Profile control chart based on maximum entropy

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\textbf{ABSTRACT}
Monitoring a process over time is so important in manufacturing processes to reduce wastage in money and time. Some charts as Shewhart, CUSUM, and EWMA are common to monitor a process with a single intended attribute which is used in different kinds of processes with various ranges of shifts. In some cases, the process quality is characterized by different types of profiles. The purpose of this article is to monitor profile coefficients instead of a process mean. In this paper, two methods are proposed for monitoring the intercept and slope of the simple linear profile, simultaneously. In this regard, two methods are compared here. The first one is the linear regression, and another one is the maximum entropy principle. The $T^2$-Hotelling statistic is used to transfer two coefficients to a scalar. A simulation study is applied to compare the two methods in terms of the second type of error and average run length. Finally, two real examples are presented to demonstrate the applicability of the proposed chart. The first one is about semiconductors, and the second one is about pharmaceutical production processes. The performance of methods is relatively similar. The maximum entropy plays an important role in correctly identifying differences in the pharmaceutical example, while linear regression did not correctly detect these changes.

\textbf{KEYWORDS}
Simple linear profile; Maximum entropy principle; Linear regression; $T^2$-Hotelling control chart; Average run length.

\section{Introduction}
Control charts have been widely used to monitor industry and manufacturing processes. Much researches have been done on how to monitor and detect shifts in the process or system, which is important to have suitable supervision on equipment performance. Kopnov and Kanajev (1994) studied on burn breakdown of a special process and obtained an optimum limit respect to the existing costs on a degradation process. Haworth (1996) showed how to use multivariate regression control charts to manage the maintenance process of the intended software. Xie et al. (2000) published a paper on controlling the process reliability and mentioned on weaknesses and strengths of some control charts such as Shewhart. Chakraborti et al. (2008) used joint statistical distributions in phase I to control the probability of earthquakes hazard and gained the probability of at least one wrong alarm during designing the control charts. They used two methods. In the first one, a certain amount was considered for the probability of false alarm, based on the Hiller (1969) and Yang and Hiller (1970) scheme. The second one concerned by
King (1954) scheme based on multivariate dependence distribution to get true and false alarms probabilities. Champ and Woodall (1987) presented a simple and efficient method, based on using the Markov chain, and obtained the exact run length properties in Shewhart control charts. CUSUM control charts have been generally used to detect smooth mean deviations. Westgard et al. (1977) have worked on a control chart combination of Shewhart and CUSUM such that both rules are simultaneously employed and illustrated its better performance by a computer simulation study. It should be noted that CUSUM control charts are suitable for predictable shifts. Sparks (2000) designed an adaptive CUSUM (ACUSUM) control chart that is efficient at signaling a range of future expected but unknown changes.

Quality control charts based on EWMA are popular tools in monitoring processes parameter shifts. Neubauer (1997) explained the basics of these chart types. Zou and Tsung (2011) and Prabhu and Runger (1997) presented some examples of the multivariate EWMA control chart. When some different attributes of a process are simultaneously intended to monitor, one of the most common control charts is $T^2$-Hotelling. Aparisi (1996) expressed the $T^2$-Hotelling plot as an easily used chart and calculated a comparative control table of $T^2$. Aparisi and Haro (2001) provided a way that increases the power of the test in the $T^2$-Hotelling charts so that the shifts are detected faster than the other way. Alfaro and Ortega (2008) introduced a more powerful plot than $T^2$-Hotelling. Generally, $T^2$-Hotelling control charts are an extension of univariate Shewhart control charts.

Profiles are different models applied in the cases that the products or process quality is characterized by a functional relationship between a response (dependent) and one or more explanatory (independent) variables. Woodall et al. (2004) reviewed on how to monitor profiles in manufacturing processes. Woodall (2007) has presented a general framework to control processes based on the profiles. Smith and Livesey (1992) and Quercia et al. (2012) studied the maximum entropy and profile. Krogh and Mitchison (1995) worked on a profile family of DNA that had different disordered subfamilies and solved the optimum problem by maximum entropy principle.

In this paper, we are working on a new method of monitoring a production process instead of monitoring its corresponding mean. Therefore, we apply a simple linear profile for this aim. The simple linear profile is a functional relationship between a response and one explanatory variable, such a linear regression model. This paper aims to find out suitable control limits for the simple linear profile coefficients. One way of estimating is by applying the regular regression parameter estimations. Besides, we engaged one more method of estimating parameters named as maximum entropy principle. The basic step in maximum entropy is to get the unknown distribution function of an available dataset. The final result is called maximum entropy distribution. In the end, the unknown coefficients are approximated via this specified distribution. In most cases in the real world, the distribution function of a dataset is passive and has to be estimated beneficially. So, we explain it while describing our method in approximating the profile coefficients. In the end, some simulation examples and real data studies are added to make a good comparison between the traditional and the maximum entropy methods.

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The structure of the rest of the present paper is as follows: In section 2, Shannon entropy and maximum entropy distribution are rendered, because they are needed to compute the estimated values of profile coefficients. Some literature and basic definitions of profiles are provided in Section 3. In section 4, the maximum entropy methods and the linear regression ($LR$) are applied to estimate the coefficients of a simple linear profile, and control limits based on the $T^2$-Hotelling statistic for two methods are obtained, which are adequate in detecting inappreciable shifts. Furthermore, a simulation study is done in section 5. Section 6 presents an example of real data on the semiconductor production process and compares two proposed methods in the case. Section 7 consists of a real pharmaceutical example, and the maximum entropy principle’s power is demonstrated. In the end, conclusions are available in the last section.
2. Bivariate maximum entropy distribution

Shannon entropy, introduced by Shannon (1948), has been widely used as an information criterion to obtain the probability density function based on known knowledge of the available dataset applied in some fields of studies like computer science, physics, and economics, etc. For example, the distributions of financial variables, stock returns, and incomes can be gained by the maximum entropy concept just by defining some intentional constraints. The manner of estimating the maximum entropy distribution was presented first by Jaynes (1957). For more information, see Zellner and Highfield (1988), Wu (2003), Wu and Perloff (2007), and Chu and Satchell (2009). Others like Kagan et al. (1973) and Shore and Johnson (1980). Some more papers on the multivariate states were reproduced such as Jones (1976), Urzúa (1988), Costa et al. (2003), Kouskoulas et al. (2004), Bhattacharya (2006), Ebrahimi et al. (2008), Pougaza and Djafari (2011), Pougaza and Djafari (2012), and Mortezanejad et al. (2019). For example, Fallah et al. (2019) worked on a capability index in the manufacturing process whose distribution has been obtained via maximum entropy principle.

First of all, to determine bivariate maximum entropy, let \( X \) and \( Y \) be two random variables whose joint density and distribution functions are \( f_{X,Y}(x, y) \) and \( F_{X,Y}(x, y) \), respectively. Their joint Shannon entropy is as below:

\[
H(f) = -\int \int_{\mathcal{S}(X,Y)} \log f_{X,Y}(x, y) \, dF_{X,Y}(x, y),
\]

where \( \mathcal{S}(X,Y) \) is the joint support set of \( X \) and \( Y \), and

\[
dF_{X,Y}(x, y) = \frac{\partial^2 F_{X,Y}(x, y)}{\partial x \partial y} \, dx \, dy = f_{X,Y}(x, y) \, dx \, dy.
\]

