PROGRAMMABLE GENERATOR DEDICATED TO THE PREOPERATIVE COCHLEAR STIMULATION

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ABSTRACT

This study is about specific signal generation useful for preoperative electrical stimulation of the cochlea. The proposed generator was intended to check the state of the cochlea's nervous zones of one candidate to cochlear prosthesis apparatus. In fact, this cochlear stimulator would allow the insertion of an electrode into the round window to verify the state of intact nervous zones. Such clinical diagnosis is a useful preoperative evaluation to assure the effectiveness of this apparatus.

Originalities in preoperative stimulation techniques of the cochlea were then presented. The overall conceived system included one electronic stage for signal generation dedicated to the stimulation of the nervous zones, as well as a communication software offering to clinicians the control by a graphical module displayed on a host-computer screen. This study was based on a fundamental criterion that was the flexibility and handiness during clinical experimentation. The system for cochlear stimulation was henceforth an electronic apparatus driven by a processor, a 'micro controller', which could be interfaced to the host-computer. The latter displays a graphical module reassembling all the stimulation possibilities around a great flexibility and handiness.

In fact, the 'micro controller' used has allowed the generation of different forms of signals for stimulation: thanks to its programming, it was also possible to adjust with great flexibility different parameters such as the stimulation rhythm, the frequency, the amplitude and the stimulation pulses' shape. The signals' shapes proposed here were various: the rectangular shape frequently used, the triangular shape in staircase with different orders and the serrated shape (saw teeth shape) in staircase with different orders. The two latter shapes give multiple forms when varying the order of the staircase evolution.

This great variety in the stimulation signals' shape as well as the provided handiness would permit to clinicians better exploration of the cochlea's nervous zones before chirurgical intervention. This would give more information on hearing capacities of patients and on the implant type (one electrode or multi-electrode).

Keywords:, cochlear prosthesis, stimulation signals nervous zones

INTRODUCTION

Patients suffering from deep or total deafness could be rehabilitated nowadays by the use of cochlear prosthesis. This apparatus would assure some hearing while transforming the captured sound by a microphone into electrical stimulation impulses for stimulating the nervous zones of the cochlea. The stimulation would involve the start of nervous impulse transmission which would be propagated until the cerebral cortex for subjective interpretation (Zouari, 2002 ; Ben Hamida, 1998 ; Ben Hamida *et al*., 2000).

Before deciding the number and the site of stimulation electrodes, the clinicians would need to test the cochlea's nervous zones that are capable to transport a nervous impulse (Zouari, 2002 ; Ben Hamida, 1998 ; Ben Hamida *et al*., 2000 ; Estev-Frayss *et al*., 1989).

The state of cochlea's nervous zones (neuronal population) is a primordial parameter to predict results of implantation (surgical intervention). The purpose of electrical stimulation tests is useful in determining before intervention, the capacity of the patient to interpret an electric signal stimulating the cochlea. In the absence of any auditory sensation the test becomes negative. If there are some auditory sensations, this positive reaction would constitute an argument for the cochlear implantation (Fritze & Eisenwort, 1984).

Several stimulators were conceived during the past few years. They could deliver an electrical square signal (current) that could vary from approximately 0µA to 500µA. The signal frequency could vary from 50Hz to 1600Hz, where the stimulus cadence is fixed to 1Hz (500ms on/off) (House & Brackmann, 1973). It is the simple subjective tests that would permit to know the audition threshold and so the dynamic ranges of auditory sensation. It would also permit to predict that the implant would give results (Broks *et al*., 1985). This type of test is interesting because it would offer an efficient selection of candidates subject to this kind of intervention, and would predict the degree of success of such a procedure (Graham & Hazell, 1977).

Cochlear stimulation is achieved by a flexible system using a processor and a "micro – controller". The flexible stimulator could deliver stimulation wave in square shape, in triangular shape or in 'saw teeth' shape. With this variety in wave shapes, which is highly recommended by clinicians, one could make experimental stimulation with various possibilities. It would certainly permit the advantage of internal ear exploration by offering to clinicians more suppleness during tests and during pathological diagnosis (Zouari, 2002).

