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(54) Titre : PROCESSUS D'ASSEMBLAGE, DE PRODUCTION ET D'ASSURANCE QUALITE RELATIFS A DES ETIQUETTES DE SURVEILLANCE DE CONFORMITE ELECTRONIQUE (ECM)

(54) Title: ASSEMBLY, PRODUCTION AND QUALITY ASSURANCE PROCESSES RESPECTING ELECTRONIC COMPLIANCE MONITOR (ECM) TAGS

(57) Abrégé/Abstract:
The Med-ic™ Electronic Compliance Monitor (ECM) addresses the problem of patient non-compliance with prescribed medication. The Med-ic™ ECM provides precise information about the patient's use of blister-packaged medication in clinical research and general pharmacy settings. Using an on-board central processing unit (CPU), the Med-ic™ ECM records the time each tablet or capsule is expelled from the blister package, keeping a record for later analysis. At the time of refilling or follow-up visit, the information is downloaded to the research assistant's, physician's or pharmacist's computer where it can be displayed graphically. The data can be stored for later analysis. Production of a Med-ic™ ECM Tag involves numerous steps. These steps incorporate certain methods and technologies to accomplish their objective. The current invention describes this process.

ABSTRACT

The Med-ic™ Electronic Compliance Monitor (ECM) addresses the problem of patient non-compliance with prescribed medication. The Med-ic™ ECM provides precise information about the patient's use of blister-packaged medication in clinical research and general pharmacy settings.

Using an on-board central processing unit (CPU), the Med-ic™ ECM records the time each tablet or capsule is expelled from the blister package, keeping a record for later analysis. At the time of refilling or follow-up visit, the information is downloaded to the research assistant's, physician's or pharmacist's computer where it can be displayed graphically. The data can be stored for later analysis.

Production of a Med-ic™ ECM Tag involves numerous steps. These steps incorporate certain methods and technologies to accomplish their objective. The current invention describes this process.

ASSEMBLY, PRODUCTION AND QUALITY ASSURANCE PROCESSES RESPECTING ELECTRONIC COMPLIANCE MONITOR (ECM) TAGS

The present invention relates to the steps involved in the assembly, production and quality assurance processes respecting electronic compliance monitor (ECM) tags, and in particular respecting Med-ic™ tags of Information Mediary Corporation.

Description of Steps Involved in Producing a Med-ic™ ECM Tag

Each step in the production of a Med-ic™ ECM Tag is explained in detail. The steps are explained in chronological order and with particular reference to the drawings and representations appended hereto.

Step 1: PCB Printing

Printed Circuit Boards (PCBs) are printed on a sheet of flexible substrate in 5-inch x 4-inch format. Figure 1.1 shows a sheet of PCBs.

The four holes around each PCB are used to locate an automatic soldering machine to install electronic components on the PCB.

Step 2: Soldering Components on the PCB

Electronic components are installed on the PCB using an automated soldering machine. A sheet of PCBs (Figure 1.1) is placed on the soldering machine's customized jig. The jig has protrusions on its surface that allow a sheet of PCBs to be located precisely. Once the sheet is in place, the components are soldered to the PCB. Figure 2.1 shows components positioned on a PCB.

Step 3: Transferring Firmware to the PCBs

Firmware is software specifically designed to control microcontroller operations. Firmware is saved in individual files and uploaded to IMC's website. Each file contains a Tag Firmware Version and a unique Tag Identification (ID) Number. These files are downloaded to a Personal Computer (PC) connected to a Wouter Box.

The Wouter Box is a specialized piece of hardware that allows 20 PCBs to be programmed and serialized simultaneously. Figure 3.1 shows a Wouter Box.

The Wouter Box is connected to a Nail Bed comprising 100 pins to allow the 20 PCBs to be programmed simultaneously. The Nail Bed enables simultaneous transfer of 20 firmware files from a Wouter Box to 20 PCBs. A Nail Bed is shown in Figure 3.2.

Figure 3.3 illustrates the process of transferring firmware from a PC to a Wouter Box to a Nail Bed to 20 Med-ic ECM Tags.

To control the transfer of firmware, “Big Burner”, also known as QA1 software, is used. Big Burner software is installed on a PC connected to a Wouter Box. Figure 3.4 shows the screenshot of Big Burner software.

In addition to transferring firmware, Big Burner also verifies that the oscillator calibration coefficient is not corrupted due to poor contact between the Nail Bed pins and PCBs. Big Burner automatically marks any PCBs that were not successfully programmed with the firmware, so these tags can be removed from the assembly process. Figure 3.5 shows a screenshot of Big Burner displaying a failed attempt at programming one of 20 PCBs.

Step 4: Battery Installation on the PCBs

Once the PCBs are programmed, 3.3-volt batteries are installed on them manually by soldering. Figure 4.1 shows a PCB with installed battery

Step 5: Protective Foam Placement on the PCBs

A layer of protective foam is applied to the PCBs. Since both sides of the foam are adhesive, foam is glued to the PCBs. The front side of the foam identifies the PCB Type (i.e., Med-ic™) and the Firmware Version. The backside of the foam has a protective paper layer attached. When gluing the foam to the PCBs, this paper is peeled off to expose the adhesive. The backside of the foam is then attached to the PCBs. Figure 5.1 shows the front and backsides of the foam and a single PCB with foam attached.

Step 6: Foam Placement on the PCBs

Another adhesive foam is glued to the back of the PCBs. This allows the option of attaching PCBs to any paper material. Paper from one side of the foam is peeled off and that side is attached to the back of the PCB. The other side of the foam is left with its protective backing in place. When the PCB is to be glued onto a paper material the protective backing is removed and the PCB attached. Figure 6.1 shows the front and back of the foam. Figure 6.2 displays one side of the foam from which the protective backing has been removed to expose its adhesive. Figure 6.3 illustrates the application of the foam to the back of a PCB. Figure 6.4 shows a PCB with foam attached to its back.

Step 7: PCB Sheet Separation

A sheet of PCBs is cut into 20 separate PCBs. These PCBs are now known as Tags.

Battery Life Measurement:

To assure the quality of the batteries attached to the Tags, battery life is now measured.

The rate of loss of energy from batteries is often irregular, making it difficult to measure and predict. Factors such as quality, lithium content, connections of anode and cathode, and condition of the separator and electrolyte system can contribute to inconsistency in energy depletion.

IMC has developed a special firmware, "Battery Test Firmware", to monitor the energy and voltage level of a battery through its entire life. Battery Test Firmware checks and records the energy and voltage level of a battery at regular intervals. Recorded information is displayed when the Tag is scanned on the RF reader connected to a PC loaded with IMC's software.

Tags are randomly chosen from a production batch after they have been completely assembled. These selected Tags are then programmed with the Battery Test Firmware using Big Burner software. A resistor of low tolerance (approximately 0.1%) is connected to each programmed Tag. This resistor serves as a reference unit for the battery voltage measurements. These Tags are stored in IMC's warehouse where they are scanned to view the battery's energy and voltage level history. The functional life of a lithium battery is approximately 2 years.

Step 8: Quality Assurance Check on each Tag

Each Tag is checked with Quality Assurance 2 (QA2) software. To communicate with the Tag, QA2 software uses the CertiScan™ Reader. A Tag is placed on the reader to start communication with the QA2 software. The procedure of placing the Tag on a reader is also referred to as scanning. Figure 8.1 shows the Certiscan™ Reader and a Tag being scanned.

QA2 checks Timer 1 and battery voltage. Any Tag that fails either of these tests is deemed unacceptable for further use. Tags that pass these checks are assigned unique ID Numbers that are saved to a QA2 floppy disc. In addition, the test results for each Tag are also saved. On completion of this step only successfully programmed and readable tags have passed through the inspection process. Figure 8.2 shows screenshots of QA2 software.

Step 9: Shipping and Handling

Tags that pass QA2 are placed in a plastic Tray. A Tray holds 80 Tags and 20 Trays form a Lot. (1 Lot consists of 1600 Tags). Each Lot also includes a floppy disc containing the ID numbers and QA2 test results for all Tags in that Lot. Three Lots are placed in one Box.

One percent of the Tags is held back for quality testing and is sent to the IMC engineering office. Boxes of tags are shipped to the user.

Figure 9.1 shows a tray containing 80 Tags and the floppy disc for the Lot to which this Tray belongs.

Description of Steps Involved in Producing a Printed Sensor Grid (PSG) Compatible with a Med-ic™ ECM Tag

Background Information

A paper production facility designs and manufactures paper to work with Med-ic™ ECM Tags. A PSG is then printed on its surface. The PSG is also known as a Grid.

A Grid consists of conductive and resistive paths connected to a Tag by stitching with conductive thread. This puts the Tag and Grid in electrical continuity. Details of connecting a Tag to a Grid are described in Step 12. The connection between the Grid and the Tag enables the tag to monitor the electrical characteristics of the Grid. The electrical circuit comprised of a connected Tag and Grid is shown in Figure B1.

Operations of the Circuit

In Figure B1, components residing on the Tag and the Grid are enclosed in rectangles labelled “Tag” and “Grid”. Power is supplied to this circuit by a 3.3 Volt battery (V_{dd}).

Initially, Switch 1 is closed to allow V_{dd} to charge the Capacitor. The Limiting Resistor prevents overflow of current to the Capacitor. When the Capacitor is charged to approximately 1.1Volt, the Comparator records a Value of 1. This indicates that the Capacitor’s charged value is higher than the Comparator’s threshold value. Figure B2 shows the operation of charging a Capacitor.

When the Comparator records Value of 1, a Timer is set to zero. The Capacitor is discharged to Ground through the components of the Grid. Closing Switch 2 allows the Capacitor to discharge to Ground. Current flows first from the Capacitor to a Reference Resistor on the Grid. When the current reaches the point of the Resistors in parallel (Figure 1B with R2 in parallel with G_Switch 2), it chooses the path of least resistance and passes through the closed G_Switch. After passing through all closed G_Switches, the current goes through closed G_Switch 2 to ground. Figure B3 shows the path taken by the current discharged from the Capacitor.

A Diode in the circuit prevents the current from flowing through the Limiting Resistor. Therefore current is forced to take the path shown in figure B3. The Reference Resistor is three times bigger than any other Resistor in the grid circuit. Since the printing of a grid can vary from grid to grid, the Resistors can also vary. The Reference Resistor provides an average value for a specific Tag to establish a relative current when the Capacitor is discharging.

As soon as the Capacitor begins discharging, a Timer is started to measure the time it takes for the Capacitor to discharge. Once the Capacitor's discharge value reaches the Comparator's threshold value of 1.1 Volts, the Comparator records a Value of 0 and stops the Timer. The time measured by the Timer is stored in the EPROM of the microcontroller.

If G_Switch 2 in the grid is opened, as shown in Figure B4, the current's path changes. Current now flows through R2, the path of least resistance. The path through R2 increases the time for the Capacitor to reach the threshold value of the Comparator.

The Microcontroller compares the opening and closing times of G_Switch 2. If the times do not match, the Microcontroller decides that G_Switch 2 is open.

Step 10: Printing Sensor Grids

Electronic components such as resistors and conductive traces are printed on the paper's surface. Silver ink is used to print conductive traces and Carbon ink is used to print resistors (resistive paths). These printed elements are collectively referred to as a Grid.

A Tag and Grid form an electronic circuit that allows the Tag to monitor the Grid for changes in its electrical characteristics. Figure B1 shows schematically the circuit formed by the Tag and the Grid. However, the Grid is printed on paper as shown in Figure 10.1. This Grid behaves and operates as described under Background Information.

The Flexographic printing process is used to print the Grids. Figure 10.2 illustrates the step-by-step application of coating and inks to the paper's surface.

As described in Figure 10.2, Step 1 involves choosing the paper thickness. Ten- or 12-point paper is generally used.

In Step 2 a layer of Curable Ultraviolet (UV) Coating is applied to the paper. This coating prevents cracks from forming in the resistive or conductive paths when the paper is bent. Cracks can interfere with the electrical continuity of the paths causing the system to malfunction.

In addition, paper is composed of fibres, making its surface irregular and sensitive to changes in temperature and humidity. Changes in a paper's surface architecture alter the electrical characteristics of paths printed on it. Curable UV Coating makes the paper's surface more uniform and resistant to temperature and humidity effects.

UV Coating also provides extra flexibility if the paper has a clay coating. Clay coating is applied to paper to make it glossy. The clay coating is brittle and can crack when the paper is bent. Consequently, Carbon or Silver ink paths applied directly to the clay coat could lose their electrical continuity. Application of Curable UV Coating to the clay coat prevents this. In Step 3, Resistors and Traces are printed with Carbon or Silver ink.

Step 4 involves applying another layer of Curable UV coating. This layer is applied on top of both Carbon and Silver inks and serves as an insulator to prevent electrical contact with outside sources other than the Tag. This coat also fills in the pores of the Carbon and Silver ink, serving as a bonding material. The Grid shown in Figure 10.1 is obtained on completion of the four steps in Figure 10.2.