Let’s find the joint maximum entropy distribution of \( X \) and \( Y \) under these constraints based on mathematical expectation definitions:

\[
E(h_i(X,Y)|F) = \int \int_{\mathcal{S}(X,Y)} h_i(X,Y) \, dF_{X,Y}(x,y)
\]

\[
= m_i(x,y), \quad i = 1, \ldots, r,
\]

where \( r \) is the number of constraints, \( m_i(\cdot) \)'s are arbitrary moments functions toward \( i = 1, \ldots, r \), for example, one choice of \( m_i(x, y) \) can be \( \overline{xy} = n^{-1} \sum_{j=1}^{n} x_i y_i \) whose value is computed by the existence dataset, and \( n \) is the size of each sample. In equation (1), \( x \) and \( y \) are the observations of \( X \) and \( Y \) variables, and \( F \) is their true joint distribution function. But, it does not determine, so our aim in this section is to approximate it via the maximum entropy principle. \( h_i(X,Y) \)'s for \( i = 1, \ldots, r \) are intended functions according to \( m_i(\cdot) \)'s, for instance if \( m_i(x, y) = \overline{xy} \), then its corresponding \( h_i(X,Y) \) is \( XY \). To approximate the unknown joint distribution function \( F \) or density function \( f \) via maximum entropy principle, we need to apply the Lagrange function based on Shannon entropy and some optional constraints in (1) as follows:

\[
L(f, \lambda_0, \ldots, \lambda_r) = -\int \int_{\mathcal{S}(X,Y)} \log f_{X,Y}(x,y)dF_{X,Y}(x,y) - \lambda_0\left\{\int \int_{\mathcal{S}(X,Y)} dF_{X,Y}(x,y) - 1\right\}
\]

\[
- \sum_{i=1}^{r} \lambda_i\left\{\int \int_{\mathcal{S}(X,Y)} h_i(x,y)dF_{X,Y}(x,y) - m_i(x,y)\right\}.
\]
The coefficient equation of $\lambda_0$ ensures that the result is a density function according to this fact:

$$\int \int_{\mathcal{S}(X,Y)} dF_{X,Y}(x,y) = 1.$$  \hspace{1cm} (2)

So by differentiation the Lagrange function respect to $f$, we get an equation as a function of $f$:

$$\frac{\partial L(f, \lambda_0, \ldots, \lambda_r)}{\partial f} = -\log f - 1 - \lambda_0 - \sum_{i=1}^{r} \lambda_i h_i(X, Y).$$

Then, the following equation has to be solved respect to $f$:

$$\frac{\partial L(f, \lambda_0, \ldots, \lambda_r)}{\partial f} = 0.$$ 

Finally, the density of maximum entropy is derived:

$$f_{X,Y}(x,y) = \exp(-1 - \lambda_0 - \sum_{i=1}^{r} \lambda_i h_i(x,y)), \quad (x,y) \in \mathcal{S}(X,Y).$$ \hspace{1cm} (3)

The Lagrange coefficients $\lambda_0, \ldots, \lambda_r$ have to be computed by substituting function (3) in desired constraints (1) and (2), then the maximum entropy coefficients can be calculated by solving a system of equations respect to $\lambda$s, and we will explain more in the following. In the next section, we intend to calculate the coefficients of the profile based on the maximum entropy principle and make a comparison with the linear regression method and its coefficients.

3. Profiles definition

The profile consists of a response variable and one or more independent or explanatory variables that are used to review and monitor a manufacturing process over time. It can be presented as a simple linear regression such as Mahmoud and Woodall (2004), and Gupta et al. (2006) reported. Kang and Albin (2000) have expressed two techniques to monitor a multivariate profile by the $T^2$-Hotelling control chart. Mahmoud et al. (2007) have presented a manner based on likelihood ratio statistics to analyze the data of phase I. In the literature of profiles, such papers as Quandt (1958), Holbert (1982), Hawkins (1989), Kim and Siegmund (1989), Kim (1994), and Chen (1998) are available. They have worked on how to detect shifts or change points of processes using simple linear profiles. Lawless et al. (1999) have given some examples of linear profiles in automotive engineering. Kang and Albin (2000) have presented two examples of different situations of producing products with profiles. Some authors such as Mandel (1969), Hawkins (1991), Hawkins (1993), Zhang (1992), and Wade and Woodall (1993) have monitored linear profiles via regression adjusted control charts.

Profiles have several types like simple linear profile, multivariate linear profile, multiple linear profile, polynomial linear profile, generalized linear profile, and nonlinear profile. However, in this paper, our focus is on a simple linear profile. First of all, suppose that $n$ fixed points of observations are exist from variable $X$, $k$ random samples are obtained from the response variable $Y$ over time. Also, assume that in controlled situation response or dependence variable $Y$ and independent or explanatory variable $X$ are modeled as below that is called simple linear profile:

$$y_j = a + b x + \varepsilon_j, \quad j = 1, \ldots, k,$$ \hspace{1cm} (4)

where $k$ is the number of total samples that each of them has size $n$, $x$ is the observations of the independent variable $X$, and intrinsic error $\varepsilon_j$ is an independent random variable with a
normal distribution of zero mean and fixed variance of $\sigma^2$. The intercept $a$ and slope $b$ in the model are named as profile coefficients. The model (4) is similar to simple linear regression, but their discrepancy is in the witnessing vector of $X$. In the regression model, there are different vectors of $y_j$ and $x_j$ for each sample, and the model is $y_j = a + b \cdot x_j + \varepsilon_j$ for $j = 1, \ldots, k$. But in the profile model, there are only different vectors of response like $\tilde{y}_j$, and the same vector of $x$ is used for different observation vectors of $Y$ as they can be seen in (4) where we have a fixed vector of $x$ for each $k$ sample.

In this paper, our purpose is to monitor these profiles coefficients $a$ and $b$ of a process instead of monitoring the process mean the duration of passing the time, and we interest in observing possible shifts by the changes of the desirable coefficients.

### 4. Calculation of profile coefficients

In this section, we present a new method of finding profiles coefficients based on the maximum entropy principle. The result is comparing with the linear regression coefficients. As we mentioned before, there are two coefficients $a$ and $b$. In the following, we will define a two-dimension vector-like $(a, b)$. Therefore, we applied the $T^2$-Hotelling statistic to reduce the dimension to 1. Then, we plot these values and calculate $ARL_0$ and $ARL_1$ in section 5 for a range of small shifts in both manners. Here we have three shift types on intercept, slope, and simultaneous of both as a mixed model. Finally, their second type of error $\beta$ is simultaneously plotted to judge them. Let $x = (x_1, \ldots, x_n)$ be the fixed observations of $X$. Here, we have $k$ samples of dependence variable $Y$ with length $n$:

$$(y_1, x), \ldots, (y_k, x).$$

Now we would like to calculate the among of $a$s and $b$s in $k$ samples via maximum entropy principle and linear regression. Hence, we desire to present some notations first such that:

$$\begin{align*}
m_1 &= (\hat{a}_{1-ME}, \hat{b}_{1-ME}), \ldots, m_k = (\hat{a}_{k-ME}, \hat{b}_{1-ME}), \\
l_1 &= (\hat{a}_{1-LR}, \hat{b}_{1-LR}), \ldots, l_k = (\hat{a}_{k-LR}, \hat{b}_{k-LR}).
\end{align*}$$

For instance, vector $(\hat{a}_{1-ME}, \hat{b}_{1-ME})$ includes the estimated values of coefficients in (4) using the maximum entropy principle for the first sample, and we named this vector by $m_1$. The same meaning is drawn from $(\hat{a}_{1-LR}, \hat{b}_{1-LR})$ that is called $l_1$ with the difference of estimation procedure that is regression method or least square error. In the next step, we have to estimate the unknown distribution function of each sample to calculate the corresponding coefficients $m_1, \ldots, m_k$. As mentioned in section 2, to compute the maximum entropy distribution, some favorite constraints are needed. Here, we determine six constraints which are presented as follow:

$$\begin{align*}
&\int \int_{S(X,Y)} dF_{X,Y}(x,y) = 1, \\
&\int \int_{S(X,Y)} x dF_{X,Y}(x,y) = \overline{x}, \\
&\int \int_{S(X,Y)} y_j dF_{X,Y}(x,y) = \overline{y}_j, \quad j = 1, \ldots, k \\
&\int \int_{S(X,Y)} x^2 dF_{X,Y}(x,y) = \overline{x^2}, \\
&\int \int_{S(X,Y)} y_j^2 dF_{X,Y}(x,y) = \overline{y_j^2}, \quad j = 1, \ldots, k \\
&\int \int_{S(X,Y)} xy_j dF_{X,Y}(x,y) = \overline{xy_j}, \quad j = 1, \ldots, k.
\end{align*}$$

