Developing a Dynamic Register of Security Quality and Maintenance for Medical Devices

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Abstract—**The traceability of operating actions of medical devices requires a management system under the responsibility of biomedical professionals who need to check multitude information about each action in a stage of the medical device life cycle. This system was always a «static» register of security quality and maintenance (RSQM). With the RSQM, the usual strategies performed for medical devices in hospitals have difficulties in the identification of specific risks and optimal implementation of risk reduction activities. This work proposes a "dynamic" register of security quality and maintenance (RDSQM) to correct the limitations of conventional RSQM. The RDSQM has ten folios. It is a flexible tool that can be used in computer network and will also improve the daily work in biomedical/clinical engineering**.

Keywords-assessment; database; identification; management; RDSQM, strategy, traceability.

I. INTRODUCTION

Medical devices (DM) are becoming more *sophisticated* and *complex*. The DMs are involved in *incidents / accidents on patients*, and their maintenance (or continued operation) is getting more *expensive* [1]. Therefore, it is of four main parameters that make the DM increasingly exacting and oppressive. What to mobilize all the attention both hospital managers as decision makers and actors. The regulations relating to the maintenance of the DM [2] require the hospital to tailor its own maintenance policy to these realities. Specifically, this policy should allow to ensure the quality and security of care. These are the regulations complemented by the exigencies of quality control internal and external of certain DM. The goal is to verify the integrity of the performance claimed by the manufacturer. Generally, standard replacements, software maintenance, hardware maintenance, remote maintenance and traceability [3][4][5] are among the key concepts of the main problems in the exploitation and the management of DM. In most hospitals, where there is a maintenance program, we just follow the manufacturer's recommendations for preventive maintenance[1]. However, the real context in those hospitals is not exactly what is recommended by the manufacturer. Also, this context may vary from one hospital to another one.

Actually, concerning the management of a park of medical devices, everything is for maintenance if we refer to the terminology of maintenance[6] which states the following: «The maintenance of a device is defined by the set of all technical activities, administrative and management throughout the life cycle of the device designed to maintain or restore in a state in which it can perform the required function». Likewise, any system must be maintained including embedded softwares in DM which are sometimes the cause of many incidents related to maintenance of the DM[7]. With the development of information and communication technologies (ICT), the remote maintenance progressively takes an important place in the activities of a biomedical engineering department of hospitals [5]. However, a significant proportion of materiovigilance incidents on DM are related to defects in remote maintenance and data traceability defects as well as the multitude of data [1].

Thus, to ensure traceability of the exploitation actions of DM, it requires developing a DM management system under the responsibility of an identified professional, so that all actions are traced [6][8]. This is perfectly in adequacy with the recommendations [1]. So, biomedical professionals must have the documents required for the exploitation of DM. In addition, it is important to check a multitude of information after a maintenance action on the scale of the NF EN 13306 [6]. These information are aggregated and available in a register. In the daily practices of biomedical services, every hospital must to record maintenance operations which are quality control or security made on a DM since its acquisition until its disposal [3]. To that end, good biomedical practices recommend referring to the NF S 99-171 [2][9] to establish «a model of register security quality and maintenance (RSQM)». In this context, we note that the information required for the management of DM are more specific and categorized. They are based either on Fennigkoh and Smith model, on Wang and Levenson Algorithms [1][10][11][7], or on a nomenclature. We can mention for example the *equipment inventory criteria*,

the criteria for calculating the index for device management, the *criteria for calculating the index of preventive maintenance priority* and *Index Noiret* [12].

Recent studies respectively - on *the literature review regarding the inspection and maintenance of DM* [1] - on *the contribution of the operational safety concepts of DM* [13] - on *performance indicators of a biomedical maintenance policy* [14], concluded that, for the selection of better maintenance strategy:

- a large number of tangible and intangible criteria and conflict should be considered [1][14];
- it is necessary to use a comprehensive framework for prioritizing critical DM [1][13];
- future strategies should benefit from the additional empirical studies based on management theories [1][14];
- professionals need to measure between the other Up-time and the failure rates of DM [1][13];
- who must use? appropriate techniques and methodologies to make decisions based on appropriate risk analysis[1][14];
- professionals must use new maintenance models risk base that will integrate the various uncertainties in the hospital environment [1] [13][8].

Above all, we believe it is necessary preliminary. This will to establish a reliable data collection support for the realization of the points reached by the work of [1][13][14][8]. This is why the objective of this work is to provide such a support in the form of a dynamic register of security quality and maintenance (RDSQM) including all the information used for each DM.

II. MATERIAL AND METHOD

The main material is made up of different sheets and forms commonly used in receiving phases, installation, commissioning, maintenance operations and disposal of a DM. After identifying and analyzing those sheets, we first compiled and computerized them. Then we classified them in the following order: 1^{rst}: *Receipt Form*; 2nd: *Equipment Individual Form*; 3rd: *Inspection and Control of the Operation Form*; 4th: *Quality Assurance Inspection Form*; 5th: *Quality Control Form*; 6th: *Intervention Order Form*; 7th: *Description of the Device Form*; 8th: *Work Order Form*; 9th: *Operations Description Form*; 10th: *Results of operations Form*.