Paper is not the only material on which the Grid can be printed. Polymer film and paper backed Foil can also be used.

A layer of adhesive is applied to the bottom surface of the paper, as shown in Figure 10.3.

When the paper is heated, this adhesive melts and attaches the paper to other surfaces with which it is contact. This process is explained in Step 15.

The paper with its printed Grid is then Die Cut. Figure 10.4 shows a die cut paper.

Referring to Figure B4, G_Switch 2 is opened intentionally to change the current's path. To open a switch on a Grid (see Figure 10.1) a section of the conductive path must be broken completely. A person needs to apply pressure on a specific section of the Grid to break that section. This action is taken when a blister package of medication is placed inside the paper with the plastic blisters protruding through the die cut holes in the paper, and the paper is heat sealed to enclose the blister package. This process is described in Step 14.

The Grid is aligned with the individual blisters in such a way that pushing a tablet through the backing of the blister package will break the associated Path of the Grid. This forces the current to take a resistive path. However, breakage of the conductive path may occur in other sections of the Grid if pressure is not applied properly. To facilitate breaking in the appropriate area of the Grid, Die Cutting is used to score patterns around areas of the Grid that are required to serve as switches. Figure 10.5 shows a Die Cut Grid.

When a tablet is expelled from its blister, it breaks the path in the section of the Grid at the associated scored area. A semi-circular pattern of scores prevents creases from forming on conductive paths when heat-sealed paper with an enclosed blister package is deformed. Creases cause resistance changes in the conductive paths, resulting in malfunction of the system. Figure 10.6 shows a broken path with its associated score pattern.

The scoring pattern acts like a door, allowing the tablet to break the grid and slide out.

Step 11: Checking Grid Resistances

Once the paper Grid has been die cut, a unique ID Number is assigned to it. The Grid's resistances must then be verified. Grid resistances must fall into a range for that Grid to be acceptable.

Generation of ID Number and verification of the Grid's resistances is done by IMC's Package Quality Assurance One (PQA1) Software. PQA1 is installed on a PC with Label Maker and Multimeter connected to PC. When launched, PQA1 automatically detects if the Label Maker and Multimeter are connected and operating. It also checks that a specific database and connection to it exist. This database contains all the ID Numbers for various types of paper substrate. Once PQA1 has verified that the peripherals and database are connected, it allows a user to enter the type of paper being checked. When the <Print> button is pressed, PQA1 retrieves a unique ID Number for that type of paper and generates a label, using Label Maker, with that number printed on it. This label also contains a barcode representing the ID Number. Figure 11.1 shows a screenshot of a paper type entered into PQA1 software.

The Label is pasted on the paper adjacent to the Grid and shows the ID Number of that paper Grid. PQA1 completes Step 1 and progresses to Step 2, where it displays the Unique ID Number and enables a user to measure the Grid's resistances.

A Grid consists of two smaller grids. The reason for dividing the Grid into sub-grids is that if one grid fails the other is not affected and the overall Grid would still operate. It also reduces the overall magnitude of resistance by half.

The resistances are measured using a Multimeter with its probes first placed on common and Grid 1, and then on common and Grid 2. Resistances are read automatically by the Multimeter and transmitted to PQA1 software. Figure 11.2 shows a Grid and identifies the sub-grids and areas where the probes are placed.

PQA1 software accepts the measured resistances and checks if these resistances fall into an acceptable range. If a resistance is outside the range PQA1 highlights that resistor's field in colour red. Figure 11.3 shows a screenshot of PQA1 software with both steps completed.

When the <Submit> button is pressed, PQA1 records the resistances measured to a database with reference to that particular Grid ID Number.

Further Quality Assurance (QA) is conducted on 32-Dose and 18-Dose Grids by measuring each printed Resistor. Figure 11.4 shows a 32-Dose Grid with Silver ink Pads printed on it to enable measurement of each Resistor (black, Carbon ink path).

The Contact Pad divides each Resistor into two parallel resistors. The resistance of an individual Resistor can be determined by placing the two probes of a Multimeter on the adjacent Contact Pads. This procedure allows non-destructive testing of the Grid. A Nail Bed can be used to automate the procedure.

When paper with a Grid printed on it is bent the resistance of the grid changes. Such changes in resistance could cause the attached Tag to record incorrect events. (The attachment method is described in Step 12). To address this problem, a second, mirror Grid is printed on the obverse of the paper. Grids printed on both sides of the paper substrate provide a stable resistance value to the Tag when the Grid is bent.

Explanation of Resistance Variation:

Total resistance is based on the length of the Resistor and resistance per square unit of printed resistor. Equation E11.1 shows the relationship:

$$R_{Total} = Length * (R_{\Omega} / square) \quad (E11.1)$$

A Resistor printed on paper is shown in cross-section in Figure 11.5. The total resistance of this resistor (R1) is equivalent to its length (L1) multiplied by the resistance per square unit.

If the paper is bent convexly, as shown in Figure 11.6, the total resistance (R_1) of the Resistor will change since the length of the Resistor increases. The new resistance R_2 is greater than R_1.

Conversely, if the Grid is bent concavely the Resistor's length is decreased and total resistance R3 will be less than R1. This is illustrated in Figure 11.7.

If a mirror Grid is printed on the back of the paper substrate, bending will cause R2 to increase on one side and R3 to decrease on the other, giving the expected resistance R1. The two Grids on opposite sides of the paper must both be in electrical continuity with the Tag as illustrated in Figure 11.8. The equivalent circuit created by this method is shown in Figure 11.9.

Step 12: Stitching Paper with a Tag

Grids passing QA and having unique ID Numbers attached progress to a Stitching station. Here, a Brother BAS-311F-0 Automated Stitching Machine (Figure 12.1) attaches the Tag to the appropriate points of the printed Grid using silver conductive thread. Figure 12.2 shows a Tag stitched to a Grid.

A Tag stitched to a Grid records the time of any significant resistance change in the Grid. IMC implements a unique method to calculate precise time.

Calculation of Time by the Tag

Time calculated by the PC is assumed to be accurate as it is synchronized with an Atomic Clock. The PC's clock is updated at interval T1 of every second. After 60 intervals, the PC updates the minute counter. IMC's Tag uses an Oscillator containing a crystal resonator to calculate time. The Oscillator updates the Tag's clock every interval T2. In general, the accuracy of the time calculated by the Oscillator is determined by the quality of the crystal resonator. T2 is 1 second plus or minus delta Δ. Delta Δ is the error introduced by the crystal resonator. Figure 12.3 shows the PC's accurate time interval T1 of one second and the oscillator's time interval T2.

Equation E12.1 shows the relationship between T_1 and T_2.

$$T_1 = T_2 \pm \text{delta } \Delta \qquad \text{(E12.1)}$$

If the crystal resonator is of good quality, delta Δ, will be small. However, accurate crystal resonators are expensive, as they require time to calibrate to the correct frequency.

To reduce delta Δ, IMC developed a method that uses the firmware on the reader to calculate the precise time recorded by the Tag.

This method adjusts the interval T_2 of the Oscillator so the counter incremented at T_2 coincides with the CPU clock counter change. When a Tag is scanned on a Reader, the Reader records the time on its clock and Tag's counter value and notes them as T_{sync1} and N_{local1}, respectively. When the Tag is scanned again, the Reader again records its clock time and stores the counter value of the Tag. These values are noted as T_{sync2} and N_{local2}.

The Reader applies equation E12.2 to calculate the T_2 value by which the Tag's Oscillator should be adjusted.

$$T_{2new} = (T_{sync2} - T_{sync1}) / (N_{local2} - N_{local1}) \qquad (E12.2)$$

The Reader uses T_{2new} and equation E12.3 to adjust all the times recorded by the Tag. Individual event times recorded by the Tag are denoted as T_{event}.

$$T_{event} = T_{sync1} + (\text{Tag's counter}) * T_{2new} \qquad (E12.3)$$

Step 13: Checking the Connection between the Tag and the Grid

A stitched Tag and Grid forms an electronic circuit as shown in Figure B1. To verify that this circuit has been created the connection between the Tag and the Grid must be verified. The Tag's internal components such as the Timer must also be tested.

IMC's Package Quality Assurance 2 (PQA2) software does these tests. PQA2 requires a Barcode Scanner, Certscan™ Reader, and Digital Camera to be connected to the PC on which is installed PQA2. PQA2 is launched and a stitched Grid and Tag unit is placed on the Certiscan™ reader. While on the Reader the barcode label attached to the Grid's substrate is scanned. by the barcode scanner. PQA2 receives the scanned result, which is the ID Number of that Grid, and checks with the database to confirm it is a valid ID Number. If the check fails, PQA2 notifies the operator of the problem and requests the next Grid and Tag unit for scanning. If the ID Number is valid, PQA2 sets the Tag's ID Number to match the Grid's ID Number. It also tests the Tag's Microcontroller Timer, instructs Tag to measure the Grid resistances, and compares these measured resistances with a predefined resistance range and with the resistances determined by PQA1.

If all operations are successful, PQA2 judges this Grid and Tag assembly acceptable for use and displays "PASS" on its screen. Figure 13.1 shows a screenshot of a stitched paper judged as "PASS" by PQA2. If any of the operations fail, PQA2 prohibits the user from using that Grid and Tag unit and displays "FAIL" on its screen.

Regardless of Pass or Fail status, a digital image of the Grid and Tag unit is taken automatically by PQA2 for future reference. PQA2 then permits the user to save all the results of its operations by pressing <Submit>. Once <Submit> is pressed, PQA2 saves all its results to the database with reference to the Grid and Tag unit ID Number. Figure 13.2 shows a PQA2 workstation with the peripherals attached to the PC and PQA2 software operating.

Step 14: Inserting the Blister Package into the Stitched Paper

A blister package containing medication is inserted into a stitched Grid and Tag unit. The type of paper used depends on the type of blister package being inserted. Figure 14.1 shows the front and back of a 14-Dose blister package.

A 14-Dose paper Grid is required to accommodate a 14-Dose blister package. The paper has cut outs with precise dimensions and locations that allow a blister package to be inserted. Figure 14.2 shows a 14-Dose paper with and without a blister package inserted.

The Paper substrate is folded to create a package containing the Grid, attached Tag, and blister package. Figure 14.3 shows and describes the steps to fold the paper substrate.

Step 15: Heat-Sealing

The folded paper in Step 5 of Figure 14.3 contains a blister package and stitched Tag. The folded paper is now heat-sealed to create a functional package. The folded paper is placed in a Heat-seal machine at 320° Fahrenheit for 7 seconds. Figure 15.1 shows a picture of the Heat-seal machine.

Before placing the folded paper in the Heat-Seal machine, a rubber mat is put in place. The mat prevents the blister's plastic tablet covers inside the folded paper from crumpling. The mat has thick wells in which the blisters fit. Figure 15.2 shows a rubber mat for a 14-Dose blister package. Figure 15.3 shows the location of the rubber mat in the Heat-seal machine.

The temperature of Heat-Seal machine is set by a dial on the machine. A temperature gauge indicates the current temperature. A lever closes the top over the bottom.

The rubber mat is placed inside the Heat-seal machine and the lever is pulled to close the unit. The machine is heated to 320° Fahrenheit. Once this temperature has been reached, the lever is pulled again to open the machine. The folded paper substrate, with the blister package inside, is placed on top of the mat. Figure 15.4 shows the folded paper in the heated machine.

The lever is pulled to close the machine, as shown in Figure 15.5.

The machine is kept closed for 7 seconds. During this time the adhesive on the paper substrate melts and glues the package together with the blister package, Grid and attached Tag enclosed. This sealed unit is now referred to as a Med-ic™ Digital Package. Figure 15.6 shows the front and back of a Med-ic™ Digital Package.

The foregoing has described the steps involved in the production of a Med-ic™ ECM tag. It is understood that variations in the method could be effected without departing from the spirit of the invention. It is also understood that the present method could be applied to other products of a similar nature.

CLAIMS

1. A method of assembling, producing, and assuring the quality of an electronic compliance monitoring tag, comprising the steps as described.