(5)
Since our knowledge, the first equation is the guarantee for the result being a valid density function. So, we find the Lagrange coefficients \( \lambda_0, \ldots, \lambda_r \) in somehow that the final \( f_{X,Y}(\cdot, \cdot) \) be a density function. To do that, we have to institute the function of (3) in each equation of the system. Then, the system equations (5) has to be solved for Lagrange coefficients. It is obvious that the estimated joint distribution functions of \( X \) and \( Y \) are going to be obtained via maximum entropy concept for each sample \( (y_j, x) \), \( j = 1, \ldots, k \). Now we have \( k \) distribution functions according to each sample. \( a \) and \( b \) in maximum entropy principle are approximated as follows:

\[
\hat{b}_{j-ME} = E_j[(X - \overline{X})(Y - \overline{Y})]/E[(X - \overline{X})^2],
\]

\[
\hat{a}_{j-ME} = E_j(Y) - \hat{b}_{j-ME} E(x), \ j = 1, \ldots, k,
\]

where \( E_j(\cdot) \) and \( E(\cdot) \) are the mathematical expectation functions based on the maximum entropy estimation of density function \( f_{X,Y}(x, y) \). Corresponding linear regression coefficients are computed with \( k \) different samples too:

\[
\hat{b}_{j-LR} = \frac{\sum_{i=1}^{n} (X_i - \overline{X})(Y_{ij} - \overline{Y})}{\sum_{i=1}^{n} (X_i - \overline{X})^2},
\]

\[
\hat{a}_{j-LR} = \overline{Y}_j - \hat{b}_{j-LR} \overline{X}, \ j = 1, \ldots, k.
\]

Our goal is to plot \( m_1, \ldots, m_k \) and \( l_1, \ldots, l_k \) to detect shifts of a process instead of monitoring its means. To do this, we use \( T^2 \)-Hotelling statistic for all samples \( j = 1, \ldots, k \) as below, and we name them \( T^2_{j-ME} \) and \( T^2_{j-LR} \) for the maximum entropy and regression methods, respectively:

\[
T^2_{j-ME} = (\overline{m}_j - \overline{m})' S^{-1}_m (\overline{m}_j - \overline{m}), \ j = 1, \ldots, k,
\]

\[
T^2_{j-LR} = (\overline{l}_j - \overline{l})' S^{-1}_l (\overline{l}_j - \overline{l}), \ j = 1, \ldots, k,
\]

where \( \overline{m} \) and \( \overline{l} \) are means related to \( m_1, \ldots, m_k \) and \( l_1, \ldots, l_k \), and also they are two-dimension like all \( \overline{m}_j \) and \( \overline{l}_j \). \( S_m \) and \( S_l \) are the estimations of the variance-covariance matrix of \( m_1, \ldots, m_k \) and \( l_1, \ldots, l_k \), respectively, because all \( m_j \) and \( l_j \) contain the estimation values of coefficients. Moreover \( S^{-1}_m \) and \( S^{-1}_l \) are their corresponding matrix inverse. Then, we apply two different upper control limits (UCL) to check \( T^2 \)'s to be in statistical control. It is worth to mention that the lower control limits (LCL) are 0, because this statistic is always positive. The first UCL used here is based on Fisher distribution that is the same for all \( T^2_{j-ME} \) and \( T^2_{j-LR} \), \( j = 1, \ldots, k \):

\[
\begin{align*}
UCL_F &= \frac{p(k+1)(k-1)}{k-p} F_{\alpha,p,k-p}, \\
LCL &= 0,
\end{align*}
\]
where $p$ is the number of profile coefficients that are 2 here. If the number of samples $k$ is more than 100, the control limits are changed to:

$$
\begin{align*}
UCL_F &= \frac{p(k-1)}{k-p} F_{\alpha,p,k-p}, \\
LCL &= 0.
\end{align*}
$$

The second control limits are quantile of $T^2_{1-ME}$, ..., $T^2_{k-ME}$ and $T^2_{1-LR}$, ..., $T^2_{k-LR}$. These control limits are different for the maximum entropy and linear regression methods:

$$
\begin{align*}
UCL_{ME} &= q_{ME}, \\
UCL_{LR} &= q_{LR},
\end{align*}
$$

where $q_{ME}$ and $q_{LR}$ are $(1 - \alpha)\%$ $T^2$-Hotelling quantile values of the maximum entropy and linear regression techniques, respectively, and $\alpha$ is the first type of error determined 0.05 in this paper. The two methods are suitable for discovering soft changes as we pointed before. $ARL_0$ and $ARL_1$ are estimated for smooth shifts of intercepts and slopes in the simulation study section to illustrate this assertion.

5. Simulation study

In this section, we would like to use previous methods to find out shifts in a simulated dataset. Then, we would like to compare the abilities of the maximum entropy principle and the linear regression method. To do this, we first need to describe $ARL_0$ and $ARL_1$ that are our tools to make a comparison. Average run length ($ARL$) of control charts is a suitable way to decide the sample size. $ARL$ is the average number of in-control samples that have to be plotted before detecting an out of control sample. $ARL_0$ is usually calculated based on the first type of error $\alpha$ for uncorrelated data as below:

$$
ARL_0 = \frac{1}{\alpha},
$$

where $\alpha$ is the probability when an in-control sample reaches the control limits. $ARL_0$ is usually used to calculate the performance of control limits. $ARL_1$ is applied to discover shifts in the process means named as out of control $ARL$ and defined as below:

$$
ARL_1 = \frac{1}{1 - \beta},
$$

where $\beta$ is the second type of error described as a probability of being in statistical control when a mean shift occurs. In the following section, we need to explain two different phases in controlling a process. Usually, the control checking of a process consisted of phase $I$ and $II$. The purpose and performances of these two phases are different, and researchers should pay attention to the differences. In phase $I$, some previous data is available under favorable conditions whose purpose is to get some information about the dispersion and stability of the process and to model its performance under desirable qualifications. Appropriate control limits are gained based on the available information. Then, it is checked whether the process has been in-control during this period or not and whether these available control limits are reliable for phase $II$ or not. Furthermore, $ARL_0$ should be calculated in this phase too. In phase $II$, there is some information from phase $I$ such that the process was in a stable state and the necessary parameters were estimated in phase $I$. In the second phase, control limits of phase $I$ are used to checking the process being in-control or not. The most important purpose of this phase is to detect faster any undesirable shifts or changes in the process parameters. Control charts in phase $II$ are based on the $ARL_1$. Woodall (2017) implied to disturbance of the theoretical and
practical issues of statistical quality control in phases I and II. Furthermore, how to collect information in phases I and II have been mentioned in the article. Let’s first look at a small simulation example and explain the steps to finding control limits using this article’s methods. The simulated data example are in Table 1. As mentioned before, some constraints are needed to find the maximum entropy distributions like (5). For simplicity, the applied constraints for this example are:

\[
\begin{align*}
&\int_{S(X,Y)} dF_{X,Y}(x,y) = 1, \\
&\int_{S(X,Y)} x dF_{X,Y}(x,y) = \bar{x}, \\
&\int_{S(X,Y)} y_j dF_{X,Y}(x,y) = \bar{y}_j, \ j = 1, \ldots, 4 \\
&\int_{S(X,Y)} xy_j dF_{X,Y}(x,y) = \overline{xy}_j, \ j = 1, \ldots, 4.
\end{align*}
\] (10)

| $y$ | $x = 0.05$ | $x = 0.1$ | $x = 0.15$ | $x = 0.2$ | $\bar{y}$ | $\overline{xy}$ |
|-----|------------|------------|------------|------------|-----------|----------------|
| 1   | 0.135      | 1.434      | 1.228      | 2.133      | 1.2325    | 0.1902375     |
| 2   | 0.955      | 1.143      | 1.493      | 2.058      | 1.41225   | 0.1994        |
| 3   | 0.207      | 1.122      | 1.35       | 1.948      | 1.17175   | 0.1794125     |
| 4   | 0.179      | 0.915      | 1.154      | 2.435      | 1.17075   | 0.1901375     |

