see chapter 4.5.5).

Tube systems

The M.blue can be ordered as an individual valve unit or as a shunt system with integrated catheters (internal diameter 1.2 mm,

external diameter 2.5 mm). These catheters are designed for MIETHKE valves or MIETHKE shunt components with a connector outer diameter of 1.9 mm.
The catheters are made from silicone and contain barium sulphate. This ensures that the X-ray image is clearly visible.
For a new connection of catheters and connectors, the catheters must be carefully secured with a ligature to the valve's connectors or shunt components.

3.15 FUNCTIONAL SAFETY AND COMPATIBILITY WITH DIAGNOSTIC PROCEDURES

- *M.blue* together with the entire shunt system can safely withstand pressure of up to 100 cmH_2O occurring during and after surgery.
- Nuclear magnetic resonance (MRI) examinations up to a field strength of 3 Tesla or computed tomography (CT) examinations can be performed without danger or impairment to the valve function. The *M.blue* is MR Conditional. The *Catheters* are MR Safe. *Reservoirs*, *Prechambers*, *Burrhole Deflectors* and *Titanium Connectors* are MR Conditional. The stylet is MR Unsafe.

CAUTION

In MRI imaging *M.blue* creates artefacts that are larger than the valve itself.

The conditions for MRI security of the products are found on our website:
https://miethke.com/downloads/

3.16 SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

The summary of safety and clinical performance (SSCP) can be downloaded from the following address:
https://www.miethke.com/downloads/

4 PROPERTIES *M.blue*

4.1 PRODUCT DESCRIPTION

4.1.1 *M.blue* VARIANTS

The *M.blue* is available in a range of different variants. They differ in the pre-set pressure level of the differential pressure unit.

Differential pressure unit	Adjustable gravitational unit
0 cmH_2O	0–40 cmH_2O
5 cmH_2O	0–40 cmH_2O
10 cmH_2O	0–40 cmH_2O
15 cmH_2O	0–40 cmH_2O

These variants are also available as shunt systems and can come with the following components: *Ventricular Catheters*, *Peritoneal Catheters,Prechambers*, *Reservoirs*.

4.1.2 SCOPE OF DELIVERY

Box content	Number
M.blue Shunt system sterile packaging	1
Instructions for use for *M.blue*	1
Patient Implant Card (IC)	1
IC label	6
Patient label	6
Insert regarding the Patient Implant Card	1
Pressure level recommendation	1

4.1.3 STERILITY

WARNING

The products must not be used if the packaging or the product is damaged or after the expiry date.

The products are sterilised with steam under strictly controlled conditions. The respective expiry date is printed on the packaging.

4.1.4 REPEATED USE AND RESTERILISATION

WARNING

The product must not be resterilised or reprocessed in any other way as the safe functioning and sterility of the product cannot be guaranteed.

Products that have already been implanted in a patient must not be reused either on the same or a different patient in order to minimise the risk of infection.

4.1.5 PRODUCT LIFETIME

The technical lifetime of the medical device *M.blue* is 15 years. Patient-specific circumstances or known side effects such as biological deposits or infection can shorten the lifetime and make revision necessary. In a favorable case, the real lifetime can also exceed the expected time span.

4.1.6 SINGLE-USE PRODUCT

This product is intended for single use. Reprocessing may lead to significant changes to the properties of the *M.blue*. No guarantee can be assumed for the functional safety of resterilised products.

4.1.7 PRODUCT CONFORMITY

The product meets current regulatory requirements.
The requirements stipulate the comprehensive documentation of the whereabouts of medical devices used in humans. The individual identification number of the medical device should therefore be recorded in the patient's medical records to ensure complete traceability.

4.2 IMPORTANT SAFETY INFORMATION

4.2.1 SAFETY INSTRUCTIONS

Important! Read all safety instructions carefully before using the product. Follow the safety instructions in order to avoid injuries and life-threatening situations.

