



M.blue[®]

THE BALANCED WAY OF LIFE
INSPIRED BY YOU



Instructions for Use



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1 Adjustable gravitational unit

2 Sapphire ball

3 Tantalum weight

4 Rotor

5 Differential pressure unit

6 Sapphire ball

7 Micro-coil spring

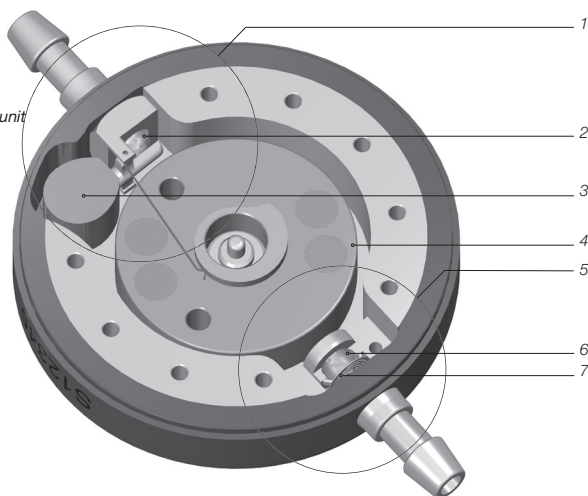


Fig. 1: Cross section of M.blue

CAUTION: Federal law restricts this device to sale by or on order of a physician!

INDICATION

The M.blue Adjustable Shunt System is used for cerebrospinal fluid (CSF) shunting.

CONTRAINDICATIONS

The implantation of medical devices is contraindicated if the patient has an infection or suspected infection (e.g. meningitis, ventriculitis, peritonitis, bacteraemia, septicaemia) in the region affected by the implantation.

WARNINGS

Frequent pumping can result in excessive drainage and thus lead to pressure conditions outside the normal physiological range. The patient should be informed

about this risk.

The catheters should only be blocked with a sheathed clamp and not directly behind the valve as they might be damaged otherwise.

Contamination in the solution used for testing can impair the product's performance.

Pressure admission through the single-use syringe should be avoided both at the proximal and the distal end .

The adjustable valve should not be implanted in an area that makes the detection or palpation of the valve difficult (e.g. underneath heavily scarred tissue).

When adjusting, please ensure that the opening pressure is changed by a maximum of 16 cmH₂O per adjustment process; otherwise errors may result.

X-ray confirmation may still be necessary for patients with scalp thicknesses greater than or equal to 5 mm thick.

The *M.blue plus Compass* should be placed centrally over the valve, otherwise incorrect determination of the opening pressure may occur.

If a magnetic field is being applied and pressure is applied to the valve at the same time, thus triggering the brake mechanism, it is not possible to rule out valve adjustment. In MRI imaging *M.blue* creates artefacts which are larger than the valve itself.

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

Because of the magnets inside the *M.blue plus Instruments*, *M.blue plus Instruments* may not be used in the vicinity of active implants such as heart pacemakers. Furthermore, there is risk of damage to MRI instruments in their vicinity. Therefore, usage of *M.blue plus Instruments* is forbidden in such locations!

For people using cardiac pacemakers: It is possible that the function of the pacemaker is influenced by the implantation of a *M.blue*.

Do not resterilize.

PRECAUTIONS

Patients must be carefully monitored after implantation. Reddening of skin or tightness in the area of the drained tissue may be indications of infections at the shunt system. Symptoms such as headache, dizziness, confusion or vomiting often occur in conjunction with shunt dysfunction. These symptoms and a leakage within the shunt system require the immediate replacement of the affected shunt component or the entire shunt system.

The entire implanted shunt valve and components system should be inspected to confirm the correct pressure settings and ensure there are no movements, kinks, or blockages in the relevant device system components using X-ray imaging immediately post-implantation procedure.

If the *M.blue* valve is implanted with other manufacturer's component, please refer to other manufacturer's corresponding directions for use.

ADVERSE REACTIONS AND INTERACTIONS

In the treatment of hydrocephalus with shunts, the following complications may arise (as described in the literature): Infections, blockages caused by protein and/or blood in the cerebrospinal fluid, over-/underdrainage or in very rare cases noise development, altered mental status, headaches, lethargy, irritability, vomiting, changes in vision, difficulty walking, loss of consciousness, seizures, hemorrhage, or death. Violent shocks for the outside (accident, fall) may put the integrity of the shunt system at risk.

TECHNICAL DESCRIPTION

M.blue is a valve made from 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 body position of the patient, the influence of the tantalum weight on the sapphire ball and thus the valve opening pressure changes. Via a rotor (4), the pretension of the torsion spring connected to the lever can be changed through the skin. This way, the influence of the tantalum weight on the sapphire ball can be influenced and thus 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.

FUNCTION OF THE VALVE

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

Horizontal position

In the horizontal position, the gravitational unit is always open and does not offer any resistance.

Consequently, the opening pressure of *M.blue* in the horizontal position is characterised by the fixed differential pressure unit pre selected at implantation to be either 0, 5, 10 or 15 cm H₂O. It is not adjustable. The main operation method used by the adjustable differential pressure unit is shown in Fig. 2a and b.