Then, the Lagrange functions have to be written for each sample $j = 1, \ldots, 4$:

\[
L(f, \lambda_0, \lambda_1, \lambda_2, \lambda_3) = -\int_{S(X,Y)} \log f_{X,Y}(x,y) \ dF_{X,Y}(x,y) - \lambda_0 \left\{ \int_{S(X,Y)} dF_{X,Y}(x,y) - 1 \right\} - \lambda_1 \left\{ \int_{S(X,Y)} x \ dF_{X,Y}(x,y) - \bar{x} \right\} - \lambda_2 \left\{ \int_{S(X,Y)} y \ dF_{X,Y}(x,y) - \bar{y} \right\} - \lambda_3 \left\{ \int_{S(X,Y)} xy \ dF_{X,Y}(x,y) - \overline{xy} \right\}.
\]

Now, after deriving and placing zero, like the steps in Section 2, we get the following functions, which is a similar equation to (3) as well:

\[
f_{X,Y}(x,y) = \exp(-1 - \lambda_0 - x\lambda_1 - y\lambda_2 - xy\lambda_3), \ (x,y) \in S(X,Y), \ j = 1, \ldots, 4.
\] (11)

In the next step, the conditions will be upgraded using function (11) as following for $j = 1, \ldots, 4$:

\[
\begin{align*}
&\int_{S(X,Y)} \exp(-1 - \lambda_0 - x\lambda_1 - y\lambda_2 - xy\lambda_3) dx dy = 1, \\
&\int_{S(X,Y)} x \exp(-1 - \lambda_0 - x\lambda_1 - y\lambda_2 - xy\lambda_3) dx dy = 0.125, \\
&\int_{S(X,Y)} y_j \exp(-1 - \lambda_0 - x\lambda_1 - y\lambda_2 - xy\lambda_3) dx dy = \bar{y}_j, \\
&\int_{S(X,Y)} xy_j \exp(-1 - \lambda_0 - x\lambda_1 - y\lambda_2 - xy\lambda_3) dx dy = \overline{xy}_j.
\end{align*}
\] (12)

So, the system of equations (12) contains four unknown parameters $\lambda_0, \ldots, \lambda_3$, and has to be solved concerning them. The number of samples is 4, so system (12) has to be solved four times to find out the maximum entropy distributions of 4 samples. All Lagrange coefficients are available in Table 2 as well. For instance, the maximum entropy distribution of the first sample is:

\[
f_{X,Y_1}(x,y) = \exp(-1 + 3.070517 - 7.57113 x - 0.9876531 y - 0.4731329 x y), \ (x,y) \in S(X,Y).
\] (13)

The next stage is to get the profile coefficients via the maximum entropy method using the
Table 2. The coefficients of maximum entropy distributions are calculated via solving systems of equations containing 4 unknown parameters $\lambda_0$, $\lambda_1$, $\lambda_2$, and $\lambda_3$.

| Groups | $\lambda_0$ | $\lambda_1$ | $\lambda_2$ | $\lambda_3$ |
|--------|-------------|-------------|-------------|-------------|
| 1      | -3.070517   | 7.57113     | 0.9876531   | 0.4731329   |
| 2      | -2.840981   | 7.714995    | 0.7845862   | 0.2433592   |
| 3      | -3.114455   | 7.584808    | 1.0323813   | 0.476777    |
| 4      | -3.167204   | 7.50769     | 1.0872566   | 0.606953    |

obtained distributions for samples. The formulas (6) and (7) are used to figure out $m_1$, $\ldots$, $m_k$. For example, the procedure to get $m_1$ is:

$$EX = \int \int_{S(X,Y)} x f_{X,Y}(x,y) dx dy = 0.125,$$

$$E[(X - EX)^2] = \int \int_{S(X,Y)} (x - EX)^2 f_{X,Y}(x,y) dx dy = 0.01573245,$$

$$EY_1 = \int \int_{S(X,Y)} y f_{X,Y}(x,y) dx dy = 0.9547399,$$

$$\hat{b}_{1-ME} = \frac{1}{E[(X - EX)^2]} \int \int_{S(X,Y)} (x - EX)(y - EY_1) f_{X,Y}(x,y) dx dy = -0.3843313,$$

and

$$\hat{a}_{1-ME} = EY_1 - \hat{b}_{1-ME} EX = 1.0027813,$$

where $f_{X,Y}(\cdot, \cdot)$ is defined in equation (13). All steps are done for samples, and the results are in Table 3. $T_{ME}^2$ values are based on the formula (8). The upper control limit $UCL_{ME}$ is the quantile 95% of the $T_{ME}^2$, which is 1.963768.

Table 3. Estimated profile coefficients are calculated via maximum entropy method. The last column is contained their corresponding $T^2$-Hotelling values.

| Groups | $\hat{a}_{ME}$ | $\hat{b}_{ME}$ | $T_{ME}^2$ |
|--------|--------------|--------------|-----------|
| 1      | 1.0027813    | -0.3843313   | 0.8160215 |
| 2      | 1.2503569    | -0.3165483   | 1.9671948 |
| 3      | 0.9607011    | -0.3586005   | 1.9443471 |
| 4      | 0.9114218    | -0.3984706   | 0.9042891 |

Table 4. Estimated profile coefficients are calculated via linear regression method. The last column is contained their corresponding $T^2$-Hotelling values.

| Groups | $\hat{a}_{LR}$ | $\hat{b}_{LR}$ | $T_{LR}^2$ |
|--------|---------------|---------------|----------|
| 1      | -0.2145       | 11.576        | 0.1067833|
| 2      | 0.4975        | 7.318         | 2.0360719|
| 3      | -0.146        | 10.542        | 1.4706997|
| 4      | -0.581        | 14.014        | 1.8363376|

The steps are so simple for the linear regression as a classical statistical method. The result of
this procedure is in Table 4. Its upper control $UCL_{LR}$ is the quantile 95% of the $T^2_{LR}$ and is 2.006112. The upper control limit based on Fisher distribution is 71.25, so far from logic. The same steps have to be done for data in phase II to find the maximum entropy distributions and their corresponding profile coefficients. The difference between phase I and phase II calculation is related to get the values of $T^2$-Hotelling statistics. In this case, the formulations (8) and (9) are applied with $S_m, \overline{m}, S_l, \overline{l}$ from the phase I data set. More information is available in Montgomery (2007).

Let’s show the performance of the methods by calculating $ARL_0$ for the simulation data set. To start the main simulation study, first of all, we simulate 100 samples with size $n = 5$ from model $Y = 2 + 3X + \varepsilon$, where $\varepsilon$ has a normal distribution of mean 0 and variance 0.1. The fixed observation vector of $X$ for all 100 samples is $(2, 2.2, 2.4, 2.1, 2.7)$. For these datasets, we calculate upper control limits of Fisher distribution, the 95 present quantile in maximum entropy, and linear regression respectively:

$$\begin{align*}
UCL_F &= 6.303865, \\
UCL_{ME} &= 5.591411, \\
UCL_{LR} &= 5.80042.
\end{align*}$$

Then, 1000 sets of the correct model are simulated again to calculate $ARL_0$. These are $ARL_0$ for the maximum entropy technique:

$$ARL_0 = \begin{cases} \\
\frac{1}{0.069} = 16.949 \simeq 17, & UCL = UCL_F, \\
\frac{1}{0.068} = 12.5 \simeq 13, & UCL = UCL_{ME}, \end{cases}$$

and the related $ARL_0$ for the linear regression method are:

$$ARL_0 = \begin{cases} \\
\frac{1}{0.06} = 16.666 \simeq 17, & UCL = UCL_F, \\
\frac{1}{0.071} = 14.084 \simeq 15, & UCL = UCL_{LR}. \end{cases}$$

