Design of an Automated Perfusion Pump

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Abstract

The design and construction of an automated perfusion pump commenced as part of an industrial affiliates program in 1998 that continued through to a final year project in 1999, both as part of a biomedical engineering degree at Flinders University. This work has continued this year through a NHMRC funded research position in the Department of Gastroenterology at the Repatriation General Hospital.

Introduction

Many disorders can affect the motility of the upper gastrointestinal system leading to symptoms such as difficulty with swallowing and aspiration of gastric contents. Perfusion pumps are a diagnostic tool used to assess such motor function. They provide a constant flow of fluid to a manometric assembly that is placed within the GI tract. The assembly, which can have up to 32 internal lumina, measures pressures within the GI tract via external pressure transducers. Each measurement channel consists of a pressure transducer and flow resistor in series, with the resistor located proximal to the transducer, and the assembly distal to the transducer. Water and carbon dioxide, soured from a pressurised reservoir and gas cylinder respectively, are perfused through the system in sequences via connections between measurement channels (see figure 1). These flushes facilitate the removal of any bubbles that would affect the accuracy and fidelity of the pressure measurements.

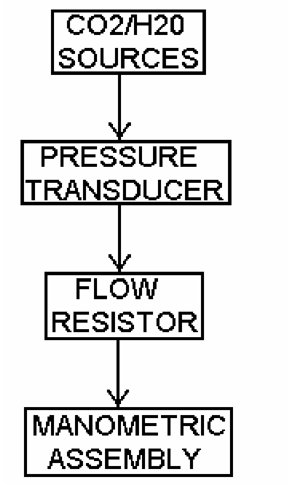


Figure 1: Outline of setup for a measurement channel.

Standard perfusion pumps require the user to manually open and close valves to control the various flushing sequences. With a large number of channels this is time consuming and increases the possibility of errors, potentially leading to inaccurate measurements and misdiagnosis. Therefore, an automatic pump was designed and constructed. The automated perfusion pump had the following specifications:

- It must be fully automated,
- Allow for the perfusion of water and carbon dioxide in defined sequences,
- Contain appropriate safety mechanisms,
- It must be autoclaveable for sterilisation purposes,
- The system must have minimal compliance to ensure maximum fidelity of recording,
- N-channel arrangement possible,
- Channels electrically isolated from each other (to allow independent measurement of electrical potential),
- Relatively cheap
- Conform to relevant Australian standards for medical devices,
- Facilitate automatic calibration of pressure transducers,
- Mechanism to indicate the perfusate reservoir has run out,
- Channel spacing a maximum of approximately 2cm, and
- Easy to use.

To realise the automation aspect of the system the manual valves were replaced with custom designed pneumatically operated pinch valves. The specifications of the pneumatic pinch valve were:

- Operational with driving pressures of approximately 200kPa in the control line,
- Operational with pressures up to 200kPa in the perfusion line,
- Autoclaveable,
- Easily manufactured,
- Mechanically simple,
- Normally open and normally closed positions available in a single valve,
- Operational with various sized silicone tubing (range of 2.4-5mm outside diameter), and
- Controllable using PC activated solenoids.

Discussion

A pneumatically operated pinch valve was chosen for several reasons. Firstly, pneumatic control of the valves removes the need for medically graded power sources that would be required with the direct use of electronically controlled solenoids. The solenoids used in the system to control the valves are not situated in the direct line of flushing and are electrically isolated via air/plastic lines from the perfusate. A pinching mechanism was selected for its effective occlusion method. It is also a simple mechanical design and can be easily machined, hence manufactured. It also allows the user to easily remove tubing from the occlusion site. The pinch valves control several different characteristics of the pump and therefore both normally closed and normally open positions were required.

The first task performed in designing the pinch valve was to determine the most effective occlusion method. Using an appropriately designed test rig it was found that two rounded surfaces required the least amount of force to occlude the tubing, therefore it was decided to incorporate this occlusion method into the valve design.