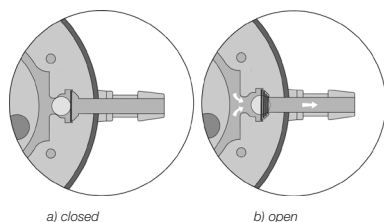


Fig. 2: Operation of the differential pressure unit

In Fig. 2a the valve is closed, hence drainage is not possible.

If the patient's intraventricular pressure (IVP) exceeds the spring force of the micro-coil spring, the sealing ball moves out of the cone, leaving a gap for CSF drainage (Fig. 2b).

Vertical position

As the patient's body moves from prone to vertical, the gravitational unit closes the discharge channel in the proximal part of the valve (Fig. 3a). Thus, the opening pressure of *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. Drainage is only possible once the sum of IVP and hydrostatic suction is greater than the opening pressure of both units (Fig. 3b). For individual adaptation of the opening pressure to the patient, a valve opening pressure between 0 and 40 cm H₂O can be selected for the adjustable gravitational unit.

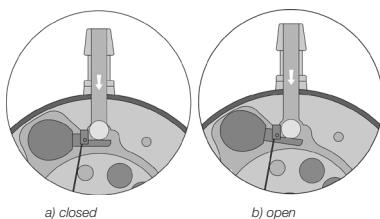


Fig. 3: Gravitational unit in vertical body position

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

SELECTION OF APPROPRIATE PRESSURE LEVEL

Horizontal position

In the lying position, the gravitational unit has no influence on the valve opening pressure. In this position, the valve opening pressure is thus determined exclusively by the differential pressure unit. In this case, the pressure level should be set in accordance with the clinical picture and indications. By default, a differential pressure unit with an opening pressure of 5 cm H₂O is recommended.

Vertical position

The *M.blue* opening pressure for the vertical body position is calculated from the sum of the opening pressure in the differential pressure unit and the adjustable gravitational unit. Patient height, activity level and potentially increased abdominal pressure (obesity) should be taken into account in selecting the opening pressure for the gravitational unit (see pressure level recommendations at <https://www.miethke.com/produkte/downloads/>).

This is a non-binding recommendation for the attending physician. According to his diagnosis, the physician decides each case independently, without instructions and individually.

PRESSURE RATING IDENTIFICATION IN X-RAY IMAGES

The selected pressure level for *M.blue* should always be verified using the *M.blue plus Compass* and x-ray template, but it can also be checked using an x-ray image. With the help of the X-Ray template - included in the *M.blue plus Instruments Set* - the adjusted opening pressure of the adjustable gravitational unit and the opening pressure of the fixed differential pressure unit can be identified. The rotor setting is decisive in this case. The four magnets in the rotor can be seen on the x-ray image as white points and are located opposite each other in pairs. Two additional burr holes (right and left next to the magnet pairs) on one side of the rotor can be used as orientation. They can be seen as black points on the x-ray image. This side can be designated as the rotor rear side. The two front magnets are on the opposite side. The space between these two magnets can be considered as the as the triangle tip. The pressure level can be read off using the orientation of this intermediate space (Fig. 4). The triangle tip can take up any position except the space labelled as a non-adjustable area in Fig. 4. This means that the opening pressure of *M.blue* can be variably adjusted from 0 up to 40 cm H₂O. In order not to read the pressure setting laterally reversed, in the plan view of the valve a recess with the tantalum weight to the right of the proximal connector is visible in the housing ring (Fig. 4).

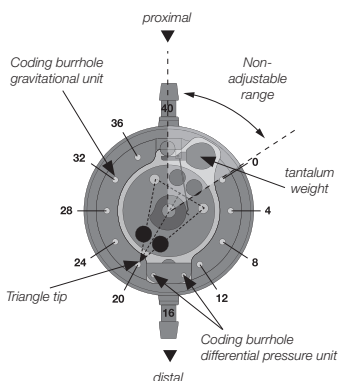


Fig. 4: Schematic representation of the *M.blue* valve in X-ray image

The direction of the triangle tip indicates the pressure setting of the gravitational unit.

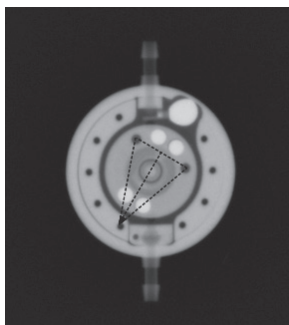


Fig. 5: X-ray image
(adjustable gravitational unit preset to 20 cmH₂O; differential pressure unit: 5 cmH₂O)

The pressure level of the differential pressure unit can be recognised in the X-ray image by the encoding (Fig. 5). The following pressure levels are possible for the differential pressure unit:

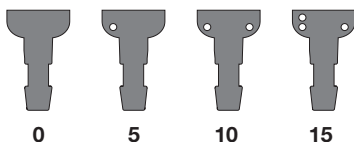
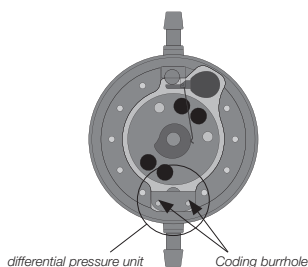


Fig. 6: Pressure ratings encodings of the differential pressure unit

APPLICATION OF *M.blue plus Instruments*

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

The *M.blue plus Compass* is used for localizing and reading the adjustable gravitational

unit of M.blue.

