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Real-Time Monitoring and Diagnosis of Environmental Protection Systems by Artificial Neural Networks Case study: Pharmaceutical Isolator

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ABSTRACT/RESUME

Abstract: *The main objective of this work is the study of risk analysis, in the field of pharmaceutical production. Some dangers can affect pharmaceutical companies' personnel, as well as their internal and external environment, during the manufacturing process. Furthermore, the current regulations that governs this very sensitive field of manufacturing and the standards which are scrupulously very sharp. Also see the technical complexity of the industrial systems implemented. These three parameters constitute a real problem to be solved. To do this, we have developed an intelligent technique for monitoring these protection systems, in real time, in order to protect the personnel and the environment. This technique is mainly based on the use of an artificial neural network (ANN) which detects and localizes any anomalies that may occur at any time in the protection system. The experiment was carried out on an isolator belonging to BEKER Laboratories (a medecine manufacturing and development company in Dar El Beida-Algers). The test results allowed us to define the good and bad areas of the isolator operation. We concluded that, it is possible to define defaults in real time, using our new technique.*

I. Introduction

The research and development and the pharmaceutical production are subject to many requirements such as national regulations and international standards.

However, in order to answer to these requirements, this industry is faced with several constraints and risks, which have a direct impact on the operator, the product and the environment.

Medecines are toxical products which may affect both the operator and the environment.

As a preventive solution, the researchers and industrials have invested in new protection systems such as (laminar flow hoods, isolators, etc….).

Despite all these measures taken by investors, the equipment can fail at any time due to several causes and variations. Consequently, we are in a critical state, where the real issue of our research work arises, to respond positively to this effect, we developed an original, very efficient real-time monitoring approach based on new artificial intelligence techniques such as artificial neural networks, the detection of faults and the accuracy of the monitoring parameters will be controllable.

II. Environmental risk analysis Control

II.1 Introduction

The production of certain medecines (dry, liquid, injectable, etc.) require an isolation system to avoid any risk affecting operators and their internal environment as well as the external one.

In this work we studied in detail an isolation system widely used in the pharmaceutical industry.

II.2 Description of the BEKER laboratory workshops

BEKER Laboratories is the pharmaceutical company producing drugs. It has been established in Dar El Beida-Algeria since 2005. It consists of several workshops which are:

Research and development department - Production department - Quality control laboratory - Utility department Engineering& maintenance Department…etc.

II.3 Selection of the studied system

The pharmaceutical isolator is the most strategic equipment in the research and development workshop, therefore any failure of the last will cause a risk on people and the environment.

In addition, respect of good manufacturing practices and other criteria related to the quality of the product are very important in this industry, hence the accuracy of all the physical parameters of this system such as pressure and velocity, are needed.
It is therefore clear that the parameters of the isolator must be tolerated according to international standards and regulations for the manufacture of medicines.

II.4 Study of the selected protection system

II.4.1 Description of the isolator

The equipment is manufactured [1], by ESCO and of Model: SCI. It is designed, practically, in the same way as a clean room. It is used to isolate contaminated air from the surrounding environment and ensure sterility inside.

Figure 1. *Isolator ESCO [5].*

II .4.2 Operating principle of the isolator

Ambient air is drawn by a fan through the ULPA (**U**ltra **L**ow **P**articulate **A**ir) filter, located above the isolator, and is directed to the handling area.
The sucked air ensures the pressure difference between the handling area and the transfer airlock, and then the air from the airlock is forced out through an extractor. The air is filtered by another ULPA filter to protect the environment.
The pressure in the handling area is always higher than that of the transfer airlock to prevent contaminants from entering the handling area through the transfer airlock.