Application number/numéro de demande: 2493410

Figures: 1.1- 2.1- 3.1- 3.2 - 3.3- 3.4- 3.5- 4.1- 5.1 - 6.1 - 6.2- 6.3
6.4- 7.1 - 8.1 - 8.2 - 9.1 - 10.4 - 10.5 - 12.1 - 12.2 - 13.2
[redacted] 14.1 - 15.1 - 15.2 - 15.3 - 15.4 - 15.5 - 15.6

DRW

Unscannable items
received with this application
(Request original documents in File Prep. Section on the 10th Floor)

Documents reçus avec cette demande ne pouvant être balayés
(Commander les documents originaux dans la section de préparation des dossiers au
10ième étage)

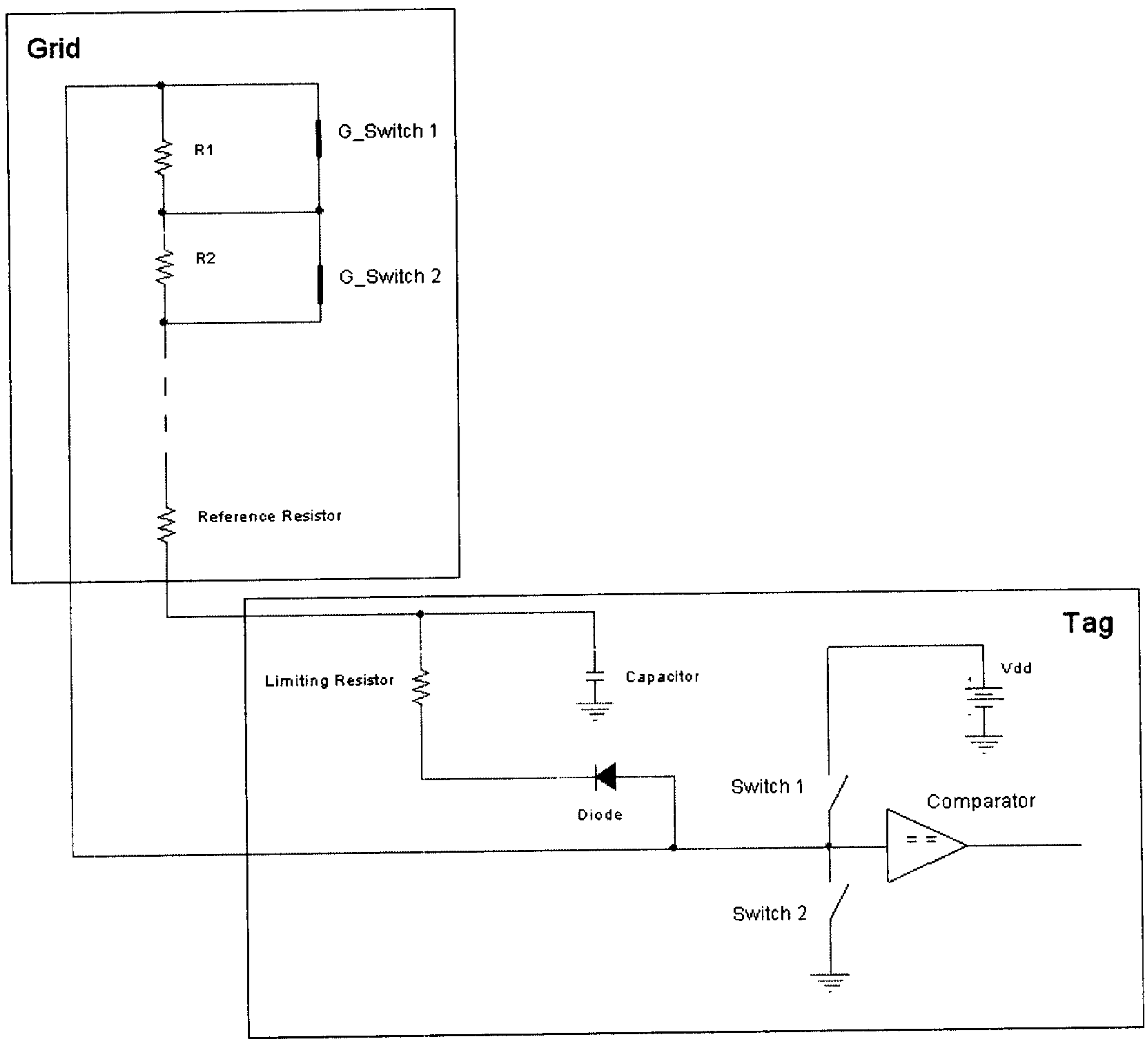


Figure B1: Grid and Tag circuit

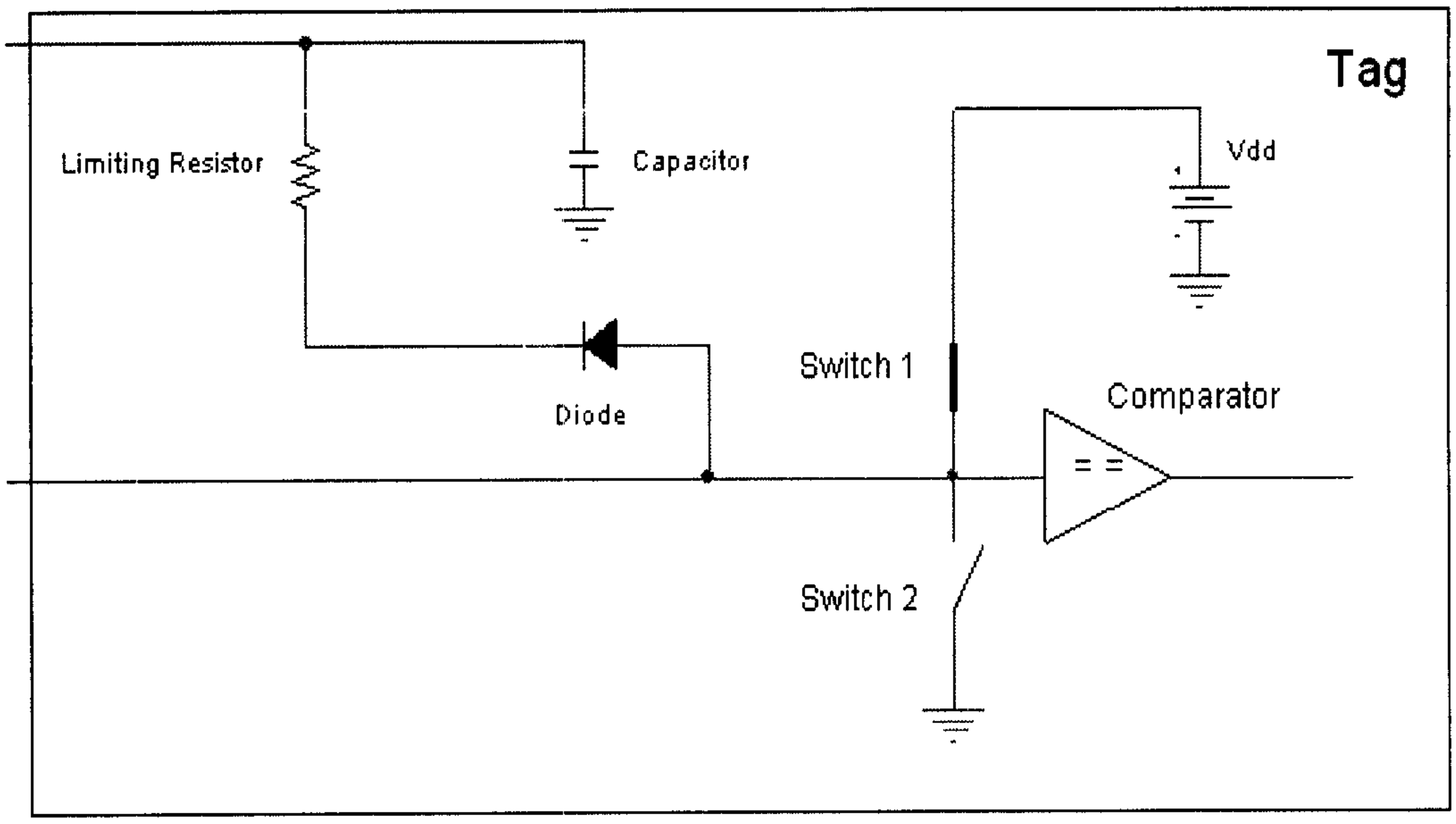


Figure B2: Operation of charging a Capacitor

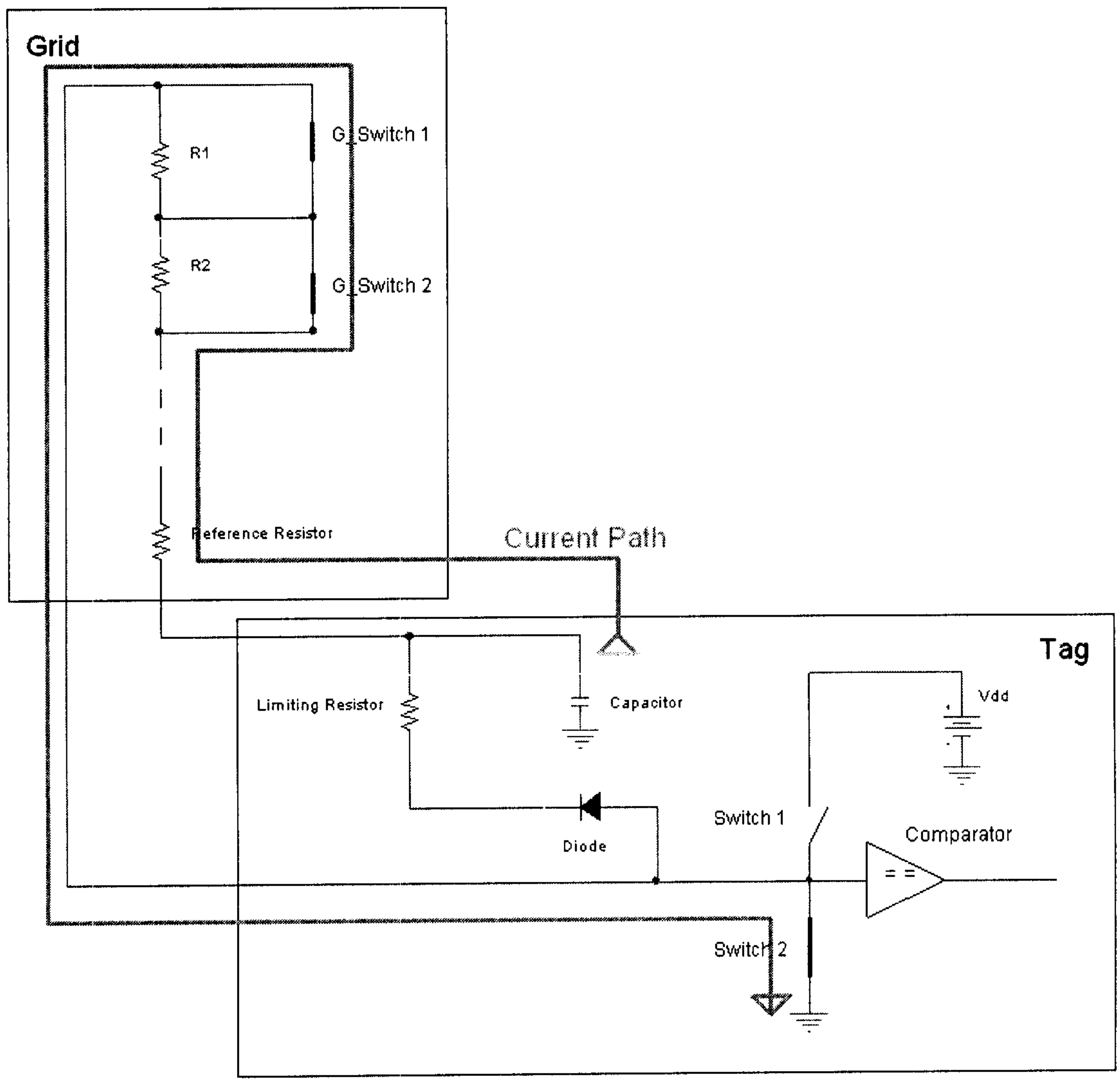


Figure B3: Current path when discharged from the Capacitor

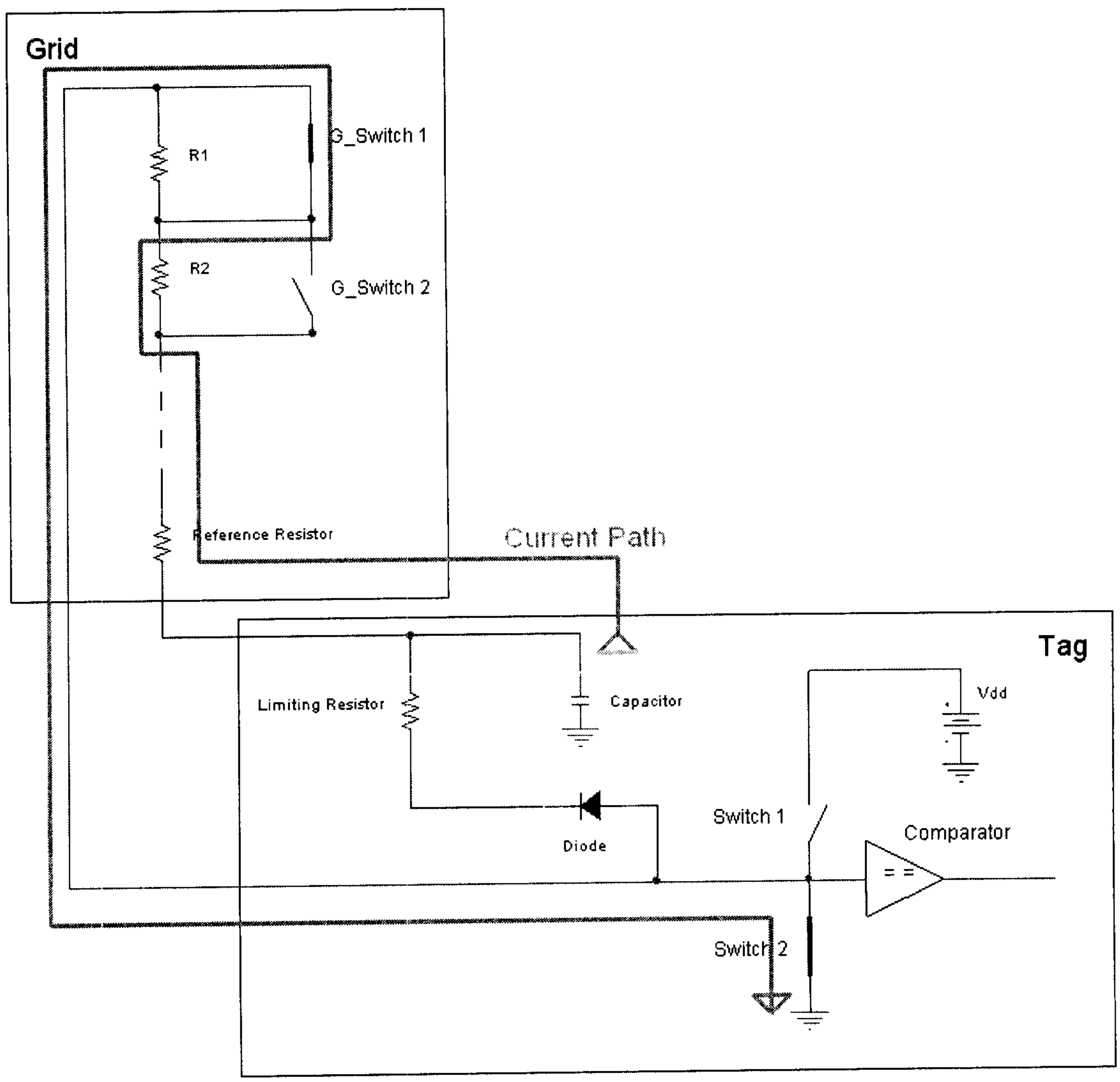


Figure B4: Current path when G_Switch 2 is open

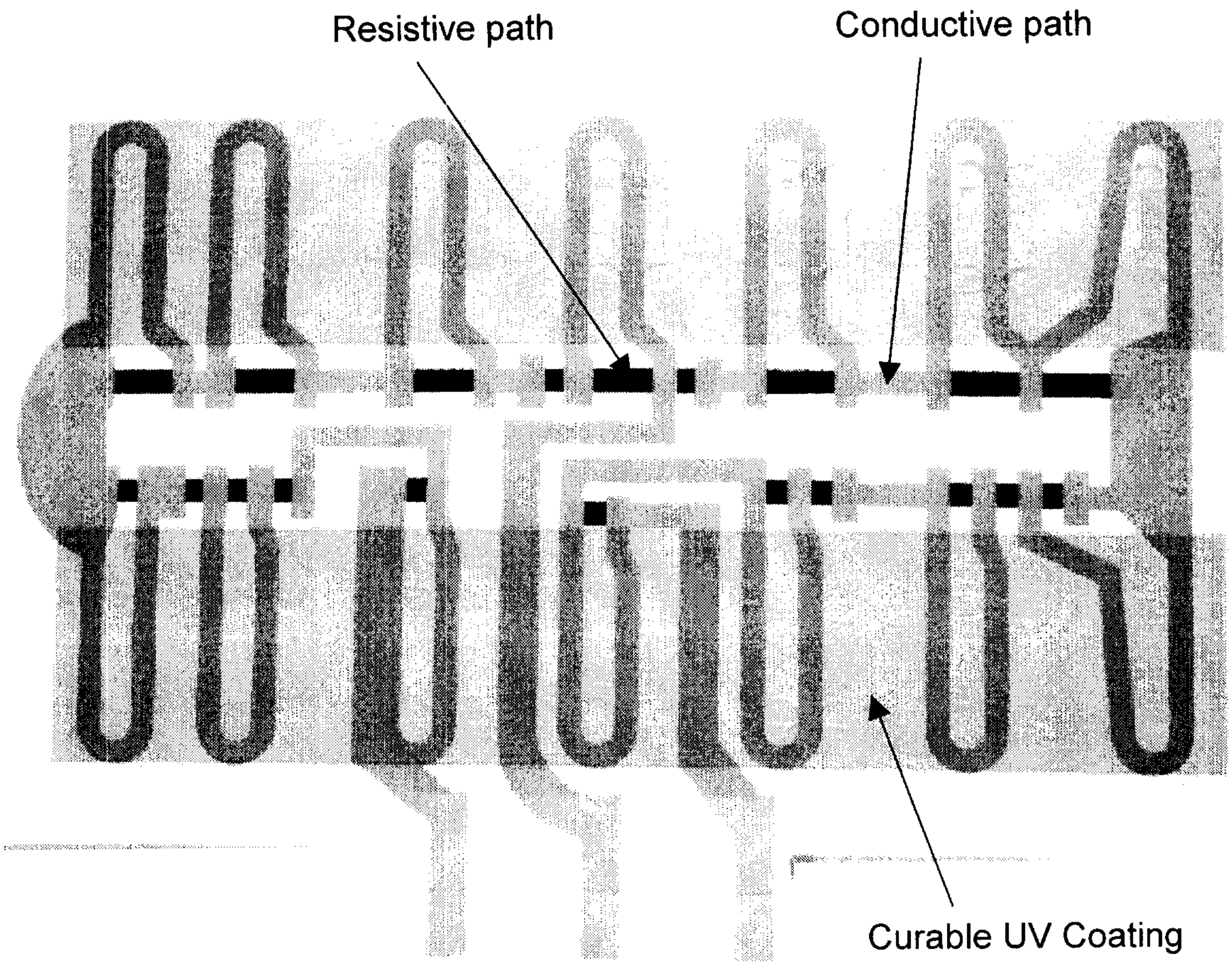
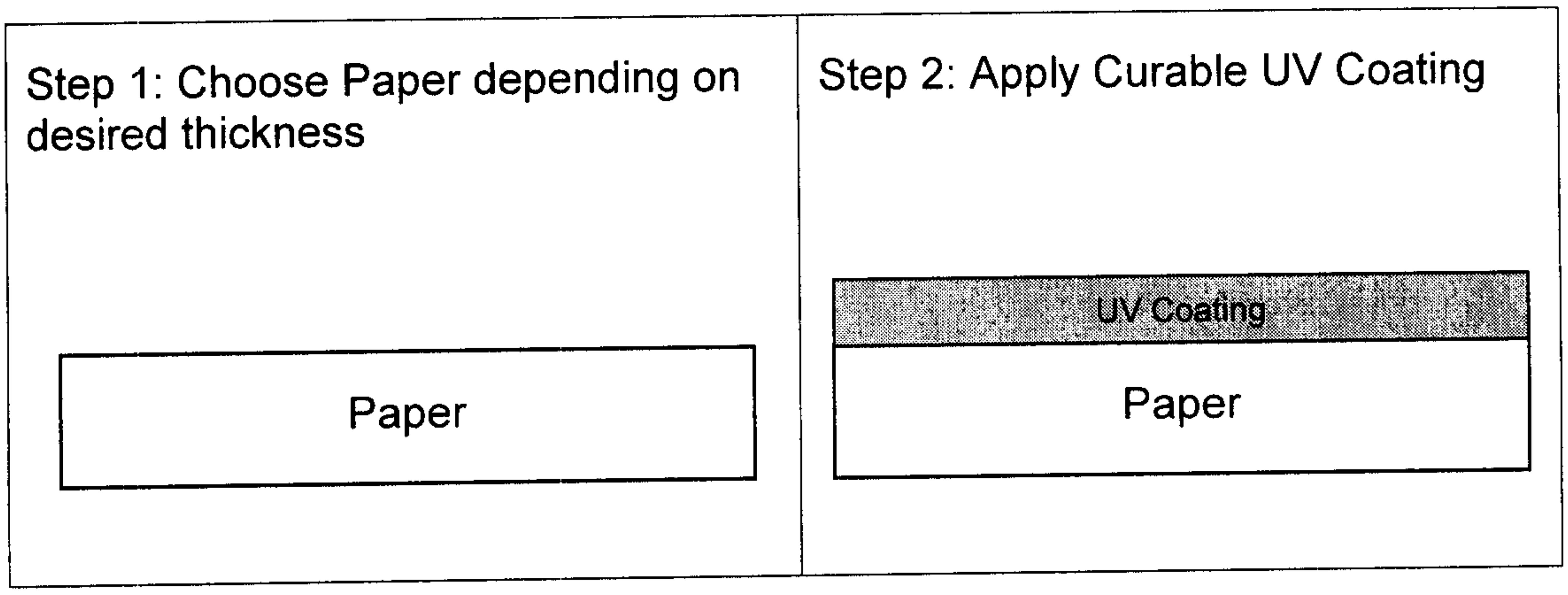