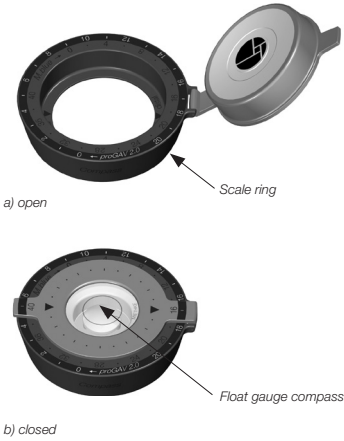


Fig. 7: M.blue plus Compass

With the M.blue plus adjustment ring the opening pressure of M.blue can be variably adjusted from 0 to 40 cmH₂O.



Fig. 8: M.blue plus adjustment ring

The opening pressure for the adjustable gravitational unit can be changed before or after implantation. It is preset by the manufacturer to 20 cmH₂O. Please carry out the following steps to adjust the valve:

1. Localizing

When the M.blue plus Compass is opened, a circular template becomes visible with which you can localize the valve in the patient's head using your index finger (Fig. 9).



Fig. 9: Localizing the valve using the M.blue Compass

The direction markings on the template show the flow direction.

2. Test procedure

In order to determine the selected pressure level, the compass is then closed again. The float gauge should now be centred by moving the instrument in the designated circular marking (Fig. 10). Once the float gauge is centred, the currently set opening pressure of the gravitational unit can be read off via the line mark on the float gauge (Fig. 10).

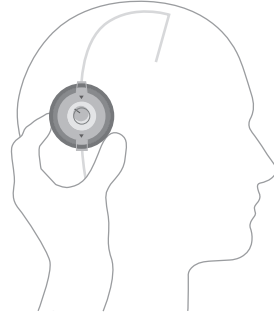


Fig. 10: Determination of the pressure level with the M.blue Compass

There are two scales on the scale ring. The opening pressure of the M.blue gravitational unit is set to the blue marked adjustment range of 0 - 40 cmH₂O of the inner scale.

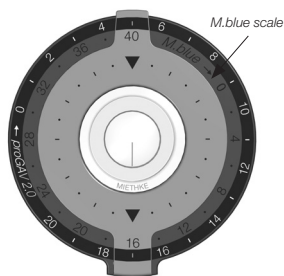


Fig. 11: Inside: M.blue scale of 0-40 cmH₂O (opening pressure of the gravitational unit in the picture example is 16 cmH₂O)

CAUTION: The *M.blue plus Compass* should be placed centrally over the valve, otherwise incorrect determination of the opening pressure may occur.

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 in the immediate vicinity of the *M.blue plus Compass* when the opening pressure is being determined. We recommend a minimum distance of 30 cm.

NOTE: Possible air bubbles inside the Compass do not affect its functionality.

3. Adjustment process

In order to adjust the opening pressure, the compass is opened, but without changing the position of the scale ring. The 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. 12)

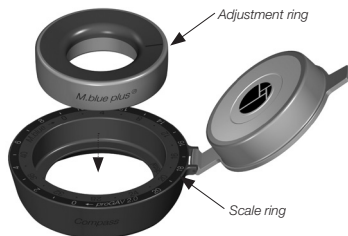


Fig. 12: Insertion of the adjustment ring

The opening pressure of the *M.blue* gravitational unit uses the adjustment range of 0 - 40 cmH₂O of the blue inner scale.



Fig. 13: Adjustment of the gravitational unit of *M.blue* (in the picture example to 32 cmH₂O)

By applying slight pressure with the index finger to the valve diaphragm located in the centre of the adjustment ring and under the skin, the rotor brake is released and the opening pressure of *M.blue* is changed to the desired value (Fig. 14).

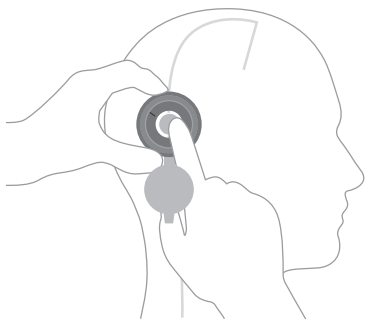


Fig. 14: Adjustment using the *M.blue plus adjustment ring*

M.blue is equipped with a feedback mechanism. If targeted pressure is exerted on the valve, an acoustic signal (a clicking sound) is audible, or a resistance can be felt to give, as soon as the rotor brake has been released due to the valve housing design. In other words the valve shows both acoustically and haptically when the pressure is sufficient for uncoupling of the brake. Once this pressure has been released the rotor is adjustment-proof again. Although the click caused by releasing the rotor brake is easily audible before implantation, this can be considerably reduced after implantation. This can be due

to the CSF filling the valve, its position and the condition of the implants surroundings. Normally, however, it should be audible to the patients themselves or through the use of a stethoscope.

Adjustment with 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 adjustment ring aligned to the desired value and press it with your index finger (Fig. 15).



Fig. 15: *M.blue plus Adjustment Assistant*

WARNING: When adjusting, please ensure that the opening pressure is changed by a maximum of 16 cmH₂O per adjustment process; otherwise errors may result.