III. Development of the hybrid approach

The work we have done throughout this study has led us to propose a hybrid approach based on the combination of the offline and online approaches.
In the Offline approach the Diagnosis [2-3-4] is based on the Failure Tree Analysis (FTA), which helps us to model the functions of different system organs, in order to be able to determine the critical elements of the system.
In the Online approach the Automated Monitoring and Diagnosis [5-6] is based on the Artificial Intelligence Model (AIM). Artificial intelligence is applied to detect and locate any faults early, which may occur on equipment, in real time

III.1 Offline approach

III.1.1 Functional modeling of the Isolator

The different functions of the Isolator are modeled by the failer tree analysis method.
The failar tree analysis is a deductive method that is used to identify the different causes that produce unwanted events.
In this case, the FTA of the isolator is carried out using:
• Feedback from BEKER Laboratory staff,
• Technical data from the manufacturer [1],
• Diagram of figure 2.
The diagram in Figure 2 shows the major components of the insulator.

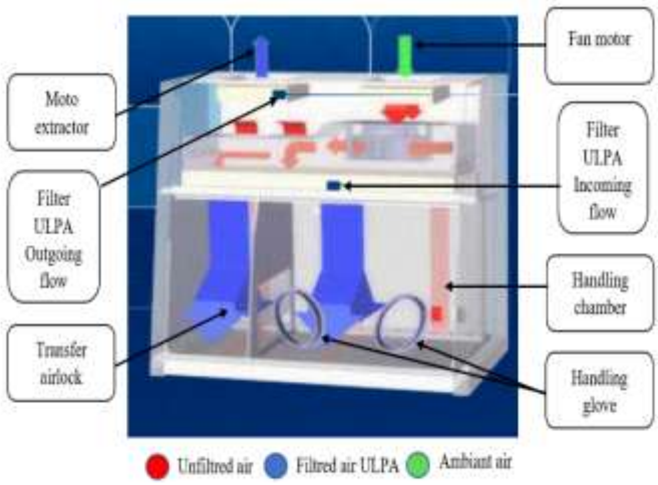

Figure 2. *Schematic diagram of the ESCO Isolator*

The main parts of the isolator of figure 2 are:
• Fan motor,
• ULPA filter incoming flow,
• Handling chamber,
• Handling gloves,
• Moto extractor,

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• ULPA filter outgoing flow,
• Transfer airlock.

The carried out work, in this first part, allowed us to model and develop the functional decomposition model of the Isolator, shown below.

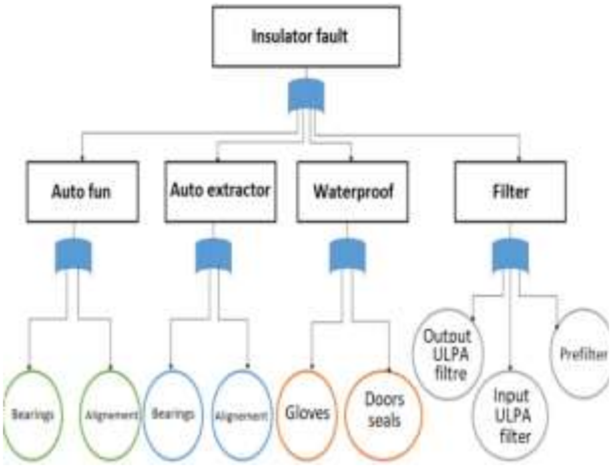

***Figure 3.** Functionnal decomposition of the studied system "Failure tree Analysis (FTA) of Isolator"*

Figure 3 shows the tree structure of the isolator's critical organs. Failure of any component can endanger the safety of people and the environment.

The undesired events detected by this functional decomposition (FTA) are:
• The danger to the safety of operators,
• Risk of environmental contamination.

The construction of this FTA also allows us to determine the probable causes of the various faults, namely:
•Filter fault: cause; clogging,
•Leak tightness: causes; Door seals and deterioration of gloves,
• Blowing fault "Fan motor": causes; misalignment, lubrication,
•Extraction fault "Extractor motor": causes; misalignment, lubrication.

III.1.2 Results of the functional analysis:

The results of the study of the risk analysis by the FTA method allowed us to evaluate the critical parameters, shown in the table below, which will be the inputs of the artificial intelligent model (AIM).

