THE DEVELOPMENT OF RENOGRAPH PROTOTYPES FOR KIDNEY FUNCTION TEST IN INDONESIA AND ITS PERFORMANCE TEST

Rill Isaris [1], Rukmono Pribadi [2], Gogot Suyitno [3]

ABSTRACT

The number of renal cases diseases was increasing during this two decades, meanwhile the number of Renograph provided for renal function studying available in the hospitals is still limited. After the economic crisis stroke Indonesia since the year 1997, imported of equipments from abroad is obstacle by the costly of their price .In order to provide the necessity of medical diagnostic instruments in hospital, BATAN developed some Renograph prototypes using nuclear technology since 1983. Five generation of prototypes have been developed and constructed since the first generation of without computer system to the fifth of with computer system operated on Windows 95/98 and 98/2000. The fourth generation identified as BI-756M common type is designed to serve as a basis for the perfection of the renograph for mass production and the fifth generation was recognized as add-on card (AOC) Renograph, operated on Windows 98/2000. The latest generation of renograph was developed by following the technical information given throughout the IAEA Technical Documentation, especially on analog circuitry and the interface to PC.

Eight unit of common type have been installed and used successfully in 8 hospitals since1987, and then 2 unit of the AOC type have been installed in two hospitals since 2001. Design and construction of these prototypes have applied the engineering rule concerning the procedures and quality assurance.

Performance and clinical testing to the prototype of AOC renograph showed that it passed all tests satisfactorily. Clinical test was carried out by the medical doctors. The performance tests showed that count accuracy of counter was 0,03% , the time error was 0,025%. Integral and differential non-linearity were satisfactory, count rate non linearity for 0.5Kcps to 2Kcps was vary from 2% to -1%. Chi-square test results to observe the statistical counting feasibility showed the χ^2 for the prototype and the Canberra NIM that parallelized connected are between 4.54 to 13.16 and 5.48 to 11.44 respectively, for the count-rate from 250 to 6700 cps. Both were within the limits as stated in the IAEA Tecdoc 602, that is between 3.325 to 16.919 for 0.95 the confidence level. The AOC can also provide for refurbishing of aged renograph instruments in the hospitals.

Keywords : *renograph prototype , development technology, nuclear medicine instrument*

INTRODUCTION

Entering the year of 1980, the use of conventional non-computerized Renograph System become diminishing and unsatisfying, because of some reasons, such as taking a long time for data calculation and for getting the result, the lack of the capacity for getting the whole kidney parameters, and non-user friendly character of equipment. The introduction of Gamma Camera Computer System since the end of the year 70th is also the reason for lack of interest in the use of conventional renograph. Then with refer to the great progress achieved on the electronic device fabrication and on the computation techniques using Personal Computer sinceearly of the year 80th , the improvement of design and refurbishment of aged renograph become interesting to be considered. The developing countries like India and China are still producing the Renograph as a single purpose, while the developed countries prefer to manufacture Gamma Camera System.

Isotope renography techniques using collimated probes have been yearly used for monitoring time-activity curve of kidney by detecting the traces of radioactive injected into the vena. The time-activity curve can be displayed on the monitor, then by using the clinical formulation, eleven kidney parameters can be calculated and displayed. The capacity of yielding diagnostic information whether qualitatively or quantitatively, the lower commercial price and operational cost compared to the other similar diagnostic equipments, bring the developed renograph system to have both the comparative and competitive advantages as the diagnostic equipment in the hospital. The non-imaging character is probably one of its weaknesses, so that the geometric counting factor is one of important factors. Improper placement of the two detector probes against the kidney positions will affect physical dimension of the renogram display result. However, this improper position of detectors can be identified by considering excretion capacity factor and urodynamic patterns of renal function, because the change is only in its distribution not in its pattern.