Example: The opening pressure is to be changed from 6 to 36 cmH₂O. The correct method is an adjustment in two stages: Initial adjustment from 6 to 22 and subsequently from 22 to 36 cmH₂O.

CAUTION: The *M.blue plus adjustment ring* emits a magnetic field. Metallic objects and magnetic storage media should be placed at a sufficient safety distance.

4. Checking after adjustment

After adjusting the valve opening pressure, it is recommended to check the selected opening pressure. To do this, please proceed as in Points 1 and 2. If the measured pressure does not agree with the required pressure settings the adjustment process should be repeated. To do this, please start at Point 3 again. Adjustment can be made difficult by swelling of the skin for a few days after the operation!

If checking the valve setting is not 100% possible using the *M.blue plus Compass*, we recommend

carrying out a check using an imaging method.

M.blue Check-mate

The *M.blue Check-mate* is supplied sterile and can be resterilized. With the *M.blue Check-mate* it is possible to carry out a pressure level change and the check before and during valve implantation directly on *M.blue*. To determine the pressure level the *M.blue Check-mate* is placed centrally on *M.blue*. The *M.blue Check-mate* automatically aligns itself over the valve. The pressure stage can be read off from the catheter in the proximal (leading to valve) direction.

If the pressure level is supposed to be adjusted, the *M.blue Check-mate* is placed centrally on *M.blue*. When doing so, the required pressure stage must point towards the proximal catheter (leading to valve). If the *M.blue adjustment gyroscope* is now pressed lightly onto the valve, the rotor brake in *M.blue* is released and the pressure level is set.

When adjusting, please ensure that the opening pressure is changed by a maximum of 16 cmH₂O per adjustment process otherwise errors can result (see Chapter "3. Adjustment process").



Fig. 16: *M.blue Check-mate*, colour: blue, pressure levels 0-40 cmH₂O

CAUTION: Because of the magnets inside the *M.blue plus Instruments*, *M.blue plus Instruments* may not be used in the vicinity of active implants such as heart pacemakers. Furthermore, there is risk of damage to MRI instruments in their vicinity. Therefore, usage of *M.blue plus Instruments* is forbidden in such locations!

It is absolutely essential to use only the *M.blue plus Instruments* to determine, adjust and monitor the opening pressure of *M.blue*.

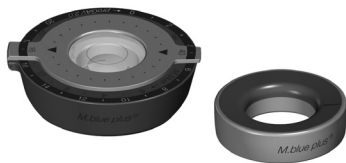


Fig. 17: M.blue plus Instruments

M.blue WITH proGAV 2.0 (M.blue plus)

The instruments can also be used for localizing, reading and setting the adjustable differential pressure unit of proGAV 2.0.

When combining the M.blue valve with the adjustable differential pressure unit of the proGAV 2.0, the M.blue valve is localised, checked and adjusted as described under points 1-4. The adjustable differential pressure unit (proGAV 2.0) can also be localised, checked and adjusted to a desired value between 0 and 20 cmH₂O with the M.blue plus Instruments, as described under points 1-4. For the opening pressure of the adjustable proGAV 2.0 differential pressure unit, the grey adjustment range of 0 - 20 cmH₂O on the outer scale of the scale ring applies (Fig. 18).

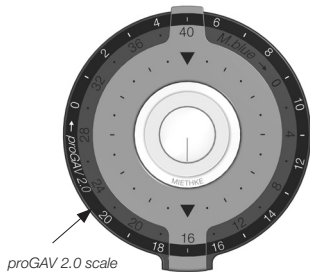


Fig. 18: Outside: proGAV 2.0 scale of 0-20 cmH₂O (opening pressure of the adjustable differential pressure unit (proGAV 2.0) in the picture example is 17 cmH₂O)

If the pressure configuration of the valve cannot be determined with complete certainty by the M.blue plus Compass, the use of imaging techniques is recommended (excluding MRI: danger of artefacts). MRI examinations must be performed at field strengths no greater than 3.0 tesla. Caution: If the site of implantation is poorly selected or if the skin over the valve is too thick, an adjustment of the adjustable unit can be difficult or sometimes impossible. The

adjustable gravitational unit then behaves like a gravitational unit with a fixed opening pressure for a given position.

The following table shows the quantitative information regarding the overall agreement rates between the X-ray and the respective verification tool for the M.blue valve. The maximum deviation from the actual valve readings used were 0, ≤ 1 , ≤ 2 , > 2 cmH₂O. For example at ≤ 2 cmH₂O 100 % of the measurements made by the M.blue plus Compass with the M.blue valve deviate not more than ± 2 cmH₂O from the actual value of the valve. The agreement rates are based on non-clinical testing with readings of 15 valves by 15 clinical users under simulated use conditions, yielding a total of 225 readings.

	= 0 cmH ₂ O	≤ 1 cmH ₂ O	≤ 2 cmH ₂ O	> 2 cmH ₂ O
M.blue plus Compass				
proGAV 2.0	60.4 %	99.6 %	100 %	0.0 %
M.blue	56.0 %	88.0 %	100 %	0.0 %

MRI examinations must be performed at field strengths no greater than 3.0 tesla.

NOTE: Please refer to the MRI Safety Information section of this Instructions for Use for MR-related safety information.