Following these tests a prototype valve was constructed by an outside contractor. An outline of this valve is shown in figure 2. The complete valve is also shown in figure 3a. This prototype proved the effectiveness of using a pneumatic pinch valve with two rounded surfaces as an occlusion mechanism and a spring to keep the selected tubing occluded in the normally closed position.

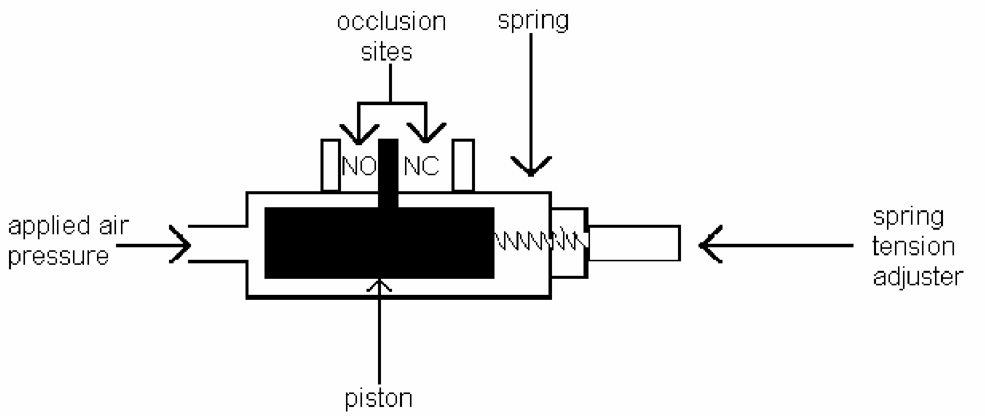


FIGURE 2: Outline of the initial valve prototype. The fundamentals of this design have been carried through to the current version, the major change being that the occlusion site is now located within the valve.

A new valve was designed based on the success of the first prototype. The design was changed slightly to bring the occlusion site in line with the applied pressure to remove any torque which may arise from two lines of force acting in the first valve, thus reducing the chance of the piston jamming. Dimensional changes were also made to facilitate 5mm tubing. The valve consisted of a piston with an o-ring and two grub screws to facilitate part of the occlusion, an outer casing with a locating screw to form the second part of the occlusion site, and an end cap. An outside contractor constructed four stainless steel (grade 304) valves (see figure 3b).

A range of generic springs were tested extensively in the valves in both the normally open and normally closed positions, which proved effective. However, it was discovered that the o-rings on the pistons were producing frictional forces within the valve. It was believed that these frictional forces could be removed with a more precise machining technique, namely CNC technology, and an alternative construction material.Terry MacKenzie, Flinders University, was consulted regarding the next iteration of the valve.

The result is shown in figure 3c. The main features that were changed are:

- Ertaxel replaced stainless steel as the construction material,
- The casing is circular,
- Both ends of the valve are open (closed by end caps),
- O-ring used around the seal between casing and cap at the air pressure site,
- Cup washer used rather than an o-ring at the occlusion site,

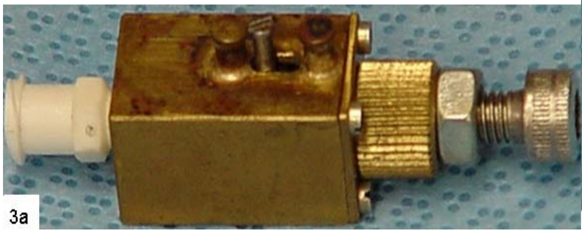
• The piston comprises of two parts, and
• Spacer used in the spring end cap to ensure the legs of the casing are not pulled together on tightening.