[1] Drs. Rill Isaris, Center for Accelerator and Material Process Technology BATAN, Yogyakarta, Indonesia
[2] Drs. Rukmono Pribadi, Center for Nuclear Equipment Engineering BATAN , Puspiptek, Serpong, Indonesia
[3] dr. Gogot Suyitno, DSR, DSKN., Dr. Sardjito General Hospital, Jl.Kesehatan Sekip, Yogyakarta, Indonesia

The experiences gained from the development of prototype of Renograph Computer System can be applied furthermore for refurbishment of aged renograph. A lot of aged conventional renograph system is still available in the hospitals. Isotope renography as one of diagnostic modalities was widely accepted, and still has good prospect as a diagnostic equipment in the hospital. The comparative advantage of renograph system lies on its capacity of yielding the information from both kidneys as individual and/or total. Meanwhile, the cost-effective, short and fast examination it offers, the fact that it does not require high skills operator, and low cost maintenance constitute the competitive one.

Since 1983, five generation prototypes of renograph system have been developed and constructed as reported by Supardiono.B, Rill Isaris (1984 & 1993). Gogot Suyitno, (1989), and Sumartono, (1993). In principle, the equipment is designed based on common nuclear spectroscopy system. It consists of two Scintillation detectors placed on dual collimators made by Pb as the shielding and directing to the target, the electronic system (LV and HV Power Supply, amplifier, Single Channel Analyzer, Timer & Counter, display devices), recorder and Personal Computer for the newest generation, as shown in Figure 1.

Renograph BI 756M is the 4th generation of prototype, it has been used as a basis to perfect renograph for fabrication as reported by Rill Isaris (1996) and Gogot Suyitno (1996).

Preliminary clinical application at hospital was started by Yogyakarta Nuclear Research Center in cooperation with 7 hospitals. Ten prototypes of this generation have been built and applied in hospitals.

After ten years application in hospitals since 1987, due to the ergonomic consideration and the pressure to follow the technology progress, some improvements are important to be considered and performed both on hardware and software parts. Innovation of technology requires at least in five demands that is : faster, smaller, easier, cheaper and smoother. So that, it is expected that the newest renograph generation will fulfill all the above consideration of technology progress.

FUNDAMENTAL

Renograph is a diagnostic equipment for renal function testing, through analyzing the time-activity curve of the distribution of radiopharmaceutical pass through the two kidneys and kidney parameters that can be calculated from the curve. In order to get a more convenience and compact instrument but still have a good performances, an engineering touch and design completion should be put to the system. Based on the evaluation to the performances and application of BI 756M Renograph and on the study of the technology progress in electronic instrumentation and computer system recently, Rukmono P.(2001) reported that a couple of improvements was performed with the following objectives :

1. To simplify the hardware design and to economize the production and operation cost (by diminishing the the electric power consumption and the optimization of the physical size by diminishing the console).
2. To modernize the software system (by simplifying the system operation, eliminating the dependency of the operation to the electronic technician, and adopting the new progress in windows.
3. To eliminate the hardware components (by replacing with the integrated and compact devices, replacing the console control with PC control, power to the detector HV is driven from the computer power system)

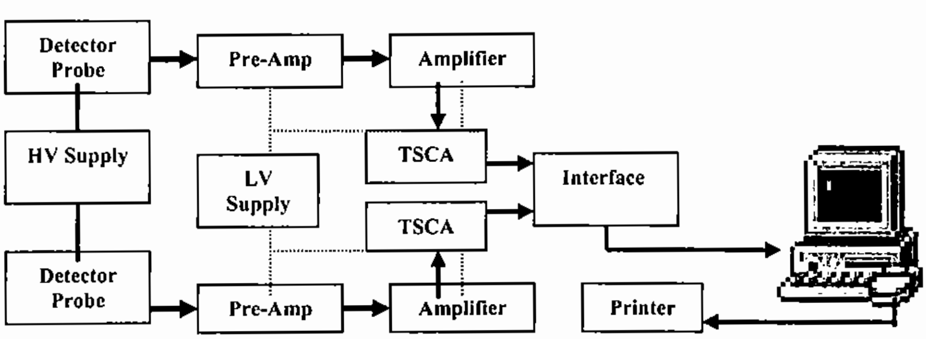

Figure 1 Block diagram of Renograph System BI 756M

The system design is set up by following the step of engineering methods, that is Design requirements, Basic Design Documents, Detail Design Documents, Procurements, Fabrication/Production, Commissioning & Acceptance Tests, and Documentation. Almost all the function of the electronic control and counting system are taken over by a new system called *Add On Card* (AOC) System which is integrated in a Printed Circuit Board. The basic principles of the AOC are as the following :