COCHLEAR PROSTHESIS: NECESSITY OF A PREOPERATIVE STIMULATION

Cochlear prostheses is a recent technological advance for auditory rehabilitation of total and deep deafness, which could be either an acquired handicap or a congenital one. The prosthesis assures an auditory perception while stimulating nervous zones electrically. It includes two parts for assuring its functioning (Figure 1): an external part permitting sounds analysis, the sounds analyzer, which generates command data for the internal part, the implant. The picked up acoustic signal would be analyzed in order to extract the most useful information to be transmitted to the internal part. The transmission is generally assured by electromagnetic coupling in order to avoid any possibility of cutaneous infection. The under cutaneous implant receives the information from the external part and generates stimuli *via* the inserted electrodes at the pertaining level of the cochlear nervous endings (zones). The efficiency of the implantation depends therefore directly on the persistence of functional auditory nervous fibers of the cochlea's patient (Zouari, 2002 ; Ben Hamida, 1998 ; Ben Hamida *et al*., 2000).

The first versions of these apparatus were conceived in analogical electronics. Currently, the conception is generally based on programmable digital techniques in order to benefit from the suppleness, flexibility and the multitudes of possibilities of stimulation. The sound analyzer is conceived around a specific Digital Signal Processor 'DSP' able to execute different stimulation algorithms. The implant, itself, includes a logical command unit conceived around different numeric stages in order to be able to execute the transmitted numeric data. The stimulation was assured by current sources piloted by this logical unit (Zouari, 2002 ; Ben Hamida, 1998).

Results of cochlear implantation concerning word understanding and interpretation appear to be variable from one candidate to another (Zouari, 2002 ; Ben Hamida, 1998 ; Ben Hamida *et al*., 2000). This variability seems to be dependent on healthy neurons, the central auditory way integrity as well as on the candidate's language level and the implant's surgical placement (Zouari, 2002). However, the main worry of the medical team would be the preoperative evaluation and the benefit that a patient would get from his cochlear prosthesis. It would be necessary to search for clinical factors that would have a predictive value of the implantation performance. Therefore, it would be necessary to study the factors that intervened in the process of neuronal degeneration and in rehabilitating phases, as age, length and deafness etiology, age at the time of implantation and intellectual state (Zouari, 2002).

Assuming that the number of functional auditory neurons has a direct effect on the capacity to integrate an electric stimulus in auditory perception, the second factor would be to evaluate the functional auditory way character. For that, one must get information on the transmission of the peripheral stimulation to the central auditory ways, while replicating the principle of the implantation. The developed tests consist in stimulating the lateral partition of the cochlea electrically while coming closer to cochlear nervous endings. The transmission of the electric signal to the auditory ways could be valued in two ways: by the study of behavioral responses to the resonant perception (subjective test) and by the registration of the auditory evoked potential (objective test). Indeed, the excitability of cochlear nerve and the central auditory ways could be established if the electric stimulation generates the auditory evoked potential (Zouari, 2002).

The subjective tests perform well by trans-tympanic stimulation of the promontory (promontory test) either by a direct stimulation to the round window that requires a surgical procedure (round window test). There might arise some difficulties due to the bony interposition between the electrode and the cochlea. It is for this reason that the direct stimulation of the round window was more extensively exercised. Nevertheless, the subjective tests involved two problems: they are not feasible for children and the interpretation of a subjective answer is difficult and could be a cause of mistakes (Zouari, 2002).

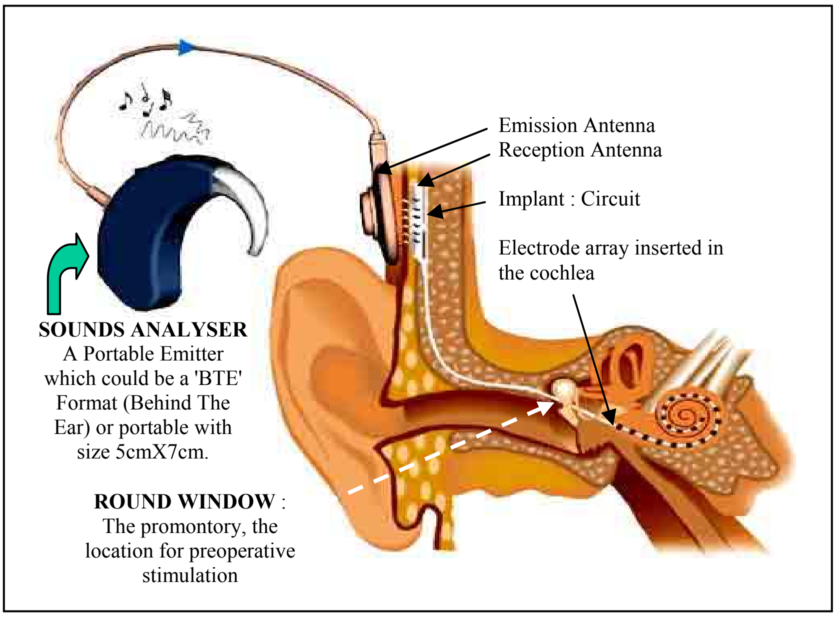

Figure 1. Main components of one cochlear prosthesis.