Figure 10.1: Grid printed on paper



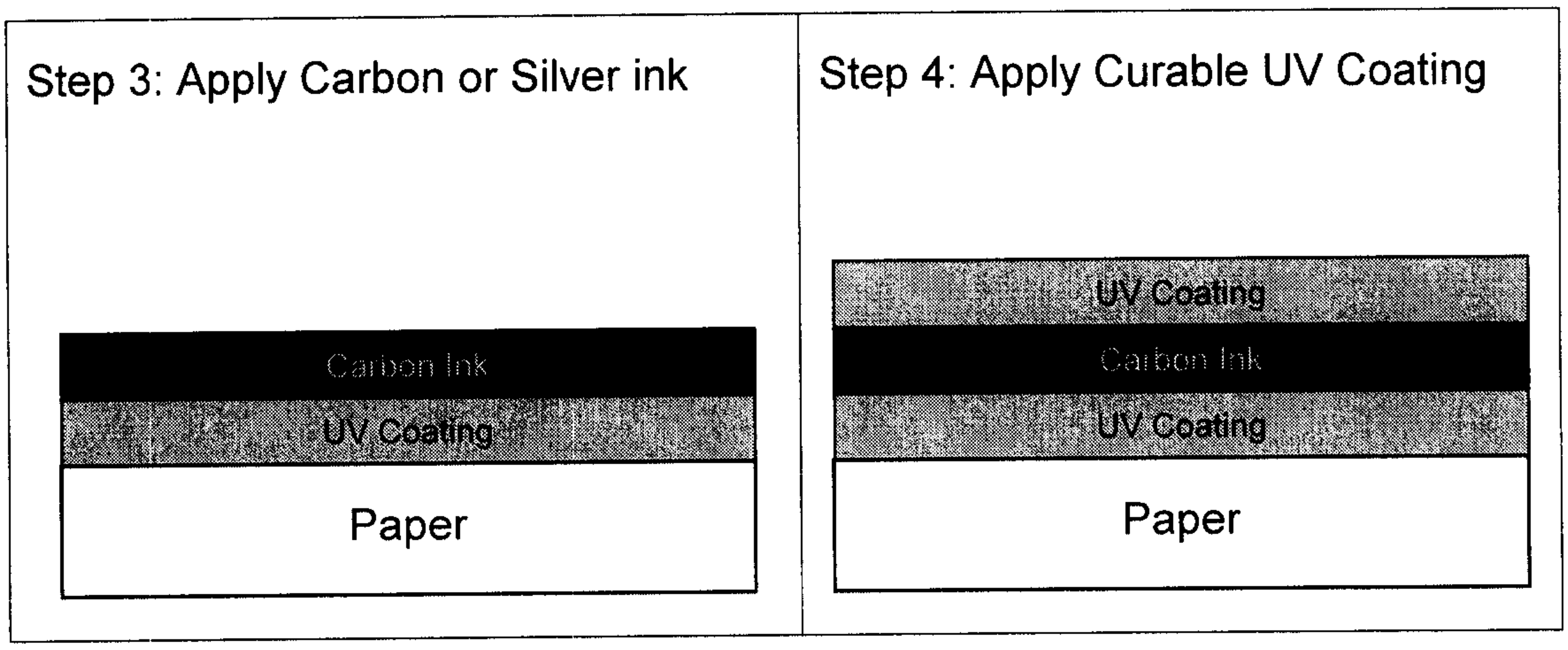


Figure 10.2: Steps in printing Grids on paper

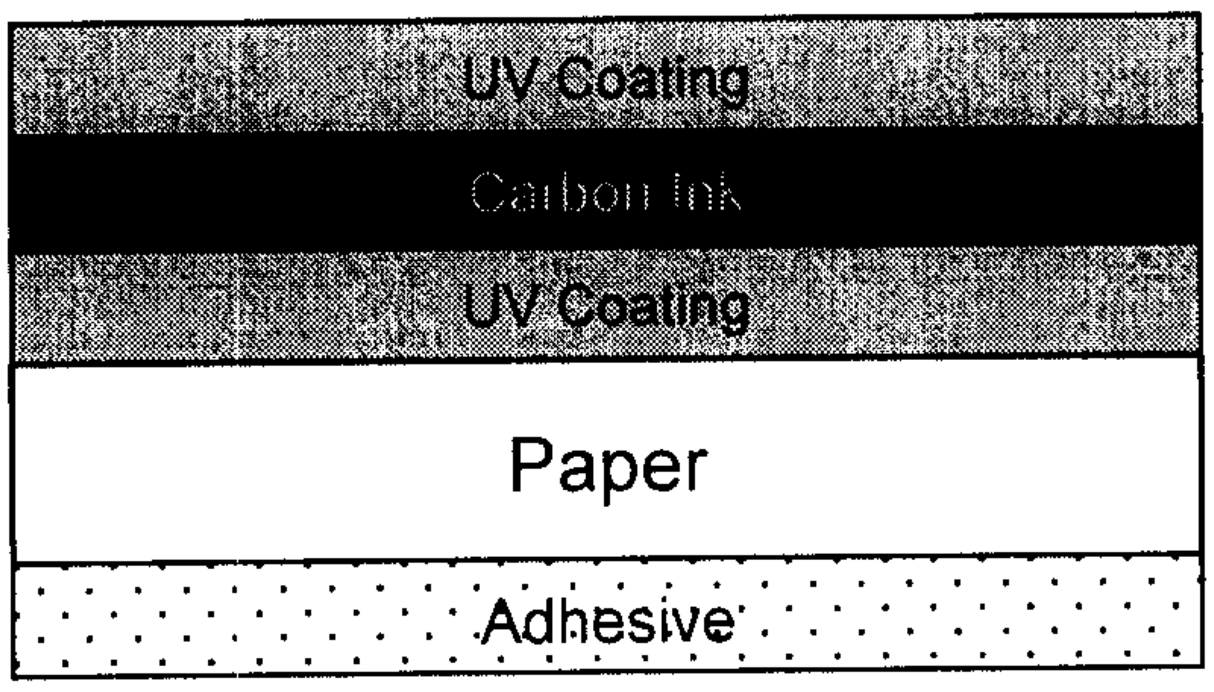


Figure 10.3: Adhesive coating on the bottom surface of the paper

Figure 10.6: Path broken when score pattern is present on the Grid

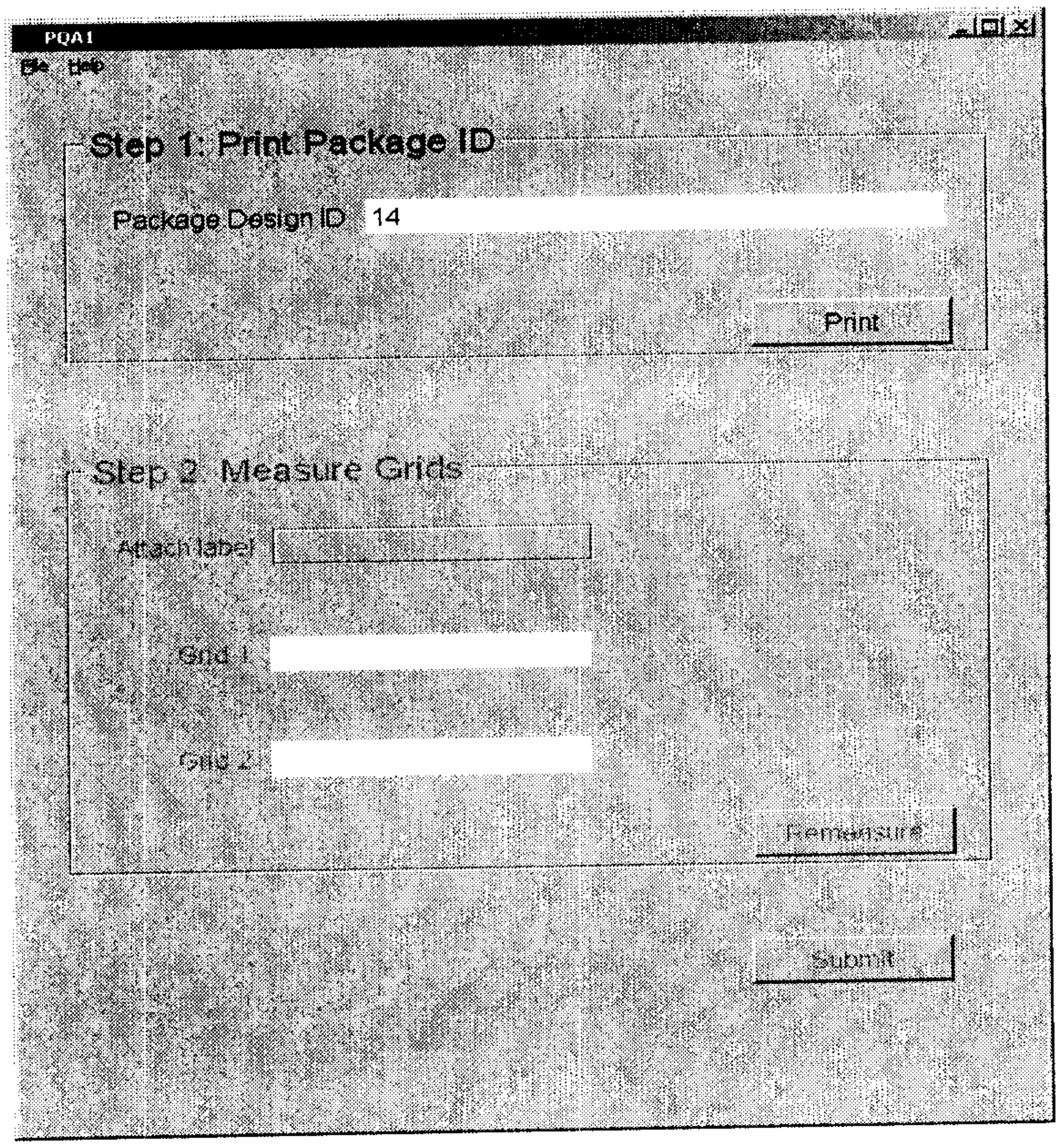


Figure 11.1: Paper type entered in PQA1 software

