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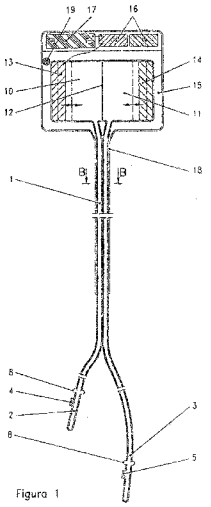

Figura 1

(57) Abstract: The invention refers to a set of devices used in the peritoneum filtration, a new medical method which replaces the hemodialysis, the peritoneal dialysis, hemodiafiltration and hemofiltration. The set of devices for the peritoneum filtration, according to the invention, has in its structure : a double lumen catheter (1) type balloon, in which the two lumens, after a common proximal part, is separated in a bifurcation in two branches (2, 3), which are chirurgical located in the right suprahepatic vein and right porta vein and through the variable diameter of the balloon (8) determines the controlled obstruction of these veins; close to each end further from de balloons 8, is located one of the preussure sensors (4, 5) which permanently measure the pressure from the cathetered veins and transmits the information to a command modulus (9); a command modulus (9) which monitors and controls the pressure from the catheterized veins, is in direct link with the proximal end of the double -lumen catheter (1), is subcutaneous implanted in the right under the clavicle area and it is programmed to action at the modifications of pressure detected by the pressure sensors (4, 5); a vesicle device through which the liquid accumulated in the abdomen gravitationally lowers into the urinary bladder and is chirurgical implanted at the level of the superior cap of the urinary bladder, device which is made of a action module, action from exterior through a remote and a vesicle element situated above the modulus. The method for the peritoneum filtration using the

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set of devices according with the invention, consists of an internal double obstruction of the right suprahepatic veins and of the right branch of the porta vein through introducing in these veins of the two branches 3 and 4 of the double lumen catheter balloon type, the narrowing done by the balloons (8) being permanent,with maximum of 50% stenosis, in concordance with the pressure from the suprahepatic veins, minitored by the system, portal hypertension being maintained between the limits of 12-18 mmHg through double adjustment of the two obstructions and the possibility to monitor by the command modulus 9 of the quantity of ascites obtained in the abdomen.

Set of devices for peritoneofiltration and the usage of it

The invention refers to a set of dispositive used for peritoneofiltration, a new medical method which replaces the hemodialysis, peritoneal dialysis, hemodiafiltration and hemofiltration.

Dialysis is the method of eliminating the residues, toxins and water excess from the blood and to re-establishment of hydroelectrolytic equilibrium. These functions are normally accomplished by the kidneys. The main forms of dialysis are hemodialysis and peritoneal dialysis. Right now hemodialysis and peritoneal dialysis are the used methods to eliminate the toxins from the body, in the case of the patients with renal insufficiency, the patients with kidneys that are incapable of functioning in eliminating the ingested toxins and the toxins that are resulted from metabolism. Dialysis is indispensable in the case of chronic renal insufficiency - terminal phase - when the renal function is reduced under 10-15% from normal values.

Hemodialysis removes residues and the excesses of water through the blood circulation through a filter, exterior-dialyzer which contains a semi-permeable membrane. The blood flows in a specific direction of the membrane, and the dialyzer in the other direction. The exchange is made depending on the dimensions of the dialyzed substances, the dimension of pores from the dialysis membrane, the positive pressure that is artificially created in the sanguine compartment or the negative pressure from the compartment of the solution from dialysis. The pressure modifications from the two compartments allow an ultra-filtration of the water when the level of fluid can induce arterial hypertension and cardiac insufficiency which happens to the patients with renal sclerosis.

In the peritoneal dialysis the residues and water are removed from the blood in a compartment found entirely in the body, using the natural peritoneal membrane, through an "exchanged dialysis". The pores from the peritoneum are bigger than the ones in the artificial membranes and assure a better purge of the molecules with medium weight. The residues and the water are accumulated in a special solution of dialysis which is introduced in the abdominal cavity which has a similar composition as the fluid composition of the blood. This method starts firstly by a chirurgical handle, which consists of introducing in the peritoneal cavity a "peritoneal catheter".

The peritoneal catheter is a tube realized from a plastic material, flexible but resistant. One of the heads of this catheter remains in the abdomen and the opposite head remains in the exterior of the abdomen through the whole period of the peritoneal dialysis. The catheter has at the end of the part which remains in the abdomen a perforated portion, which permits the growth of the capacity of diffusion of the dialysis liquid and also the taking of it to transfer it outside the body after a specific time. Through this tube it is introduced in the peritoneal cavity a quantity of 1.5 up till 2 L of dialysis liquid, creating an "artificial ascitis". The artificial asciting fluid it's introduced in the abdomen from exterior by the specialized medical personnel or by the patient. During the time in which the dialysis liquid remains in the abdomen, it is the actual exchange of substances, in which the peritoneum serves as a dialysis membrane. After the liquid is left in the abdomen for approximately 4 hours, the dialysis liquid loaded with water and other toxic dialyzed substances is evacuated gravitationally; the patient is connected to a dialysis set, it removes the liquid from the abdomen in the collecting recipient and it replaces it with a new quantity of fresh liquid, without toxins. This peritoneal dialysis method presents a major risk of bacterial super infection and presents the disadvantage of faster ageing of the peritoneum due to the usage of it during the process of transmembranal exchange which takes place continuously; the glucose solution that is introduced in the abdominal cavity and is in permanent contact with the peritoneum is in time irritated(by degradation producers of glucose and harmful substances derived from the plastic material of the dialysis bags) and it can increase the risk of appearing of sugar diabetes.

Another well-known system of dialysis is hemofiltration. Hemofiltration is a technique of continuous external purging representing an alternative to hemodialysis for patients with acute renal insufficiency in critical state, being relatively practiced in intensive therapy branch. Hemofiltration presents a lot of principal similarities with hemodialysis. In both techniques it is necessary the access to the patient's blood circulation and the blood passes an external (out of the body) circuit. However the mechanisms through which the blood composition is modified are different. Under pressure the blood enters in contact with a membrane with a high permeability, allowing the passage of water and of heavy molecular substances through a convective mechanism, similar with the physiological glomerular filtration.

Peritoneofiltration is a new method which means a new method of "auto dialysis" which can replace other methods of dialysis. It is different from all known dialysis methods, by making it possible for a in situ natural" dialysis, using peritoneum as a membrane for dialysis and simulating a production of its own ascites fluid.

Peritoneofiltration, as a new method makes the object of the patent peritoneofiltration, according to the application of patent 2010 00002/ 4.01 .2010, which consists in creating of an artificial ascites by increasing the sanguine pressure to the veins level using the peritoneum as a filtration membrane and creating the possibility to evacuate the ascites fluid directly into the urinary bladder.
Peritoneofiltration is realized chirurgical, introducing into the body devices for obtaining a portal hypertension which determines the hypertension in the mesenteric vessel; this leads to accumulation of the ascites fluid in the abdomen, liquid which can be eliminated directly in the urinary bladder due to the chirurgical maneuvers of implantation of devices in the walls of the urinary bladder.

Therefore, the devices necessary to realize a peritoneofiltration serve to the chirurgical technique ways to obtain an artificial ascites formed exclusively from the liquid accumulated in the patient's abdomen. This "artificial ascites"created by portal hypertension is similar to the peritoneal fluid which patients diagnosed with hepatic cirrhosis are producing.

The set of elements according to the application of patent 2010 00002/ 4.01 .2010 is made of a cuff on the portal vein, the level of constriction of the cuff being controlled and programmed with the help of a remote controller which is connected with an electrical circuit embedded in the cuff and in a device having a valve, mounted in a slit chirurgical at the level of the superior walls of the bladder. A prosthesis Gore-Tex is also chirurgical mounted at the level of the superior walls of the bladder. The valve assures the liquid which is accumulated in the peritoneum to pass in one way and it opens at a certain exercised pressure, respectively at a certain artificial ascites, the interior of the urinary bladder being maintained permanently dilated by the Gore-Tex prosthesis chirurgical mounted in the bladder, assuring a minimum interior cavity which will permit the gravitational elimination of the artificial ascites, throUgh the bladder, almost the same as eliminating the physiological urine.

In this new method, which is the peritoneofiltration method, the peritoneum is used as a natural dialysis membrane, without being necessary another exterior intervention during the usage of this method. More precise, the dialysis is exclusively done by the organism and the result is an evident improvement to the quality of the patients life patients which need dialysis or which used one of the other two methods well known of dialysis.

The problem which is solved by the presented invention it is a safety method used by the peritoneofiltration, more precisely obtaining a higher, safer procedure in realizing the portal hypertensions by the possibility of effective control and a more safer of it but also of the maintaining of the hypertension in the limited values of 12-18mmHg, as well as maintaining the normal limits of the volemia (maintaining of the dry weight) with deviations of maximum - 5% to +10% from the weight, all of these, through the findings of a new technical mode of realization of portal hypertension, new one, not the one mentioned in the application of patent 2010 00002/ 4.01 .2010.