***Table 1.** Evalution of monitoring parameters*

N°	Sub systems	Critical origans	Séttings
1	Filter	Prefitre	Air flow velocity Pressure airlock
		Input ULPA filter	
		Output ULPA filter	
2	Waterproof	Golves	Process chamber pressure and airlock pressure.
		Doors seals	
3	Auto fun	Alignement	Air flow velocity
		Bearings	
4	Auto extractor	Alignement	Process chamber pressure and airlock pressure.
		Bearings	

III.2 Online approach

III.2.1 The parameters of the ESCO isolator [10]

The FTA results allowed us to choose the parameters which can influence the operating state of the ESCO Isolator, namely:

- ***<u>Average air flow velocity:</u>***

It helps us to monitor the filter state and the air flow mode (laminar flow).

<u>- Pressure of the Main chamber:</u>

The pressure gives us useful information about the flow of air entering the handling chamber, set according to the required air quality (ISO Class 3).

- ***<u>Pressure of the airlock:</u>***

The pressure inside the airlock gives good information on the extractor and the state of the exhaust filter.

III.2 Development of the intelligent neural model

The developed neural model is of the multilayer network type [7-9-10-12-13] with gradient backpropagation.

It contains, three (03) input neurons correspond to the measured parameters (Average air flow velocity, handling chamber pressure and the pressure of the transfer airlock). It also contains an output layer with one (01) single neuron representing the operating state of the isolator (good or bad) and two hidden layers, one with twelve (12) neurons and another with eighteen (18).

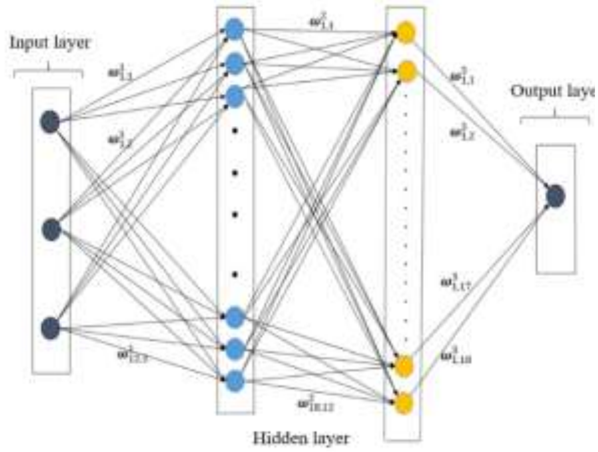

Figure 4. *Proposed Neural Model (3-12-18-1)*

III.2.1 Programming the intelligent neural model
The network parameters (3 -12 -18 -1), given in the table below, are optimized during programming [13].

Table 2. *Parameters of the intelligent module programming*

Chosen parameters	**Neuronal model (3-12-18-1)**
Network type	Multilayer network (feed-forward)
Learning type	Supervised learning
Activation function	Bipolar sigmoid
Used algorithm	Gradient back-propoagation algorithm
Error (goal) learning G	G= 0.01
Iteration number N	N=1000

III.2.2 Simulation of the gradient backpropagation algorithm
For the implementation of the learning [4] of the network by the gradient backpropagation algorithm, we proceeded [11], [13] as follows:

• Step 1) *Initialization of weights and biases:*
We have fixed the values of the weights and weighting biases using a stochastic approach in the interval [- 0.5 ,0.5].

• Step 2) *Presentation of the desired inputs and outputs:*
We have presented the values of the input vectors and specified the desired outputs. We renewed the entry for each trial and samples were taken from a set of examples that were presented cyclically until the weights were adjusted.

• Step 3) *Calculation of network outputs:*
Inputs are propagated in the network to the output.

• Step 4) *Adaptation of weights and weighting biases:*
Using the recursive algorithm; we started from the output neurons, then we proceeded step by step in the direction of the backpropagation to reach the first hidden layer. The weights are adjusted [7-8-13] such that:

$$w_{ji}(t+1) = w_{ji}(t) + \Delta w_{ji}(t) \qquad \text{(III.1)}$$

From where

$$\Delta w_{ji}(k) = \eta \delta_j(k) y_i(k) \qquad \text{(III.2)}$$

In this relationship
$w_{ji}(t)$: Weighting weight
$\delta_j(k)$: Error term for neuron j
η : Term of gain called learning rate

If neuron j is an output neuron, therefore $\delta_j(k)$can be calculated by

$$\delta_j(k) = (y_{dj}(k) - y_j(k). f_j'(S_j(k)) \qquad \text{(III.3)}$$

If the neuron j belongs to a hidden layer, therefore $\delta_j(k)$ can be calculated by :

$$\delta_j(k) = f_j'(S_j(k)) \sum_l \delta_l(k) w_{lj} \qquad \text{(III.4)}$$

All these stages of programming and simulation of the learning of the developed model (3 -12 -18 -1) are represented and simplified by the flowchart [13] in the figure below.