POSSIBLE SHUNT COMPONENTS

M.blue can be ordered as a shunt system in a range of configurations. These configurations can be combined with the accessories presented below. In each case, versions for paediatric hydrocephalus and for hydrocephalus in adults are available.

Reservoirs

The use of a reservoir in combination with shunt systems provides options for the withdrawal of cerebrospinal fluid, administration of drugs and pressure control.

Thanks to an integrated check valve in the SPRUNG RESERVOIR and the CONTROL RESERVOIR, cerebrospinal fluid can be pumped towards the valve, thus making it possible to

check the distal part of the drainage system as well as the valve catheter. During the pump action, access to the ventricular catheter is closed. The use of reservoirs does not increase the opening pressure of the shunt system. Puncturing the reservoir should be performed as perpendicular as possible to the reservoir surface with a maximum cannula diameter of 0.9 mm. A stable titanium floor prevents the bottom surface from being pierced. 30 punctures are possible without any restrictions.

WARNING: Frequent pumping can result in excessive drainage and thus lead to pressure conditions outside the normal physiological range. The patient should be informed about this risk.

Burrhole deflector

Because of the tight fit on the ventricular catheter, the burr hole 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 "Implantation").

TUBE SYSTEMS

M.blue can be ordered as an individual valve unit or as a shunt system with integrated catheters (interior diameter 1.2 mm, exterior diameter 2.5 mm). The supplied catheters do not fundamentally change the pressure-flow characteristics. If catheters by other manufacturers are used, a tight fit must be ensured. In any case, catheters have to be carefully fixed with a ligature to the valve's titanium connectors.

IMPLANTATION

Positioning of the ventricular catheter

Several surgical techniques are available for positioning the ventricular catheter. The required skin incision should be made in form of a lobule pedicled towards the draining catheter. If a burr hole deflector 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 a burr hole reservoir or a *SPRUNG*

RESERVOIR is used, then the ventricular catheter is implanted first. Once the introducing stylet 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 burr hole reservoir connected, with the connection secured with a ligature. When using a shunt system with a *CONTROL RESERVOIR*, a burr hole deflector is included. The deflector is used for adjusting the length of catheter to be implanted and for its positioning inside the ventricle. The ventricular catheter is deflected, and the *CONTROL RESERVOIR* is put into place. Post procedural inspection of the entire implanted valve and component system should be obtained with either X-ray or CT imaging.

Positioning of the valve

The adjustable gravitational unit in *M.blue* is set to an opening pressure of 20 cmH₂O upon delivery. This opening pressure can be changed to a different pressure before implantation.

A location behind the ear is suitable as an implantation position, whereby the implantation height has no influence on the valve function. The adjustable valve 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 incision with a pocket for the valve should be made. The catheter is then pushed forward from the burr hole to the selected valve implantation location, shortened if necessary, and secured to the *M.blue* with a 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 embossed blue surface of the valve with the arrow markings points to the outside.

Therefore, if a shunt system in which the valve has been pre-fitted with a burr hole reservoir is being used, only the occipital access should be used.

NOTE: *M.blue* is position-dependent. For that reason, care must be taken to implant the valve parallel to the body axis.

CAUTION: The catheters should only be blocked with a sheathed clamp and not directly behind the valve as they might be damaged otherwise.

Positioning of the peritoneal catheter

The access site for the peritoneal catheter is left to the surgeon's discretion. For example, it can be applied paraumbilical or at the height of the epigastrium. Likewise, various surgical techniques are available for positioning the peritoneal catheter. The recommendation is to pull the peritoneal catheter using a subcutaneous tunnelling tool from the valve to the intended position, if necessary with the aid an auxiliary incision. The peritoneal catheter that is usually securely attached to *M.blue* 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.

VALVE TEST

Preoperative valve test

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 continuous if saline solution can be extracted (Fig. 19).

WARNING: Contamination in the solution used for testing can impair the product's performance.

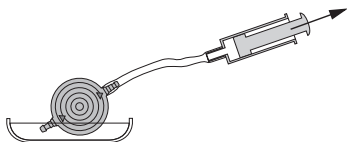


Fig. 19: Patency test

WARNING: Pressure admission through the single-use syringe should be avoided both at the proximal and the distal end (Fig. 20).

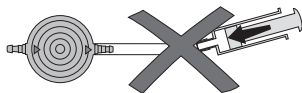


Fig. 20: Avoidance of pressurisation

VALVE TEST PRIOR TO IMPLANTATION

Each *M.blue* valve has been tested to ensure that the performance specifications given on the label are always met. The dynamic performance characteristics of the shunt cannot be tested in a static test performed in the operating room. If the surgeon wishes to verify, prior to implantation, that the shunt meets the specifications given by the manufacturer, the following test can be performed in the operating room. Caution: Always take care that sterility is maintained and particle contamination is avoided.