The set of devices according to this invention is build from:

a) A double lumen catheter balloon type, in which the two lumens, after a proximal common part is separated by a bifurcation and the paths are separated as two separate catheters, in two branches, which are chirurgical located in the right suprahepatic veins and right port and through the variable diameter of the balloons, which are created at the ends

of the two branches, determines a controlled obstruction of these veins; near each end, distant from the balloons, is located one 4 and 5 pressure sensor which permanently measure the pressure from the veins which were catheter and transmits the information to a command modulus ; close to each end, far from the balloons with variable diameters, is located a pressure sensor which permanently measures the pressure from the veins which were catheter.

b) A command modulus directly connected at the proximal end of the double lumen catheter which monitor and control the pressures from the veins which were catheter, being implanted subcutaneous under the right clavicle bone and programmed to operate to the modifications of pressure detected by the pressure sensors.

c) A vesicle device through which the liquid accumulated in the abdomen gravitationally lowers into the urinary bladder and which is chirurgical implanted at the superior urinary bladder's cap, element which is constituted from an action modulus , acting from the exterior through a remote and a vesicle element situated above the action modulus ;

The peritoneofiltration method using the set of devices corresponding to the invention uses a double internal obstruction into the right suprahepatic vein and at the right branch of the portal vein by introducing in these veins the two branches of the double lumen balloon type catheter, the realized constriction will be permanent, with maximum of 50% of stenosis , in concordance with the pressure from the suprahepatic veins, monitored by the system, the portal hypertension will be maintained between the limits of 12-18mmHg through the double adjustment of the obstructions and the possibility of monitoring the quantity of ascites obtained in the abdomen by the command modulus.

The advantages of the device according to the invention and to the usage of it are the following:

- the absence of the side effects of the portal hypertension (esophageal varix, digestive bleeding, hepatic insufficiency)

- Permanent control of the quantity of ascites produced;
- A higher level of socialization due to the controlled diuresis;
- The absence of the "aggressive" risks of the portal vein.

Below is given an example of how the device is realized and the usage of it combined with the figures which represent:

Fifgurel : transversal section of the catheter and the command modulus

Figure 2: detail of the link (connection) of the two expansion rooms from the command modulus with the two lumens from the catheter

Figure 3: seeing in the B-B section of the double lumen catheter

Figure 4: detail for an end of a branch of one catheter

Figure 5: urinary bladder having placed on the its superior cap a vesicle device

Figure 6: seen device placed on the superior vesicle cap from above (top)

Figure 7: vertical plan section through the action modulus with the canal closed

Figure 8: vertical plan section through the action modulus with the canal open

Figure 9: horizontal plan section through the action modulus with the canal closed

Figure 10: horizontal plan section through the action modulus with the canal opened

Figure 11: block scheme of pressure control in the veins

Figure 12: initializing a start and auto verification of the components of the control modulus scheme

Figure 13: scheme of the program functioning for pressure control in the lumens of the catheter

Figure 14: scheme of the command modulus electrical operating

Figure 15: scheme of the transfer of liquid from peritoneum into the bladder

Figure 16: scheme of the command modulus electrical operating for evacuation of the liquid from the abdomen into the urinary bladder

Figure 17: functioning of the Hall sensor scheme

Below is an example of how to realize a peritoneofiltration using the set of devices according to the invention.

Devices according to the invention are constituted from:

a) a double lumen balloon type - new type catheter
b) a command modulus positioned at the proximal end of the double lumen catheter
c) a chirurgical implanted vesicle device on the wall of the urinary bladder.

The **double lumen catheter** 1 balloon type- new type is a flexible tube with cylindrical form made of silicon material, having at one end a bifurcation which separates two branches 2 and 3. This double lumen catheter balloon type is a new type of catheter not like the well known pressure balloon. According to the invention the catheter is a two branches catheter. Like this, after a proximal 1 common part of the catheter, the length 30-40cm, the two lumens of the catheter are separated in a bifurcation and this way their paths are separated in two branches 2 and 3 which appear as two different catheters of different length, each one continuing one path 10 -12 cm, respectively 15 - 20 cm until the end.

Close to each end of the branches 2 and 3, is located one of each pressures sensor 4 and 5 which permanently measure the pressure of the veins that were catheter.

In the double lumen 1 catheter, each one of the lumens, in the length of the catheter, has an interior closed compartment 6, with an elastic wall and full of variable quantities of serum and another external compartment 7 with a hard wall communicating with the exterior and having the possibility to wash periodically.

The lumen of each catheter (lumen of the external cover/peel) on its whole length is 7 F (21mm)

The distal extremities of branches 2 and 3 of the catheter 1 are chirurgical implanted in the right portal vein, respective right suprahepatic vein.

On both ends of the two branches 2 and 3, the cover of the hard exterior compartment 7 is interrupted by two windows which allow the elastic wall of the internal compartment 6 to emphasize when it is inflated by pressure in the interior

(inflated balloon). In this way are created the pressure balloons 8, on each branch 2 and 3 of the catheterl , which will create a bigger or a smaller level of obstruction on the portal right vein or on the right suprahepatic vein and produce hypertension at the level of these veins.

At the proximal extremity of the unique branch of the catheter we introduce the command modulus 9, which is tightly attached with it. This is the second element of the set according to the invention and includes:

- an electric-pump with MP membrane made of:
  - o two expansion rooms 10 and 11 full with serum(one for each of the lumens sections 6 and 7 of the catheter) and are separated by a flexible- membrane wall 12,
  - o Two electro-valves 13 (V1) and 14(V2) which compress or leave distended the compartment (section) of expansion 6 towards the branches 2 and 3 of the catheter.
- A room for serum washing 15
- A microcontroller electronic circuit 16
- A 3,6V micro-battery accumulator 17

The double lumen catheter 1 is tightly connected with the command modulus presented in figure 1.

The command modulus 9 is closed in pod 18 which is extended composing the common part of the two lumens of the catheter 1 until the bifurcation of it, from where the branches 2 and 3 remain uncovered.

This command modulus 9 is implanted subcutaneous under right clavicle area(as it is a pace-maker for controlling the cardiac frequency). The command modulus 9 has an access port 19 for compartment 7 of the catheter 1.

The two expansion rooms 10 and 11, full with serum, have elastic walls and are tight, communicating directly with interior compartment 6 of the catheter. In the interior of those 2 expansion rooms 10 and 11, on the opposite walls, are positioned the two electro-valves 13 (V1) and 14(V2).

The electronic circuit 16 from the command modulus 9 is a integrated programmable microcontroller circuit. It is supplied from the micro-battery accumulator 17 and it's connected to 5 pressure sensors and they are:

Two pressure sensor 4(S1) and 5(S2) placed intravascular, on the two branches 2 and 3 of the double lumen catheter 1;

- Three pressure sensors 20(S0), 21(S3) and 22(S4) placed in the command modulus 9.

The electronic circuit 16 of the pressure sensor reader 20(S0), 4(S1), 5(S2), 21(S3) and 22(S4) perform also the command for the electro-valves 13(V1) and 14(V2) are being programmed to operate specifically at different pressures detected intravascular.

The command modulus 9 is provided with an antenna 25.

The command modulus 9 is pre set before the implant, being programmed to operate specifically on the modifications of the pressure detected by the sensors.

This system of operating through the command works thus: modifications of pressure from the suprahepatic vein and respective, the portal vein, are read by the pressure sensors 20(S0), 4(S1), 5(S2), 21(S3) and 22(S4), by the action of a feed-back system at the level of the circuit 16 from the command modulus 9. This command opens or closes the electro valves 13(V1) and 14(V2) simultaneous starting the electro-pump (MP) in the + way (pressure increase) having the effect of enlarging the expansion rooms 10 and 11. The movement is made separately for each electro valve, with effect for each one of the branches 2 and 3.Therefore, the balloon from the level of a specific branch will decrease or increase dimensions and will decompress or compress the vein in which is introduced.

The command modulus 9 is pre set, being configured before subcutaneous implant, depending on the characteristics of each patient. This pre setting is done by authorized medical personnel, during the hospitalized days for initiating the peritoneofiltration.

The command modulus 9 is wireless connected to a computer, not being shown in the pictures, provided with a soft which will monitor the level of stenosis of the

suprahepatic veins and the portal vein and will memorize these data which could be read afterwards by the medical personnel, when periodic controls are made.

The control soft is programmed to be updated daily with information which receives from the command modulus 9, through an antenna 23 that is included in it. These information are regarding the pressure measured by the sensors 4(S1) and 5(S2) from the two veins and the pressure created in the expansion rooms 10 and 11 measured by the sensors 20(SO), 21(S3), 22(S4). The patient is permanently in contact with the local or regional medical center which will be able to monitor and supervise 5.000-10.000 patients. The same data will be sent online through the information system to dialysis centers that are interested. The soft is programmed and is able to limit the stenosis level of the suprahepatic veins to maximum 50% from the initial value and to limit the exaggerated inflation.

The command modulus 9 will assure the contraction of the two balloons 8 at the same time or at different times, depending on the pressures read by the vascular sensors 4(S1) and 5(S2) and by the pre setting of the command chip 16. The pre settings are conceived in a way that limits or avoid the level of stenosis of the suprahepatic veins to maximum 50% from the initial value. This way it will be obtained the necessary ascitis quantity for the peritoneofiltration to be effectuated. In this conditions it can be produced a sufficient pressure which will ensure the continuity in obtaining of an artificial ascites ("urine"). The permanent control of the portal pressure in the right suprahepatic vein and the right branch of portal vein, between the limits of 12-18 mmHg, determine a real confidence in the procedure of peritoneofiltration, practically disappearing any risk of eventual side effects specific to the presence of ascites in the abdominal cavity(ex: esophageal varix etc). If the natural pressure from the portal vein increases over 18mmHg(by ingesting of liquids in excess or any other causes), the controlling chip 16 depressurizes the balloons 8 and notifies the patient regarding the danger of "noxious" portal hypertension; the patient will be educated by the medical personnel that in this situation, to limit the consumption of liquids and/or or to present himself/herself to Regional Medical Control Center .