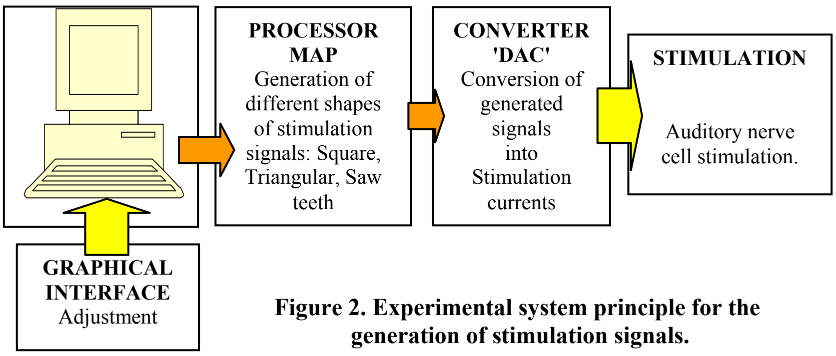

Figure 2. Experimental system principle for the generation of stimulation signals.

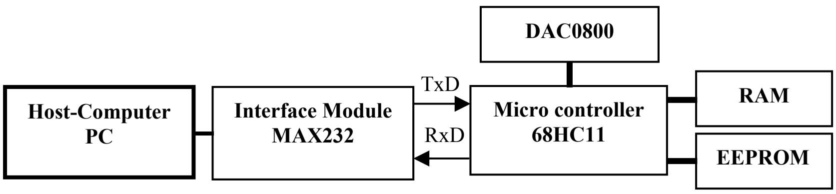

Figure 3. Stimulation system synopsis.

To overcome subjective test deficiencies, the utilization of an objective method becomes necessary. One of these methods is to record the precocious auditory evoked potential generated by electric stimulation of the cochlea. The stimulation could be applied very well either on the promontory or on the round window.

The main purpose of our research is to conceive an original promontory stimulator that could be programmable, supple and computer-assisted. The objective is to provide to clinicians a flexible and effective tool providing better information on neurons in the cochlea. The stimulator is destined to provide various stimuli: packets of waves of different shapes, which would be adjusted in rhythm, in frequency and in amplitudes (Zouari, 2002).

EXPERIMENTAL SYSTEM: GENERATION OF STIMULATING SIGNALS

Currently, very few clinical tests provide information on the internal functional state of the auditory system. Current clinical tests consist in stimulating the nerve cells of the cochlea by an electrical signal delivered by one electrode placed on promontory next to the round window or on the round window itself. A second 'ground' electrode would be placed on the mastoid (Estev-Frayss *et al*., 1989 ; Rsdorff *et al*., 1988).

The proposed device could provide a clinical test by using different shapes of waves with several frequencies and amplitudes (Figure 2). This would permit certainly the measure of different useful parameters as the auditory sensation according to the frequency and the intensity, the different thresholds as for pain, for intensity (smaller audible intensity variation), and for discrimination in frequency (smaller audible frequency variation) (Zouari, 2002, Abel, 1972).

Thanks to the utilization of a processor, a 'micro controller' (type 68HC11 of Motorola), which is a flexible processor in utilization, it was possible to generate different types of stimuli while starting with the square wave generally used, then by moving on to other various waves in staircase shape that could converge to a 'triangular' form or to a 'saw teeth' form (Zouari, 2002; Tavernier, 1997).

Micro controllers are circuits that regroup the basic elementary modules of a microprocessor in one 'chip'. One could find in these type of circuits a central unit, a memory, the input and the output peripherals, an analogue to digital converter 'ADC' and other useful modules that are integrated according to the 'micro controller' application. These existing functionalities in such a 'micro controller' are going to be exploited in order to conceive a stimulator of the promontory while respecting the essential points such as ease of manipulation, compatibility and adaptation (Zouari, 2002 ; Tavernier, 1997 ; Delsol, 1976). Also a clinical assistance tool was provided in the form of a software allowing clinicians the adjustment of stimulation parameters from a host-computer. The generator with its stimulation stage thus conceived and achieved should be then interfaced to the host-computer.