They are the number of previous samples to observe one point out of the $UCL$ limit that means the false alarm when the process is in an appropriate situation because we simulate all datasets from the true model. This means that the process is in statistical control, so the larger value of $ARL_0$, the better choice of control limits. Therefore false alarm occurs later and less. It can be concluded from $ARL_{F}$ that when the $UCL$ is fewer and more sensitive, the first type of error is increased. On the other, it is reduced when the corresponding $UCL$ is less sensitive. Now we are keen on simulate datasets in shifted models and testing these two methods to detect the changes of the process means. Here we provide three shifted models containing intercepts, slopes, and a mixture of intercepts and slopes shifts as follows:

$$\begin{align*}
I : \ Y &= (2 + s) + 3X + \varepsilon, \\
II : \ Y &= 2 + (3 + s)X + \varepsilon, \\
III : \ Y &= (2 + s) + (3 + s)X + \varepsilon,
\end{align*}$$

where shift $s$ is started from 0.01 till 0.32 and the steps are 0.01:

$$s = \{0.01, 0.02, 0.03, \ldots, 0.3, 0.31, 0.32\}.$$
derive from all plots that the more shifts, the more sensitive control limits for detecting changes in a procedure. In Figure 1, the best method is the maximum entropy principle while using $UCL_{ME}$ quantile, and the worse model to detect shifts is the linear regression method using the upper Fisher control limit $UCL_F$, and their discrepancy is obvious on the figure. In Figures 2 and 3, this discrepancy is becoming lesser, because slope shifts effect more on process data, and in the third plot, there are intercept and slope shifts together. Eventually, we can conclude based on the curves that when shifts increase, the probabilities of false alarms decrease. Furthermore, we provide $ARL_{18}$ for all three models in Tables 5, 6, and 7 which are based on several shifts in intercepts, slopes, and a mixed model of intercepts and slope. The same conclusion of plots can drown from tables too. As it can be seen in the figures and the tables, these two detections ways are proper for smooth shifts, but the way based on maximum entropy discovers much sooner than the linear regression method. These ways can be applied in some manufacturing processes which should not have small shifts and always should be insensitive desirable situations like pharmaceutical products or expensive procedures, potential changes should be detected earlier to avoid wasting wealth.

6. Real dataset on semiconductor production process

In the manufacturing process, detecting all unexpected shifts is very important. There are many different ways for different situations to deal with out of control processes. The technicians have to choose a controlling method which detects them as soon as possible. There are some restrictions on the result products of processes that unwanted changes are forbidden even for some small shift. Many classical methods based on the mean control charts are disabled to detect a soft shift. In this paper, we explain two methods of detecting soft changes, the maximum entropy manner, and the classical linear regression. We compared them via simulation study in section 5, but here a real data example is represented. The initial profile dataset is from Zou et al. (2007), whose process is on deep reactive ion etching process ($DRIE$) from semiconductor manufacturing that contains two phases $I$ and $II$. They mentioned in their paper about the source of data that "in the ($DRIE$) process, one of the most important quality characteristics is the profile of a trench that may significantly impact the downstream operations (May et al. (1991)). The desired profile is the one with a smooth and vertical sidewall, as indicated in
Figure 2. The values of the second type of errors for the slope shift in model II: \( Y = 2 + (3 + s)X + \varepsilon \).

Figure 3. The values of the second type of errors for the intercept and slope shifts in model III: \( Y = (2+s)+(3+s)X+\varepsilon \).

the center sample of Figure 4”. The first dataset is included 18 samples with size \( n = 11 \), and the observed vector of independent variable is \((-2.5, -2, -1.5, -1, -0.5, 0, 0.5, 1, 1.5, 2, 2.5)\). The second set that is for phase II has consisted of 14 samples of the same size as the first set.

We aim to check the second phase of the process via suitable statistical control limits to see the possible defective products. By the way, in Zou et al. (2007), they noted that the last sample of Phase II with the number 14 is out of control. Thus, our control limits should detect these changes in the process. Therefore, we calculate the \( UCL_F \) control limit based on Fisher distribution and compare it with our presented \( UCL_{ME} \) and \( UCL_{LR} \). It is worth mentioning again that the control limit \( UCL_F \) is based on mean control, but other control limits are based on profile coefficients control limits. Hence, to find out the \( UCL_{ME} \) limit, we have to compute
the maximum entropy distributions of all 18 samples. We provide the Lagrange coefficients of the maximum entropy principle according to constraints (5) in Table 8. There are six coefficients. Based on what we said in section 4 and 2, $\lambda_0$ guarantees the maximum entropy distribution to be valid. Then, profile coefficients of all 18 maximum entropy distributions are calculated in Table 9 as well with their $T^2$-Hotelling values. The coefficients of the regression method are provided for this sample in Table 10, and their $T^2$-Hotellings are in the last column on the right for each sample. Till here, we get some important information form the situation of the in-control

Table 5. $ARL_{18}$ are provided for intercept Shifts where the columns $LR_F$ and $LR_Q$ are related to linear regression method using $UCL_F$ and $UCL_{LR}$, and columns $ME_F$ and $ME_Q$ are for maximum entropy principle with two upper control limits $UCL_F$ and $UCL_{ME}$ respectively.

| Shifts | $LR$ method | $ME$ method |
|--------|--------------|--------------|
|        | $UCL_F$ | $UCL_{LR}$ | $UCL_F$ | $UCL_{ME}$ |
| 0.01   | 19.607 | 15.625 | 17.543 | 12.500 |
| 0.02   | 20.408 | 18.518 | 14.925 | 11.363 |
| 0.03   | 14.492 | 12.048 | 10.101 | 8.620 |
| 0.04   | 13.698 | 11.494 | 10.989 | 8.333 |
| 0.05   | 12.345 | 10.309 | 9.433  | 7.299 |
| 0.06   | 9.259  | 7.462  | 7.299  | 6.060 |
| 0.07   | 9.174  | 7.936  | 6.896  | 5.847 |
| 0.08   | 7.633  | 6.329  | 6.060  | 4.784 |
| 0.09   | 6.622  | 5.494  | 5.000  | 3.861 |
| 0.10   | 5.747  | 4.807  | 4.424  | 3.484 |
| 0.11   | 4.950  | 4.219  | 3.731  | 3.134 |
| 0.12   | 3.472  | 3.030  | 2.890  | 2.433 |
| 0.13   | 2.941  | 2.583  | 2.525  | 2.114 |
| 0.14   | 2.500  | 2.197  | 2.100  | 1.808 |
| 0.15   | 2.016  | 1.821  | 1.745  | 1.557 |
| 0.16   | 1.776  | 1.647  | 1.605  | 1.449 |
| 0.17   | 1.594  | 1.455  | 1.445  | 1.310 |
| 0.18   | 1.418  | 1.342  | 1.295  | 1.206 |
| 0.19   | 1.270  | 1.210  | 1.183  | 1.112 |
| 0.20   | 1.221  | 1.169  | 1.165  | 1.119 |
| 0.21   | 1.161  | 1.140  | 1.121  | 1.075 |
| 0.22   | 1.094  | 1.068  | 1.070  | 1.040 |
| 0.23   | 1.066  | 1.054  | 1.049  | 1.033 |
| 0.24   | 1.038  | 1.024  | 1.023  | 1.015 |
| 0.25   | 1.017  | 1.011  | 1.007  | 1.004 |
| 0.26   | 1.015  | 1.010  | 1.010  | 1.003 |
| 0.27   | 1.007  | 1.005  | 1.004  | 1.002 |
| 0.28   | 1.002  | 1.001  | 1.001  | 1.001 |
| 0.29   | 1.001  | 1.000  | 1.000  | 1.000 |
| 0.30   | 1.001  | 1.000  | 1.000  | 1.000 |
| 0.31   | 1.000  | 1.000  | 1.000  | 1.000 |
| 0.32   | 1.000  | 1.000  | 1.000  | 1.000 |

Figure 4. Illustrations of various etching profiles form of a $(DRIE)$ process. (Adapted from Zou et al. (2007).)
 process. The next step is to specify beneficial control limits to use them for monitoring the rest of the process data. Thus, we obtain:

\[
\begin{align*}
UCL_F &= 8.150644, \\
UCL_{ME} &= 4.857291, \\
UCL_{LR} &= 4.857291.
\end{align*}
\]