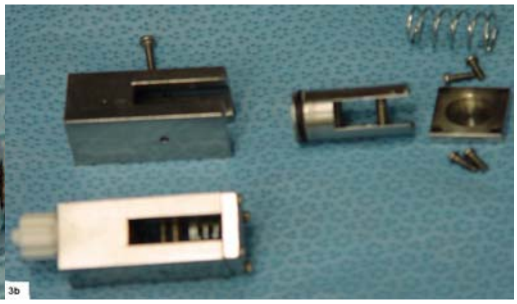
The springs are unchanged from the previous version. An initial valve run was produced using manual machining techniques with an Erta based material, Ertaxel (see figure 3c). Another run was ordered using CNC technology with Delrin as the construction material(see figure 3d). Although Delrin is not repeatedly autoclaveable it was deemed mechanically suitable. This has resulted in a cheaper valve that is suitable for the majority of potential users. These valves have been tested extensively and have proved to be extremely effective with the cup washer on the piston reducing the friction introduced by the o-ring in the previous valve. The occlusion sites on the current valve is shown in figure 3e.

A 22-channel pump was constructed for testing purposes and preliminary patient studies. Its outline is shown in figure 4. A relay board was designed to interface with the digital ports on a National Instruments digital control card. The relays control the outputs of a bank of solenoids that apply an air pressure to their particular pinch valves, hence controlling their state. The transducers interface with a preamplifier box that in turn interfaces with the analog ports on the control card.

Extensive testing has been performed to determine the most effective setup sequence. This sequence is outlined in figures 5a-5g. There are numerous interchange steps utilised within this defined sequence which were inserted because it was found that switching more than one valve at a time produced bubbles in the system, most likely due to turbulence. These bubbles affect the fidelity of pressure measurements. It total, the setup of the system takes around 15 minutes and requires no user intervention.

Numerous safety mechanisms have been considered in the event of a power failure to depressurise the system and direct perfusion away from the patient. All solenoids used in the system are normally closed so that all control lines are vented to atmosphere if the power fails. This is backed up with normally closed pinch valves on all main inlet lines (PPV1-3). In addition, the valve located in the channel (PPV4) uses the normally closed side to take the perfusate to the assembly. The manifold valve (PPV5) is normally open and the channel valve (PPV4) utilises the normally open side to take the perfusate to the waste water. Therefore, in the event of a power failure all perfusate is prevented from either entering the system via the main inlet lines of from leaving the system via the assembly. Instead all perfusate is directed away from the patient line and towards the waste water.