1) AOC is a ISA Bus type
2) AOC function as Dual Single Channel Analyzer (SCA) and Dual Counter
3) The SCA plus Digital to Analog Converter (DAC) is designed to make the possibility of its function in fully software driven.
4) The AOC card can be mounted in the PC slot system

The modernization of software is aimed at several reasons as the following:

- To improve the simplicity of system operation: by operating under window software, it will be easier in operation and manipulation, it is possible to use mouse, interface graphic/icon, and print by various printer.
- The examination results are saved in disk, it can be copied into floppy disk if necessary. The name of file is defined by software, based on year, month and day as well as the name of patient on that day.

Renogram curves of those two kidneys can be printed individually in BW, or by superimposed in colour. Kidney function parameters can also be displayed or not. When opening the previous file (retrieving), there will be the preview of patient's data and renogram curve displayed in the monitor.

By those new performances, two units of Add On Card Renograph have been successfully constructed and installed in Yangon General Hospital Myanmar and Bethesda Hospital Jogyakarta. Since 1987 there are 11 units Renograp prototypes have been utilized by several hospitals as shown in Table 1.

METODOLOGY

The AOC Renograph is a non-imaging nuclear medicine instrument, but enabling to yield the renogram curve and the renal function parameters. The block diagram of AOC Renograph namely PNR 757 is shown in Figure 2. Radioisotope tracer such as ^{131}I hippuran or ^{99m}TC DTPA was injected through intra-vena to the patient, and in seconds the tracer will reach the kidneys. In kidney paranchym, the tracer will enter into neuphron system and then flow out to the bladder. Two NaI(Tl) detectors detect the radioactive distribution of the tracer as the function of time on the right and left kidneys. The input signals from the detectors then amplified and shaped by the preamplifier (PA). These pulses are analyzed by AOC unit which consist of Amplifier, Single Channel Analyzer (SCA), Counter and Interface for communication with PC. The amplifier stage consist of pole zero cancellation and two complex pole filter stage with 2 μ-seconds shaping time constant. This stage amplified the signals and shaped them into Gaussian with short time constant.

The SCA selected pulses which have correspond energy to the radiopharmaceutical used to the kidney that passing the gate. The SCA setting is done by DAC's which are fully software operated. The counting pulse out from SCA then is counted by a Digital Counter. Further data are stored into the PC memory for analyzing and for data preparation.

The software was written in Basic and compiled as an executable file, and operated on Windows 98/2000 environment.

Table 1 Renograph prototypes produced by BATAN

No	Type/Generation	Year & Quantity	Capacity	User Hospital
1	BMF 752, NC	1987 (1)	Time activity curve (TAC)	Dr.Sardjito Jogya
2	BMF 753, C on DOS	1990 (1)	TAC and 8 kidney parameters (KP)	Dr.M.Djamil, Padang
3	BI 754, C on Windows 31	1993 (1) 1994 (1)	TAC and 10 KP	Dr.Soetomo, Surabaya, RS Centra Medika, Surabaya
4	BI 756M, C on Windows 95/98	1995 to 1999 (5)	TAC and 12 KP	RS.Mataram, Dr.M.Djamil, RS Garut, RSPP Sukanto, Jakarta, RS.PKU Bantul
5	PNR 757, C on Windows 98/2000	2001 (1) 2004 (1)	TAC and 12 KP	Yangon Gen.Hospital , Myanmar, RS.Bethesada Jogyakarta.