The monitoring of the pressure, the functioning of the controlling system and its effects over the pressures from the interior rooms of the catheter are performed as it follows:

The monitoring and control system is based on a specialized integrated circuit from the "Microcontroller" family. This minicontroller contains the following elements that are not positioned in the pictures (schemes):

- **Nucleus microprocessor:** UCP which includes ALU, controlling unit, general use and addressing registers
- **On-chip memory (of data and program):** RAM, ROM(EPROM, flash)
- Digital IN/OUT: more ports of digital I/O. Their functioning is dictated by programming of a *configuration register.*
- **Timer-counter circuits:** events counting, measuring time intervals, time determination of an event, generating of rectangular signals with a some frequency, control of electric operations (actions) etc.
- **Analogical IN/OUT:** integrates circuits ADC or DAC with more than one channel, analogical comparators, anti alloying filters.
- **Other communication interfaces:** USB, wireless.

The functioning mode of the microcontroller:

The program written in the microcontroller's memory accomplishes the control instructions of the venous pressures read on the pressure sensor S1 (located on venous portal catheter) and depending on the measured value it commands the opening of the valve V1 and the starting of the pump MP until it reaches the pressures prescribed in the program and its measured through sensor SO. In the moment when it is realized the prescribed pressure and it's confirmed by the sensor SO, the valve V1 is closed and simultaneously closes the pump MP. The remained pressure in the catheter is read in the sensor S3. Afterwards it is measured the value of pressure on sensor S2 (located on the venous suprahepatic catheter) and depending on the value measured it commands the opening of valve V2 and the starting of the pump MP until it reaches the pressure prescribed in the program, measured through sensor SO, valve V2 is closed and simultaneously closes pump MP. The remaining pressure in the catheter is read in sensor S4.

All the information measured are stored in time and are available to analyze and process having the date and time of its reading. These dates can be sent "online" with the help of the antenna 23 towards a computer from the medical network to help

monitor the patient, to correct some parameters which make this process more efficient. This information sending is done using encrypted information, having a maximum secure communication. The USB connection is available only before the implantation of module 9 at the patient and it has the role of testing and transferring of information for the producer.

Supplying the microcontroller 16 it is done from a micro accumulator 17 of 3.6V/950mAh and this is an integrated part of the device.

V 1 and V2 are hydraulic electro valves in miniature

S 1 and S2 are micro sensors of sanguine attached in the frontal part of the two branches 2 and 3 of the catheter 1.

SO, S3, S4 are micro sensors of pressure located in the interior of the modulus.

MP Electro pump with membrane, has the role of expansion vessel of the hydraulic liquid.

The functioning diagram of the microcontroller is given in the figures and they are:

- Initializing when started and auto verifying components in figure 12
- Normal functioning of the program is given in figure 13.

Surgical implant of the double lumen catheter new type, according to the invention requires the following materials and steps:

Materials:

a) introducer set of 7 F (French, waves 1 F = 3 mm) ;

b) Guide threads 0.035 Inch Terumo type;

c) Guide thread 0.035 Amplatz type;

d)catheter with double lumen of 7F; these are provided with two distal branches at the end of which it is a balloon of 18mm(54F).The diameter of the distal balloon it is of 5.5cm and are similar to the ones used for angioplasty;

e) Transjugular puncture needle Rosch of 35 cm ;

f) Set TIPS (porto systemic shunt)

g) Angioplasty balloons of 8,10,12 mm;

h) Syringe and puncture needles;

i) Substance of iodated contrast (300 osm - 200ml)

Surgical technique

The procedure is realized under fluoroscopic guidance and general anesthesia. It is being puncture the internal right jugular vein (VJIR) with the help of an ultrasound exam of 7.5MHz. it is introduced on the needle a guidance thread of 0.035 Inch to the inferior vena cava (VCI). On the guidance thread it is placed the double lumen catheter in the right suprahepatic vein (VSHR). Then the catheter is removed and the guidance thread remaines in the suprahepatic vein. On the guide thread it is introduced the needle for transjugular puncture which is before placed into a special introducer set, made of a metallic cannula wrapped in a plastic case.

The cannula with the puncture needle is removed medial in the lumen of the right suprahepatic vein; it rotates 90 degrees towards the anterior and its being punctured the right portal intrahepatic vein. The puncture needle is removed and its introduced on the catheter the guidance thread Amplatz type until the splenic vein or in the superior mesenteric vein. On the guidance thread it is placed the angioplasty balloon which is interhepatic expanded to realize a canal between the two vascular systems.

This approach it is being used also in the portal hypertension treatment at the patients with the hepatic cirrhosis (TIPSS - name from the acronym : Tranjugular Intrahepatic Portosystemic Shunt Stent). The command modulus 9, which carries constructive elements of automatization located in direct link with the superior terminal end of the double lumen catheter 1 is stopped and is placed in a subcutaneous pocket realized through a small incision in the area of the right collar bone.

The fluoroscopic examination and the control ultrasound permit the verification of the correct location of the balloons 8 in the vascular systems.

This interventional technique permits a double vascular approach, on one side in the port system and on the other side in the right suprahepatic vein tributary for the systemic circulation. Thus, the interventional technique permits the placing of a balloon in the right suprahepatic vein and the approach of the port system by placing a similar balloon in the interior of the splenoportal axis.

The **bladder device** 24, the third element of the set according to the invention, is made of an action modulus 25 and a bladder element 26 placed above the modulus. The bladder device 24 is surgical fixed, through the bladder element 26, at the superior bladder wall(bladder cap) through a pubo-umbilical incision and median

laparatomy. The bladder element 26 has the role to protect the action modulus 25 in the interior of the abdomen. It is made up of a hard material, preferable silicon.

During the surgical procedure, the bladder cap is identified, isolated and a dissection is executed. An incision in the peritoneum and in the bladder cap wall is made. In the incision of the 2cm effectuated, it is placed the device 24 and it is fixed through the clamps 27, to make a slit 28 (an opening) of 3mm in the bladder cap. At the end of the procedure we fasten the bladder device at the bladder wall and we perform the parietorafia anatomica.

The action modulus 25 of the bladder device 24 is build up of a superior plate 29 and a inferior plate 30. The two plates each have one orifice in their middle -31 and 32- and these orifices are arranged with a common axis in the action modulus 25.Between the two plates 29 and 30 it is a rotating valve 33, electric driven through an ensemble made up of micro-engine 34 and a cockle 35. The valve's movement 33 in the rotating ways determines the opening or the closing of the access towards the slit 28 from under the bladder device 24.The movement of the valve 33 it is done around the axis 36, at an angle of 25 ° and it's limited by two electrical limiters. To close or open the device 24 above the slit 28, the ensemble micro-engine - cockle 34,35 positions an orifice 38 in the rotating valve 33 which will open or close a canal 39 between the two plates 29 and 30, canal made up by overlapping of the three orifices 31,38 and 32.

In the interior of the command modulus 25 its placed a 3.6V battery 40, which supplies with energy an integrated circuit of electronic action 41. The integrated circuit of electronic action 41, also supplies the micro-motor 34 situated also in the interior of the action modulus 25. A Hall sensor 42 (S5), located outside the bladder device 24 and in the exterior of the bladder, it is connected at the integrated command circuit 41 and it reads the presence of the remote. The locating of the Hall sensor 42 it's subcutaneous done in the inferior abdominal wall.

The functioning of the bladder device 24 its represented in fig. 15, which illustrates the mode in which the transfer of liquid from peritoneum into the bladder is done.

Depending on the pressures acchived, which can be controlled through an electronic module in the balloons 8, the artificial ascites is created and it will be transferred in the urinary bladder through the slit 28. The transfer of the liquid from the peritoneum in

the bladder is done voluntarily by the patient through the remote 43, keychain type. The patient puts the remote 43 close to the area in which the Hall sensor 42 it's implanted. The transfer can be done at variable periods depending on the quantity of urine produced through peritoneofiltration. This means that, one you action the remote 43, commutator 44 will action de shift of the rotating valve 33 which will open the canal 38 from the action module 25m, for 20-30 seconds, time in which in which the peritoneal fluid accumulated will gravitationally drain into the bladder. After these 20-30 seconds, the canal 39 will automatically close through the shifting of the rotating valve 34. The closing of the canal 38 will be hermetically. The hermetic closing of the canal will permit the creation of a bladder pressure which will ensure a physiological urination. Another opening of the canal 38 from the action modulus 25 will be possible only through another action of the remote 43 by the patient.

The loss of the amino acids and salts trough the artificial ascites will be compensated through the patients administration, at precised times, of solutions in concentrations that will be established later, depending on the case and on the obtained results. A solution of amino acids, vitamins, salts which get lost through the artificial urination can be one that contains, 100g of watery solution, 3.8 protein grams and 8 essential amino acids. The dose will not exceed 250ml daily and depending on the loss, will have a balanced content, established by the doctor.

It has been ascertained from the exposed material above that the most important information from the course of the procedure carried on of the peritoneofiltration are: to watch the pressure in the portal vein, to watch the fluid and to command the elimination of the ascites created directly in the bladder of the patient at pre-established times. In this method the ascites liquid has to be obtained by creating, controlling and maintaining the portal hypertension at limit values of 12-18 mmHg. These limits of the portal hypertension could not determine side effects. As a result, the adjustment of the portal hypertension is very important for the success of the method. The devices according to the invention assure a severe control at the portal hypertension level, through the double obstruction: an adjustable obstruction at the right branch of the suprahepatic vein and an adjustable obstruction at the branch of the porta vein. The double adjustment of the two obstructions, will assure the

maintaining of the limits of 12-18 mmHg in portal hypertension and also the possibility to monitor the quantity of ascites obtained in the abdomen.