⚠ **WARNING**

- **The products must not be used if the packaging or the product is damaged or after the expiry date.**
- **Due to the risk of injury resulting from incorrect use of the product, the instructions for use must be carefully read and understood before the product is used for the first time.**
- **Prior to use, it is essential to check the product for completeness and integrity.**

4.2.2 COMPLICATIONS, SIDE EFFECTS, PRECAUTIONS AND RESIDUAL RISKS

The following complications can occur in conjunction with the *M.blue*:

- Headaches, dizzy spells, mental confusion, vomiting in cases of possible leakage from the shunt system and shunt dysfunction
- Redness/irritation of the skin and tightness around the implantation site as an indication of a possible infection at the implant
- Occlusions caused by protein and/or blood components in the cerebrospinal fluid
- Overdrainage/underdrainage
- Noise development
- Allergic reaction / intolerance to product materials

Violent external shocks (accident, fall etc.) may put the integrity of the shunt system at risk.
As a precaution, a physician must be consulted immediately if the patient suffers from skin rashes and tightness, severe headaches, dizzy spells or similar.

The following residual risks exist when using the *M.blue*:

- Persistent headache
- Severe infection (e.g. sepsis, meningitis) / allergic shock
- Acute and chronic hygroma/subdural haematoma
- Cerebrospinal fluid accumulations
- Tissue damage/puncture
- Skin irritation
- Local shunt irritation /allergic reaction

4.2.3 REPORTING OBLIGATION

All serious incidents (damage, injuries, infections, etc.) occurring in relation to the product must be reported to the manufacturer and the responsible state authority.

4.3 PATIENT EDUCATION

The attending physician is responsible for informing the patient and/or his/her proxy in advance. The patient is to be informed about warnings, precautions, contraindications, precautionary measures to be taken as well as restrictions on use in relation to the product. (Ch. 4.1.5, 4.2, 4.5, 4.7).

4.4 TRANSPORT AND STORAGE

The medical devices must always be transported and stored in a clean and dry place.

4.4.1 TRANSPORT

Transport conditions

Temperature range for transport	-30 °C … +40 °C

4.4.2 STORAGE

Storage conditions

Temperature range for storage	room temperature

4.5 USE OF THE PRODUCT

4.5.1 INTRODUCTION

The *M.blue* is a posture-dependent valve with an adjustable gravitational unit and a pre-set differential pressure unit.
The *M.blue* is used for shunting cerebrospinal fluid (CSF) into the peritoneum in the treatment of hydrocephalus. Valves and Reservoirs are placed in suitable positions along the course of the shunt.

4.5.2 SAFETY NOTICES AND WARNINGS

⚠ **WARNING**

- **The correct flow direction must be strictly observed as per the arrows. Incorrect implantation will result in flow prevention and underdrainage.**
- **The gravitational unit of the *M.blue* is posture-dependent. For that reason, care must be taken to implant the gravitational unit parallel to the body axis.**
- **The adjustable MIETHKE valve should not be implanted in an area that makes the detection or palpation of the valve difficult (e. g. underneath heavily scarred tissue).**

⚠ **WARNING**

- **During placement, it must be ensured that adjustable MIETHKE valves are positioned a maximum of 10 mm below the skin surface to make it easier to locate the valve as well as to read and adjust the valve pressure level. If the implantation site is unfavourably chosen or the skin above the valve is too thick (skin and tissue thickness greater than 10 mm), it may no longer be possible to locate the valve as well as read and adjust the valve pressure level. The valve then works with a fixed pressure level.**
- **Silicone is extremely electrostatic. Care must be taken to avoid the catheters coming into contact with dry cloths, talcum powder or rough surfaces. Clinging particles could lead to tissue reactions.**
- **When using sharp instruments, care should be taken to avoid cuts and scratches in the silicone elastomer.**
- **It must be ensured that the ligature is not tightened excessively. Damage may result in a loss of integrity of the shunt and thus necessitate a revision.**
- **The catheters should only be blocked with an atraumatic clamp and not directly behind the shunt component (e.g. valve, reservoir or connector) as they might be damaged otherwise.**

⚠ **CAUTION**

- **Frequent pumping of the Reservoir can result in excessive shunting and thus lead to pressure conditions outside the normal physiological range. The patient should be properly informed about this risk.**
- **If a magnetic field is being applied and pressure is applied to the valve at the same time, thus triggering the brake mechanism, and adjustment of the valve cannot be ruled out.**
- **In MRI imaging *M.blue* creates artefacts that are larger than the valve itself.**

4.5.3 REQUIRED MATERIALS

The *M.blue* is designed so that it can be safely used with the shunt components described in chapter 3.14.
Catheters with an inner diameter of 1.2 mm and an outer diameter of 2.5 mm should be used for connection. In any case, catheters have to be carefully secured with a ligature to the connectors of the shunt components. Any kinks in the catheter must be avoided.