Note : NC = Non-Computerized , C = Compatible to PC

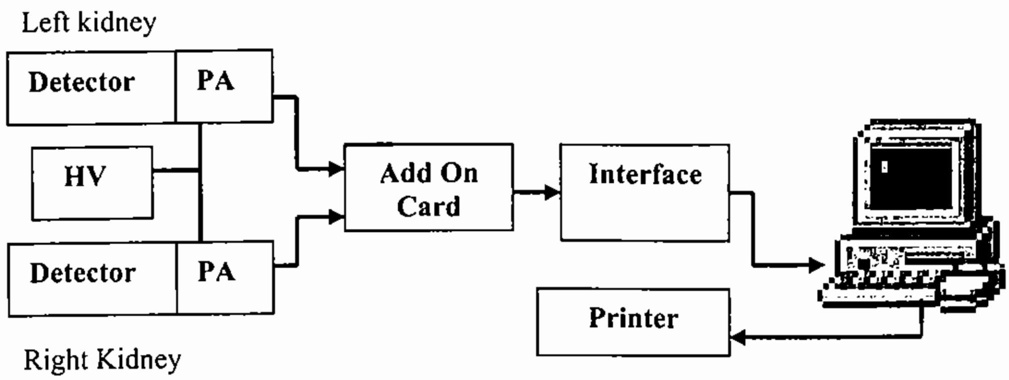

Figure 2 Block Diagram of AOC Renograph

From the textbook and according to Gelfand, M.J et.al. (1988) the normal radioactive distribution time activity curve of kidney is shown in Figure 3. Analyzing was made by investigating the shape of curve and the kidney parameters calculated. The five parameters can be calculated from the curve are :

1. T_{max}(time used to reach the peak),
2. $T_{1/2Max}$ (T_{max} – time used to reach the ½ of the peak high),
3. $T_{2/3Max}$ (T_{max} – time used to reach 2/3 of the peak high),
4. C_{max} = counting at peak position,
5. C_{10} = counting at T=10 minutes. And six next parameters can be calculated from the formula, i.e.:
6. The Up-slope : TUS = $[C_{max} - C_{T1}] / C_{max}(T_{max} - T_1)$, C_{T1} = counting at time = T_1
7. The Down-slope $T_{1/2}$:
   TDS $T_{1/2} = [C_{max} - C_{T(1/2)}]/C_{max}.T_{1/2}$,
   $T_{1/2}$ = time at counting = ½ C_{max}
8. Down-slope $T_{2/3}$:
   DS $T_{2/3} = [C_{Max} - C_{T(2/3)}] / C_{max} . T_{2/3}$
9. Renal-index :
   $$RI = \int_{T_1}^{T_2} C_{Left}(t).dt / \int_{T_1}^{T_2} C_{Right}(t).dt$$
10. Relative Up-Take (%) = Capacity of each kidney (Right or Left) to up-take the injected tracer (total), or for example the Right Kidney (with R notation) :
    $$= \frac{[C_{R(At\ phase\ 2)} - C_{R(At\ phase1)}]}{[C_{R(ph-2)} - C_{R(ph-1)}]+[C_{L(ph-2)} - C_{L(ph-1)}]}$$
11. Percentage Individual Excretion (%) is percentage excrete of the up-take tracer by individual kidney (normally take after T = 10 minutes), for example, the right kidney (R) :
    % Excrete = $[C_{R(ph-2)} - C_{RT(10)}] / C_{R(ph-2}$

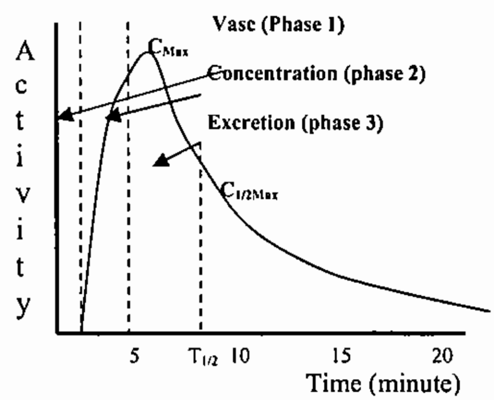

Figure 3 Time activity curve of normal kidney (from study Gelfand,M.J et.al)

PERORMANCES TEST AND RESULTS

To guarantee the reliability of the system, some appropriate testing and examination to the performance of equipment have been carried out, among others are counting accuracy, time accuracy, integral and differential non-linearity, count-rate non-linearity and statistic counting feasibility (chi-square test).