Test method

Equipment required for this test:

- sterile fluid reservoir or water bath
- sterile fluid 60-cm water manometer with millimeter grading and three-branch faucet at the base
- sterile syringe, 30 cc to 50 cc
- sterile 5- μ tip filter
- sterile tube adapter
- sterile silicone tube

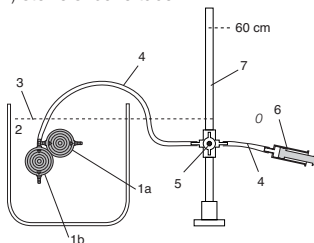


Fig. 21: Test setup

- M.blue* a) horizontal, b) vertical
- water bath, 3. constant water level, 4. silicone tube, 5. three-way tap, 6. single-use syringe with syringe filter, 7. manometer

Setting up the equipment

- Position the manometer and the water bath in such a way that the zero point of the manometer and the fluid level of the water bath are at the same height (Fig. 21).
- Fill the syringe, with the 5- μ tip filter attached, with sterile water (always use the 5- μ tip filter when topping up the syringe). Remove the tip filter when the syringe is full.
- Connect the syringe, the manometer and the silicone tube. Use the tube adapter if necessary (Fig. 21).

- d) To release all air from the test assembly, turn the three-way faucet as shown in Fig. 22.
- e) Immerse the silicone tube in the sterile water bath and rinse it with the sterile water from the syringe.

Calibrating the equipment

- a) Turn the three-way faucet as shown in Fig. 23 and fill the manometer to at least 5 cmH₂O.
- b) With the silicone tube immersed in the water bath, turn the three-way faucet so that the syringe is isolated from the manometer (see Fig. 24).
- c) Allow the water column in the manometer to drop.
- d) The water column should stop dropping at the zero point. Adjust the zero point of the manometer to fluid level of the water bath, if necessary.
- e) The manometer has now been calibrated to the zero-level of the water bath. Fixate the manometer to maintain its position in relation to the water bath.

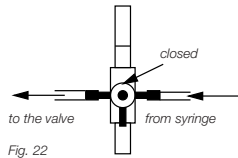


Fig. 22

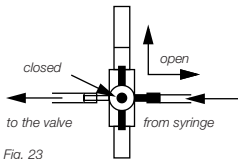


Fig. 23

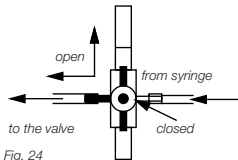


Fig. 24

Test procedure

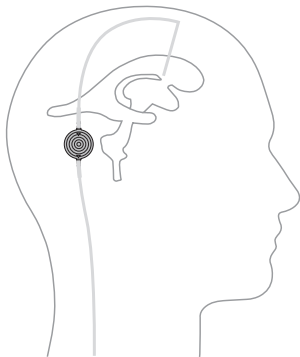
Please note: During the test the shunt must be submerged in the water bath. The zero point of the manometer must be aligned with the water level of the water bath in order to obtain correct results.

- a) Connect the sterile shunt to be tested to the already assembled, sterile test equipment.
- b) Turn the three-way faucet as shown in Fig. 23 and fill the manometer to 10 cmH₂O above the expected opening pressure. (Example: For testing a *M.blue*, having an opening pressure setting of the fixed DP-unit of 5 cmH₂O and the adjustable gravitational unit of 20 cmH₂O, the manometer is filled to 15 cmH₂O with the shunt in the horizontal position and to 35 cmH₂O with the shunt in the vertical position).
- c) Turn the three-way faucet as shown in Fig. 22 so that the manometer is isolated
- d) Remove all air from the shunt and the test setup by carefully rinsing it through with sterile water from the syringe.
- e) Immerse the sterile shunt in the sterile water bath. The distal part of the shunt must be under water to obtain valid test results.
- f) Carefully maintain a flow through the shunt and turn the three-way faucet as shown in Fig. 24 to isolate the syringe. As soon as the three-way faucet is in the correct position, the water column should begin to drop. The syringe is now isolated from the valve and it is not necessary anymore to maintain its flow. Repeat steps b) to f) if the water column fails to drop.
- g) Allow the water level in the manometer to drop for 2 to 2.5 minutes. Read the resulting pressure at the manometer

**TEST RESULTS OF
PREIMPLANTATION TEST**

The following table shows results, which should be achieved by this method, for some selected pressure levels:

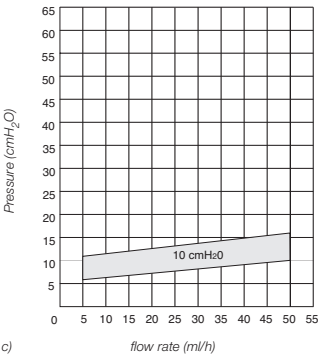
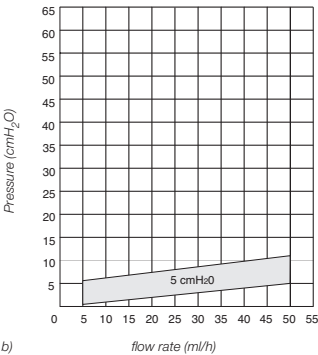
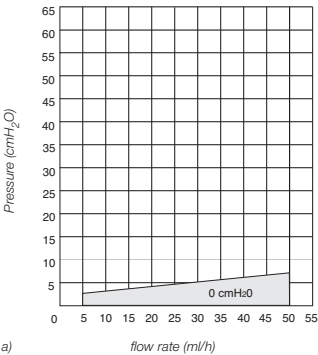
Pressure rating (cmH ₂ O)		Acceptable pressure ranges (cmH ₂ O)	
DP-unit	gravitational unit	horizontal posture	vertical posture
0	0	0-5	0-6
0	20	0-5	10-25
0	40	0-5	20-45
5	0	0-8	0-8
5	20	0-8	12-30
5	40	0-8	22-50
10	0	5-15	5-15
10	20	5-15	15-35
10	40	5-15	25-55
15	0	7-20	7-20
15	20	7-20	17-40
15	40	7-20	27-60



PRESSURE-FLOW CHARACTERISTICS

Horizontal position

The pressure flow characteristics for the M.blue differential pressure unit are shown below for pressure levels 0, 5, 10 and 15 in the horizontal valve position.