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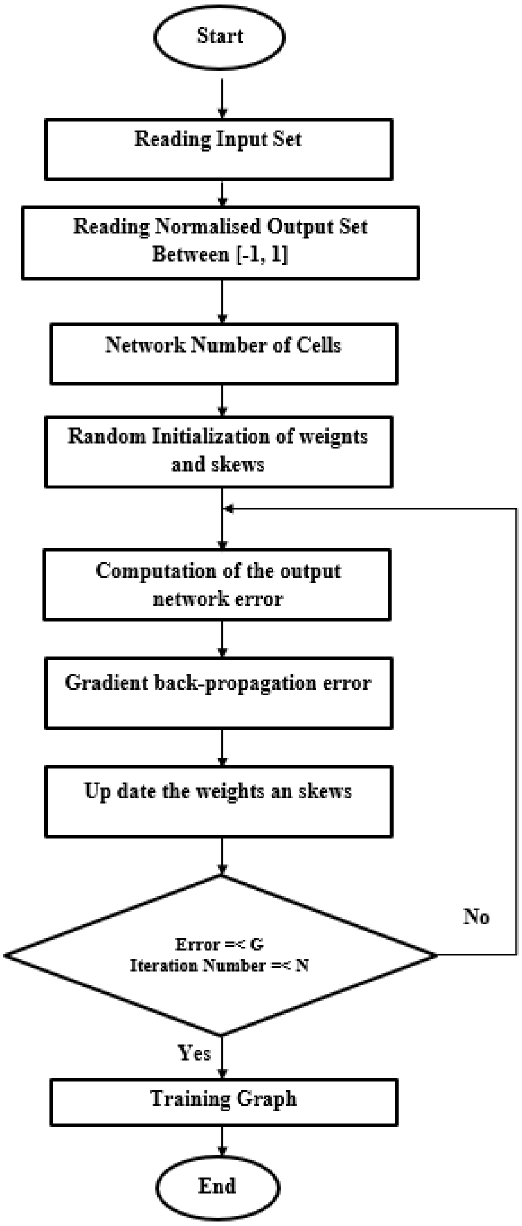

Figure 5. *Flowchart of the developed gradient backpropagation algorithm*

IV. Simulation and results

Here we presented the simulation of the neural network training (3 -12 -18 -1) and its different tests and results. This neural model is set to monitor the BEKER Laboratory pharmaceutical isolator in real time.

IV.1. Learning

The simulation of the network learning phase (3 -12 -18 -1) is presented in Figure 6. The latter shows that the learning converges after 120 iterations with an error of 0.01. This explains the rapid learning of the developed neural network.

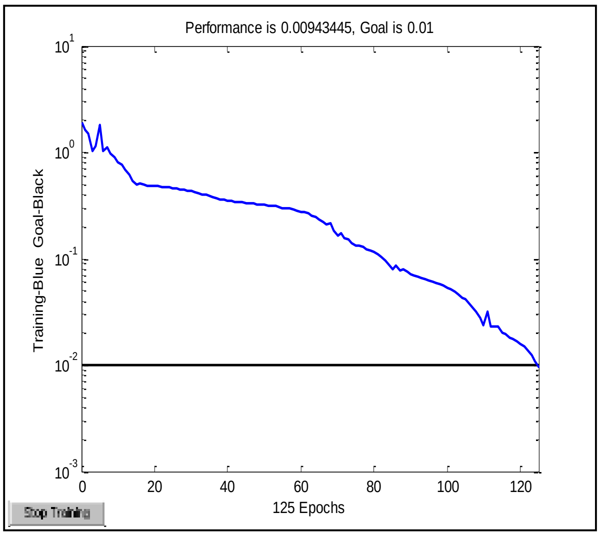

Figure 6. *Network training simulation (3-12-18-1)*

IV.2. Simulation of network outputs (3-12-18-1)

After learning, we simulated the outputs to test the reliability of the detection of the network.