COUNT AND TIME ACCURACY

To observe the count and time accuracy of AOC Renograph, the test set up was shown in Figure 4. The system accuracy is compared to the standard nuclear counting instrument made by Canberra. The AOC Renograph under test and Canberra Amp/TSCA and Counter/Timer are parallels connected to a PB-4 Pulse Generator and simultaneously activated for counting. Start and stop for the output pulse from Pulse Generator was done manually.

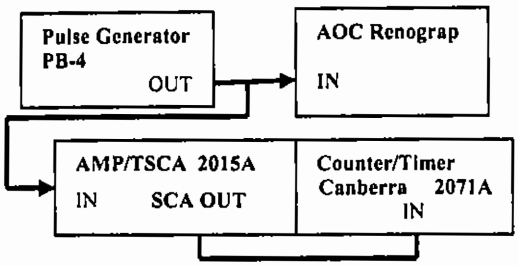

Figure 4 Count and time accuracy test

For the count accuracy test, the Pulse Generator was set for counting repetition rate of 1, 5, 10 and 15 KHz , while for time accuracy test the system updates the counter for every 4 seconds to observe how stable and good is the time accuracy. Table 2 and 3 shows the result of the test.

The time error is about 0.25% which is in theoretical maybe interesting, but has no influence on the result, because the series of 4 second measurements have the same time deviation. This deviation will give a total time extension of 6 seconds for 40 minutes time measurement and will not lead in a false interpretation to the presented renogram curve.

INTEGRAL AND DIFFERENTIAL NON-LINEARITY TEST

The feature of non-linearity of a nuclear instrument is absolutely important when multiple energy line have to be analyzed. In renograph application only a single source (^{131}I or ^{99m}Tc was measured. The renograph emulation software requires a spectrum test. During this test, the operator has to set the region of interest (ROI) and the corresponding electronically SCA settings are performed by software.

The overall integral non-linearity test results are presented in Table 4 and drawn in Figure 5. This is the sum of the NaI(Tl) detector, Preamplifier, Amplifier and SCA together.

Table 2 Count Accuracy Test Results

Counting Repetition Rate	Counting by 2017A Canberra Counter	Counting by AOC Renograph under test
1 kHz	11507	11507
5 kHz	50520	50505
10 kHz	114624	114593
15 kHz	149038	149019

Table 3 Time Accuracy Test Result

Repetition rate	AOC Renograph under test	Canberra NIM System	Error (%) (deviation)
1 kHz	4156	4146	+0.25
5 kHz	20202	20152	+0.25
10 kHz	40610	40510	+0.25
15 kHz	63783	63933	+0.25

Table 4 Integral Non-Linearity Test Result

Element	Energy (keV)	Peak Channel		Deviation in Channel
		Presented by software	Calcu-lated	
^{137}Cs	662	230	230	0
^{131}I	364	125	126.5	-1.5
^{99m}Tc	140	52	48.6	+3.4

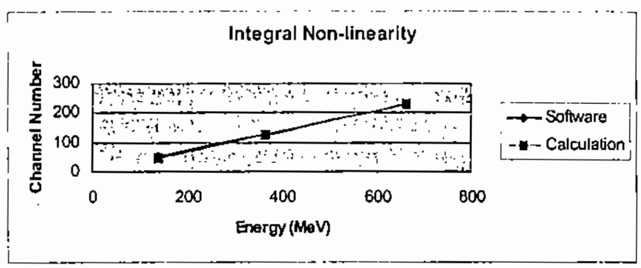

Figure 5 Integral Non-Linearity Curve AOC-Renograph

Table 4 was a first fit using ^{137}Cs source as a reference. NaI(Tl) spectra has never a straight calibration line (energy vs peak channel) , therefore, the fit is acceptable.