After the ranking we proceeded to determining the content of each form and presentation based on static models available in the literature. To have a dynamic register, we used the tabs in the Microsoft Office Word 2007 Developer menu. In the Register organization, each one is a folio.

Finally, we have created a database link https://fr.groups.yahoo.com/neo/groups/Labo_Virtuel_Gbm_Epac_Benin/. This is a Yahoo Group to facilitate the making available of RDSQM in a network of professionals in the field of biomedical / clinical engineering in hospitals.

III. RESULT

Because of the particularity of RDSQM, the result of this work is in the form of series of folios. Each folio holds at least on one page. Folios are organized in a required number of sections (sect.) that must be respected. In some folios, fields and the contents of the sections are not to be changed. They can be modified in some folios depending on the equipment. The 10 folios include a total of 51 sections. A record of the cover page must be considered. Parts of 3.1 to 3.11 show the results.

A. Abbreviations Register cover page

Hospital : Put here the name of the hospital

Country : Put here the country

City : Put here the city

Street Address : Put here the hospital address

Dynamic Registry of Security Quality and Maintenance (RDSQM) containing the information on the optimal and safe operation of the biomedical device

Put here the device name

Folio Number	Folio Name	Applied	Not Applied	Date of completion
1/10	*Receipt Form* (**4 sect.**)	☐	☐	22/03/2015
2/10	*Equipment Individual Form* (**7 sect.**)	☐	☐	22/03/2015
3/10	*Inspection and Control of the Operation Form* (**2 sect.**)	☐	☐	22/03/2015
4/10	*Quality Assurance Inspection Form* (**2 sect.**)	☐	☐	22/03/2015
5/10	*Quality Control Form* (**9 sect.**)	☐	☐	22/03/2015
6/10	*Intervention Order Form* (**3 sect.**)	☐	☐	22/03/2015
7/10	*Description of the Device Form* (**9 sect.**)	☐	☐	22/03/2015
8/10	*Work Order Form* (**6 sect.**)	☐	☐	22/03/2015
9/10	*Operations Description Form* (**4 sect.**)	☐	☐	22/03/2015
10/10	*Results of operations Form* (**5 sect.**)	☐	☐	22/03/2015

Responsible technician: Put here the name of the responsible technician
Creation date of registry:

B. RDSQM /Folio 1/10 : Receipt Form of a new medical device

SHEET N°0000001

Date_____: 22/03/2015

Technician Name: To Choose

Section-1: Identification and description of the device according to the nomenclature CNEH : Version : To choose		
Family equipment_____ : To choose **Family Code**_____ : To Choose **Equipment Function**___ : To Choose_PERFUSION/NUTRITION/TRANSFUSION_To Choose_To Choose **Function Code**_____ : **Equipment**_____ : **Equipment Code**_____ : **CNEH Code**_____ :		
Device : xxxxxxxxx	**Category** : To choose	
Etage/Local :	**Unit** :	**Clinical Department** :

Section-2 : Features				**Section-3 : Information relating to the purchase / renewal**		
1	Make			**1**	Date of receipt	22/03/2015
2	Inventory Number			**2**	Installation date	22/03/2015
3	Model No.			**3**	End Date Warranty	22/03/2015
4	Serial No.			**4**	Purchase price (UF)	0,00
5	No supplier			**5**	Replacement cost (UF)	0,00
6	Manufacturer			**6**	Theoretical lifetime (year Old)	
7	functional unit			**7**	Frequency of preventive maintenance	
8	Note operating			**8**	Intervention Oder No	
9	Risk Assessment note			**9**	No. Purchase Order	
10	Maintenance note			**10**	No. received	