In this way, the lymphatic's and the arterioles will better support the pressure created in the two branches (3,4) of the catheter (1) through internal double obstruction of the right suprahepatic vein and the branch of the right porta vein.

The realized obstruction according to the invention with the set of devices will be permanent, with maximum of 50% stenosis, together with the pressure in the suprahepatic veins, monitored by the system.

All the exposed conditions are fulfilled by the set of devices according with the invention in a safer way than the external clamping of the porta vein as it is shown in the patent request 2010 00002 / 4.01 .2010 for the obtaining of portal hypertension.

Peritoneofiltration as a method which can replace dialysis came from a research done on patients with uraemia and ascites due to different causes, like congestive cardiac insufficiency and nephrotic syndrome. We monitorised 12 patients, being excluded the patients with hepatic illness. Paracentesis were done, with the drainage of the pathologic fluid from the abdominal cavity through abdominal puncture, obtaining app. 1.5-2 l of peritoneal fluid which has been examined, comparing with the blood obtained from the same patient. The result showed the same uremic toxines values in the two fluids. After a month we perform peritoneal dialysis on the same patients; in the peritoneal fluid of the same patient the exams showed a decrease of 5 times lower in the uremic toxines values, comparing to the blood. This shows that through draining of the ascites liquid from the abdomenwe obtain a more rapid improvement in the concentration of uremic toxins. These experiments have driven to the solution of realizing a system of elements that, once sururgical placed, could produce a portal hypertension which determines the "induced" ascitis. This ascitis has been proven to be loaded with toxins at the same values of the ones in the blood. Also, it has been established that once the ascites fluid has been eliminated, the detoxification has been realized at better values than the parameters achieved through dialysis.

The results of this experiment are shown below.

The first tests concerning the ascites fluid compared with the dialysis fluid from the 12 patients studied according to the invention were the ones in table 1.

Table 1

BIOCHEMICAL - ASCITIS LIQUID

Number of patients	Urea **mg%**	Creatinine **mg%**	Protein **g%**	Glucose **mg%**	Uric **acid mg%**
1	301	11	2,7	69	6,3
2	299	10	2,5	69	6,2
3	301	12	2,6	65	6,2
4	299	10	2,5	66	6,2
5	300	12	2,6	70	6,4
6	302	10	2,5	70	6,3
7	301	11	2,6	65	6,3
8	302	12	2,7	67	6,1
9	303	11	2,6	69	6,3
10	305	12	2,6	72	6,3
11	304	11	2,7	71	6,5
12	307	10	2,6	75	6,5

BIOCHEMICAL - SER UM

Number of patients	Urea **mg%**	Creatinine **mg%**	Protein **g%**	Glucose **mg%**	Uric **acid mg%**
1	311	11,2	6,3	98	6,9
2	310	11	6,2	96	6,8
3	312	11,2	6,4	95	7

4	309	11,1	6,5	100	6,4
5	314	11,3	6	99	6,6
6	314	11,3	6	97	6,7
7	311	11,2	6,4	101	6,9
8	310	11,4	6,5	100	6,9
9	315	11,2	6,2	96	6,8
10	312	11,1	5,9	98	6,9
11	315	11,2	6	98	7
12	311	11,2	6	98	6,7

BIOCHEMICAL -PERITONEAL Liquid

After a month from removing the ascites

Number of patients	Urea **mg%**	Creatinine **mg%**	Protein **g%**	Glucose **mg%**
1	64	2	56	43
2	66	2,3	57	45
3	66	2,2	59	44
4	63	2,2	60	47
5	66	2,1	56	48
6	65	2,3	58	41
7	60	2,2	60	43
8	61	2,2	58	42
9	66	2,2	56	45
10	64	2,1	60	46
11	62	2,3	59	44
12	65	2,3	57	40

BIOCHEMICAL - SERUM (Dialysis)

Number of patients	Urea mg%	Creatinine mg%	Protein g%	Glucose mg%
1	136	7,3	56	99
2	135	7,6	57	100
3	136	7,4	59	98
4	137	7,5	60	97
5	139	7,4	56	99
6	137	7,3	58	101
7	138	7,7	60	101
8	140	7,5	58	98
9	136	7,2	56	99
10	138	7,1	60	102
11	135	7,1	59	98
12	137	7,1	57	96

This study has shown the following medium values obtained:

a) For natural ascites: urea 302 mg%+/-36, creatinine 11 mg%+/- 3,05, protein 2,6g%+/- 0,7, glucose 69 mg%+/-11, uric acid 6,3mg%+/- 1,4.

b) for the serum from the same day: urea 312 mg%+/- 43, creatinine 11,2+/-1,8, glucose 98mg%+/- 20, protein 6,2g%+/- 1,7, uric acid 6,8mg%+/-2,4.

The medium values obtained a month after the removal of the ascities were:

a) in the peritoneal fluid: urea 64 mg%+/-21, creatinine 2,2 mg%+/-1,4, glucose 44 mg%+/-16, protein 58 mg%+/-18;

b) for the serum on the same day: urea 137 mg%+/-45, creatinine 7,35+/-1,9, glucose 99 mg%+/-19.

Conclusions: by using the peritoneofiltration, the urea and the creatinine levels in the peritoneal fluid are much higher than the ones obtained with peritoneal dialysis and

this method gives us the possibility to adjust the them by fixing the volume of the "induced" ascitis, according to the method presented in the invention. Also, the protein loss is comparable to the quantities in the peritoneal dialysis.

DEMANDS:

1. Set of devices for peritoneofiltration using the peritoneum as a membrane of dialysis and stimulating the production of its own ascites liquid accumulated in the abdomen. **Characterized by:** for the obtaining of a higher safety in the procedure of realizing of portal hypertension, has in the making of:

One double lumen catheter (1) balloon type, in which the two lumens, after a proximal common part, its separated in a bifurcation and it separates its trajectories like separate catheters, in two branches (2,3), which are chirurgical located in the right suprahepatic vein and right portal vein and through he variable diameter of the balloon (8) determines a controlled obstruction of those veins; close to each end, distal towards the balloons 8, is located one of each pressure sensor (4,5) which permanently measure the pressure from the catheterized veins and transmits the information to a command modulus(9);

A command modulus(9), which monitor and controls the pressure from the catheterized veins , is in direct link/connection with the proximal end of the double lumen catheter (1), being implanted in right under clavicle area and programmed to action at the modifications of pressure detection of the pressure sensors (4,5);

A vesicle device (24) through which the liquid accumulated in the abdomen comes down gravitationally in the urinary bladder and which is chirurgical implanted at the level of the superior cap of the urinary bladder, device which is made of a action

modulus (25), operated from the exterior through a remote and an vesicle element(26) situated above the modulus (25);

2. Set of devices for the peritoneofiltration according to the demand 1, **characterized by:** each one of the lumens, in the length of the catheter (1), has a interior compartment (6) closed, with an elastic wall and full with serum and another compartment at the exterior (7) with a hard wall and communicating with the exterior through the access port (19) and having the possibility to wash periodically.

3. Set of devices for the peritoneofiltration according to the demand 1, **characterized by:** the command modulus (9), is made of a electro pomp with an MP membrane having two expansion rooms(10,1 1) with flexible walls, full with serum, with one for each one of the lumens of the compartments (6,7) of the catheter (1) and which are separated by a flexible-membrane wall (12), two electro-valves(13,14) opposites of the membrane (12) which compresses or leaves the expansion compartment(6) to relax towards the branches(2,3) of the catether; a room(15)to wash with serum; an electronic circuit (16) and a 3.6 V micro-battery accumulator (17).

4.Set of devices for the peritoneofiltration according to the demand 3, **characterized by:** electronic circuit (16)is a circuit integrated microcontroller programmable supplied from the micro-battery accumulator (17)and it is connected with five pressure sensors and they are: two pressure sensors (4,5) placed intravascular, on the two branches (2,3) nof the double lumen catheter (1) and three pressure sensors (20,21 ,22) placed in the command modulus(9).

5. Set of devices for peritoneofiltration according to the demand 3, **characterized by:** an electronic circuit (16) that reads the pressure sensors (20,4,5,21 ,22) effectuates and commands for the electro-valves (13,14) being programmed to action at different pressures detected intravascular.

6. Set of devices for the peritoneofiltration according to the demand 1, **characterized by:** the command modulus(9),is closed in a case (18) which is extended and covers

the common part of the two double lumens of the catheter (1) until its bifurcation, from where the branches (2,3) remain uncovered.

7. Set of devices for the peritoneofiltration according to the demand 1, **characterized by:** the command modulus (9) has a access port (19) for the compartment (7) of the catheter (1), through this port-access being able to supply compartment (7)from exterior with serum.

8. Set of devices for the peritoneofiltration according with demand 1, **characterized by:** the action modulus(25) of the vesicle device (24) is made of a superior plate(29) and an inferior plate (30), the two plates each having in the middle an orifice(31,32), arranged with a common axis in the action modulus (25); between the two plates (29,30) is situated a rotating valve(33) electric action through an ensemble made of a micro-motor (34) and a cockle(35).

9. Set of devices for the peritoneofiltration according to the demand 8, **characterized by:** the movement of the valve (33) in rotating way determines the closing or the opening access towards a slit (28) from under the vesicle device (24) chirurgical practiced in the superior cap of the bladder.

10. Set of devices for the peritoneofiltration according to the demand 9, **characterized by:** the movement of the valve (33) it is done around the axis(36), at an angle of 25° and it is limited by two electrical limiters (37).