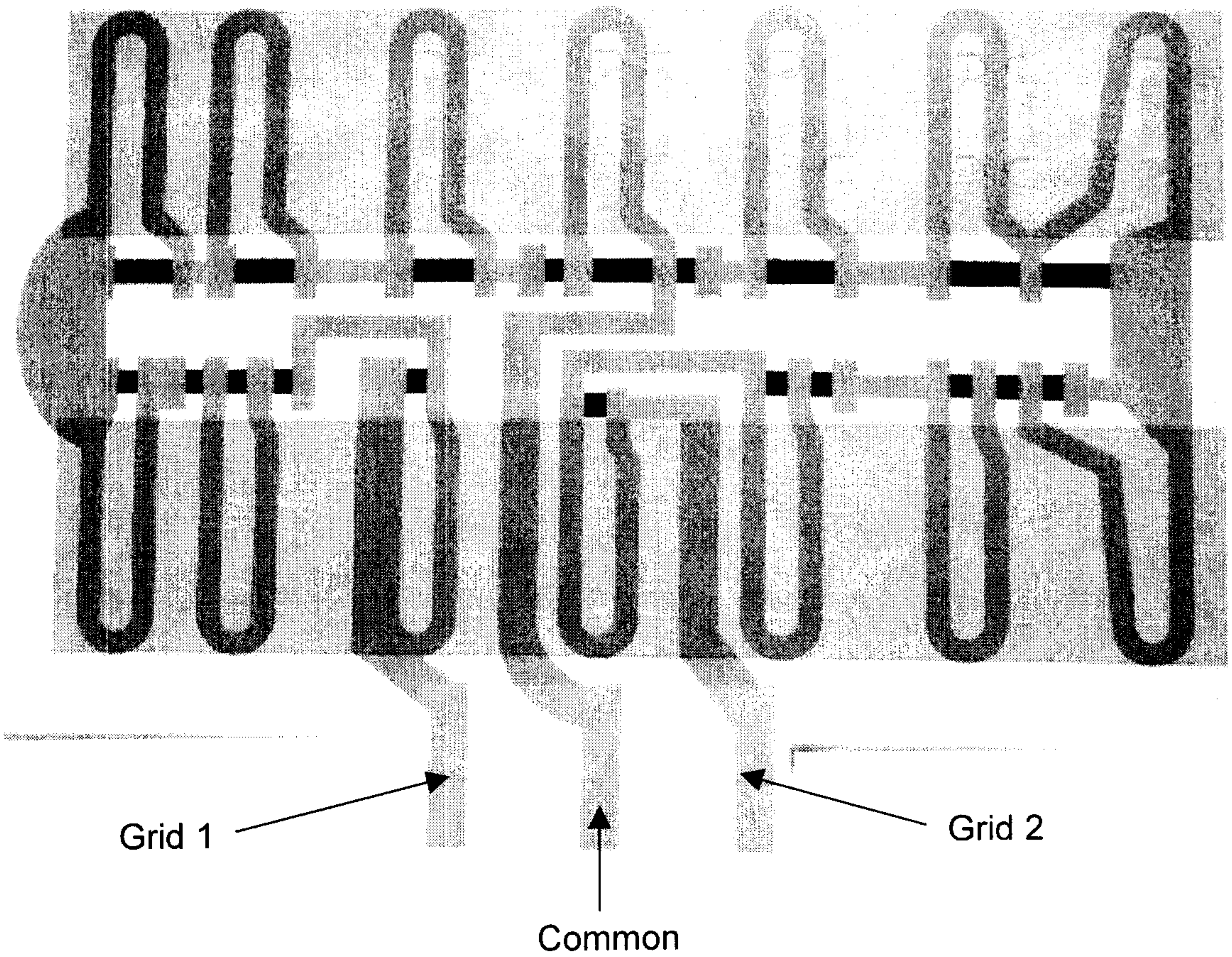


Figure 11.2: Picture of a Grid

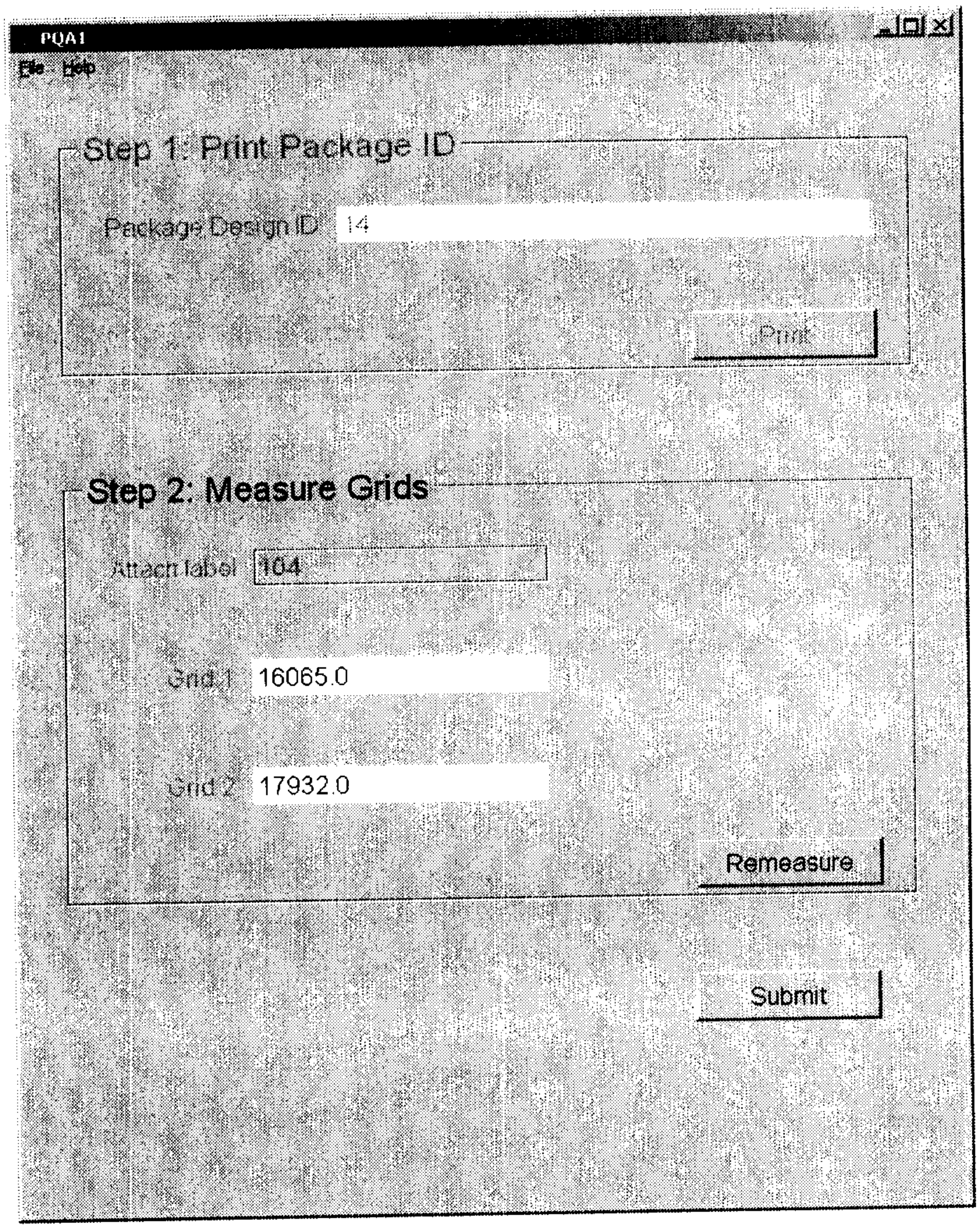


Figure 11.3: Screenshot of PQA1 with both steps completed

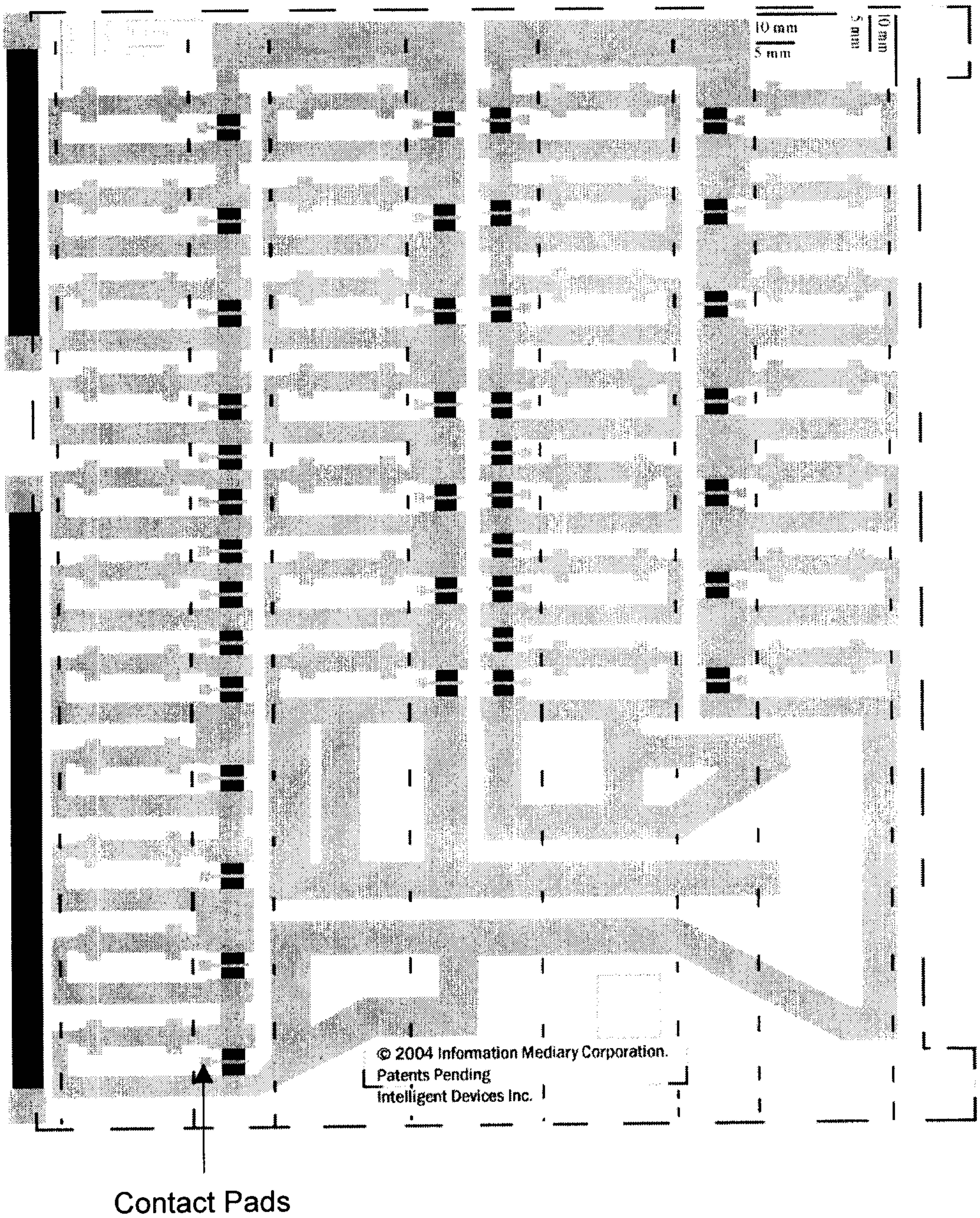


Figure 11.4: 32-Dose Grid showing Silver ink Contact Pads

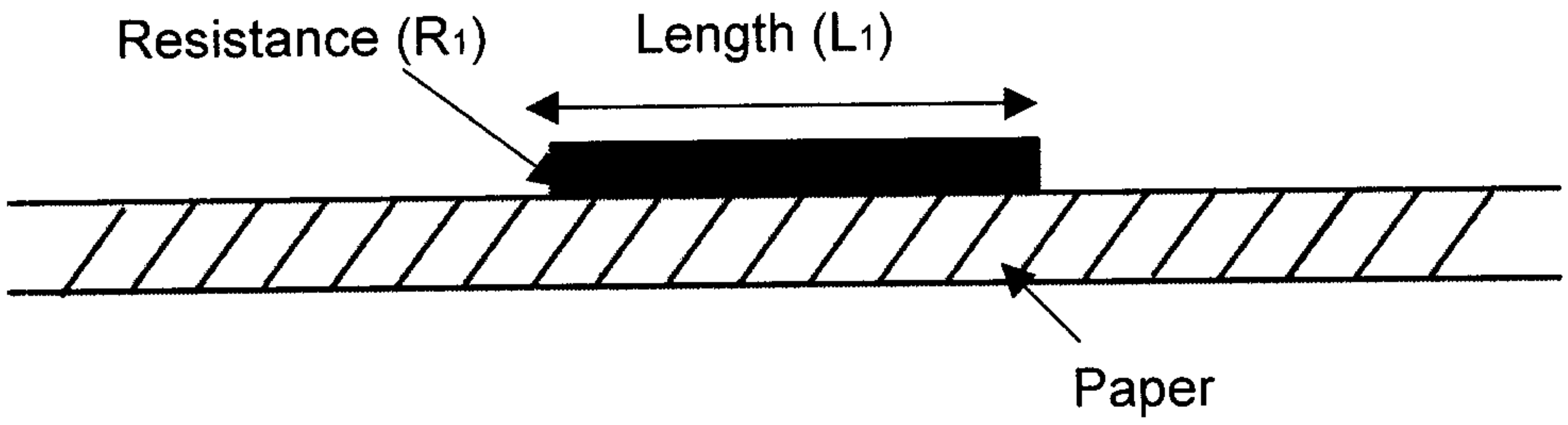


Figure 11.5. Cross-section of a printed Resistor

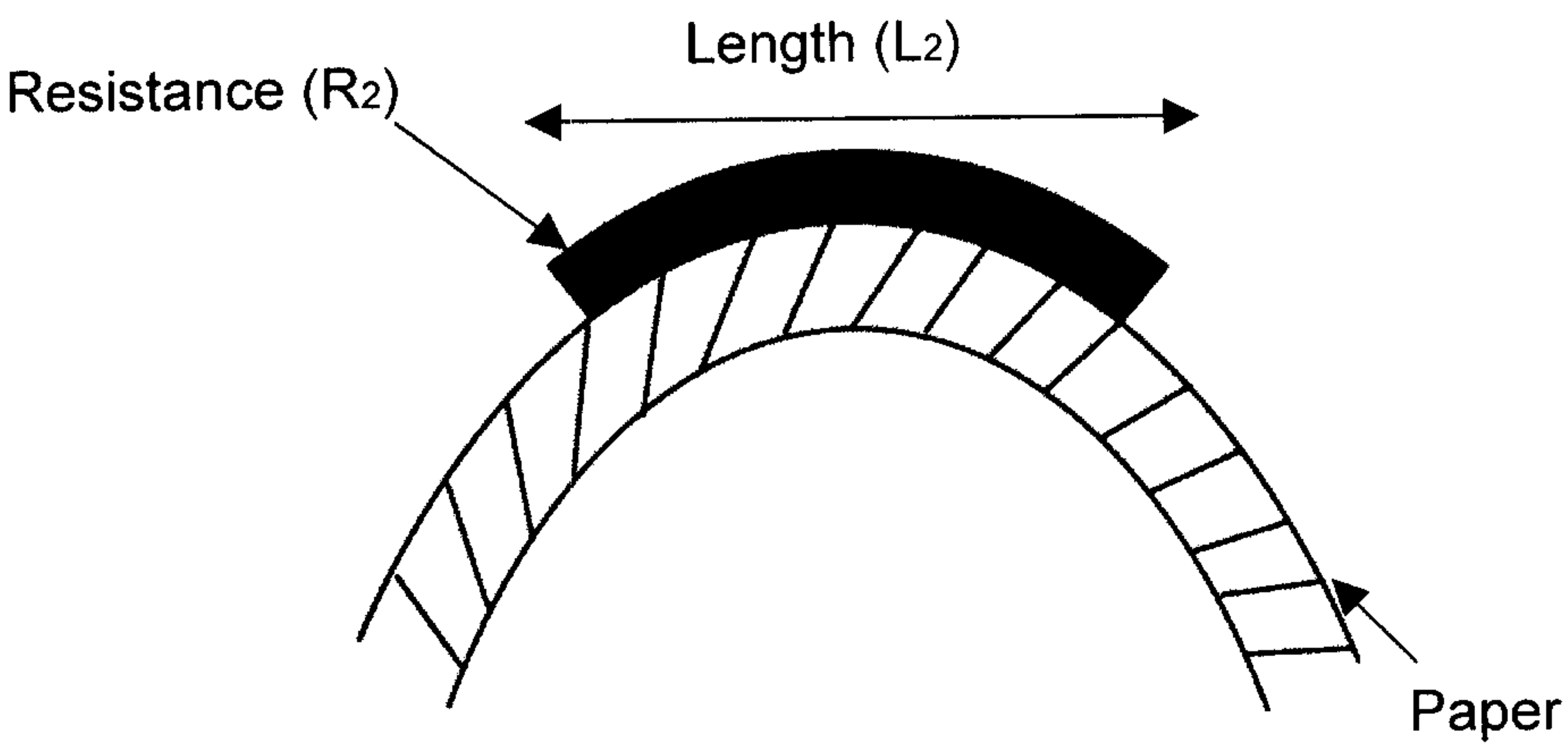