Section-4 : Commentary

C. RDSQM /Folio 2/10 : Equipment Individual Form

SHEET N°0000001

Section 1 : Device	
Device name : xxxxxxxxxxxx	
Inventory Number : xxxxxxxxxxxx	
Manufacture : xxxxxxxxxxxx	
Model : xxxxxxxxxxxx	**Serial N°** : xxxxxxxxxxxx
Country of origin : xxxxxxxxxxxx	**Year of manufacture:** xxxxxxxxxxxx
Section 2 : External power supply	
☐ **Voltage Required**: xxxxxxxxxxxx	☐ **Intensity required** : xxxxxxxxxxxx
☐ **Water**: xxxxxxxxxxxx	☐ **Oil** : xxxxxxxxxxxx
☐ **In other fluid/air/gas** : xxxxxxxxxxxx	☐ **Fuel/diesel** : xxxxxxxxxxxx
Section 3 : State (Status) current of the device	
☐ Functional and service ☐ Functional and off ☐ Maintenance required ☐ Out of service	
Reason why the device is functional and off or out of service : xxxxxxxxxxxx xxxxxxxxxxxx xxxxxxxxxxxx	
☐ Not repairable Special elimination Condition? ☐ Yes ☐ No	
Spares available: ☐ Yes ☐ **No. If yes, which? How Much? And where are find them?** xxxxxxxxxxxx xxxxxxxxxxxx	
Section 4 : Manuals available	
☐ **User's manual** ☐ **Number of copies** : ☐ **Place** : xxxxxxxxxxxx	
☐ **Maintenance Manuel** ☐ **Number of copies** : ☐ **Place** : xxxxxxxxxxxx	
☐ **Others** (xxxxxxxxxxxx) ☐ **Number of copies** : ☐ **Place** : xxxxxxxxxxxx	
Section 5 : User of Device	
☐ Physicians ☐ Nurses ☐ Laboratory technician ☐ Students	
☐ Internal ☐ Other (specify) : xxxxxxxxxxxx	
Section 6 : Responsible of the device	
The owner of the device (the clinical department), if applicable: xxxxxxxxxxxx	
Person to contact: xxxxxxxxxxxx	**Phone N°**: xxxxxxxxxxxx
Actual location of the device: xxxxxxxxxxxx	**Will he displaced?** ☐ **Yes** ☐ **No**
If yes, where? xxxxxxxxxxxx	
Section 7 : Assessment of the Device (Date of the last assessment : 22/03/2015**)**	
1) Class CE : To choose **2)** Electrical Class : To choose **3)** Type : To choose	
4) Index of materiovigilance (Indix_Mat [1 to 15]) :Assess Indix_Mat(IR+AC+AR+I+C) = M = _____	
5) Preventive maintenance priority Index (I_{pmp}) : Assess I_{pmp} = (M*R*U*G) ϵ [1 to 15000] = _____	
6) Criticality (**CR**) accordance with Method **PIEU. CR=(P*I*E*U)= _____** Interpretation : To Choose **P**= Index Failures = : **Assess** / **I** = Importance= **Assess** / **E** = Condition = **Assess** / **U**= Utilization= : **Assess**	
7) Device Management Criteria (GM). Indix_GM ϵ [3 to 20]. Indix_GM is the index of inventory priority criteria (According Fennigkoh and Smith Model). **Indix_GM** = Function + Risks + Maintenance = _____ **Function** of the device : **Assess** / **Risks** to clinical application: **Assess** / **Maintenance** required : **Assess**	
8) Classification index (index_EM). Index_EM = **Indix_GM** + **Historical** = _____ **Historical** of failures / incidents: **Assess**	
9) Notation index of the device management (NGM ϵ [5 to 30]) (According Wang and Levenson algorithm) **NGM** = Mission + 2*Risks + 2*Maintenance = _____ **Mission** = Level of importance of the mission: **Assess**	
10) Notation index adjusted of the device management (**NGM_adjusted**) = (Mission+ 2*Maintenance)***U**+ 2*Risks **U** ϵ [0 to 100%] = Use rates of the device = _____ **NGM_adjusted** = _____	
11) Workload inspection and preventive maintenance : **To Choose** Workload: _____ (Hours)	
12) Index of Noiret (IN ϵ [0 to 910]) = a+b+c+d+e+f+g+h+i = _____ Interpretation : **To Choose** a- Working conditions (Usage): **Assess /** b- Turn Around time: **Assess /** c- Age of the device : **Assess** d- Interdependence : **Assess /** e- Complexity and accessibility: **Assess** / f- Cost : **Assess** g- Origin of the device: **Assess** / h- Robustness and accuracy: **Assess /** i- Product loss: **Assess**	

D. RDSQM /Folio 3/10 : Inspection and Control of the Operation Form

SHEET N°0000001

Section 1 : Device						
Device Name : **Device of hypo-hyper Thermotherapy (e.g.)**[15] **Localization :** **Manufacture :** Choisir **Model :** **Serial N° :** **Verification Number** :x To choose **checking**						
Section 2 : Checkpoints						
Checkpoints				**Complies (yes / no)**	**Measures to be taken**	**Measures taken (Date/parafe)**
a)	Condition of the chassis			To Choose		
b)	Condition of the connecting hose			To Choose		
c)	State power cord and the voltage reducer			To Choose		
d)	Condition of the lights and alarms			To Choose		
e) Flow Rate	Mode	Liter (minute)		To Choose		
	warming			To Choose		
	Cooling Down			To Choose		
	Enabling flow switch			To Choose		
f)	Activation of the level sensor			To Choose		
g)	Controlling the cold water tank			To Choose		
h)	Cover temperature control			To Choose		
	Setpoint value	display	Thermometer	To Choose		
	55uF/12,77°C			To Choose		
	77uF/25°C			To Choose		
	105F/40°C			To Choose		
Display within a range ± 1 ° C (1.8 ° F) temperature Setpoint.				To Choose		
Reading of the thermometer in a range of ± 1 ° C of the Setpoint.				To Choose		
i)	High temperature safety thermostat			To Choose		
	Setpoint relay security			To Choose		
j)	Thermometer control test			To Choose		
k)	Test patient temperature display			To Choose		
	Resistance of the probe	Display of T ° C		To Choose		
	1355 Ω	37°C ± 0,3°C		To Choose		
	1667 Ω	32°C ± 0,3°C		To Choose		
l)	Low temperature safety thermostat			To Choose		
m)	Resistance to ground less than 0,5ohm			To Choose		
n)	Current leakage			To Choose		
	Chassis (connected to earth)10 µA			To Choose		
	Chassis (not connected to earth)100µA			To Choose		
	Patient probe 50µA			To Choose		

E. RDSQM /Folio 4/10 : Quality Assurance Inspection Form

SHEET N°0000001

Section 1 : Device

Device Name : **Volumetric respirator (For example)**[15]

The owner of the device	:	**Inspected By**	: Choisir
Type of Device	:	**Manufacture**	: Choisir
Model N°	:	Serial **N°**	:
Hour meter	: _____	**Localization**	**:**