11. Set of devices for the peritoneofiltration according to the demand 7, **characterized by:** in order to open or close the vesicle device (24) above the slit(28), ensemble micro-motor cockle (34,35)positions and orifice (38) in the rotating valve(33) which will open or close a canal (39) between the two plates (29,30), canal made of overlapping of the three orifices (31,38 and 32).

12. Set of devices for the peritoneofiltration according to the demand 1, **characterized by:** a Hall (42) sensor, subcutaneous positioned in the inferior abdominal wall, outside

the vesicle device (24)and outside the urinary bladder, is connected to a circuit integrated by command (41) situated in the action modulus (25) which reads the presents of a remote (43) and commands the opening or closing of a canal(39).

13. The method of peritoneofiltration using the set of devices according to the demand 1, **characterized by** the increase of the pressure in the port system and to realize ascitis is made of a double internal obstruction of the right suprahepatic vein and the right branch of the portal vein by introducing the two branches (3,4) of the double lumen catheter (1) type balloon in these veins , obstruction made by balloons (8) being permanent, with maximum of 50% stenosis, concordant with the pressure from the suprahepatic veins, monitored by the system, portal hypertension being mentioned between the limits of 12-18 mmHg through double adjustment of the two obstructions and the possibility to monitor by the command modulus (9) of the quantities of ascitis obtained in the abdomen.