Figure 11.6: Effect on resistance of convex bending of a Grid

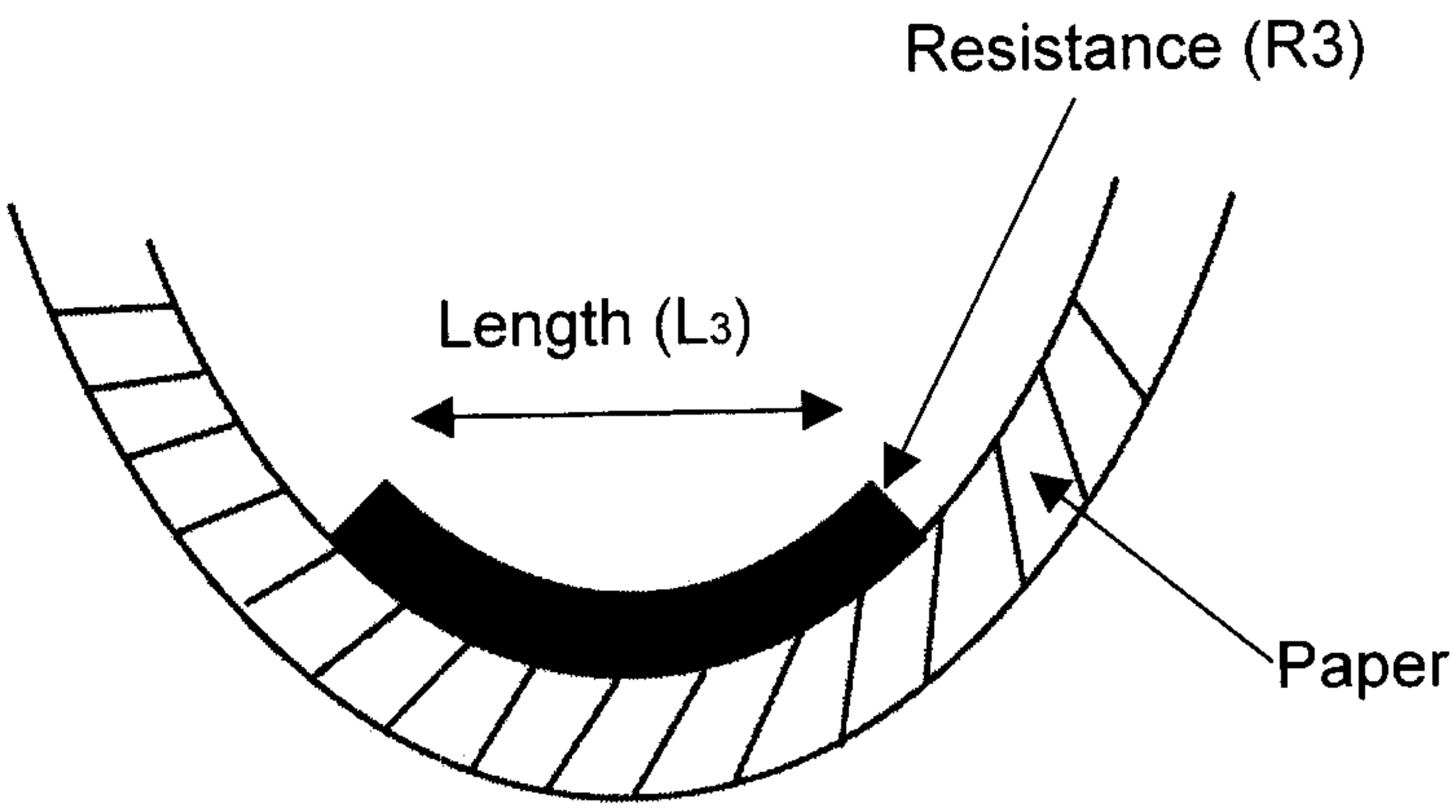


Figure 11.7: Effect on resistance of concave bending of a Grid

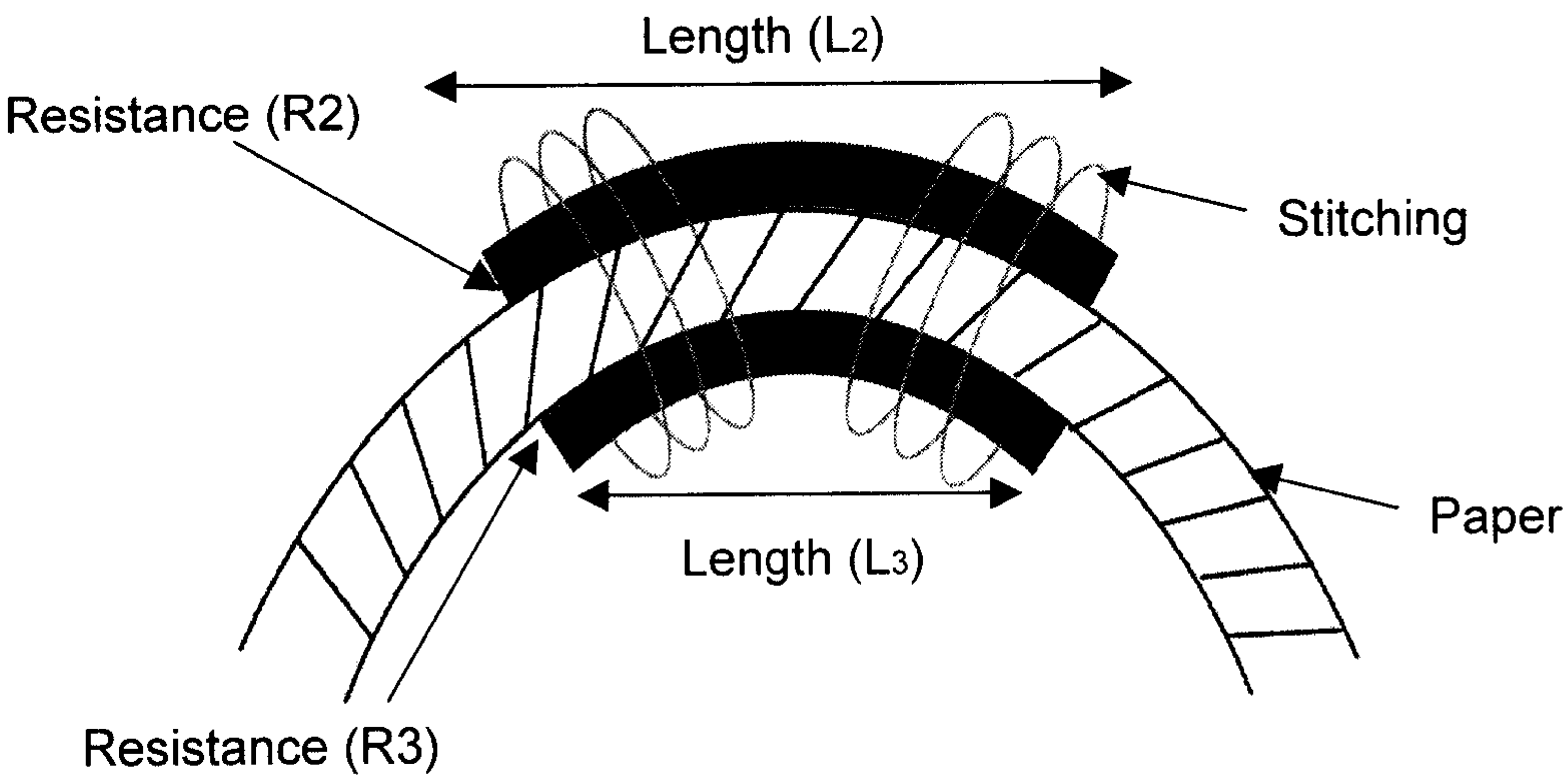


Figure 11.8. Paper with mirror Resistors connected by conductive stitching

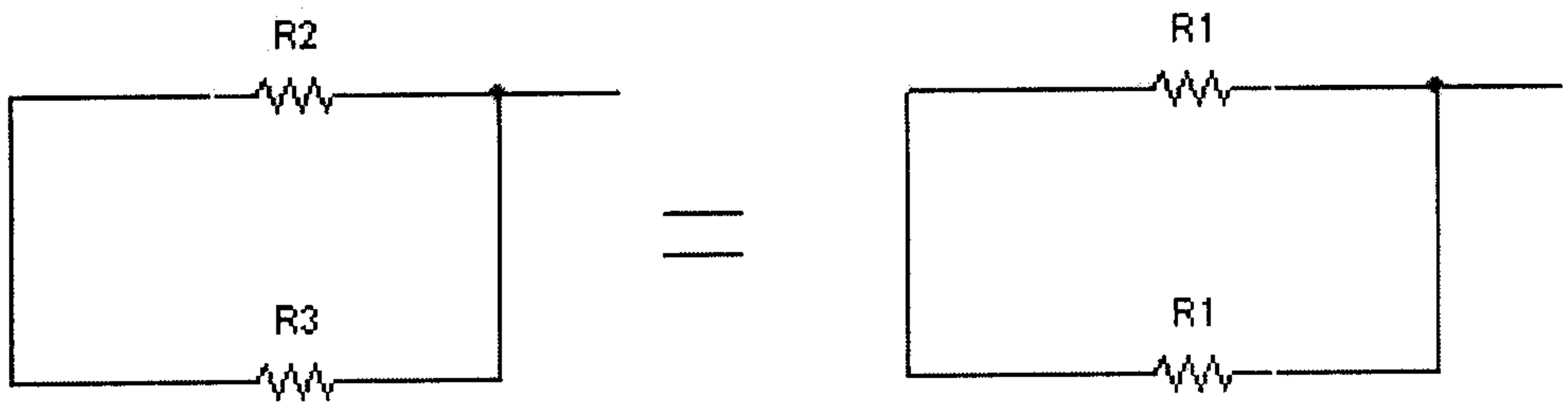


Figure 11.9. Equivalent circuit representation of electrically continuous mirror Resistors