Technical features of the experimental system:

The experimental system conceived around a 'micro controller' map allowed the generation of various stimulation signals. It contained the following features (Figure 3):

- Autonomy: the electronic stage includes its own 'micro controller'.
- Interfacing with a host-computer 'PC' by a RS-232 link set, to a speed of 9600 bauds;
- Other features such as a 32k bytes RAM extension, a 32k bytes EEPROM extension, and a 'DAC' of the type DAC0800, that converted the numeric signals generated by the 68HC11 'micro controller' to analogical current for stimulation (Zouari, 2002 ; Tavernier, 1997 ; Delsol, 1976).

The electronic part for the stimulation stage permits the generation of different adjustable stimulation wave shapes amplitudes, frequencies and stimulation rhythms. The operation of this part is controlled by the 'micro controller' and managed by two software types: the first one is written in machine language, 'the assembler', intended for the programming of the 'micro controller'. The second one, piloting the user-interface, is foreseen for the programming of the link set in 'JAVA' language. These two programs, in 'assembler' and in JAVA, permitted the communication of the map with the host-computer and gave the user the possibility of making adjustments. Indeed, it would be possible to select the type of stimuli, the frequency and the intensity of the signal as well as the selection of stimulation duration (Ts) and relaxation duration (Tr) (Figure 4) (Zouari, 2002).

Technical specification and originalities of the proposed stimulation signals:

After several meetings with the specialized clinical teams, the most desirable experimental strategy and approach were agreed upon.

The first proposed stimulation wave shape recommended was the square shape. The stimulation would take place by a stimulus packet delivered at a cadence going up to 25pps (packet per second). This chosen stimulation rhythm margin would be appropriate for the propagation of the auditory nervous impulse. The stimulation current could vary approximately from 0µA to 1mA according to the electric stimulation standards (Ben Hamida, 1998), and the frequency of the stimulus could go up to 8kHz audible frequencies (Figure 4).

The determination of the deafness degree and the hearing thresholds for frequency and by amplitude is crucial. Indeed, in the clinical domain, it is always desirable to have a largely supple and efficient stimulator in order to permit the diagnosis of the different pathological cases.

The originality in this proposed rapproach, was the stimulation of cochlea's nerve endings by other current wave shapes (Zouari, 2002). The 'micro controller' allowed different programming possibilities. I twas thus possible to get a rich choice of stimulii for various pathological cases. This would be useful in exploring other fibers capable of transmitting nerve impulses.

The following figure illustrates the construction principle of the shapes of these stimulation waves. Note that in this diagram only one period stimulus is given. However, at the time of stimulation, the stimulus would be repeated to a chosen frequency that could achieve 8000Hz, so as to describe all the hearing frequencies, and would be given by packet of stimuli at a cadence going up to 25pps as mentioned in the case of a square wave (Zouari, 2002). Different orders of these shapes of stimuli waves were possible until 2^8=256.

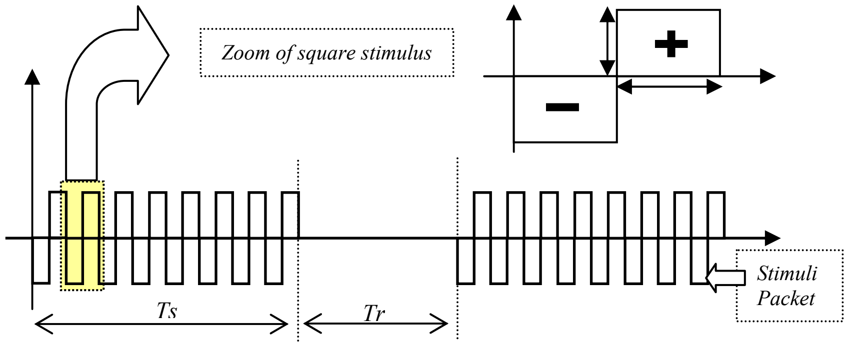

Figure 4. Square wave shape for the stimulation.