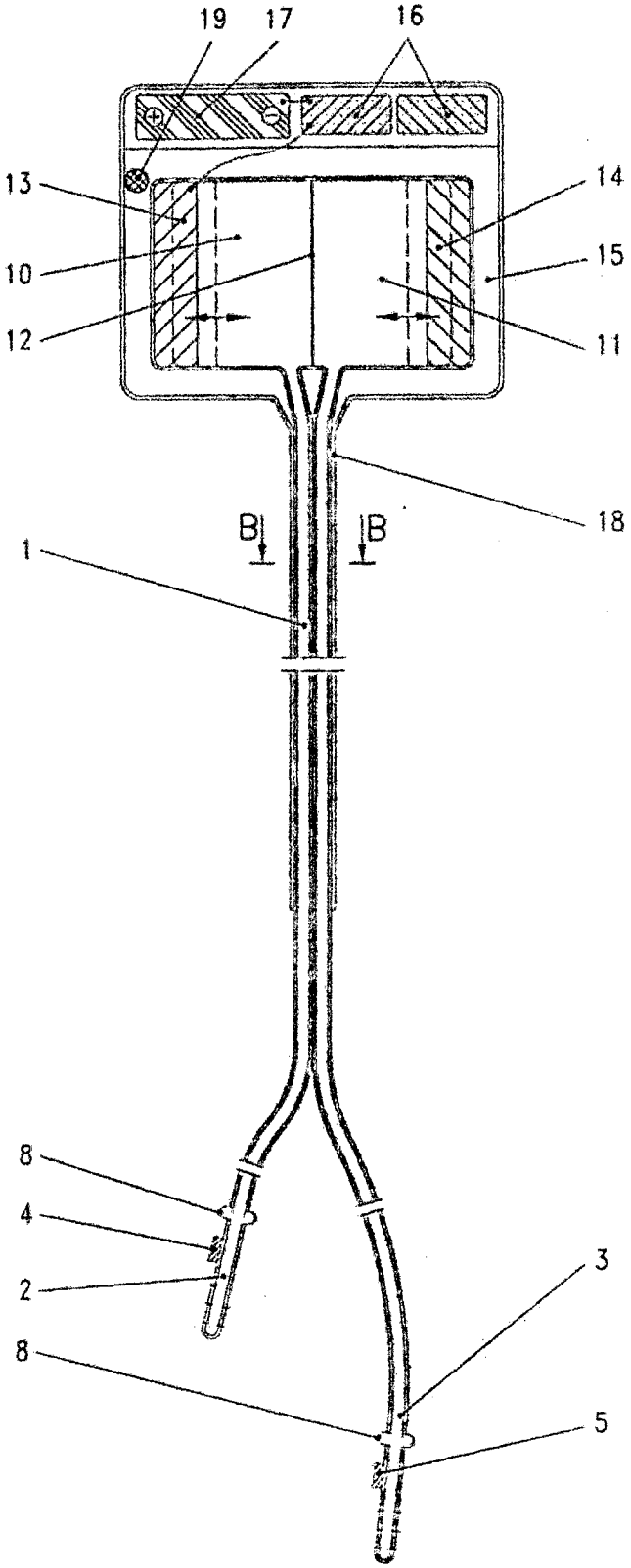

Figura 1

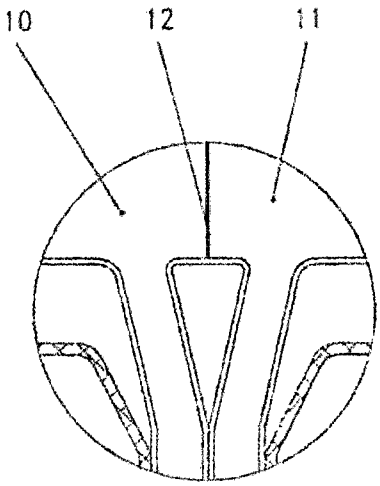

Figura 2

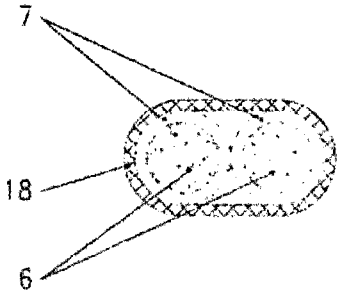

Figura 3

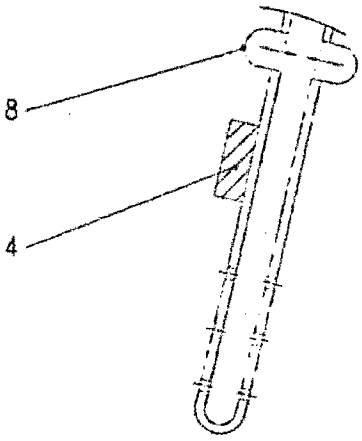

Figura 4

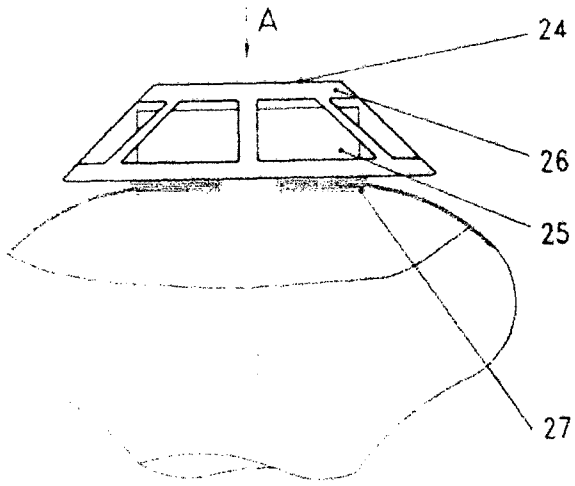

Figura 5

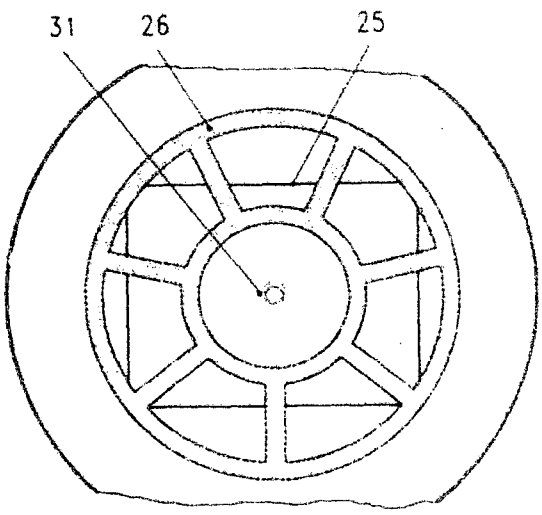

Figura 6

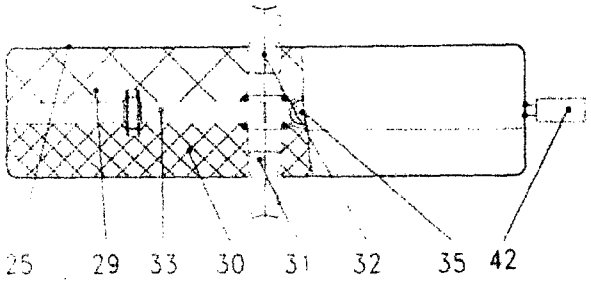

Figura 7

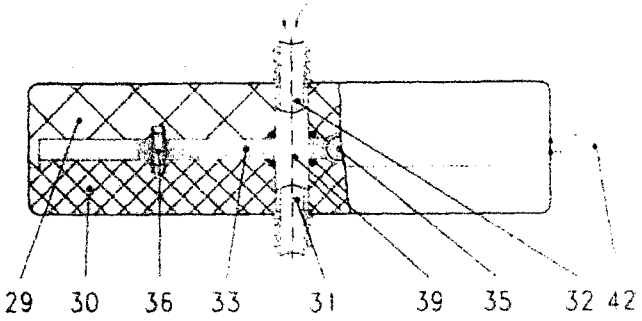

Figura 8

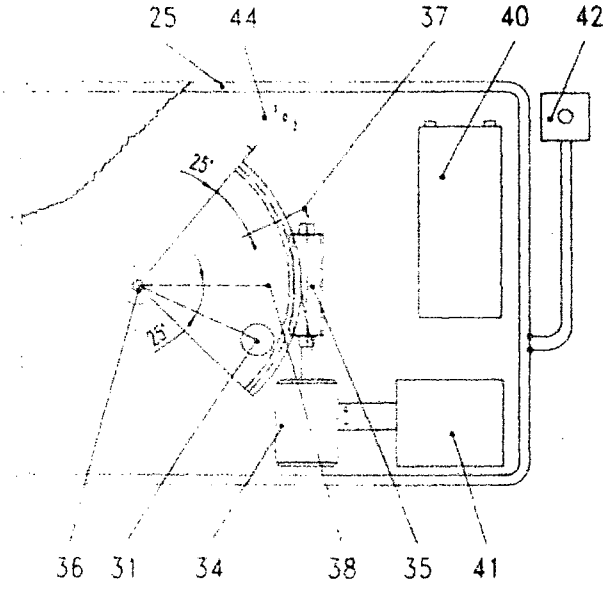

Figura 9

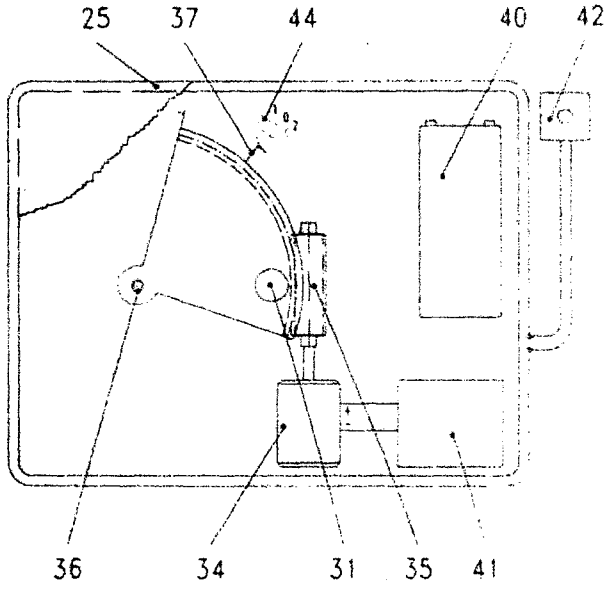

Figura 10

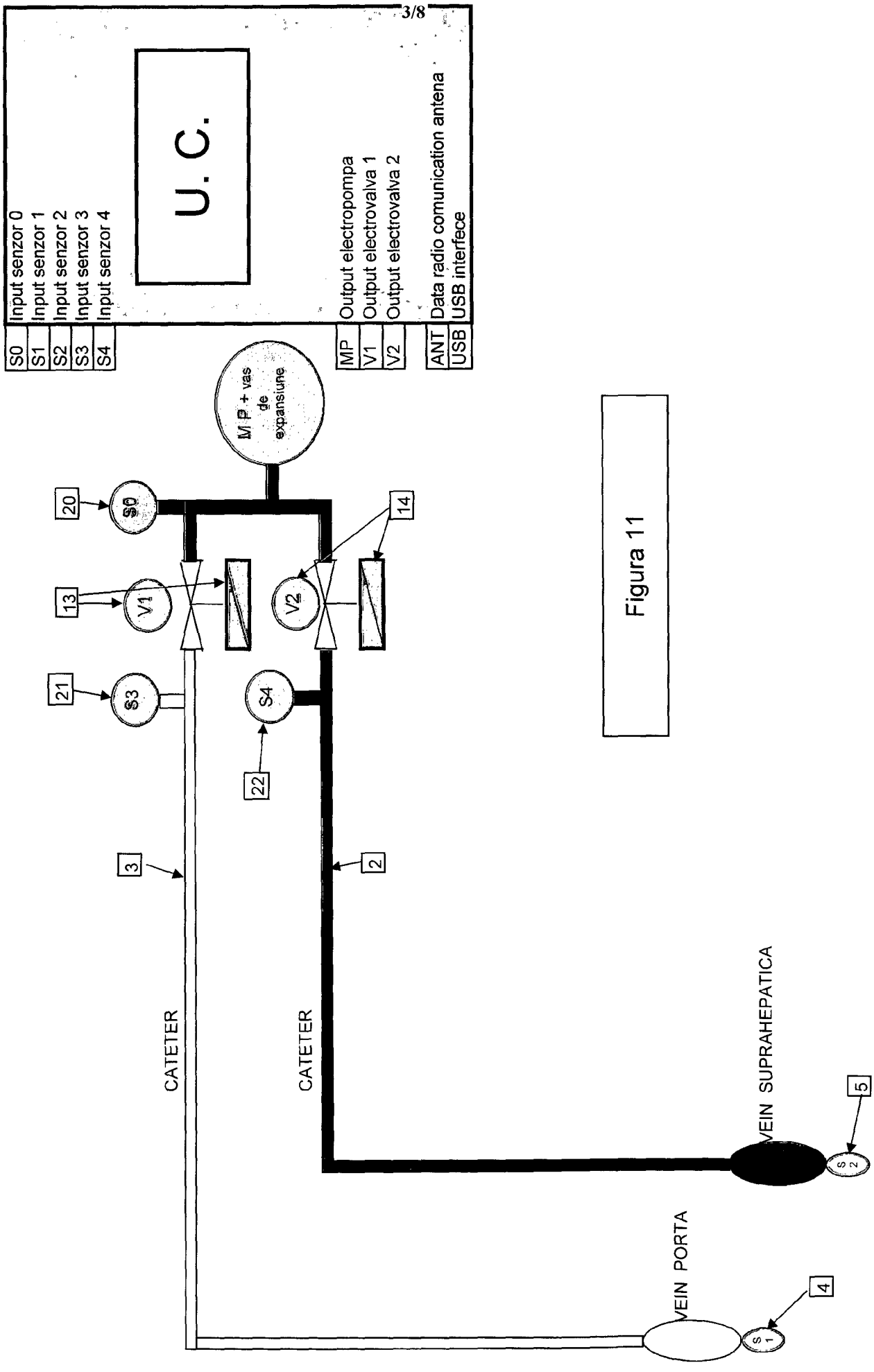
U. C.
Input senzor 0
Input senzor 1
Input senzor 2
Input senzor 3
Input senzor 4
Output electropompa
Output electrovalva 1
Output electrovalva 2
Data radio comunication antena
USB interfece
S0
S1
S2
S3
S4
MP
V1
V2
ANT
USB
M P + vas de expansiune
20
14
13
21
22
3
2
CATETER
CATETER
VEIN SUPRAHEPATICA
VEIN PORTA
5
4

Figura 11

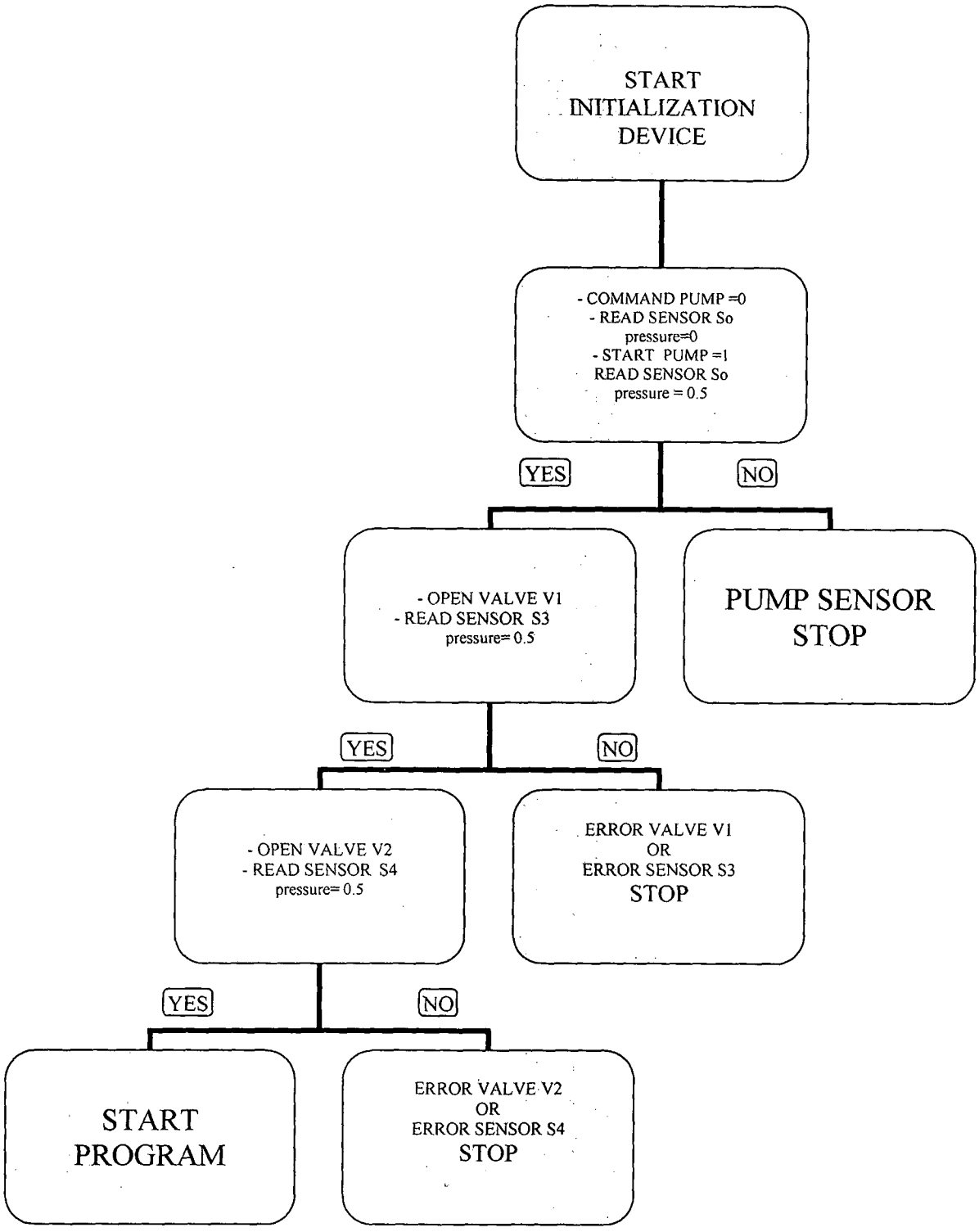
START
INITIALIZATION
DEVICE
- COMMAND PUMP =0
- READ SENSOR So
pressure=0
- START PUMP =1
READ SENSOR So
pressure = 0.5
YES
NO
- OPEN VALVE V1
- READ SENSOR S3
pressure= 0.5
PUMP SENSOR
STOP
YES
NO
- OPEN VALVE V2
- READ SENSOR S4
pressure= 0.5
ERROR VALVE V1
OR
ERROR SENSOR S3
STOP
YES
NO
START
PROGRAM
ERROR VALVE V2
OR
ERROR SENSOR S4
STOP