Date : **Verification Number** :x To choose **checking**

Section 2 : Checkpoints

POINT	APTE	A/N	TASK QUALITATIVE	POINT	APTE	A/N	TASK QUALITATIVE
1.1	To Choos	☐	Chassis / Box	**3.1**	To Choos	☐	Safety valve
1.2	To Choos	☐	Assembly parts	**3.2**	To Choos	☐	Sensitivity
1.3	To Choos	☐	Wheels / Brakes	**3.3**	To Choos	☐	Apnea alarm
1.4	To Choos	☐	Power cord	**3.4**	To Choos	☐	Low oxygen pressure alarm
1.5	To Choos	☐	Voltage Reduction	**3.5**	To Choos	☐	Low-expiration alarm
1.6	Yes	☐	Breaker / fuse	**3.6**	To Choos	☐	Minute volume Alarm
1.7	Yes	☐	Tubes / Hoses	**3.7**	To Choos	☐	Low positive expiratory pressure alarm
1.8	To Choos	☐	Cables/rope	**3.8**	To Choos	☐	Spontaneous ventilation continuous positive airway pressure alarm
1.9	To Choos	☐	Connectors	**3.9**	To Choos	☐	High flow alarm
1.10	To Choos	☐	Transducers	**3.10**	To Choos	☐	Temperature alarm
1.11	To Choos	☐	Filters	**3.11**	To Choos	☐	High FiO2 alarm
1.12	To Choos	☐	Commands	**3.12**	To Choos	☐	Low FiO2 alarm
1.13	To Choos	☐	Heater / Humidifier	**3.13**	To Choos	☐	Failure cycle alarm
1.14	To Choos	☐	Engine / Pump / Ventilator	**3.14**	To Choos	☐	Stop ventilation alarm
1.15	To Choos	☐	Connector / Charger	**3.15**	To Choos	☐	I / E report alarm
1.16	To Choos	☐	Indicators / Displays	**3.16**	To Choos	☐	Low air pressure alarm
1.17	To Choos	☐	Calibration / User / Auto-controller	**3.17**			
1.18	To Choos	☐	Alarm / Lock	**3.18**			
1.19	To Choos	☐	Audible signals	**3.19**			
1.20	To Choos	☐	Labelling	**3.20**			
1.21	To Choos	☐	Accessories	**3.21**			
1.22				**3.22**			
2.1	To Choos	☐	Resistance grounding	**4.1**	To Choos	☐	Additional tasks
2.2	To Choos	☐	Maximum leakage current	**4.2**	To Choos	☐	Cleaning
2.3	To Choos	☐	Leak tests	**4.3**	To Choos	☐	Lubrication
2.4	To Choos	☐	Controlled ventilation mode	**4.4**	To Choos	☐	Calibration
2.5	To Choos	☐	Mode controlled ventilatory support	**4.5**	To Choos	☐	Calibration of controllers
2.6	To Choos	☐	Synchronized Intermittent Ventilation mode	**4.6**	To Choos	☐	Calibration switches
2.7	To Choos	☐	Spontaneous ventilation mode in continuous positive airway pressure	**4.7**	To Choos	☐	Calibration of transducers
2.8	To Choos	☐	Inspiratory assistance	**4.8**	To Choos	☐	Calibrating the compressor circuit breakers
2.9	To Choos	☐	Nebulizer function	**4.9**	To Choos	☐	Replacement filters
2.10	To Choos	☐	Flow (conventional mechanical ventilation / Synchronized Intermittent Ventilation)	**4.10**	To Choos	☐	Replacement of compressor filters
2.11	To Choos			**4.11**	To Choos	☐	Inventory of used parts
2.12	To Choos	☐	Flow (sigh)	**4.12**			
2.13	To Choos	☐	Sigh function	**4.13**			
2.14				**4.14**			
2.15				**4.15**			