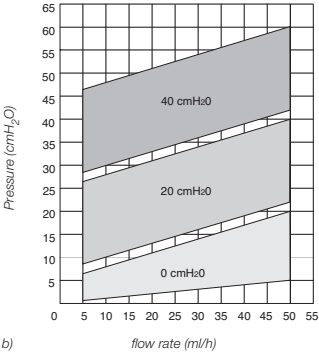
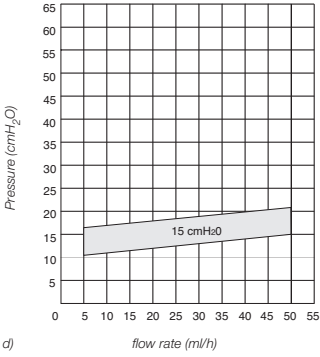


Fig. 25: Pressure-flow characteristics of selected pressure levels of M.blue in the horizontal body position: a) M.blue 0 b) M.blue 5 c) M.blue 10 d) M.blue 15

Vertical position

In the vertical body position, the M.blue opening pressure is based on the setting of the differential pressure unit and the adjustable gravitational unit. The pressure flow characteristics for various pressure stage settings in the vertical body position are shown below.

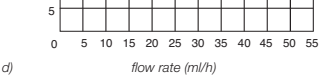
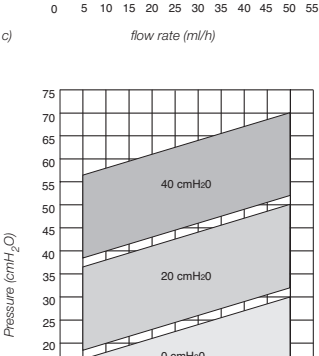
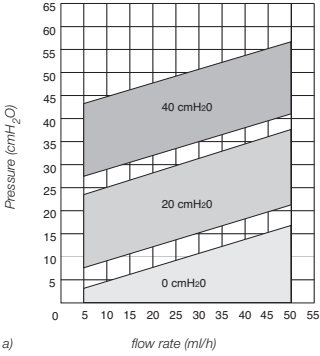


Fig. 26: Pressure-flow characteristics of selected pressure levels of M.blue in the vertical body position: a) M.blue 0 b) M.blue 5 c) M.blue 10 d) M.blue 15

The opening pressure refers to a reference flow of 20 ml/h.

TEST ON REFLOW SAFETY

This test is carried out with the same equipment as the pre-implantation test. The shunt is carefully filled with sterile saline solution from the syringe before the air is removed from it (Fig. 27). The shunt is connected against the direction of flow (see arrow on the shunt). The outlet of the shunt has to be at the zero level of the manometer. The manometer is filled up to 14 cmH₂O (Fig. 28). The three-way faucet is used for unblocking the flow to the shunt and blocking the flow to syringe. In this setup, no more than 2 drops (0.1 cc) per minute should emerge from the proximal part of the shunt (Fig. 29). Caution: Be careful to maintain sterility and to avoid particle contamination.



Fig. 27

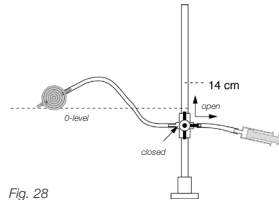


Fig. 28

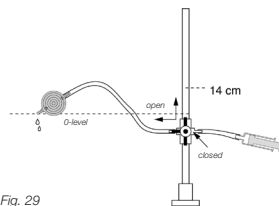


Fig. 29

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.

FUNCTIONAL SAFETY AND COMPATIBILITY WITH DIAGNOSTIC PROCEDURES

These medical devices are constructed in such a way as to ensure their precise and reliable operation over long periods of time. However, no

guarantee can be given that these medical devices may not require replacement for medical or technical reasons. These medical devices are able to resist positive and negative pressures up to 200 cmH₂O during and after implantation. These medical devices have to be stored in a clean and dry environment at all times.

Nuclear magnetic resonance (MRI) examinations up to a field strength of 3 Tesla or computed tomography (CT) examinations can be performed without risk or impairment to the valve function. The valve is MR conditional. The supplied catheters are MR safe. Reservoirs, deflectors and connectors are MR conditional.

WARNING: If a magnetic field is being applied and pressure is applied to the valve at the same time, thus triggering the brake mechanism, it is not possible to rule out valve adjustment. In MRI imaging *M.blue* creates artefacts which are larger than the valve itself.