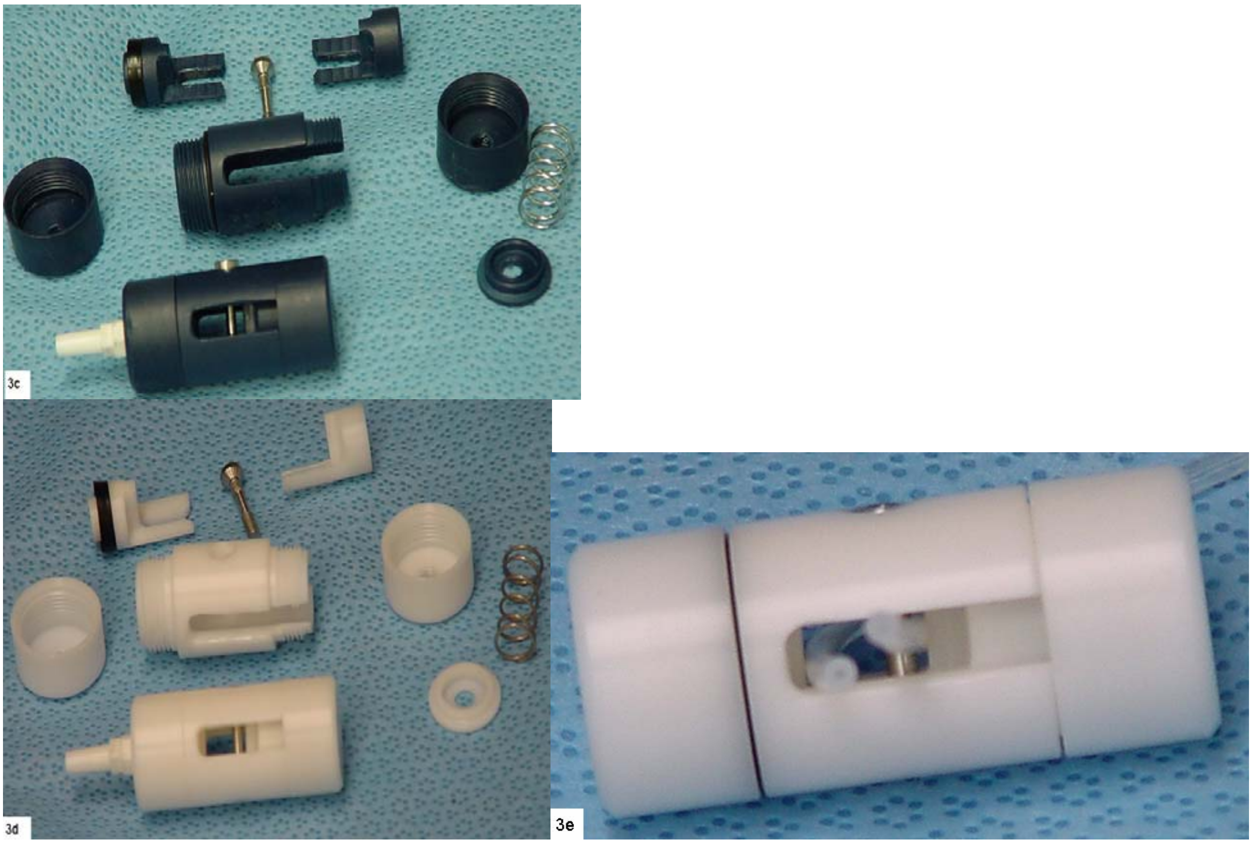


Figure 3: These figures represent the valve at various stages throughout the design progress in chronological order, from 3a-3d. Valve 1 (3a) was constructed to verify the efficiency of the occlusion design. The force exerted by the spring could be adjusted via the screw to further test the effectiveness of using a spring to achieve appropriate occlusion. Following the success of the design characteristics in valve 1, valve 2 (3b) was designed and constructed. Valve 3 (3c) was designed to further improve the valve's effectiveness. Valve 4 (3d) was constructed using the same design as valve 3, however Delrin was used as the construction material and CNC technology was used. 3e shows the two occlusion sites; normally open on the left side, normally closed on the right side.

Following is part 2 of James Higham's paper on an Automated Perfusion Pump.

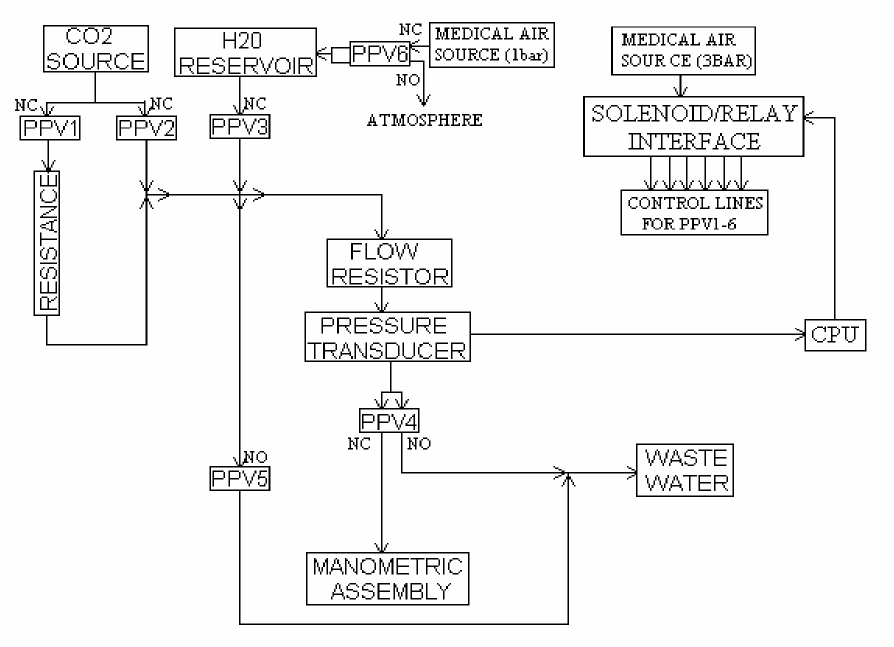


Figure 4: Construction outline for a single channel pump system. PPV1-PPV6 represent the pinch valves used.