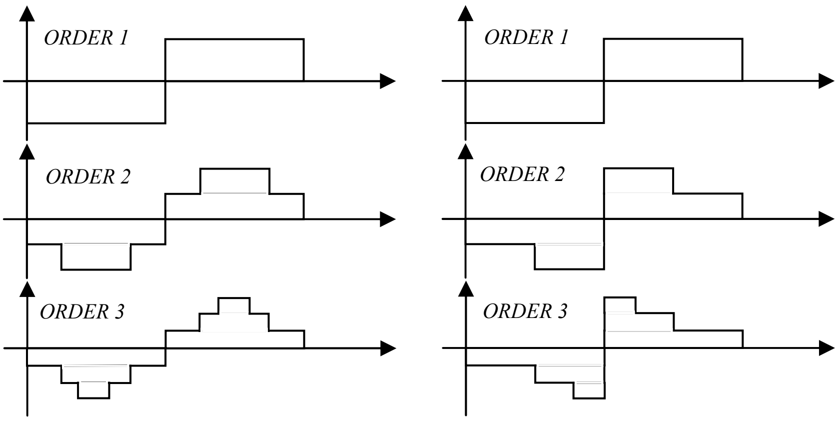

Figure 5. Shapes of stimulation waves in staircase evolution limited to the order three.

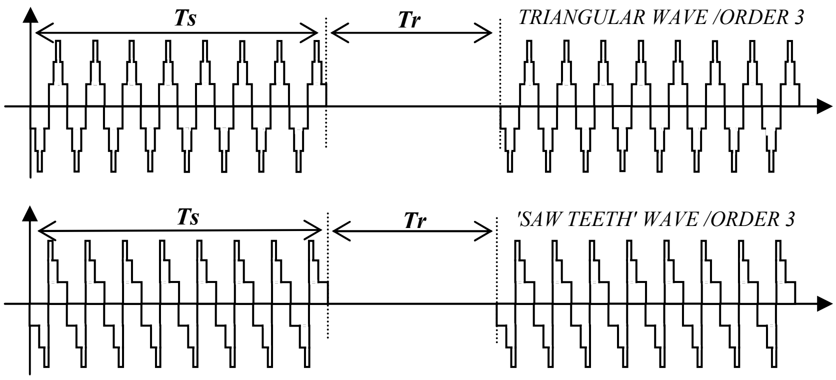

Figure 6. Packets of stimuli (staircase form) in triangular and 'Saw Teeth' wave shapes (Order three).

For the order 256, the form of the stimulation wave becomes nearly linear to recover a triangular shape or a 'saw teeth' shape: it is about the highest resolution that makes part between other choices indicating the flexibility of use (Figure 5, 6) (Zouari, 2002). On the other hand, these two supplementary waves' shapes that have been added to the square wave, and that have been increased by order variation, could certainly give better results in preoperative assessment of auditory remainder, the remaining hearing cells.

Through this approach the limits in frequency and in amplitude were expanded and a flexibility of choice concerning stimulation rhythm was provided. The clinicians would have more possibilities to assess the auditory sensation of patient according to the frequency and the intensity of the stimuli as well as in relation to the pain threshold and to the frequency discrimination (Zouari, 2002 ; Abel, 1972).

Figure 5 illustrates the principle of shape construction of stimulation waves in staircase evolution limited to the order three. Figure 6 gives packets of stimuli (staircase form) in triangular and 'Saw Teeth' wave shapes (for order three).

SOFTWARE ASPECT OF THE SIGNALS' GENERATION SYSTEM

The used 'micro controller' offers the advantage of being programmable directly from the host-computer, from a serial port, while permitting the interfacing with an external RAM (Tavernier, 1997). It permits indeed the material resource adaptation to the user's needs. It was necessary to establish the communication set between the 'micro controller' and the host-computer, in order to get stimulation adjustment commands *via* the computer. With this message, the 'micro controller' gives the order to all modules of the map to begin the treatment and to generate the desired stimulus. Subsequently, a software distributed in two main parts was written:

Part 1: 'micro controller' programming:

The program written in assembler code and saved in the 'micro controller' memory was also composed of two parts:

- One program written in RAM constituting the main program, since it manages the different under programs saved in the 'micro controller' EEPROM. At the start, it receives the user requests to know the type of the signal to generate : its frequency, its amplitude, the time Ts for stimulation, the time T_r for relaxation and the stimulation rhythm. It stocks them then in five memory zones having each a size of two bytes in RAM. After that, it points toward the program of treatment to be followed finally by the program of signal generation (Tavernier, 1997).
- Program stocked in EEPROM gathering one subprogram of receipt, permitting so the receipt of data through the harbor set under the norm RS-232, one subprogram of treatment and one program of signal generation (Tavernier, 1997).