F. RDSQM /Folio 5/10 : Quality Control Form

SHEET N°0000001

Section-1 : Device identification					
Device Name: Dialysis generators (for example)					
Type : xxxxxxxxxxxxx		**Make:** : xxxxxxxxxxxxx	**Model** : xxxxxxxxxxxxx	**Serial N°** : xxxxxxxxxxxxx	
Inventory N° : xxxxxxxxxxxxx		**Software Version N°** : xxxxxxxxxxxxx	**Hour meter** : xxxxxxxxxxxxx		
Date :		**Verification Number** :x To choose **checking**			
Section-2: Devices tests (checked and calibrated) Refer to the manufacturer's technical manual					
Description		Model / Type	Serial N°	Date of last calibration	
1	Multi-function controller	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
2	Conductivity controller	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
3	Temperature controller	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
4	Pressure controller	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
5	pH controller	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
6	Flow controller	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
7	Chronometer	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
8	Test piece or balance	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
9	Multimeter	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
10	Electrical safety tester or equivalent	xxxxxxxxxxxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxx	
//	//	//	//	//	
Section-3 : Qualitative aspects: General performance				**NA**	**Conforms**
1	**Smooth running self test**			☐	To Choose
2	**Functioning of disinfection :** If chemical: smooth rinse cycle and absence of residual products with appropriate testing the product			☐	To Choose
3	**Functioning of disinfection :** If heat: smooth cycle			☐	To Choose
4	**Functioning audible alarms**			☐	To Choose
5	**Display: Visual inspection of the condition of the screen lights**			☐	To Choose
6	**Saving parameters to the dialysis mode restart in case of power failure**			☐	To Choose
7	**General condition**: Visual inspection of cleanliness			☐	To Choose
8	**General condition**: Mobility and effectiveness of the brakes			☐	To Choose
9	**General condition**: Visual inspection of dialyzers supports and supports room			☐	To Choose
10	**General condition** : cover, case, stand			☐	To Choose
11	**General condition**: External elements: clean air filters and operation of the ventilator			☐	To Choose
12	**Electrical Safety**: Cable and the socket Integrity			☐	To Choose
13	**Electrical Safety** : Leakage current on applied parts of the patient			☐	To Choose
Section-4 : Qualitative aspects: Circulation Extra Body (CEB)				**NA**	**Conforms**
14	**Functioning of the air detector**			☐	To Choose
15	**Functioning of blood detector**			☐	To Choose
16	**Venous pressure, blood pressure, blood pressure other :** Control of PV and PA alarms: Trigger and feedback on clamps and blood pump			☐	To Choose
17	**Clamps A / V (arterial and venous):** Occlusivity			☐	To Choose
18	**Clamps A / V (arterial and venous):** Functionality			☐	To Choose
19	**Blood pumps A / V (arterial and venous) Occlusivity:** general state of rotors			☐	To Choose
20	**Blood pumps A / V (arterial and venous) :** Test external bonnet release			☐	To Choose
21	**Pump heparin :** Smooth operation and mechanical assembly			☐	To Choose
22	**Uniponcture :** Smooth operation			☐	To Choose
23	**Socket PNI :** Smooth operation on a cycle according to manufacturer's specification			☐	To Choose
Section-5 : Qualitative aspects: Fluid Parties (dialyzer)				**NA**	**Conforms**
24	**External elements :** Good condition of dialysate hoses			☐	To Choose
25	**External elements :** Good condition of the withdrawal site			☐	To Choose
26	**External elements :** Filters supports integrity			☐	To Choose
27	**External elements :** Presence and integrity of pipettes			☐	To Choose
28	**External elements :** State of water supply system			☐	To Choose
29	**External elements :** State of rejection circuit			☐	To Choose
30	**Leakage of blood :** Control of the trigger and functioning alarms			☐	To Choose
31	Checking the outbreak of the derivation of the bath in case of alarm: **functionality and activation**			☐	To Choose
32	**Ultrafiltration system :** Smooth functioning as specified by the manufacturer (exceptionally may be performed on machine open)			☐	To Choose
Section-6: Quantitative aspects: General performance (*3= Tolerances according to manufacturer specification)				**NA**	**Conforms**
33	**Functioning of disinfection:** If chemical : aspirated volume (*4)			☐	To Choose
Section-7 : Quantitative aspects: Circulation Extra Body (CEB) (*3)				**NA**	**Conforms**
34	Venous pressure, arterial pressure , blood pressure other (* 4 = Measured value equal value claimed)			☐	To Choose
35	Blood pumps A / V (arterial and venous): Flow (* 4)			☐	To Choose
Section-8 : Quantitative aspects: Fluid Parties (dialyzer) (* 3)				**NA**	**Conforms**
36	**Dialysate: Temperature** (*4)			☐	To Choose
37	Conductivity (*4)			☐	To Choose
38	Pressure (*4)			☐	To Choose
39	Flow (*4)			☐	To Choose
40	**pH** (*4)			☐	To Choose
Section-9 : Comment and Conclusion: Put on a separate reference sheet : xxxxxxxxxxxxx					
Operator Name: xxxxxxxxxxxxx			Date of the next verification:		

G. RDSQM /Folio 6/10 : Intervention Order Form

SHEET N°0000001

Section-1 : Request for intervention	
Clinical department : Xxxxxxxxxxxxxxxxxxxxxxxx	
Date: _____	
Physician or technician reporting the problem: Xxxxxxxxxxxxx	
Localization of the device : Xxxxxxxxxxxxx	
Description of the problem : Xxxxxxxxxxxxxx Xxxxxxxxxxxxxx Xxxxxxxxxxxxx	
Day and hour:	
Section -2 : Raised for intervention	
Name of the engineer or technician in charge of the intervention: To choose	
Start date and time of the Intervention: _____	
Action taken: Xxxxxxxxxxxxxx Xxxxxxxxxxxxxx Xxxxxxxxxxxxxx Xxxxxxxxxxxxx	
The problem was he solved? To Choose	
Date and time of the End Intervention: _____	
A follow-up is it necessary? To Choose	**When follow-up there will be carried out?** Xxxxxxxxxxxxx
Section -3 : The provisions of the Follow-up	
Name of the engineer or technician in charge of the intervention:: Xxxxxxxxxxxxx	
Date and time of the Start Intervention:: _____	
Action taken: Xxxxxxxxxxxxxx Xxxxxxxxxxxxxx Xxxxxxxxxxxxxx Xxxxxxxxxxxxxx	
The problem was he solved? To Choose	
Date and time of the End Intervention: _____	
Another follow-up is it necessary? (If yes to continue) : To Choose	
Following consists: Xxxxxxxxxxxxxx Xxxxxxxxxxxxxx Xxxxxxxxxxxxxx Xxxxxxxxxxxxxx	