The differential non-linearity measurement in the classical method of a fixed window versus energy will not lead to a correct data interpretation, because of a low resolution spectrometer system (Scintillation). In addition, the ROI of a low energy peak requires less channel than those peaks of higher energy. The available pulse generator does not permit a proper amplitude setting and dial reading as it is essentially needed for the test.

COUNT RATE NON-LINEARITY

The renograph should have a good count-rate non-linearity, because it has to process a higher count rate at the beginning of the measurement and then decreases during the later measurement. Therefore, the count-rate non-linearity will influence the renogram curve and this can lead into a false data interpretation. Two method were used to measure this feature, i.e. a) by using a random pulse generator and b) by using the ^{131}I radiation source. Table 5 shows the count-rate test result of AOC Renograph by using Pulse Generator and ^{131}I source and also compared with the reading by the Canberra NIM System. From Table 5 then the count-rate non-linearity can be drawn as shown in Figure 6. It shows that the count-rate linearity is –2% and –5% for the count rate of above 1 kHz using Pulse Generator and ^{131}I source respectively , this might be due to instability of the base line of pulse generator amplifier signal, so that some pulses exceed the SCA window of AOC. This condition was also the same to the display on the Canberra NIM system.

Table 5 Count Rate measurement using ^{131}I Source and Pulse Generator

Count Rate	Using ^{131}I Source		Using Random Pulse Generator	
	Add On Card	NIM System	Add On Card	NIM System
0.5 Kcps	2193	2210	2174	2015
	2251	2128	2196	2026
	2212	2142	2142	2023
	2283	2211	2204	2041
	2215	2207	2154	2017
1 Kcps	4502	4529	4311	4215
	4465	4461	4353	4240
	4553	4548	4307	4232
	4379	4389	4303	4197
	4387	4411	4365	4251
2 Kcps	8090	8117	8259	8156
	7967	8087	8233	8157
	8012	8144	8224	8166
	8167	8282	8178	8140
	8197	8237	8130	8142
5 Kcps	19509	20454	20487	20909
	19543	20587	20367	20910
	19170	20158	20595	20925
	19853	20861	20491	20854
	19775	20511	20437	20885

In normal application the count rate from the radioactive distribution on the kidneys varies from 1.5 kcps to 0.5 kcps during 15 minutes, that means the non-linearity of AOC Renograph in this region meets the requirement , i.e less than 1 % as shown in Figure 6.

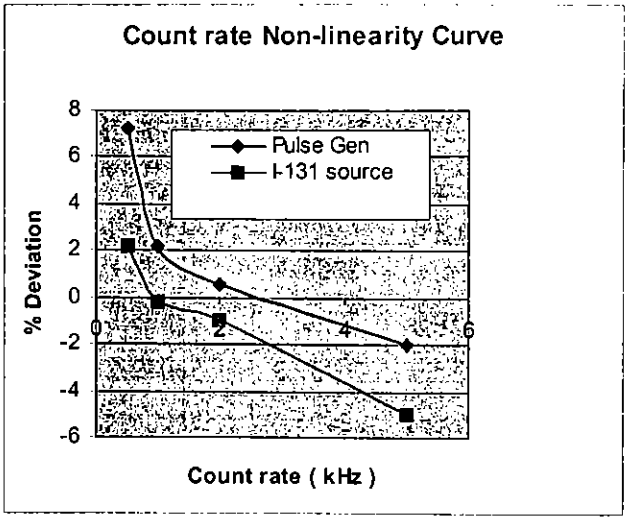

Figure 6 Count rate Non-Linearity Curve

Chi-SQUARE TEST

This is a QC test to examine whether the counting system of AOC Renograph is statistically feasible or not. This test will give the indication of non-linearity of the registered pulses with a constant count rate. The output from Detector-Preamplifier is fed simultaneously to AOC Renograph and Canberra NIM Counting System. The setting of these two systems is electronically made the same, and for each count rate position, a set of 10 measurements are taken and then the average count is calculated.

The counter and the system under test were simultaneously started to avoid a deviation of the registered pulses which occur randomly in time. Due to the life time of the ^{131}I source, no count rate more than 6700 could be obtained. Table 6 shows the result of Chi-Square test to the system.