Conclusion

At this stage all aims outlined for the pinch valves have been met. The current valve is operational with pressures of approximately 200kPa in both the control and perfusion lines, it is autoclaveable, the design is mechanically simple, normally open and normally closed positions are available in a single valve, and with the use of CNC technology it is relatively easy to manufacture.

In regards to the system as a whole the following criteria have been met:

- It is fully automated,
- There are appropriate safety mechanisms,
- The system has minimal compliance,
- Channels are electrically isolated from each other,
- It is relatively cheap,
- The channel spacing is approximately 1.5cm, and
- It is relatively simple to use.

The following criteria have not been met:

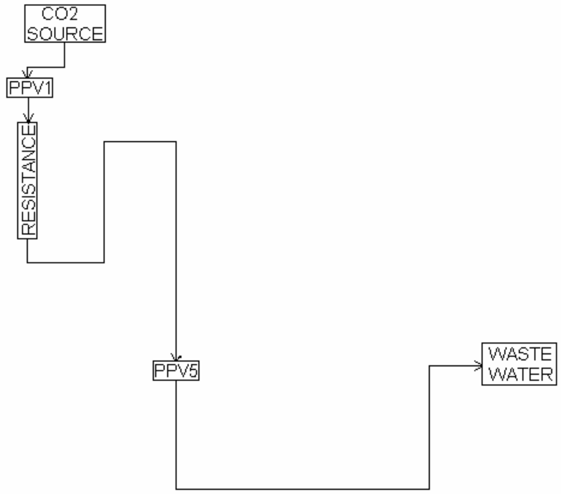
- There is no mechanism to indicate that the reservoir has run out of water- this can easily be incorporated using a liquid level sensor and an appropriate interface with the controlling software,
- N-channel arrangement not permissible- the channels have not been constructed as individual units however a redesign of the overall system could allow for this,
- The transducers are not calibrated automatically- this can be incorporated using an appropriate software routine.

The issue of conformation to the relevant Australian safety standards will need to be fully addressed in the near future.

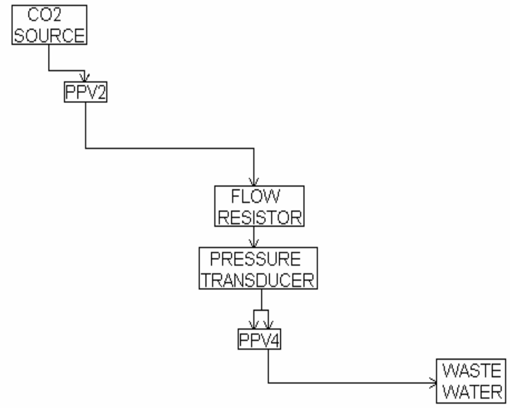
A new 32-channel system has been constructed based on the success of the 22-channel system for delivery to researchers based in Zurich, Switzerland, in mid January 2001. This system is shown in figure 6.

Acknowledgements

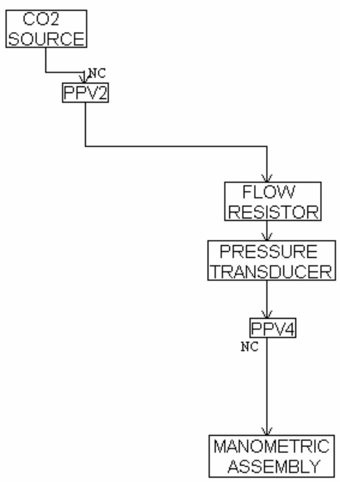
I would like to acknowledge the guidance and assistance provided by the following people; Dr Geoff Hebbard, Department of Gastroenterology, Repatriation General Hospital, Mr Robin Woolford, Biomedical Engineering, RGH, and Mr Terry MacKenzie, Engineering Department, Flinders University.