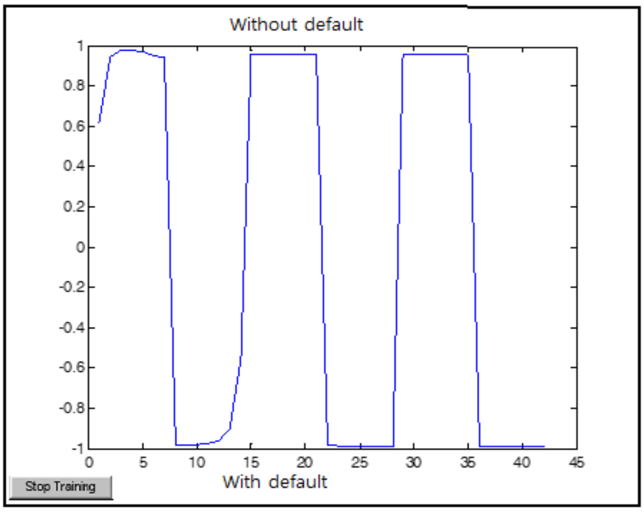

Figure 7. *Simulation of network outputs (3-12 -18-1) after learning*

In figure 7 we can observe that all the values of the good functioning set are located at "1" and those of bad functioning are located at "-1". This shows that the network has effectively recognized the desired outputs.

IV.3. Network performance evaluation (3-12-18-1)

In Figure 8 we have shown the correlation between the neural network output values (3 -12 -18 -1) and the desired (targeted) values.

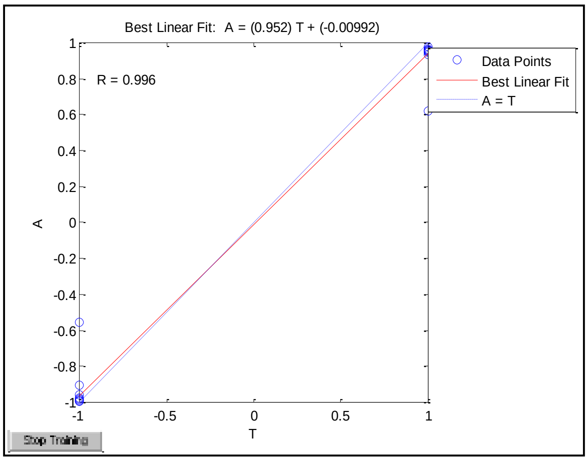

Figure 8. *Network performance (3-12-18-1)*

With: (A = 0.952 T + (-0.00992))
m = 0.952 being very close to 1.
R = 0.996
b = -0.00992 which is close to 0.
Figure (8) schow a good correlation, between the desired outputs (1 and -1) and the outputs of the neural network (3 -12 -18 -1).

IV.4. Velocity fault detection

In this test, we provoked a default which can modify the acceptable value of the average velocity of the air flow, in order to test the behavior of the network.

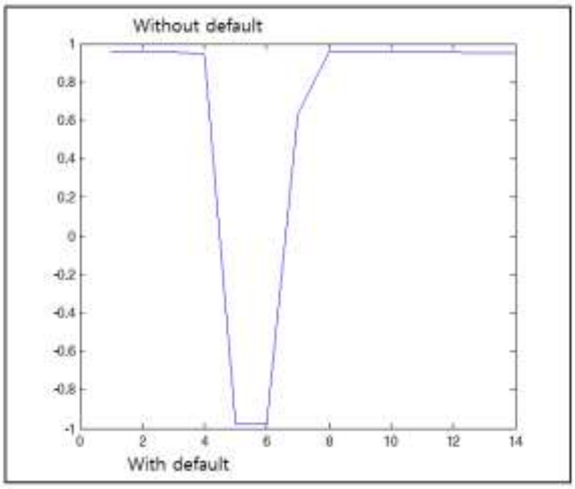

Figure. 9. *Default test "Average velocity"*

Figure 9 above illustrates the results of the test, where the network effectively detects the value of the fault.