In the subsequent stage, we have to gather some information from phase II data as before. We start it by calculation of maximum entropy Lagrange coefficients of the 14 samples shown in Table 11. Then, the profile coefficients and $T^2$-Hotellings are in Table 12. In Table 13, the profile coefficients are offered with their values of Hotelling statistics. The same conclusion of simulation results can be driven here. We know from Zou et al. (2007) that the last sample of phase II is out of control, and by using the two presented methods, the same consequence is gotten. The last one is out of control, as can be seen in Figure 5. The interesting part of the result is that the traditional method based on Fisher is unable to detect this shift.
## Table 8. The Lagrange coefficients of the maximum entropy distribution based on the in-control situation are here.

| Sample number | $\lambda_0$  | $\lambda_1$  | $\lambda_2$  | $\lambda_3$  | $\lambda_4$  | $\lambda_5$  |
|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| 1             | 2.148452      | 0.086787      | $-0.73435$    | 0.203605      | 0.258242      | $-0.06104$    |
| 2             | 2.153768      | $-0.01368$    | $-0.75237$    | 0.200085      | 0.263399      | 0.009578      |
| 3             | 2.150188      | $-0.07209$    | $-0.72613$    | 0.202509      | 0.254864      | 0.050602      |
| 4             | 2.274768      | $-0.04345$    | $-0.81836$    | 0.200726      | 0.258234      | 0.02742       |
| 5             | 2.126714      | 0.021106      | $-0.84734$    | 0.200189      | 0.306399      | $-0.01526$    |
| 6             | 2.293237      | 0.023812      | $-0.80842$    | 0.200215      | 0.250636      | $-0.01476$    |
| 7             | 2.082117      | 0.064123      | $-0.56338$    | 0.202801      | 0.216233      | $-0.04922$    |
| 8             | 2.340003      | 0.097769      | $-0.9068$     | 0.203203      | 0.275546      | $-0.05942$    |
| 9             | 2.265429      | $-0.08991$    | $-0.70341$    | 0.203606      | 0.220693      | 0.056417      |
| 10            | 2.202199      | $-0.01261$    | $-0.7537$     | 0.200068      | 0.251997      | 0.00843       |
| 11            | 2.195643      | $-0.16325$    | $-0.85185$    | 0.210633      | 0.289564      | 0.110982      |
| 12            | 2.298673      | 0.085613      | $-0.79945$    | 0.202822      | 0.246324      | $-0.05276$    |
| 13            | 2.397235      | 0.052969      | $-0.8115$     | 0.200982      | 0.230539      | $-0.0301$     |
| 14            | 2.307133      | $-0.00526$    | $-0.99678$    | 0.200009      | 0.317079      | 0.003344      |
| 15            | 2.247514      | $-0.0266$     | $-0.56266$    | 0.200402      | 0.179815      | 0.017001      |
| 16            | 2.378963      | $-0.04418$    | $-0.73862$    | 0.200752      | 0.210053      | 0.02513       |
| 17            | 2.56554       | $-0.07458$    | $-1.13947$    | 0.201342      | 0.313354      | 0.041012      |
| 18            | 2.103819      | 0.001211      | $-0.60548$    | 0.2           | 0.224705      | $-0.0009$     |

## Table 9. The maximum entropy coefficients for the 18 samples of in-control data gathering with their corresponding $T^2$-Hotellings are as below.

| Sample number | $\hat{a}_{ME}$ | $\hat{b}_{ME}$ | $T^2_{ME}$ |
|---------------|----------------|----------------|------------|
| 1             | 1.421818       | 0.118182       | 2.863782   |
| 2             | 1.428182       | $-0.01818$     | 0.700087   |
| 3             | 1.421545       | $-0.09927$     | 1.985242   |
| 4             | 1.584545       | $-0.05309$     | 0.376158   |
| 5             | 1.382727       | 0.024909       | 1.416012   |
| 6             | 1.612727       | 0.029455       | 0.422706   |
| 7             | 1.302727       | 0.113818       | 4.802159   |
| 8             | 1.645455       | 0.107818       | 2.398796   |
| 9             | 1.593636       | $-0.12782$     | 2.165594   |
| 10            | 1.495455       | $-0.01673$     | 0.137896   |
| 11            | 1.470909       | $-0.19164$     | 5.169704   |
| 12            | 1.622727       | 0.107091       | 2.161098   |
| 13            | 1.76           | 0.065273       | 3.098238   |
| 14            | 1.571818       | $-0.00527$     | 0.0367     |
| 15            | 1.564545       | $-0.04727$     | 0.25041    |
| 16            | 1.758182       | $-0.05982$     | 2.605809   |
| 17            | 1.818182       | $-0.06545$     | 4.121102   |
| 18            | 1.347273       | 0.002          | 1.936388   |
Table 10. The coefficients of the linear regression method whose $T^2$-Hotelling values are on the right column are provided for the first sample.

| Sample number | $\hat{a}_{LR}$ | $b_{LR}$ | $T^2_{LR}$   |
|---------------|----------------|----------|--------------|
| 1             | 1.421818       | 0.118182 | 2.863775     |
| 2             | 1.428182       | -0.01818 | 0.700087     |
| 3             | 1.424545       | -0.09927 | 1.98524      |
| 4             | 1.584545       | -0.05309 | 0.376158     |
| 5             | 1.382727       | 0.024909 | 1.416012     |
| 6             | 1.612727       | 0.029455 | 0.422706     |
| 7             | 1.302727       | 0.113818 | 4.802158     |
| 8             | 1.645455       | 0.107818 | 2.398797     |
| 9             | 1.593636       | -0.12782 | 2.165596     |
| 10            | 1.495455       | -0.01673 | 0.137896     |
| 11            | 1.470909       | -0.19164 | 5.169706     |
| 12            | 1.622727       | 0.107091 | 2.161099     |
| 13            | 1.76           | 0.065273 | 3.098237     |
| 14            | 1.571818       | -0.00527 | 0.0367       |
| 15            | 1.564545       | -0.04727 | 0.25041      |
| 16            | 1.758182       | -0.05982 | 2.605808     |
| 17            | 1.818182       | -0.06545 | 4.121102     |
| 18            | 1.347273       | 0.002    | 1.936388     |

Table 11. The Lagrange coefficients of the maximum entropy for each sample of phase II are calculated.

| Sample number | $\lambda_0$ | $\lambda_1$ | $\lambda_2$ | $\lambda_3$ | $\lambda_4$ | $\lambda_5$ |
|---------------|--------------|--------------|--------------|--------------|--------------|--------------|
| 1             | 2.350736     | 0.094391     | -1.05091     | 0.202642     | 0.32748      | -0.05883     |
| 2             | 2.2661       | -0.10878     | -0.81399     | 0.204617     | 0.258632     | 0.069125     |
| 3             | 2.237455     | -0.01834     | -0.72038     | 0.200149     | 0.232379     | 0.01183      |
| 4             | 2.217579     | 0.100131     | -0.7993      | 0.204152     | 0.264668     | -0.06631     |
| 5             | 2.227532     | 0.038925     | -0.70193     | 0.200701     | 0.228301     | -0.02532     |
| 6             | 2.173455     | 0.047915     | -0.63502     | 0.201241     | 0.218015     | -0.0329      |
| 7             | 2.247015     | -0.00031     | -0.56221     | 0.200001     | 0.179777     | 0.000196     |
| 8             | 2.211425     | -0.02008     | -0.63823     | 0.200209     | 0.210699     | 0.013255     |
| 9             | 2.273512     | -0.07685     | -0.5887      | 0.203114     | 0.182724     | 0.047708     |
| 10            | 2.277067     | 0.011272     | -0.73804     | 0.200052     | 0.229853     | -0.00702     |
| 11            | 2.140158     | 0.05129      | -0.61059     | 0.201535     | 0.217643     | -0.03656     |
| 12            | 2.267622     | 0.018718     | -0.56256     | 0.200195     | 0.176        | -0.01171     |
| 13            | 2.32175      | 0.019312     | -0.7868      | 0.200142     | 0.237118     | -0.01164     |
| 14            | 2.153608     | -0.08341     | -0.46953     | 0.205404     | 0.171248     | 0.06084      |
Table 12. The profile coefficients of the maximum entropy manner for the sample in phase II with their relative $T^2$-Hotelling values are gotten as below.