Figure 12

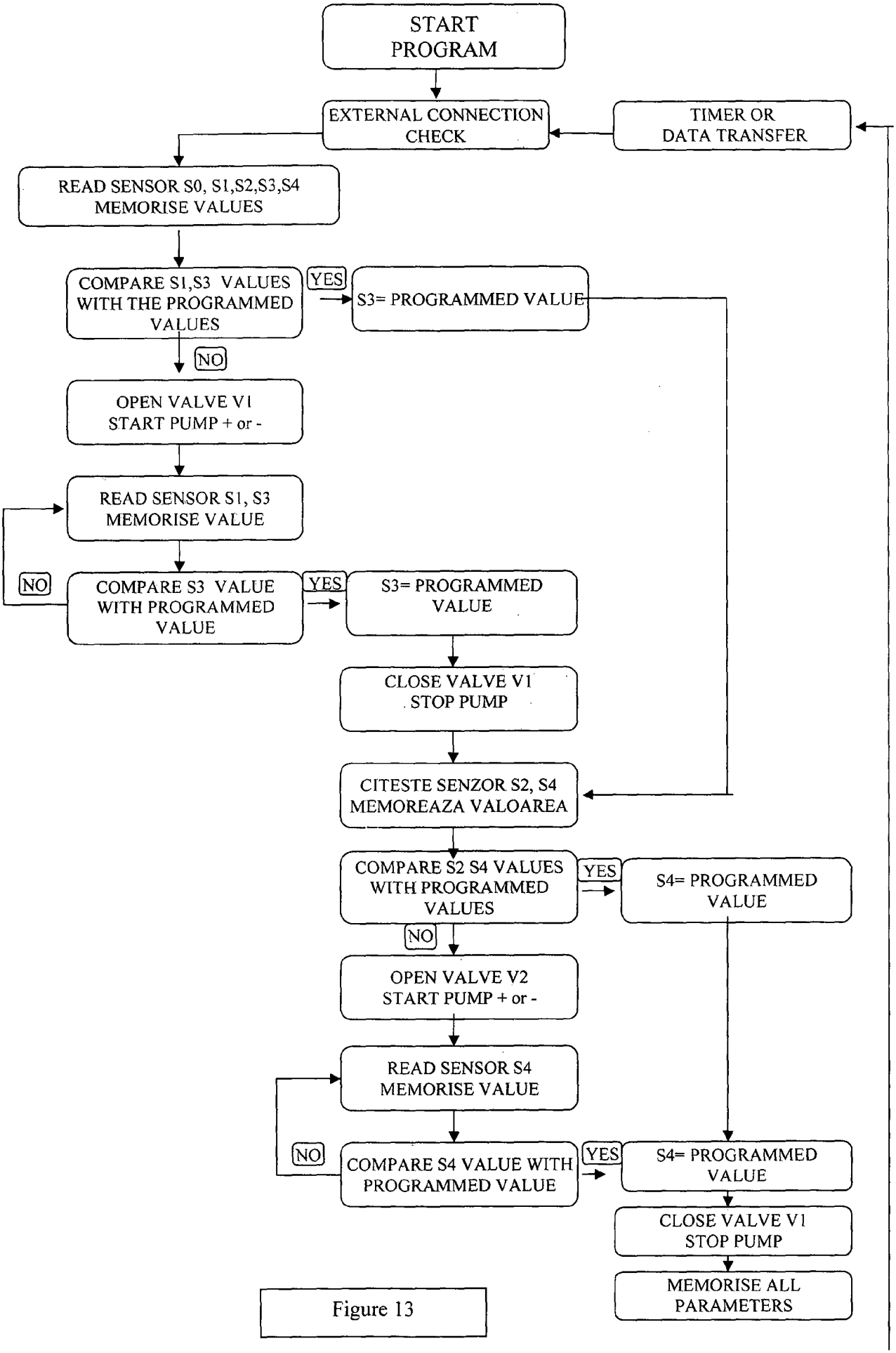
START PROGRAM
EXTERNAL CONNECTION CHECK
TIMER OR DATA TRANSFER
READ SENSOR S0, S1,S2,S3,S4 MEMORISE VALUES
COMPARE S1,S3 VALUES WITH THE PROGRAMMED VALUES
YES
S3= PROGRAMMED VALUE
NO
OPEN VALVE V1 START PUMP + or -
READ SENSOR S1, S3 MEMORISE VALUE
NO
COMPARE S3 VALUE WITH PROGRAMMED VALUE
YES
S3= PROGRAMMED VALUE
CLOSE VALVE V1 STOP PUMP
CITESTE SENZOR S2, S4 MEMOREAZA VALOAREA
COMPARE S2 S4 VALUES WITH PROGRAMMED VALUES
YES
S4= PROGRAMMED VALUE
NO
OPEN VALVE V2 START PUMP + or -
READ SENSOR S4 MEMORISE VALUE
NO
COMPARE S4 VALUE WITH PROGRAMMED VALUE
YES
S4= PROGRAMMED VALUE
CLOSE VALVE V1 STOP PUMP
MEMORISE ALL PARAMETERS

Figure 13

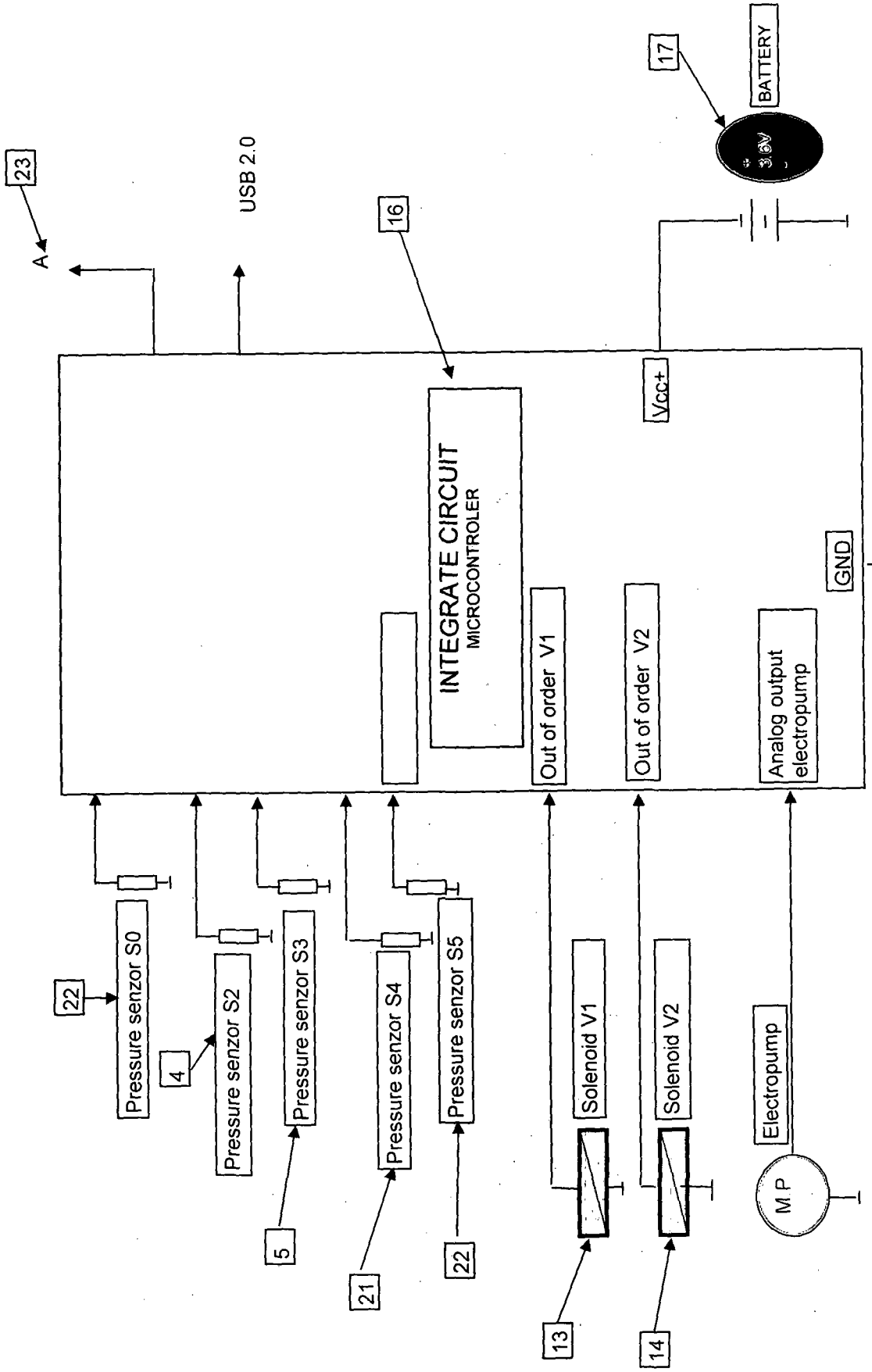
23
A
USB 2.0
16
17
BATTERY
3.6V
INTEGRATE CIRCUIT
MICROCONTROLER
Vcc+
GND
Out of order V1
Out of order V2
Analog output electropump
22
Pressure senzor S0
4
Pressure senzor S2
5
Pressure senzor S3
21
Pressure senzor S4
22
Pressure senzor S5
13
Solenoid V1
14
Solenoid V2
Electropump
M P