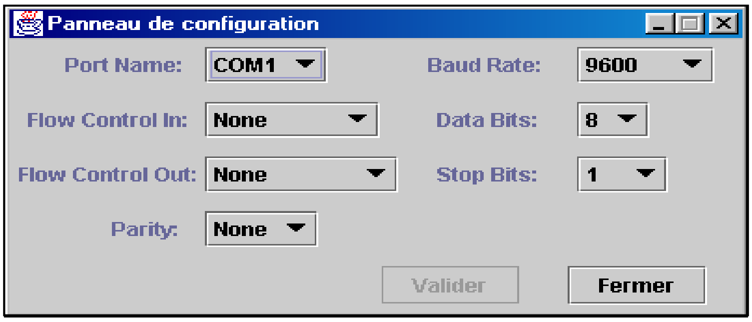

Figure 7. Configuration panel in the serial interface.

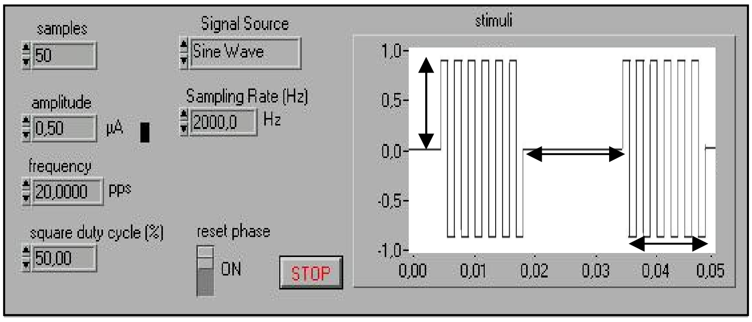

Figure 8. Graphical interface.

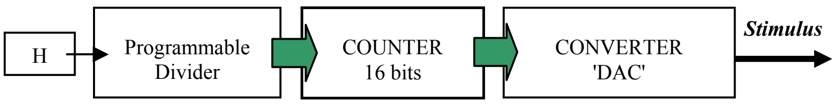

Figure 9. Procedure of the signal generation.

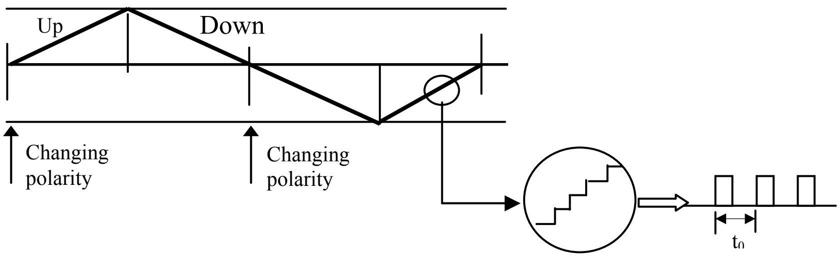

Figure 10. Generation of a staircase signal for different order (Triangular form).

Part 2: The user-interface programming:

The second software is written in 'JAVA' language. It manages the communication set between the host-computer and the 'micro controller' (under RS-232 standard), and gives the possibility to the operator to send commands to the 'micro controller'. This software includes also two essential parts:

- The interfacing set: it manages the communication between the PC and the 'micro controller'. The essential task in this program was to be able to transmit data, *via* the serial port, from the computer to the 'micro controller'. This task could be summarized at the opening of the serial port, to the characters' emission and to the closing of the serial port at the end of the communication. The principle of this technique consists in opening a file associated to a peripheral with names COM1 or COM2 on which operations of reading or writing could be done. With this principle, and by using 'JAVA' functions, a program that manages this communication set is also proposed in this study. The value of the serial port could be displayed in an icon for message at the time of the utilization of the serial link (Figure 7). Finally, on the basis of all these functions, we initialized the interfacing set under the norm RS-232 with an equal transmission speed to 9600 bauds passing in transit with eight data bits (Zouari, 2002).
- The user-interface to manage and to acquire commands of the adjustment (Figure 8). In fact, in order to have an entirely programmable map, and in order to make all parameters accessible to the user, a graphic interfacing was conceived to allow clinicians to adjust all stimulation parameters prior to stimulus generation (Zouari, 2002).