| Sample number | $\tilde{a}_{ME}$ | $b_{ME}$ | $T^2_{ME}$ |
|---------------|------------------|----------|------------|
| 1             | 1.604545         | 0.089818 | 1.511138   |
| 2             | 1.573636         | -0.13364 | 2.303208   |
| 3             | 1.550002         | -0.02545 | 0.051808   |
| 4             | 1.51             | 0.125273 | 2.482413   |
| 5             | 1.537273         | 0.055455 | 0.54043    |
| 6             | 1.456364         | 0.075455 | 1.297488   |
| 7             | 1.563636         | -0.00055 | 0.023144   |
| 8             | 1.514545         | -0.03145 | 0.137063   |
| 9             | 1.610909         | -0.13055 | 2.347447   |
| 10            | 1.605455         | 0.015273 | 0.255684   |
| 11            | 1.402727         | 0.084    | 2.090796   |
| 12            | 1.598182         | 0.033273 | 0.374238   |
| 13            | 1.659091         | 0.024545 | 0.801125   |
| 14            | 1.370909         | -0.17764 | 5.773461   |

Table 13. The profile coefficients of the linear regression method for the sample in phase II and their $T^2$-Hotellings are gathered here.

| Sample number | $\tilde{a}_{LR}$ | $b_{LR}$ | $T^2_{LR}$ |
|---------------|------------------|----------|------------|
| 1             | 1.604545         | 0.089818 | 1.511138   |
| 2             | 1.573636         | -0.13364 | 2.303204   |
| 3             | 1.55             | -0.02545 | 0.051807   |
| 4             | 1.51             | 0.125273 | 2.482413   |
| 5             | 1.537273         | 0.055455 | 0.54043    |
| 6             | 1.456364         | 0.075455 | 1.297487   |
| 7             | 1.563636         | -0.00055 | 0.023144   |
| 8             | 1.514545         | -0.03145 | 0.137063   |
| 9             | 1.610909         | -0.13055 | 2.347444   |
| 10            | 1.605455         | 0.015273 | 0.255684   |
| 11            | 1.402727         | 0.084    | 2.090795   |
| 12            | 1.598182         | 0.033273 | 0.374238   |
| 13            | 1.659091         | 0.024545 | 0.801125   |
| 14            | 1.370909         | -0.17764 | 5.773456   |
7. Pharmacy real profile data

As we know, the maximum entropy technique to estimate profile coefficients can be applied in pharmacy real data sets as well. In this paper, we explain two different ways to estimate profile coefficients. Then, we illustrate a simulation study and real data example on the semiconductor procedure. In these examples, we show the ability of the maximum entropy and linear regression to detect faults in production processes by defining some statistical control limits. In this section, we are keen on surveying another applied aspect of the maximum entropy method in manufacturing processes. The superiority of the maximum entropy principle is exhibited, while the regression method is unable to act well here. To do this, we choose a pharmaceutical industry profile dataset adapted from Shah et al. (1998). In the pharmaceutical industry, there are many processes needed to be in statistical control. For instance, in the production of a particular tablet, many characteristics must be observed for the product to have a standard and desirable quality. Ma et al. (2000) indicate that the U.S. Food and Drug Administration had to define many conductances of scale-up and post-approval changes for different types of shifted during production processes. In this regard, the statistical quality control charts have an influential position in pharmaceutical processes.

In Shah et al. (1998), there are six groups of profile data containing the response variable in four columns as the cumulative dissolution of tablets at 30, 60, 90, and 180 minutes. The different values of time are the independent variable. The sample sizes have to be 12 according to the guidance of "Dissolution Testing of Immediate Release Solid Oral Dosage Forms" Ma et al. (2000). The first group is a pre-change as a dissolve reference in different minutes. The other five batches are from post-change processes. The beneficial aspect of this study was to detect the similarity or dissimilarity of batches from the reference group. So, we use the two explained methods here to realize if there are different or not. Thus, we calculate $T^2$-Hotelling statistics for these profiles via the maximum entropy and linear regression in Tables 14 and 15. The upper
control limits at the confidence level 0.9973 are as below:

\[
\begin{align*}
UCL_F &= 26.97728, \\
UCL_{ME} &= 6.812622, \\
UCL_{LR} &= 5.883782.
\end{align*}
\]

Table 14. The $T^2_{ME}$-Hotelling of the reference pre-change group and post-change batches 1 to 5 are calculated related to the tablet dissolution in 30, 60, 90, and 180 minutes. All numbers are out of control based on $UCL_{ME}$, but the stared numbers are in-control tablets according to $UCL_F$.

| Tablet numbers | Reference | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|----------------|-----------|---------|---------|---------|---------|---------|
| 1              | 0.909599  | 2531250 | 40212322| 24964618| 16.39547*| 18160920|
| 2              | 0.425575  | 2528833 | 40139281| 24937534| 19.67239*| 18175683|
| 3              | 0.941833  | 2524719 | 40201702| 24942289| 20.27384*| 18143501|
| 4              | 1.633346  | 2523418 | 40165632| 24924941| 13.65696*| 18140601|
| 5              | 6.866841  | 2507804 | 40231679| 24950972| 38.40114*| 18161265|
| 6              | 0.704702  | 2503931 | 40195131| 24925518| 20.16521*| 18155740|
| 7              | 1.089671  | 2525108 | 40156018| 24964433| 22.48306*| 18159950|
| 8              | 2.197987  | 2524320 | 40204586| 24946082| 23.06229*| 18171547|
| 9              | 0.374201  | 2527543 | 40223125| 24961179| 26.16568*| 18151208|
| 10             | 1.313367  | 2529049 | 40190721| 24955811| 23.06229*| 18171547|
| 11             | 5.041279  | 2523157 | 40213998| 24946082| 28.3081  | 18163695|
| 12             | 2.082611  | 2521620 | 40188450| 24942734| 37.34562| 18160788|

Table 15. The $T^2_{LR}$-Hotelling of the reference pre-change group and post-change batches 1 to 5 are calculated related to the tablet dissolution in 30, 60, 90, and 180 minutes. Bold numbers are in-control respect to $UCL_{LR}$, and the stared numbers are in-control tablets according to $UCL_F$.

| Tablet numbers | Reference | Batch 1 | Batch 2 | Batch 3 | Batch 4 | Batch 5 |
|----------------|-----------|---------|---------|---------|---------|---------|
| 1              | 0.753828  | 3.605572*| 9.745365*| 22.38664*| 26.5657*| 30.8042|
| 2              | 0.545729  | 1.257303*| 66.29209| 16.15048*| 35.7986| 30.21156|
| 3              | 1.065667  | 4.79904* | 10.03773*| 16.77926*| 46.38533| 55.70723|
| 4              | 0.264546  | 3.286005*| 50.99222| 37.2213  | 23.3262*| 53.68816|
| 5              | 5.941888  | 63.69596| 7.94085* | 20.63325*| 43.57709| 25.90142*|
| 6              | 1.111635  | 77.02181| 23.14788*| 11.41718*| 48.05146| 41.27006|
| 7              | 1.135030  | 10.34709*| 49.88452| 25.84385*| 42.7708| 36.8145|
| 8              | 1.89725   | 5.027514*| 18.9799* | 19.09505*| 29.29209| 42.07779|
| 9              | 0.490227  | 0.780852*| 6.021915*| 27.74487| 39.82303| 46.06432|
| 10             | 1.574057  | 2.557472*| 28.83701| 23.89729*| 39.1091| 24.26933*|
| 11             | 3.910336  | 11.32792*| 15.90477*| 7.477256*| 40.16677| 27.39676|
| 12             | 0.790672  | 38.18567| 32.92128| 45.48335| 59.87374| 36.48986|

Shah et al. (1998) declared that all batches have unwanted changes in the amount of dissolution, and the dissolved values of batch 4 in 30 minutes are only dissimilar to the reference data. The maximum entropy reflects this reality via different $T^2$-Hotelling values in Table 14. Without any ambiguity, it is clear that all batches except batch 4 are too different from the reference assortment. Although all tablets of batch 4 are out of control based on $UCL_{ME}$, they are not as large as other batch values. So, the maximum entropy method detects undesirable changes concerning the reference group as well. Nine tablets in batch 4 are in-control according to $UCL_F$, which means that the traditional way based on Fisher distribution is unable to realize the available changes in the data. The result of the linear regression in Table 15 is quite different. This method does not completely detect changes in batch 1, and some in-control tablets based
on $UCL_{LR}$ can be seen in bold there. Also, 29 in-control samples exist related to $UCL_F$ pointed by stars. Moreover, most of the tablets in batch 4 are out of control that is far from the fact. So, decision correspondence to the linear regression method has some shortcomings. Thus, the power of maximum entropy is obvious and clear in this difficult situation, and other methods such as linear regression and Fisher distribution are unable to show the post-change of the data set in batches.