Figura 14

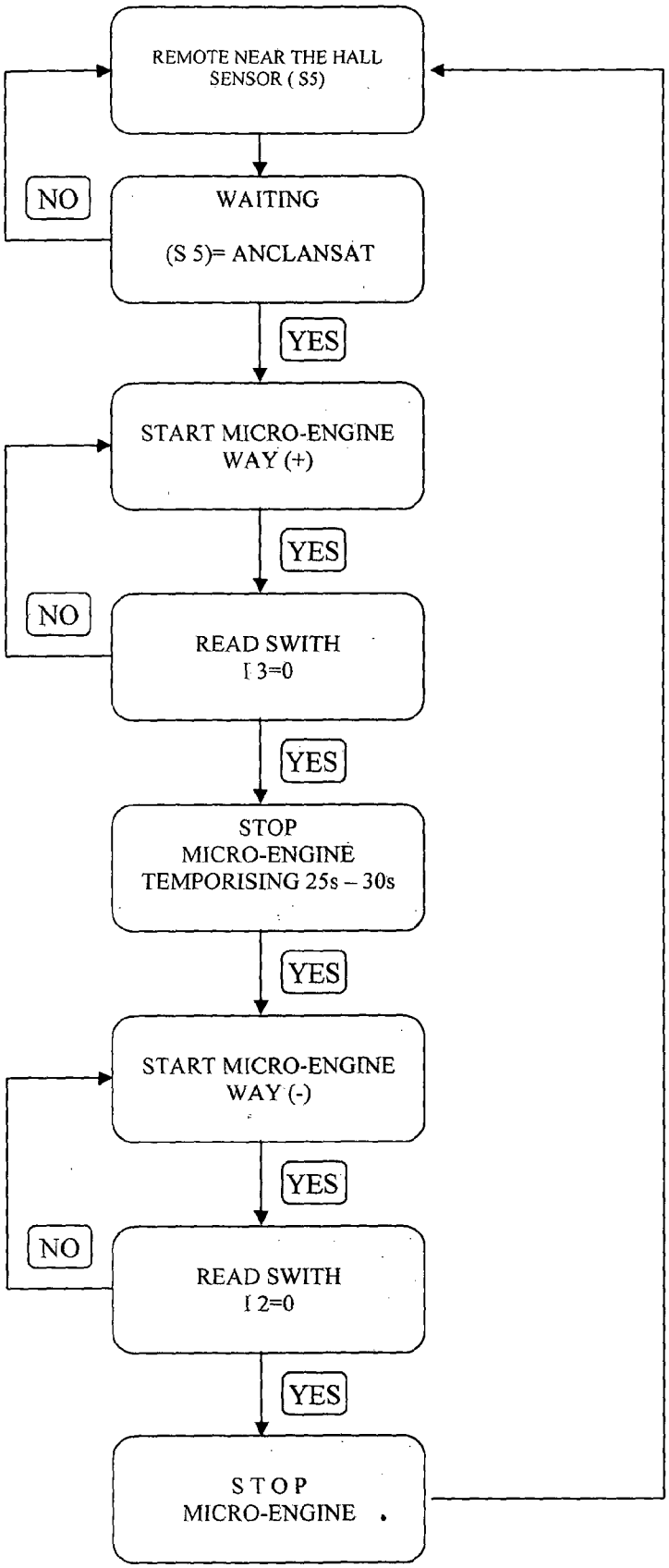
REMOTE NEAR THE HALL SENSOR (S5)
NO
WAITING
(S 5)= ANCLANSAT
YES
START MICRO-ENGINE WAY (+)
YES
NO
READ SWITH I 3=0
YES
STOP MICRO-ENGINE TEMPORISING 25s – 30s
YES
START MICRO-ENGINE WAY (-)
YES
NO
READ SWITH I 2=0
YES
STOP MICRO-ENGINE

Figure 15

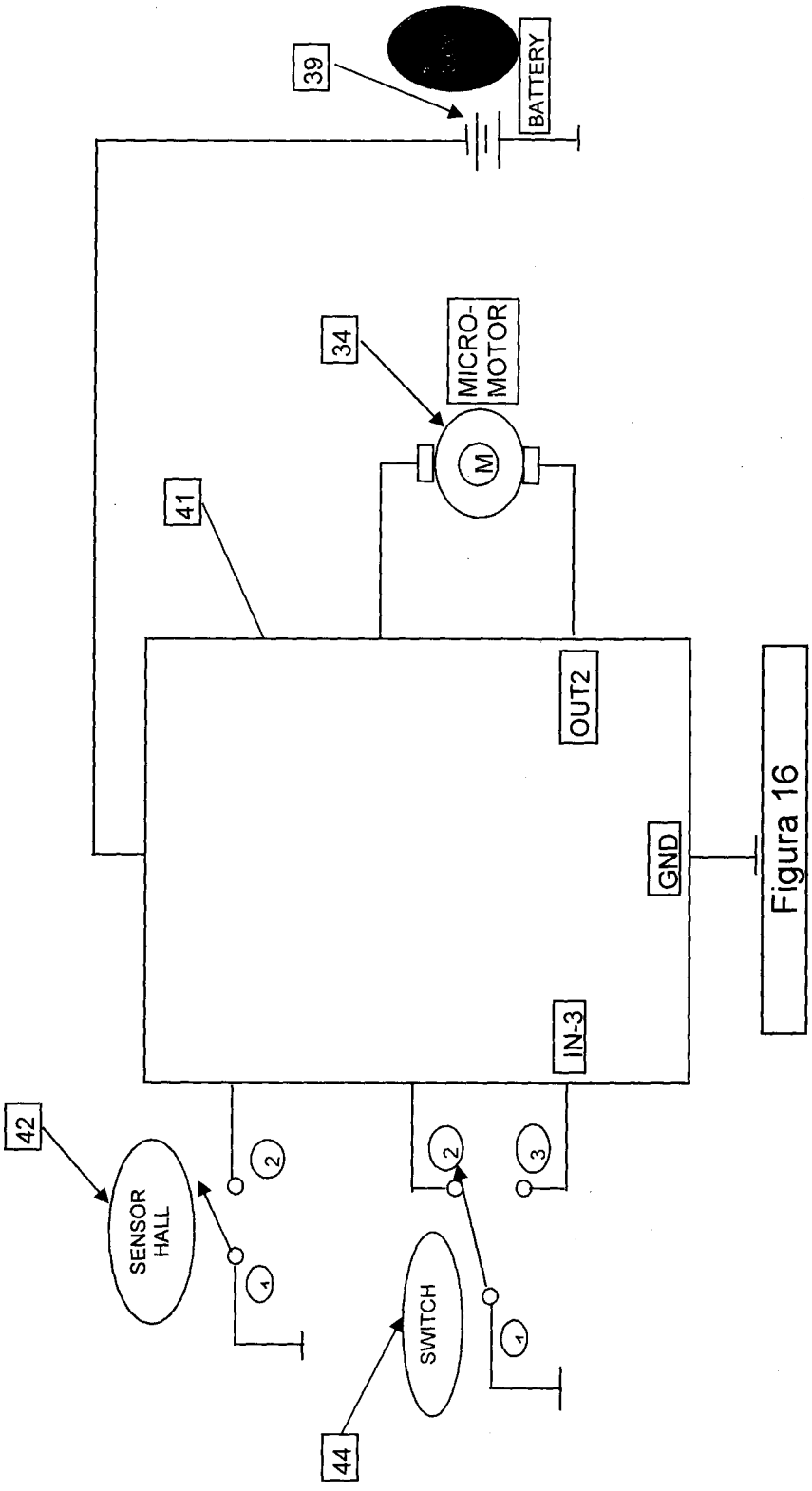

Figura 16

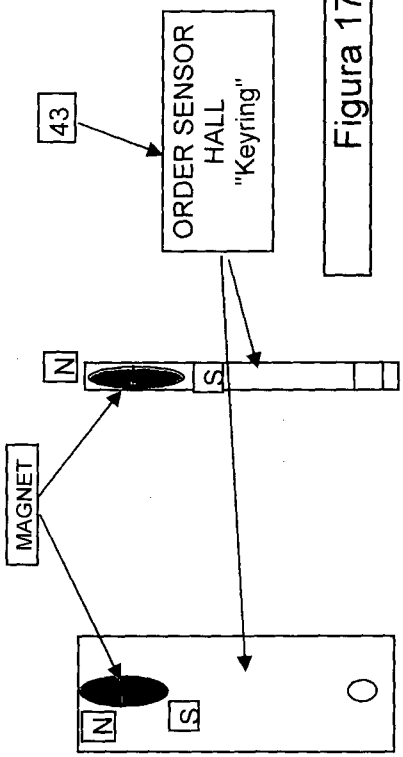

Figura 17