We observe that our network can notice from 3s that there is a fault which can modify the value of the average velocity and continue to indicate that there is a fault up to 8s when the system returns to its normal operation.

IV.5. Detection of pressure default in the handling chamber"PROCESS"

Figure 10 below shows the network detection level due to the change in the pressure values of the handling chamber.

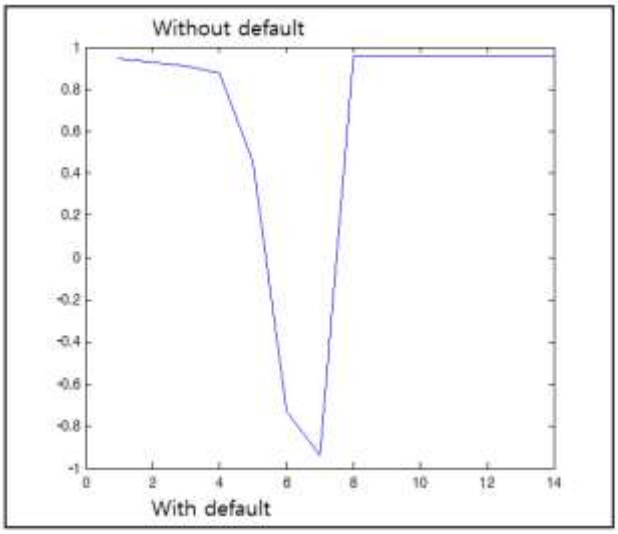

Figure 10. *Default test "Handling chamber pressure"*

It can be seen from the first seconds that network behavior follows the disturbances according to the pressure level in the main chamber, which shows the network precision and the capacity to detect faults linked to the change in pressure in the handling chamber.

IV.6. Airlock pressure default detection

Figure 11 shows the results of the test for various changes and disturbances in the airlock pressures.

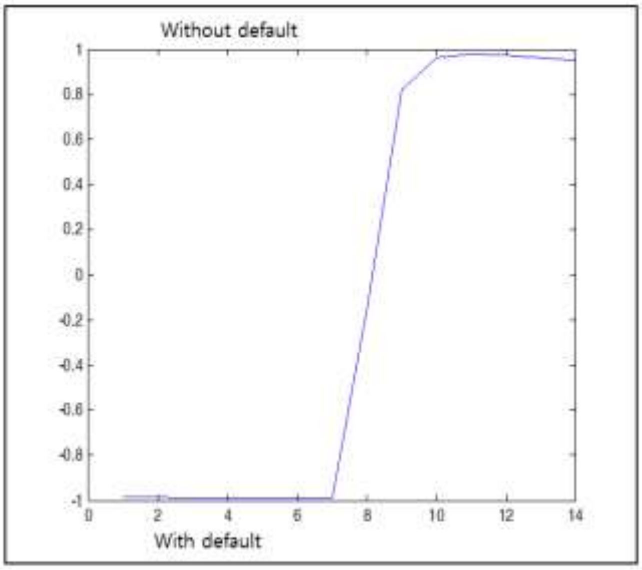

Figure 11. *Default test "Airlock pressure"*

V. Conclusion

The neural approach used allowed us to choose an optimal "3 -12 -18 -1" model that monitors, in real time, the BEKER Laboratoires pharmaceutical isolator. The simulation of the learning sets of the network has shown results, with the following qualities:

- The rapid convergence of results has been illustrated in the learning graph. Indeed, one obtained a convergence after 120 iterations whereas we fixed them at 1000.
- The phenomena of over-learning and local minimums did not appear, which showed the correct choice of the parameters of the gradient back-propagation algorithm.
- All the graphs, from fault simulation tests, showed outputs in the neighborhood of "-1", with an accuracy of 0.01, which ensures the fault detection.

Following the obtained results, the developed intelligent model is capable of detecting any anomaly in the studied system. It can be concluded that the developed model allows good supervision of the isolator. This facilitates diagnosis and makes real-time decision possible.

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