There is some other information from Shah et al. (1998). The dissolved differences of batch 2 are 15% more than the reference group at 30 minutes, but the differences reduced to less than 8% at 60, 90, and 180 minutes. In Tables 16 and 17, they are compared in the absence of the column related to minute 30. Batch 4 at 30 minutes is different from the reference group more than 12%, and the differences between this batch and the reference group ignore in the absence of 30 minutes information and become similar. The reference $T^2$-Hotelling is provided in the tables to make a reliable comparison in the absence of the 30 minutes column. The upper control limits at the confidence level $0.9973$ for this case are:

$$
\begin{align*}
UCL_F &= 26.97728, \\
UCL_{ME} &= 6.407286, \\
UCL_{LR} &= 5.864856.
\end{align*}
$$

### Table 16. $T^2_{ME}$-Hotelling of reference and some batches are presented in the absence of some information which are mentions on the top of columns.

| Tablet numbers | Reference except 30 min | Batch 2 except 30 min | Batch 4 except 30 min | Reference except 90 min | Batch 3 except 90 min | Reference except 60 min | Batch 5 except 60 min |
|----------------|-------------------------|-----------------------|-----------------------|-------------------------|-----------------------|-------------------------|-----------------------|
| 1              | 0.85972098              | 32054088              | 0.859721              | 0.6462575               | 11342273             | 1.0305838               | 7100891               |
| 2              | 0.09665851              | 31966736              | 0.096659              | 0.6621264               | 11326617             | 0.3331313               | 7108760               |
| 3              | 1.07377578              | 32042515              | 1.073776              | 0.7646651               | 11329719             | 0.8196994               | 7094211               |
| 4              | 7.93191591              | 32003090              | 7.931916              | 0.9894897               | 11320807             | 0.7515795               | 7094148               |
| 5              | 6.67355851              | 32066905              | 6.673559              | 6.4828865               | 11353565             | 6.5217488               | 7095663               |
| 6              | 1.50996478              | 32024502              | 1.509965              | 0.6737853               | 11318497             | 0.6987794               | 7099653               |
| 7              | 0.4792845               | 31984663              | 0.479285              | 0.9743507               | 11343690             | 1.5170518               | 7102175               |
| 8              | 2.32876957              | 32042369              | 2.32877               | 3.0835605               | 11334122             | 2.8849953               | 7102262               |
| 9              | 0.36990082              | 32054088              | 0.369901              | 0.3693712               | 11341106             | 0.4142522               | 7097997               |
| 10             | 0.24985908              | 32041637              | 0.249859              | 1.3754771               | 11338460             | 1.6259235               | 7104667               |
| 11             | 5.78426564              | 32055156              | 5.784266              | 3.9374103               | 11330098             | 2.4341753               | 7100702               |
| 12             | 4.92606407              | 32031147              | 4.926064              | 1.024471                | 11331677             | 0.8916272               | 7102083               |

According to Table 16, the $T^2$-Hotelling statistics values are reduced related to batch 2 and 4, which means their distances are diminished from the reference group. Batch 2 is still out of control, and the maximum entropy reflects it obviously, but batch 4 becomes similar to the reference. The conclusion of the linear regression method shown in Table 17 is quite the same. All tablets are out of control for batch 2, and almost all of them for batch 4 are in-control. Shah et al. (1998) expressed about batch 3 that the differences are more than 12% at 90 minutes between this batch and corresponding reference group information, and the differences become less than 10% in the absence of data for 90 minutes. The related $T^2$-Hotelling is in Tables 16 and 17 for when the data of 90 minutes are omitted from the data set. Also, the related amounts of reference group are available the tables, and the corresponding upper control limits at the confidence level 0.9973 are:

$$
\begin{align*}
UCL_F &= 26.97728, \\
UCL_{ME} &= 6.407286, \\
UCL_{LR} &= 5.864856.
\end{align*}
$$
The similarity of reference and batch 3 in the absence of 90 minutes is clearly rejected in the maximum entropy method. Although the $T^2$-Hotelling values are too high in this situation, they are less than the values calculated in Table 14. The result for the regression method is the same, and all dissolutions are out of control that declares that batch 3 is not equivalent to the reference. The inference can be made for the last batch. Shah et al. (1998) gave some further information about this batch as well. The difference between the batch and reference is more than 17% for all dissolutions are out of control that declares that batch 3 is not equivalent to the reference. The inference can be made for the last batch. Shah et al. (1998) gave some further information about this batch as well. The difference between the batch and reference is more than 17% for all dissolutions are out of control that declares that batch 3 is not equivalent to the reference.

The related information is in Tables 16 and 17. In both methods, the similarity between batch 5, and the reference is denied in the absence of 60 minutes of data. Although all $T^2$-Hotelling amounts of dissolutions are less than the amounts in Tables 14 and 15, and they show the existence differences, the maximum entropy decisively showed dissimilarity. The superiority of the maximum entropy principle was shown in this real situation of the profile dataset from the pharmaceutical production process.

8. Conclusion

Usually, in statistical quality control, the purpose is to find suitable statistical limits to check processes during the time to keep them in control, or to detect their shifts as soon as possible in order not to waste money and time. So many methods are used for this aim. Most of them are based on process means, and the control charts monitor them. Up to our knowledge, they are not sufficient enough to detect different kinds of shifts. Therefore, in this paper, we would like to present a profile investigation of change points according to its coefficients. Our focus was on the simple linear profile, which looks like simple linear regression. Two methods of estimating are presented here. The first one is based on the maximum entropy principle compared with the second method, which is according to the linear regression. We use a $T^2$-Hotelling statistic to reduce the profile coefficient vector.

Generally, we would like to see shifts of processes by monitoring coefficients instead of means.
To make a good comparison between their performance, we define three shifted models and calculate second errors $\beta$, $ARL_0$, and $ARL_1$, plots based on second errors are drawn. We can conclude from simulation results that both of manners can detect changes in small shifts. But the method of maximum entropy has more performance. In the end, we provide a real data study to see the results in the methods. There was a change in the testing sample, and our purpose was to detect it. This kind of shift can not be detected based on mean control limits, but in the maximum entropy and the regression method based on profiles, it was detected easily. Thus, our methods were successful in checking the manufacturing process. In the last section, a pharmaceutical industry example was presented, which show the betterness of the maximum entropy principle as well. In this example, the regression procedure acts weak. Thus, we show their performance methods in three situations, simulated example, semiconductor production, and pharmacy profiles. The ability of these two methods in the first two examples was somewhat the same, although the maximum entropy method noticed differences earlier. In the last example, the linear regression method did not correctly identify the dissimilarity, while the maximum entropy-based method did correctly identify the differences and similarities.

### Data availability statement

The data that support the findings of sections 6 and 7 are openly available in Zou et al. (2007) at https://doi.org/10.1198/004017007000000164, and Shah et al. (1998) at https://doi.org/10.1023/A:1011976615750, respectively.

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