Sequence (plane/ axis)*	Signal Void
T1-SE (parallel/long)	2,089 mm ²
T1-SE (perpendicular/short)	1,658 mm ²
GRE (parallel/long)	4,273 mm ²
GRE (perpendicular/short)	4,342 mm ²

MRI SAFETY INFORMATION

The *M.blue* programmable valve was determined to be MR Conditional (ASTM F2503- 13). According to the results of in vitro testing, a patient with the *M.blue* may undergo an MRI procedure using an MR system with a static magnetic field of 3T or less. No impact on the performance of the *M.blue* at 3T or less can be expected.

Non-clinical testing demonstrated that the *M.blue* Cerebral Spinal Fluid (CSF) Shunt Valve is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 500-Gauss/cm
- Maximum MR system reported, whole body

averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the First Level Controlled Operating Mode.

· Do not take the M.blue tools into the MR environment. They are MR Unsafe.

Under the scan conditions defined, the *M.blue* Cerebral Spinal Fluid (CSF) Shunt Valve is expected to produce a maximum temperature rise of 4.2°C after 15-minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by the *M.blue* Cerebral Spinal Fluid (CSF) Shunt Valve extends approximately 20-mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

NOTE: Important Note: To confirm that the setting of the *M.blue* Cerebral Spinal Fluid (CSF) Shunt Valve was not altered by exposure to MRI, the pressure setting can be checked using the *M.blue plus Compass* device before and after the MRI examination.

As such, the *M.blue* should not be placed in close proximity to a location, which may require an MR image. Above is a chart containing the signal void associated with the *M.blue* as tested to ASTM F 2119-07 using a 3 Tesla MR-scanner Excite General Electric Healthcare. The temperature measurement at 3T and 1,5 T showed no increased temperature caused by the implant in a worst-case scenario (static liquid) test performed at a whole-body averaged SAR of 4 W/kg. The results imply, that no additional risk due to radio frequency induced heating is caused to the patient, if the valves are implanted. Testing was conducted in accordance to ASTM F2182-11a. The *M.blue* had relatively minor magnetic field interaction, passing the deflection testing of ASTM F2052-15 with no torque produced (ASTM F2213-06) and a 23-degree deflection angle. Therefore the *M.blue* will not present an additional risk or hazard to the patient with the regards to deflection or torque in the environment of a 3 T magnetic resonance tomography.

STERILIZATION

The products are sterilized with steam under strictly controlled conditions. The double wrapping in sterile bags ensures sterility for a five-year period. The expiry date is printed on the wrapping of each individual product. If the packaging is damaged, the product must not be used in any circumstances.

REQUIREMENTS OF THE MDD (DIRECTIVE 93/42/EEC)

The Medical Device Directive requires comprehensive documentation of the whereabouts of medical devices used in humans, especially for implants. The individual identification number of the implanted valve should therefore be recorded in the patient's medical records and patient passport to ensure complete traceability.

NOTE ON THE INSTRUCTIONS FOR USE

The descriptions and explanations given in this document are based on the clinical experience available to date. It is for the surgeon to decide if surgical procedures should be changed according to his or her experience and to surgical practice.

MEDICAL DEVICES CONSULTANT

In compliance with European directive on medical devices (directive 93/42/EEC), Christoph Miethke GmbH & Co. KG has nominated medical product consultants as contacts for all product-related questions

Dipl.-Ing. Christoph Miethke
Dipl.-Ing. Roland Schulz
Michaela Funk-Neubarth
Dipl.-Ing. Thoralf Knitter
Dr. Andreas Bunge
Jan Mgel
Dipl.-Ing. Thammo Weise

Contact details can be found on the reverse of these instructions for use.

Please address any enquiries to:
AESCULAP AG

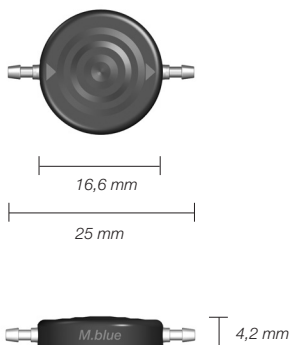
Am Aesculap Platz
78532 Tuttlingen, Germany
Phone: +49 7461 95-0
Fax: +49 7461 95-26 00
E-mail: information@aesculap.de

Service address in the US
AESCULAP Inc.
Attn. AESCULAP Technical Services
615 Lambert Pointe Road
Hazelwood, MO, 63042

AESCULAP Repair Hotline
Phone: +1 (800) 214-3392
Fax: +1 (314) 895-4420

Distributor in the US/ Contact in Canada
AESCULAP Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Phone: +1 (800) 282-9000
www.aesculapusa.com

DIMENSIONS





 CE marking according to directive 93/42/EEC

 Technical alterations reserved

Manufacturer:



Christoph Miethke GmbH & Co. KG | Ulanenweg 2 | 14469 Potsdam | Germany
Phone +49 331 62 083-0 | Fax +49 331 62 083-40 | www.miethke.com

注册人: Christoph Miethke GmbH & Co. KG 克里斯托福弥提柯股份有限公司
住所: Ulanenweg 2, 14469 Potsdam, Germany
联系方式: www.miethke.com, info@miethke.com

Distributor:



Aesculap AG | Am Aesculap-Platz | 78532 Tuttlingen | Germany
Phone +49 7461 95-0 | Fax +49 74 61 95-26 00 | www.bbraun.com

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