***NB**: This form is associated with the device. Keep it for 15 days after the intervention.*

H. RDSQM /Folio 7/10 : Description of the equipment Form

SHEET N°0000001

Section 1 : Device			
Name : To Choose - To Choose-To Choose			
N° identification in the hospital: xxxxxxxxxx			
Make :xxxxxxxxxx	**Model** : xxxxxxxxxx	**Serial N°**: xxxxxxxxxx	
Class CE : To Choose	**Class electrical :** To Choose	**Type :** To Choose	
Section 2 : Manufacturer			
Name : xxxxxxxxxxxx	**Country :** xxxxxxxxxxxx	City : xxxxxxxxxxxx	
Contact Information : xxxxxxxxxxxx	**E-mail :** xxxxxxxxxxxx	**Site-Web:** xxxxxxxxxxxx	
Section 3 : Supplier			
Name : xxxxxxxxxxxx	**Country :** xxxxxxxxxxxx	City : xxxxxxxxxxxx	
Contact Information : xxxxxxxxxxxx	**E-mail :** xxxxxxxxxxxx	**Site-Web:** xxxxxxxxxxxx	
Section 3 : User responsible: one who is currently in charge of the device			
Name : xxxxxxxxxxxx	**Country :** xxxxxxxxxxxx	City : xxxxxxxxxxxx	
Contact Information : xxxxxxxxxxxx	**E-mail :** xxxxxxxxxxxx	**Site-Web:** xxxxxxxxxxxx	
Commentary:			
Section 4 : Receipt			
Date of receipt : 30-mars-15	**Responsible of the receipt :** Choisir		
Statute of the receipt : ☐ Comply with the order	☐ No comply with the order		
Labelling of the device: ☐ Done at the date of receipt ☐ Not done on the date of receipt	**Cost (F): 1250000,00**		
Commentary:			
Section 5 : Installation & localization			
Local/Site :	**Service :**	**Installation Cost (F):: 1250000,00**	
Devices attached: Yes ☐ No ☐ **If Yes ? How many ? Quote them without detailing**			
Need Technician Training : Yes ☐ No ☐ **How many to train?:**	**Training Cost (F)** : 1250000,00		
Need UserTraining : Yes ☐ No ☐ **How many to train?:**	**Training Cost (F)** : 1250000,00		
Referential and regulatory texts:			
Section 6 : Entry into service and warranty			
Date of Entry into service: 30-mars-15	**Resp. User 1:** xxxxxxxxxxxx	**Contact :** xxxxxxxxxxxx	
Warranty period:	**Resp. User 2 :** xxxxxxxxxxxx	**Contact :** xxxxxxxxxxxx	
Start date of the warranty: 30-mars-15	**Resp. User 3 :** xxxxxxxxxxxx	**Contact :** xxxxxxxxxxxx	
Exploitation duration: xxxxxxxxxxxx	**Depreciation period estimation:** xxxxxxxxxxxx		
Commentary:			
Section 7 : Health ICT			
Software 1	**Name :**	**Version :**	**Last update: 30-mars-15**
Software 2	**Name :**	**Version :**	**Last update: 30-mars-15**
Software 3	**Name :**	**Version :**	**Last update: 30-mars-15**
Periphery & Port 1	**Nom :**	**Statute :**	**Statute :**
Periphery & Port 2	**Nom :**	**Statute :**	**Statute :**
Periphery & Port 3	**Nom :**	**Statute :**	**Statute :**
CNIL Declaration	☐ Applied	☐ No Applied	
Options :	**Number Maxi**:	**Number Bought:**	**Number Available**:
Section 8 : Equipment needed for control quality and safety			
Medical device category	To Choose To Choose To Choose		
Test equipment required	To Choose To Choose To Choose To Choose To Choose		
Section 9 : Service contracts			
Type of contracts			
Duration contract			
Performer(s)			

I. RDSQM /Folio 8/10 : Work Order Form

SHEET N°0000001

Section-1: Device					
Work Order No: Xxxxxxxxxx		**Manufacturer :** xxxxxxxxxx		Location: xxxxxxxxxx	
Equipement No :	xxxxxxxxxx	**Model N°** xxxxxxxxxx		Start date: xxxxxxxxxx	
Système ID:	xxxxxxxxxx	**Seriel N°** xxxxxxxxxx		End date : xxxxxxxxxx	
Section-2: Classification Maintenance					
Function	Category : To Choose	Function : To Choose		**Note** : --	
Risks related to the use : To Choose				**Note** : --	
Maintenance required : To Choose				**Note** : --	
Service failure : To choose				**Note** : --	
Index_EM: 00	**Class Maintenance :** xxxxxxxxxx			**Frequency of inspections:** To choose	
Class CE : Choisir	**Class electrical:** Choisir			**Type :** Choisir	
Clinical Departement : Xxxxxxxxxx				PM Sheduled:	30-mars-15
Service Procedure : Xxxxxxxxxx	Down Time :	xxxxxxxxxx		Requested:	xxxxxxxxxx
Inspector(s) : Xxxxxxxxxx	→ Service Time :	xxxxxxxxxx		Started:	30-mars-15
Inspector(s) : Xxxxxxxxxx	→ Service Time :	xxxxxxxxxx		Finshed:	30-mars-15
Work Order status : To Choose	→ Fal Mode :	xxxxxxxxxx		**Parts cost :** xxxxxxxxxx	
Commentary :					