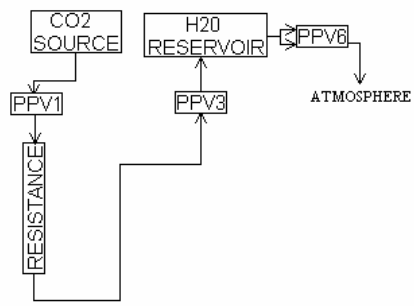
5a. The manifold is flushed with CO2 via a resistance to remove any air, the resistance controlling the flow rate of the CO2 delivery.
activated PPV1
deactivated PPV2-6



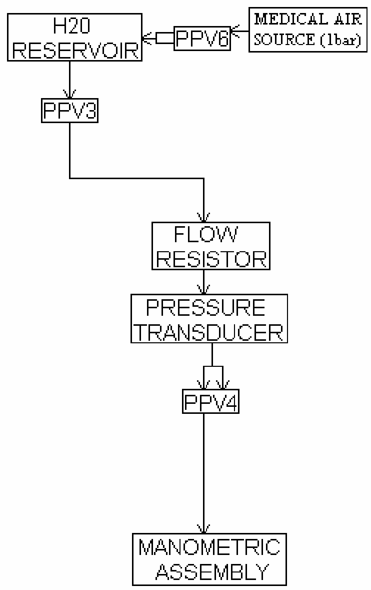
5b. CO2 perfused through to the waste water to remove the remaining air from the channel and manifold line.
activated PPV2 PPV5
deactivated PPV1 PPV3-4 PPV6



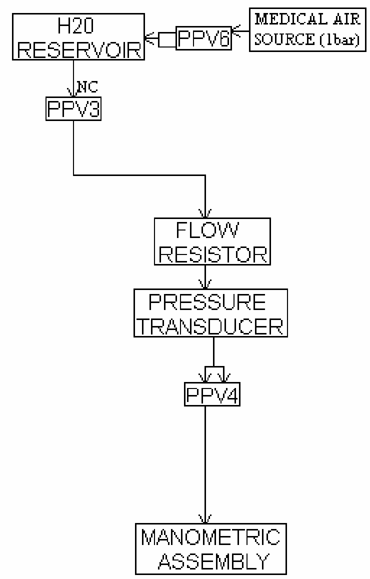
5c. Assembly is flushed with CO2 to remove all air from the remainder of the channel and assembly.
activated PPV2 PPV4-5
deactivated PPV1 PPV3 PPV6



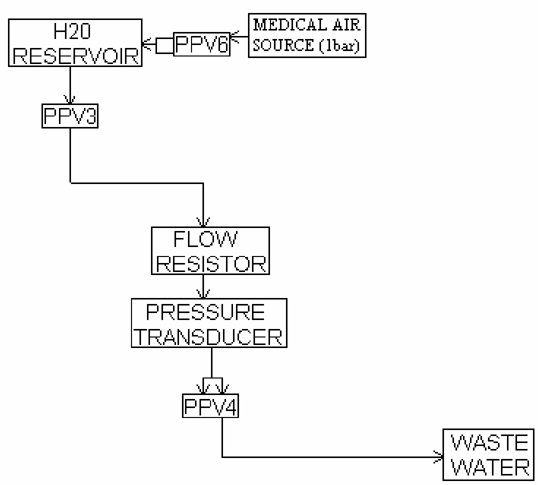
5d. Water line backflushed with CO2 via a resistance to remove air from the water line. The resistance ensures minimal turbulance is produced in the reservoir.
activated PPV1 PPV3 PPV5
deactivated PPV2 PPV4 PPV6



5e. Water is perfused through the assembly to absorb the CO_2 in the channel and assembly.
activated PPV3 PPV6
deactivated PPV1-2 PPV4-5



5f. The assembly is perfused with water to asorb the CO_2 in the channel and assembly.
activated PPV3-6
deactivated PPV1-2



5g. Water is perfused through to the waste water to absorb the remaining CO_2 from the channel and manifold line.
activated PPV3 PPV5-6
deactivated PPV1-2 PPV4

Figure 5: Figures 5a-5g outline the basic setup configuration for the system.