Referring to the table of χ^2 critical value, with 95% confidence level as the IAEA regulation (IAEA TECDOC 602), the system is statistically feasible with n = 10 if the value of χ^2 experiment between 3.325 and 16.919. Table 6 showed that the χ^2 were between 4.54 and 13.16 for AOC Renograph and between 5.48 and 11.64 for Canberra System. So, the AOC Renograph and Canberra NIM System are both within the limit required.

A set of AOC has also utilized for refurbishing an aged Renograph in Yangon General Hospital and used by the Medical Doctor during the IAEA Workshop. According to the evaluation made by Kaufmann H et.al (2001) and Gogot Suyitno (2001) all the performance tests made to the system showed a satisfactorily results.

Table 6 Chi-Square Test Result Calculation

Countrate	Canberra NIM System			AOC Renograph under tested		
	Average count	Square (Chi-average)	Chi-Square	Average count	Square (Chi average)	Chi Square
250 cps	1080.8	12579.6	**11.64**	1119.9	5080.9	**4.54**
500 cps	2058.3	20712.1	**10.06**	2106.0	19888.0	**9.44**
1000 cps	3998.3	23868.1	**5.97**	4093.0	22764.0	**5.56**
2500 cps	10232.3	56042.1	**5.48**	10281.9	112894.9	**10.98**
6700 cps	26975.3	308494.1	**11.44**	26205.5	344808.5	**13.16**

This results show that the prototype AOC Renograph met the technical feasibility to be used as a medical instrument and technically ready for large scale production.

The procedures and preparation needed for medical validation should be undertaken as an integral part of the work of nuclear medicine unit and doing by medical doctors and technologist of the unit themselves. The procedure to use the renograph system is presented in Table 7.

By estimating the need for renograph concerning to the increasing number of cases renal diseases in Indonesia recently, the wish for using the domestic product should be supported by the government. According to the recently survey made by Kunto Wiharto, (2001), the ratio of population to Nuclear Medicine Unit (NMU) is 13.3 million/NMU, this is much smaller than that in USA ~ 50,000/NMU, in Japan ~ 100,000/NMU and in Malaysia ~ 1.8 million/NMU. This means that number of NMU equipments including Renograph in the hospitals is still far from adequate. Through the partnership cooperative program with Small and Medium Local Industry, supply the new product or refurbishing of aged renograph could be fulfilled. Figure 7 and 8 show the picture and data display of BI 756M prototype.

SUMMARY

We have successfully developed a renograph with AOC system for renal function testing with good technical performances and accepted validation for clinical used in hospital. The refurbishment of Age Renograph System can be successfully achieved by using an AOC Electronic System which is compatible to a PC. This will be an interesting effort for revitalization of aged renograph system and up-grade its performance with rational cost.