Section-3: Qualitative Tests					
P	**F**	**N**	**N°**	**Qualitative Tests**	**Comments**
☐	☐	☐	1	Chassis Housing	**Rusted chassis screws**
☐	☐	☐	2	Mount	
☐	☐	☐	3	Casters/Brakes	
☐	☐	☐	4	AC Plug/Receptacles	
☐	☐	☐	5	Line Cord	Intermitten AC line cord
☐	☐	☐	6	Strain Reliefs	
☐	☐	☐	7	Circuit Breaker/Fuse	
☐	☐	☐	8	Cables	
☐	☐	☐	9	Fittings/Connectors	
☐	☐	☐	10	Controls/Switches	
☐	☐	☐	11	Battery/Charger	Dead battery 8 times in pump history; C
☐	☐	☐	12	Indicators/Diplays	
☐	☐	☐	13	Alarms	
☐	☐	☐	14	Audible signals	
☐	☐	☐	15	Labeling	
☐	☐	☐	16	Accessories	
☐	☐	☐	17	Flow-Stop Mechanism	
☐	☐	☐	18	Lockout interval (PCAS Only)	

Section-4: Quantitative Tests											
P	**F**	**N**	**N°**	**Quantitative Tests**						**Comments**	
☐	☐	☐	19	Grounding Resistance (mohm)							
☐	☐	☐	20	Maximum Leakage Currents							
☐	☐	☐	21	Chassis (µA)			Mode On ☐	Off ☐	Normal ☐	Rev ☐	
☐	☐	☐	22	Leads (µA)			Mode On ☐	Off ☐	Normal ☐	Rev ☐	
☐	☐	☐	23	Flow Rate Accuracy (%)							
☐	☐	☐	24	Flow Setting 1	set		Indicated		Actual		
☐	☐	☐	25	Flow Setting 2	set		Indicated		Actual		
☐	☐	☐	26	Flow Setting 3	set		Indicated		Actual		
☐	☐	☐	27	Occlusion Alarm			Please seeattached worksheet				
☐	☐	☐	28	Pressure Setting 1	set		Indicated		Actual		
☐	☐	☐	29	Pressure Setting 2	set		Indicated		Actual		
☐	☐	☐	30	Pressure Setting 3	set		Indicated		Actual		

Section-5: PM Checks list					
P	**F**	**N**	**Nu**	**PM Checks**	**Comments**
☐	☐	☐	32	Clean	Wiped exterior, sensors
☐	☐	☐	33	Lubricate	
☐	☐	☐	34	Replace	Screws, AC line cord

Section-6: Acceptance Checks list					
P	**F**	**N**	**Nu**	**Acceptance Checks**	**Comments**
☐	☐	☐	35	HiPot Primary Supply (CSA)	

J. RDSQM /Folio 9/10 : Operations Description Form

SHEET N°0000001

Description of operations: Case of Mobile X-ray device (for Example)[11][15]

Section 1: Type of operation		
Name of device : Xxxxxxxxxx		
N° identification of the device :	**N°Sheet of description of the device (Folio 7/10) :**	
Name technician : Xxxxxxxxxx		
Trigger for the operation : To Choose		
Assessment riks by To Choose **Score** : --		
Number of safety inspections per year : To Choose		
Number of performance inspections per year : To Choose		
Total Preventive Maintenance Checks : To Choose		
Number of preventive maintenance checks per year :		
Date of last preventive maintenance :		
Number of preventive maintenance over the year on the date of the last intervention :		
Competencies threshold required for the technician :		
Section 2: Operative procedure		
It is necessary to comply with manuals Supplied by the manufacturer of the device		
P	**Procedures**	**Is doing**
P1	Look for any signs of deterioration or lack of parts outside of the device.	☐
P2	Inspect the power cord strain relief and / sockets, looking for any signs of deterioration.	☐
P3	Switch off the unit, remove the protections available to users and check if the unit shows signs of damage.	☐
P4	Clean the internal parts and the outside of the unit with a vacuum cleaner or compressed air.	☐
P5	Look for signs of corrosion or absence of certain parts inside the device. Make the necessary repairs.	☐
P6	Look for signs of overheating or damage to electrical components.	☐
P7	Check that the maximum voltage values (kVp) and current (mA) -time exposure in accordance with manufacturer's specifications.	☐
P8	Check the operation of electromechanical stops (tube and plate)	☐
P9	Check the operation of other electrical functions.	☐
P10	Inspect batteries if any; perform the necessary maintenance.	☐
P11	Check that the fixed and movable rails offer support and satisfactory movement.	☐
P12	Check the regular operation of the drive system.	☐
P13	Check the operation of the displays if necessary.	☐
P14	Check the operation of the collimators according to specifications (automatic and manual settings).	☐
P15	Verify the correct calibration with the manufacturer's specifications.	☐
P16	Check the operation of all buttons, controls witnesses, displays and / or indicators.	☐
P17	Check the correct operation of the device in all its modes of operation.	☐
P18	Clean the outside of the unit, including all accessories, cables, control commands and displays.	☐
P19		☐
Section 3: Date & time		
Start date of the procedure : Xxxxxxxxxx	Time planned : Xxxxxxxxxx	
End date of the procedure : Xxxxxxxxxx	Time planned : Xxxxxxxxxx	
Section 4: Commentary		