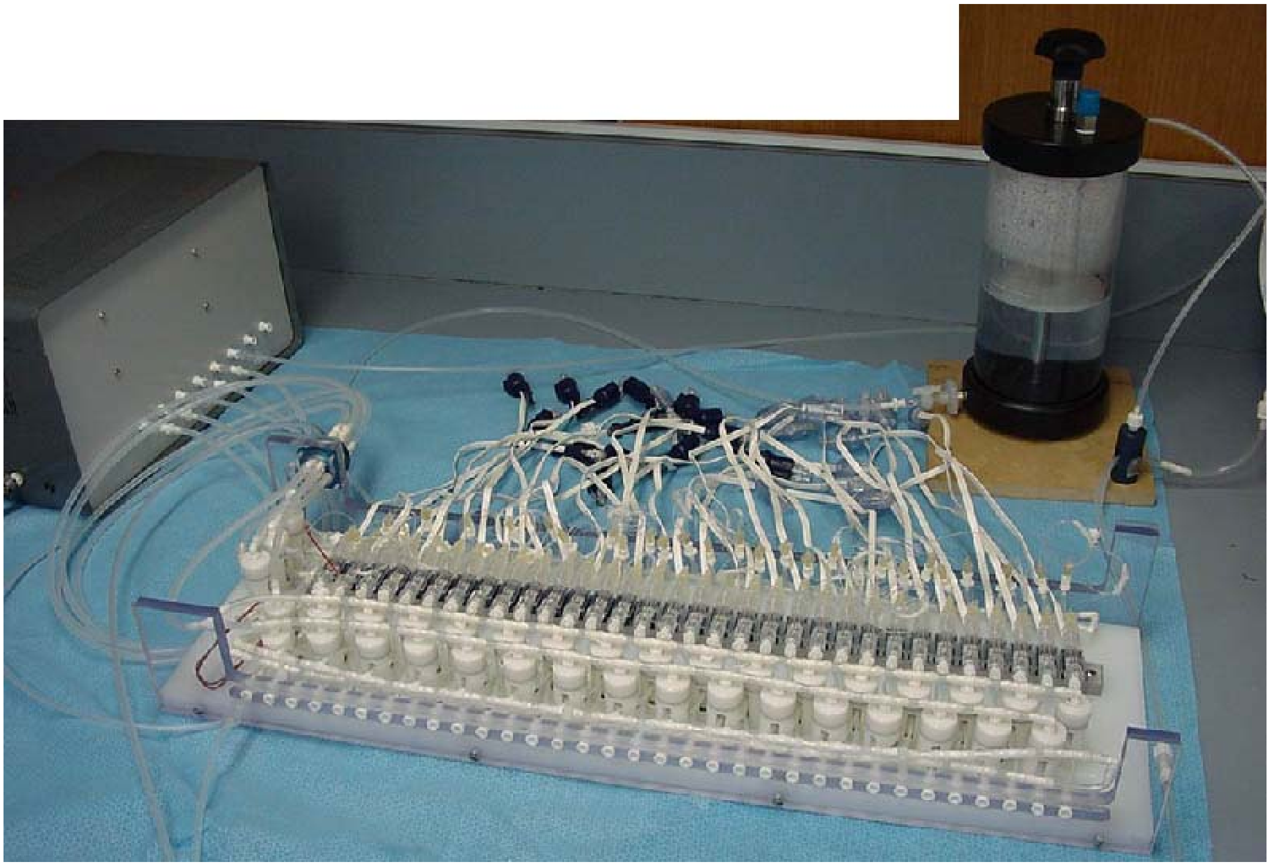


Figure 6: 32 channel system with reservoir (top right) and control box (top left) housing the solenoid/relay interface.