4.5.4 PREPARING FOR IMPLANTATION

Checking the sterile packaging

Immediately before using the product, the sterile packaging must be visually inspected in order to check the integrity of the sterile barrier system. The products should only be removed from the packaging immediately prior to use.

Preoperative valve test

The *M.blue* should be vented before implantation and checked for permeability. The most careful way of filling the valve is by aspiration through a sterile single-use syringe attached to the distal end of the catheter. The distal end of the valve is connected and immersed in a sterile physiological salt solution. The valve is patent if saline solution can be extracted (Fig. 22).

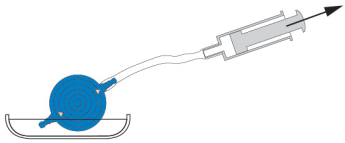


Fig. 22: Patency test

WARNING

- **Contaminants in the solution used for testing can impair the product's performance.**
- **Pressurisation with a single-use syringe should be avoided both at the proximal and the distal end (Fig. 23).**

Fig. 23: Avoidance of pressurisation

4.5.5 PERFORMING THE IMPLANTATION

Positioning of the *Ventricular Catheter*

Several surgical techniques are available for the positioning of the *Ventricular Catheter*. The required skin incision should be made in form of a lobule pedicled towards the shunting catheter or by a straight skin incision. If a *Burrhole Reservoir* - or a *SPRUNG RESERVOIR* - is used, the skin incision should not be located right above the reservoir. To avoid CSF leakage, care should be taken that the dura opening is kept as small as possible after applying the burr hole.

M.blue is available in a range of different configurations: If using a *Burrhole Reservoir* - or a *SPRUNG RESERVOIR* -, the *Ventricular Catheter* is implanted first. Once the mandrin has been removed, the patency of the *Ventricular Catheter* can be tested by checking if cerebrospinal fluid is dripping out. The catheter is shortened and the *Burrhole Reservoir* - or the *SPRUNG RESERVOIR* - connected and the connection secured with a ligature.

When using a shunt system with a *CONTROL RESERVOIR*, a *Burrhole Deflector* is included. The *Burrhole Deflector* is used to adjust the length of the catheter to be implanted and to position it inside the ventricle. The *Ventricular Catheter* is deflected by 90° and the *CONTROL RESERVOIR* put into place. The position of the *Ventricular Catheter* should be inspected after the procedure by imaging (such as CT or MRI).

Valve positioning

For ventriculoperitoneal shunting, a location behind the ear is suitable as an implantation position, whereby the implantation height has no influence on the valve function.

The adjustable valves should be touching the bone or the periosteum since pressure must be exerted on the valve during any later adjustment.

A large arch-shaped or a small straight skin cut with a pocket for the valve should be made. The catheter is pushed forward from the burr hole to the selected valve implantation location, shortened if necessary, and secured to the *M.blue* by ligature. The valve should not be located directly under the skin incision. The valve unit has an arrow in the flow direction (arrow towards distal or downwards). The surface of the valve with the arrow markings points to the outside.

WARNING

- **The correct flow direction must be strictly observed as per the arrows. Incorrect implantation will result in flow prevention and underdrainage.**

WARNING

- **During placement, it must be ensured that the adjustable throttle is positioned a maximum of 10 mm below the skin surface to make it easier to locate the throttle as well as to read and adjust the throttle level. If the implantation site is unfavourably chosen or the skin above the throttle is too thick (skin and tissue thickness greater than 10 mm), it may no longer be possible to locate the throttle as well as read and adjust the throttle level. The throttle then works with a fixed throttle level.**
- **The gravitational unit of the *M.blue* is posture-dependent. For that reason, care must be taken to implant the gravitational unit parallel to the body axis.**

Therefore, when using a shunt system in which the valve has been pre-fitted with a *Burrhole Reservoir* or a *SPRUNG RESERVOIR*, only the occipital access should be used.