K. RDSQM /Folio 10/10 : Results of operations Form

SHEET N°0000001

Section 1: Type of operation	
Name of device : Xxxxxxxxxx	
N° identification of the device :	**N°Sheet of operation description (Folio 9/10) :**
Name of operation: To Choose	**If other, please specify : Xxxxxxxxxx**
Name technician : Xxxxxxxxxx	
Section 2: Result	
Result description : To Choose	
Commentary :	
Start date : Xxxxxxxxxx	**End date of operation :** Xxxxxxxxxx
Section 3: Follow	
Follow : Xxxxxxxxxx	
Cause of operation :	
Trigger :	
Fault description :	
Section 4: Concluding Remarks	
Section 5: Procedure operative	
Operative Mode	

IV. DISCUSSION

In sum, the proposed register RDSQM in this work consists of ten forms. Each form is a specific data collection support for effective management of medical devices (DM). Such a register in hospitals must ensure that DM are secure, accurate, reliable and operate at a required performance level [1], the RDSQM will serve as an appropriate tool to achieve this goal. Specifically, the risks during the operation of DM will be more controlled. It is therefore a tool to respond to a concern raised by [1] which concluded that: *current strategies employed in health care hospitals and organizations have difficulty in the identification of specific risks and optimal application of risk reduction activities*. In the same way, following [16], we will be proactive through RDSQM integrating the overall acquisition process, indicators operating performance of DM, and especially of maintenance.

In principle, the terms of preventive maintenance are defined by the manufacturer and anticipate potential failures of the device [1]. Like risk management, the constraints of maintaining a DM should be included in the acquisition process for an effective exploitation. In the real context of use of DM, the proposed RDSQM will be easy and flexible to use to collect data that will develop a better maintenance strategy adapted to the conditions of use in a given hospital. However, it was shown that maintenance as a whole becomes expensive with the obsolescence of the device [1][17]. Moreover, according to [17], the obsolescence of a DM is defined by the following criteria: *loss of its initial performance; inadequate performance spectrum to allow the use of new medical technologies; market presence of new devices with better security*. Thus, with the RDSQM, we must monitor and evaluate obsolescence features of each DM in the medical equipment park.

The proposed RDSQM still offers two advantages. The first one is the possibility to have an operating and monitoring form DM in computer networks of a hospital, and a national, regional or international health system. This is a practice that should be encouraged with the involvement of ICT in health systems. To do this, we developed a database on a Yahoo group following the link https://fr.groups.yahoo.com/neo/groups/Labo_Virtuel_Gbm_Epac_Benin/. Any professional in Biomedical / Clinical Engineering may register on the group by sending an e-mail to labo_virtuel_gbm_epac_benin-subscribe@yahoogroupes.fr, in order to be provided with the forms. The second advantage is to be able, at all times, to make a technical and technical-clinic assessment of a medical device. These assessments were often difficult to do before this work. Because of the fact that, according to the works [1][14][8], a large number of tangible intangible and conflicting criteria should be considered but could not be identified easily. This is now possible through the RDSQM.

V. CONCLUSION

Based on the recommendations for good biomedical practices and traceability of medical devices, we have developed a new model register of security quality and maintenance (RSQM) of medical devices. We call it dynamic register of security quality and maintenance (RDSQM) of medical devices. The RDSQM is a solution approach to operational problems of medical equipment in hospitals. Indeed, the application of inspection, maintenance and optimization models of the operation of medical equipment is still in its infancy. These methods should be based on reliable operating data of the equipment. The RDSQM summarizes, compiles, prioritizes and computerizes different sheets separately proposed in the literature for the management of medical devices in hospitals. The RDSQM consists of 10 folios. Each folio of the register is a data collection support required for each phase and sub-phase of the operation process of a medical device. Therefore, current strategies employed in hospitals and health care organizations will have less difficulty in the identification of specific risks and optimal implementation of risk reduction activities. Furthermore, the registry is a tool for implementing a management database for medical devices in a park of general health care system, and especially in a hospital in a low-income country.

In the context of health care systems and hospitals in developing countries (especially in Sub-Saharan Africa) where medical devices are usually characterized by the non-existence of a strategy for monitoring database and assessment of medical devices, the RDSQM will changing favorably trends. Specifically, the RDSQM is a tool to improve the daily work in biomedical / clinical engineering. The RDSQM will serve as a mechanism and methodology of technical and clinical assessment of medical devices regardless of the health system. The RDSQM will also serve as an online database (or not) that can contribute to an integrated resource management in medical devices in the health system. Finally, the RDSQM reflects a practical way of implementing the technical and clinical assessment.

However, much is yet to be done. Future work should first realize the RDSQM portable document format (PDF). Second, we should consider how the RDSQM will take into account the mode of acquisition and the financing of medical devices to:

- develop a strategy for the real efficiency and integrated management of medical devices in a hospital environment;
- compile and conceptualize knowledge of the systemic approach on the use of medical devices in a hospital environment;
- implement and validate data management method and resource information for medical devices in healthcare system.

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