SOFTWARE ASPECT OF SIGNALS' GENERATION

It has become evident throughout this study that a great variety of stimulation wave shapes for all eventualities would be desirable for the test and preoperative diagnosis. The programming of the different waves' shapes would be made thanks to the different programming possibilities offered by the 'micro controller' that was used.

The utilization of the memory, the timer and the D/A converter (Figure 9) permitted to get the specific signal generation for the stimulation. It is about generating the classic signal that is the square wave in the first place. Then, signals in staircase forms having different orders with an evolution toward a triangular form. Finally, signals in staircase forms having different orders with an evolution toward a 'saw teeth' form. All the procedure of programming of this variety of forms was based on the following block diagram:

Timer of the 68HC11 was a very complete subset that offers to user multiple functions. The main part of this Timer is a 16 bits counter (TCNT) functioning without stop as soon as the clock of the 68HC11 starts. It begins counting from $0000 after a 'Reset' and account until $FFFF. After an overflow, it comes back then to $0000 while positioning a bit of an overflow. This counter is preceded by a programmable predivider supplied by the clock. Similarly, this Timer has three 16 bits registers of capture in entrance. These registers are foreseen for being read at all times. When the corresponding capture skewer in entrance passes to a valid level, that one would be able to define freely, the value of the 16 bits counter at this moment is copied automatically in the corresponding register. A bit of state is positioned then and an interruption could be generated, so that it is possible to date an external event.

The second important function of this Timer is called the comparison in exit, and need one of the five 16 bits registers of comparison 'in exit'. These registers that one could program the content at anytime are compared permanently with the 16 bits counter of the Timer. As soon as there is equality, a bit of state is positioned, an interruption could be generated and the corresponding skewer exit state could be changed in the desired way (Tavernier, 1997 ; Delsol, 1976). It thus becomes simple making the signal generation with programmable shape and duration.

The utilization of the memory of the Timer and of the 'DAC' converter permitted specific signals' generation for stimulation such as the square wave, signals in staircase forms having different orders with an evolution toward a triangular form and signals in staircase forms having different orders with an evolution toward a 'saw teeth' form.

For the generation of the square wave, according to the user's requests such as adjustments of the frequency, the amplitude, the rhythm and the stimulation duration, this form from the Timer and the 'micro controller' port 'B' was programmed. The combination of the Timers TOC1, TOC2, TOC3, TOC4 and TOC5 of the 68HC11 was opted for, so that a simple logical operation was sufficient to provide the desired signal.

For signals in staircase forms having different orders with an evolution toward a triangular form, we used the 'DAC' converter and the Timer's counter of the 68HC11. During the half-period, this 16 bits counter was programmed, synchronized by the programmable predivider (of period t_0) piloted by the clock, so that it would be incremented to deliver an increasing numeric information linearly. As soon as it reaches $FFFF, the counter would be decremented to deliver a decreasing numeric information linearly in one duration. It is therefore the same way for the analogical current delivered by the 'DAC' converter whose binary register is the 16 bits counter (Figure 10).

The second alternation of the signal is reconstituted according to the same process but while reversing the 'DAC' reference. The amplitude of the triangular wave thus generated could be adjusted while varying the 'DAC' reference. The frequency could be also adjusted while varying the frequency ($f_0=1/t_0$) of the predivider supplied by the clock (Zouari, 2002 ; Delsol, 1976).

For the generation of signals in staircase forms having different orders with an evolution toward a 'saw teeth' form (different orders or levels), the procedure is nearly the same (Zouari, 2002).

CONCLUSION

In this article, a survey for the generation of stimulation signals of the cochlea was presented. The preoperative stimulation is necessary to test the cochlea's nervous zones of a patient candidate to the cochlear implantation. By foreseeing maximum flexibility, the clinician has a programmable tool, flexible for experimentation and efficient. Such a tool permits to assess potential benefit levels with cochlear prosthesis apparatus before operation (implantation).

Different shapes of stimulation waves have been foreseen: this approach gave a procedure different from currently existing methods.

The proposed approach has been discussed with specialized clinical teams that have the experience concerning cochlear electric stimulation. This experimental system, extensively discussed, has been used with success as far as the generation of specific signals for preoperative cochlear stimulation is concerned. The study offers more flexibility compared to the existing models (usually using a simple square wave), and proposes a great variety in choice of other shapes of stimulation waves for all tests and clinical diagnoses.

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