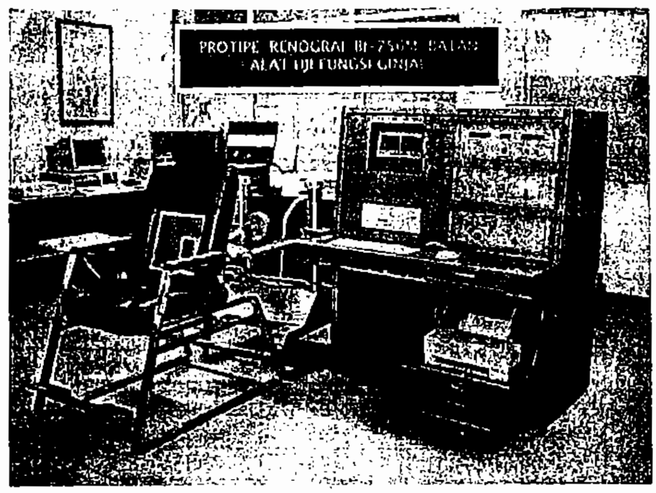

Figure 7 Renograph BI 756M

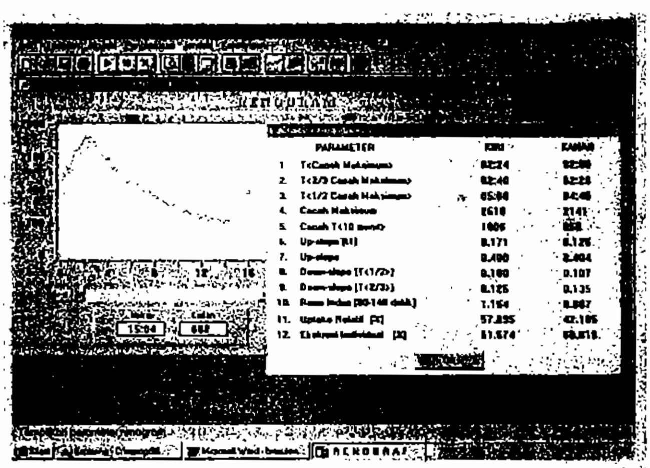

Figure 8 Renogram curve and Kidney parameters display

Table 7 The procedures to use Renograph System

Equipment & Material Required Materials	Remarks
1. Dual (or triple probes) scintillation detectors with straight-bore collimator, data processing unit (PC) and recorder	1. The third probe is used over the high bladder
2. Renograph chair for the patient to secure himself from any movement during the procedures.	2. Used to position patient up right
3. ^{131}I-OIH (30 to 50 μCi) radiopharmaceutical or ^{99m}Tc-DTPA (100 to 150μCi)	3. This to be intravenously administered
Patient Preparation **Steps**	**Remarks**
1. Dydrate patient with 250 to 750 ml of water 30 minutes before procedure 2. Have patient empty bladder before positioning for renogram	1. The amount of hydration depends on the phycisian in charge
Procedure **Steps**	**Remarks**
1. Balanced probes, this must be done to ensure equal respons from each detector	1. Use a small activity source, placed at equal distance between each probe, adjust high voltage or windows until equal count rate is reached in both probes. Do this for 10 minutes before procedures started.
2. Position patient prone, or supine or up right	2. Prone position : with arms along side of head Supine position : with arms along side the body Upright position : sitting or semi erect
3. Set the window level for	3. The primary energy 140keV for ^{99m}Tc, 364 keV for ^{131}I and 159 keV for ^{123}I.
4. Locate both kidney area properly	4. Positioning probes properly over the both kidney area.
5. Lock cart or stool and detectors	5. Ask patient to keep the positioning of the body
6. After all the systems have been checked and are in working order, administer dose (e.g 50 μCi ^{131}I-OIH)	
7. Start all the systems	7. Injected the dose (to intravena.) simultaneously (recomended with bolus injection techniques).
8. Instruct the patient not to move during procedures	
9. Renogram procedures shall complete in approximately 20 – 30 minutes or when $T_{1/2}$ is reached.	9. $T_{1/2}$ is half of the maximum counting-rate

Test results to the AOC Renograph performances showed that it passed all test satisfactorily.

Integral Non-linearity for energy becomes perfect with higher energy. Count- ate Non-linearity varies from +2% to –5% and +5% to –2% deviation using ^{131}I source and Pulse Generator respectively, but the deviation is better in the count-rate between 0.5 Kcps to 2 Kcps that is +2% to –1% when using source. The statistical feasibility counting of system is satisfy, for 0.95 confidence level with n = 10 and count-rate from 250 cps to 6700 cps, the χ^2 experiment is $3.325 < \chi^2 < 16.919$. The χ^2 result is within the limit as stated in the IAEA TECDOC 602. The renograph probes with the AOC can also be used for Up Take System with background correction feature provides by an appropriate software.

The implementation of renograph prototypes developed by BATAN for the hospital with Nuclear Medicine Unit in Indonesia is useful and appreciated. The government should support for small and medium scale production of this prototype for commercialization. Last but not least, the cooperative program between R&D center and hospitals should be enhanced and also with private or public company that producing the radiopharmaceuticals for this requirement..

NOTATION

C = Counting , cpm
(C_R = for Right kidney ,
C_L = for Left kidney)
T = Time , minute

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