Positioning of the *Peritoneal Catheter*

The access site for the *Peritoneal Catheter* is left to the surgeon's discretion. For example, it can be used in a paraumbilical application or applied at the level of the epigastrium. Likewise, various surgical techniques are available for placing the *Peritoneal Catheter*.

The recommendation is to pull the *Peritoneal Catheter* from the valve to the intended position using a subcutaneous *Tunneller*, if necessary with the aid of an auxiliary incision. The *Peritoneal Catheter*, usually securely attached to the valve, has an open distal end and no wall slits.

Following the exposure of the peritoneum or with the aid of a trocar, the *Peritoneal Catheter* (shortened if necessary) is pushed forward into the open space of the abdominal cavity.

4.5.6 POSTOPERATIVE TEST

Postoperative valve test

The *M.blue* has been constructed as a reliably functioning unit without pump or test function. The valve test can be performed by flushing, pressure measurement or pumping via a *Reservoir* or a *Prechamber*.

4.6 EXPLANTATION AND DISPOSAL

4.6.1 EXPLANTATION

The explantation of the *M.blue* should be performed according to the state of the art and in compliance with medical practice.

4.6.2 DISPOSAL

***M.blue* and shunt components**

Products and product parts not used in the implantation or surgically removed must be disposed of correctly as potentially infectious material in accordance with medical practice as well as respective regional laws and regulations.

4.7 TECHNICAL INFORMATION

4.7.1 MATERIALS THAT COME INTO CONTACT WITH BODILY TISSUE/ FLUIDS

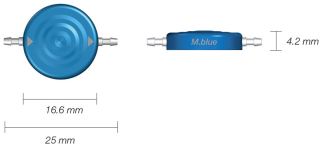
Quantitative material properties

All implantable parts of a shunt system with direct contact to body tissues or fluids are biocompatible and are composed as follows:

- Titanium alloy $TiAl_6V_4$ (ASTM F136)
- Titanium grade 1 (ASTM F67)
- Tantalum (ASTM F560)
- White sapphire Al_2O_3 (ISO 6474-1)
- Implant steel 1.4441 (ISO 5832-1)
- Silicone elastomer (long-term implantable)
- Polyester ligature

4.7.2 TECHNICAL DATA

Manufacturer	Christoph Miethke GmbH & Co. KG
Product designation	*M.blue*
Medical Purpose	Shunting of cerebrospinal fluid (CSF)
Sterilisability	Cannot be resterilised

Storage	Store in a clean and dry place room temperature
For single use only	
Sketch with outer dimensions: 	

4.8 SYMBOLS USED FOR LABELLING

Symbol	Explanation
CE xxxx	EU conformity marking, xxxx indicates the identifier of the responsible notified body
MD	Medical Device
	Manufacturer
	Date of manufacture
	Use by
LOT	Batch name
REF	Catalogue number
SN	Serial number
UDI	Unique Device Identification
UDI-DI	UDI-DI number
STERILE	Vapour or dry heat sterilised
2 STERILIZE	Do not resterilise
2	Do not reuse
	Double sterile barrier system
	Do not use if the packaging is damaged; and follow the instructions for use
	Store in a dry place
	Temperature limits
	Consult instructions for use / electronic instructions for use
	Caution

Symbol	Explanation
	Pyrogen-free
LATEX	Free of natural rubber latex, latex-free
Rx only	Indicates that in the USA, the product may only be issued to physicians.
MR	MR Conditional
?	Patient identification
31	During implantation
	Outpatient clinic or physician
	Website with patient information
#	Model number / European Medical Device Nomenclature Code

5 MEDICAL DEVICE CONSULTANTS

In compliance with regulatory requirements, Christoph Miethke GmbH & Co. KG has nominated medical device consultants as contacts for all product-related questions.
You can contact our medical device consultants at:
Tel. +49 331 62083-0
info@miethke.com

CE 0297

EN Technical alterations reserved

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