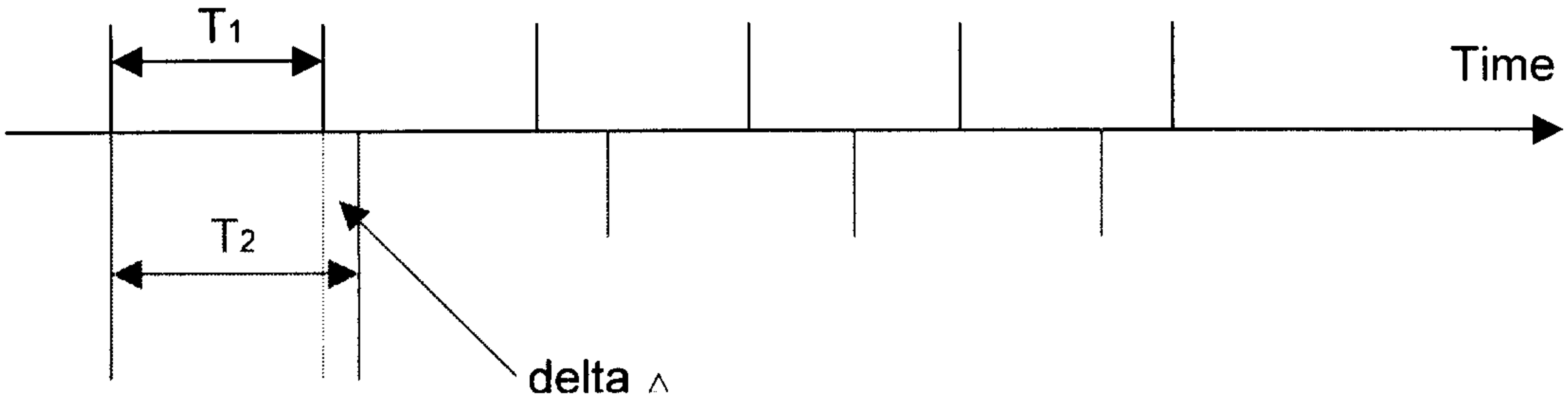


Figure 12.3: Time intervals T_1 and T_2

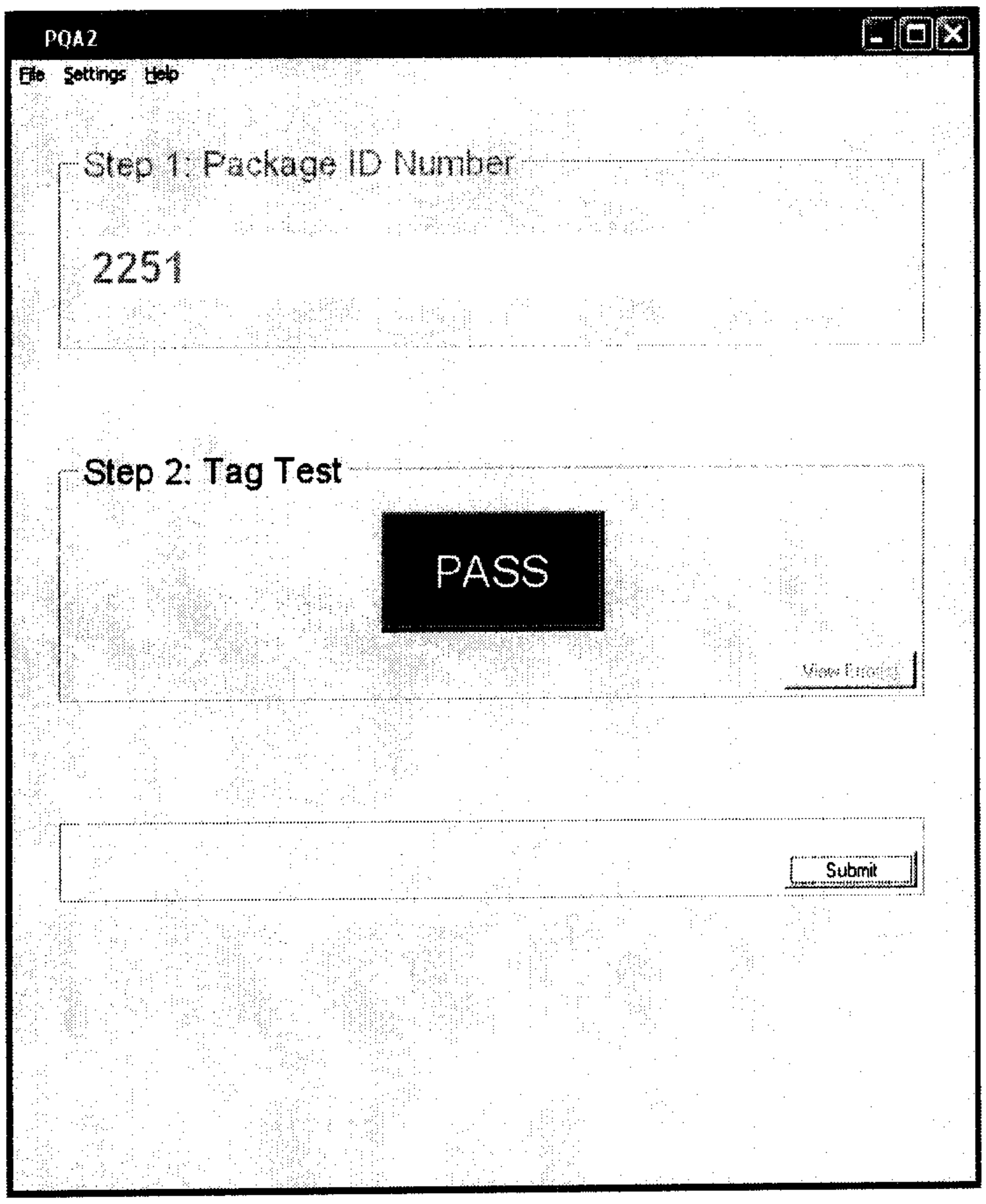
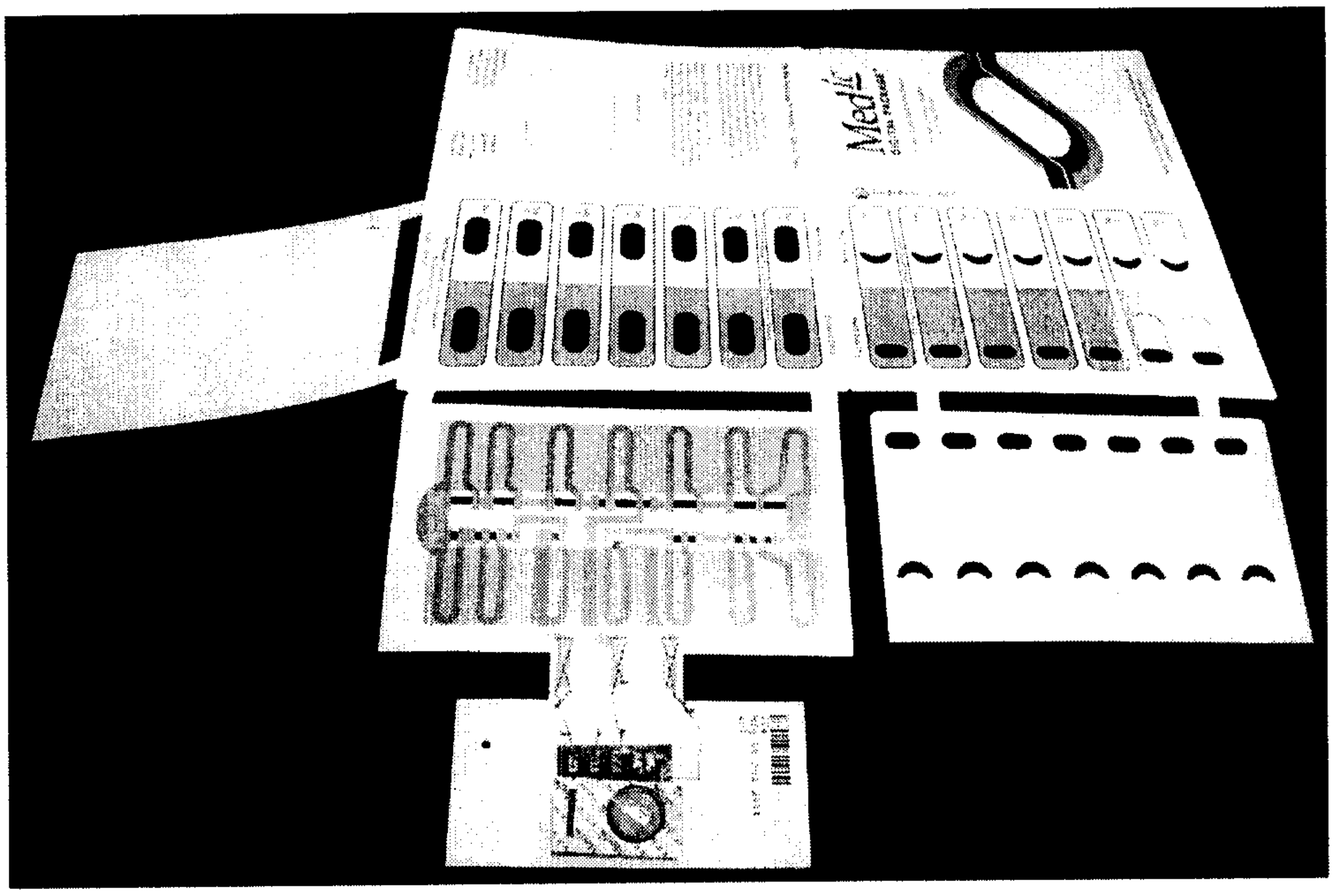


Figure 13.1. Screenshot of PQA2 software

Paper with no blister package



Paper with blister package in place

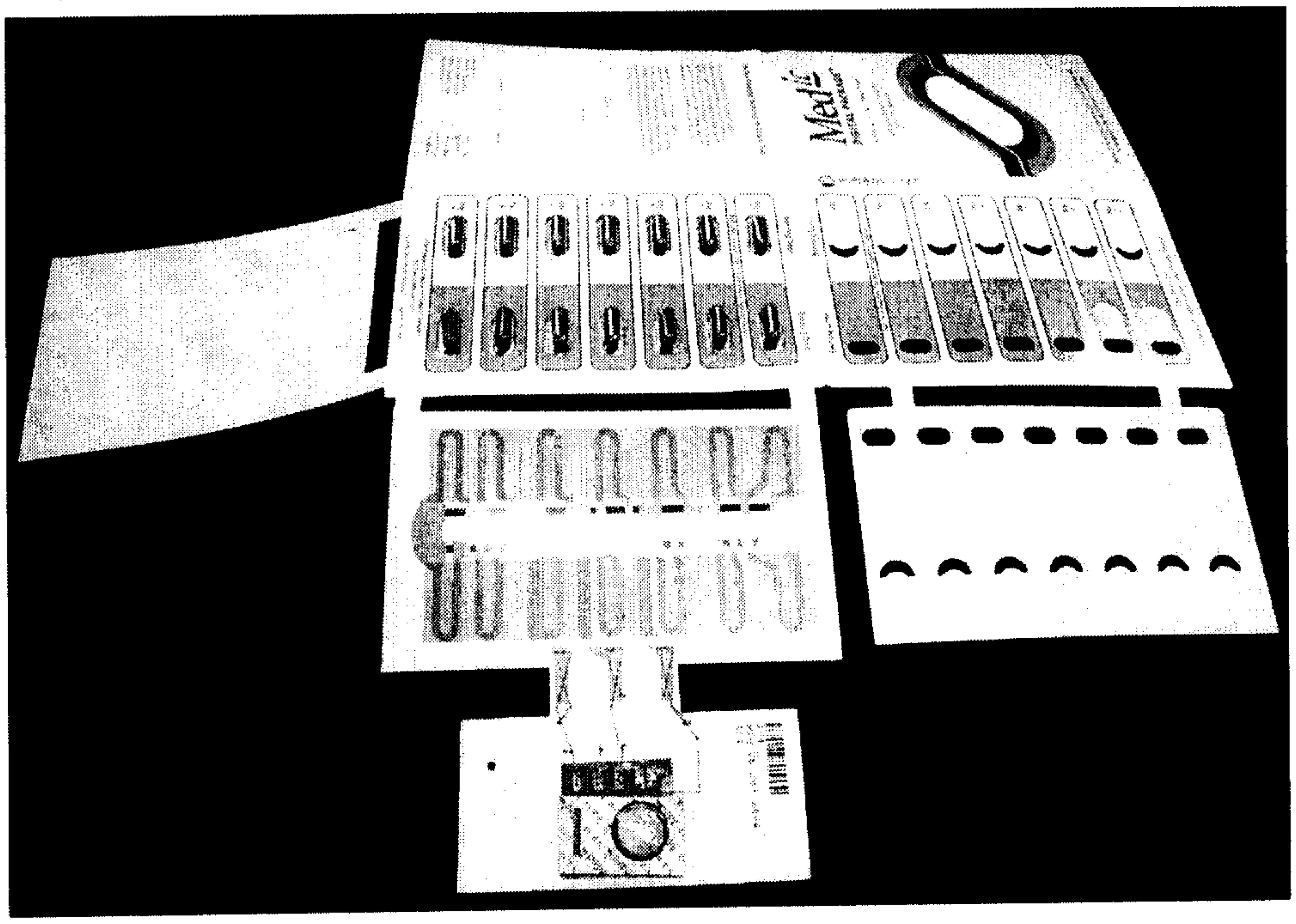
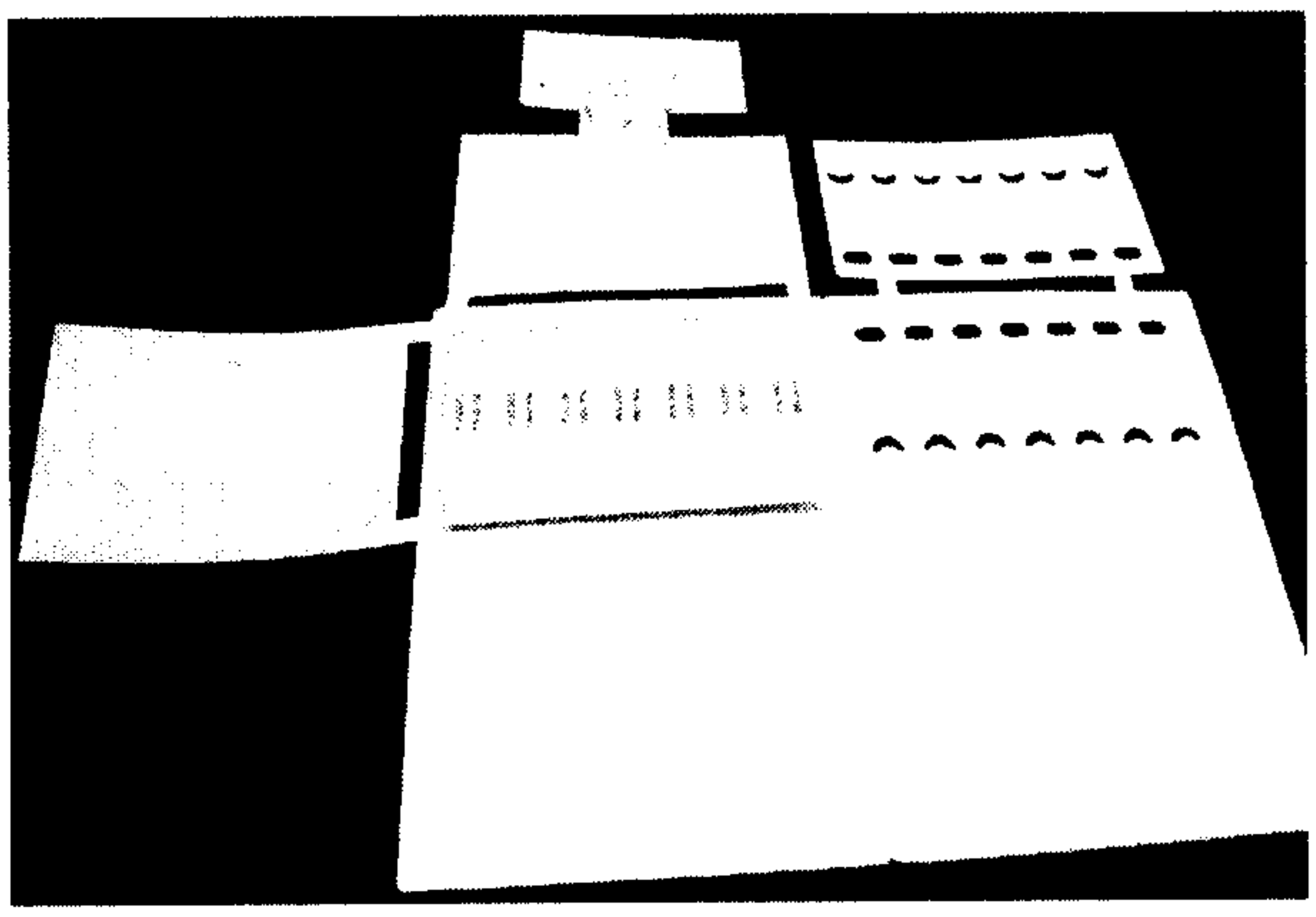
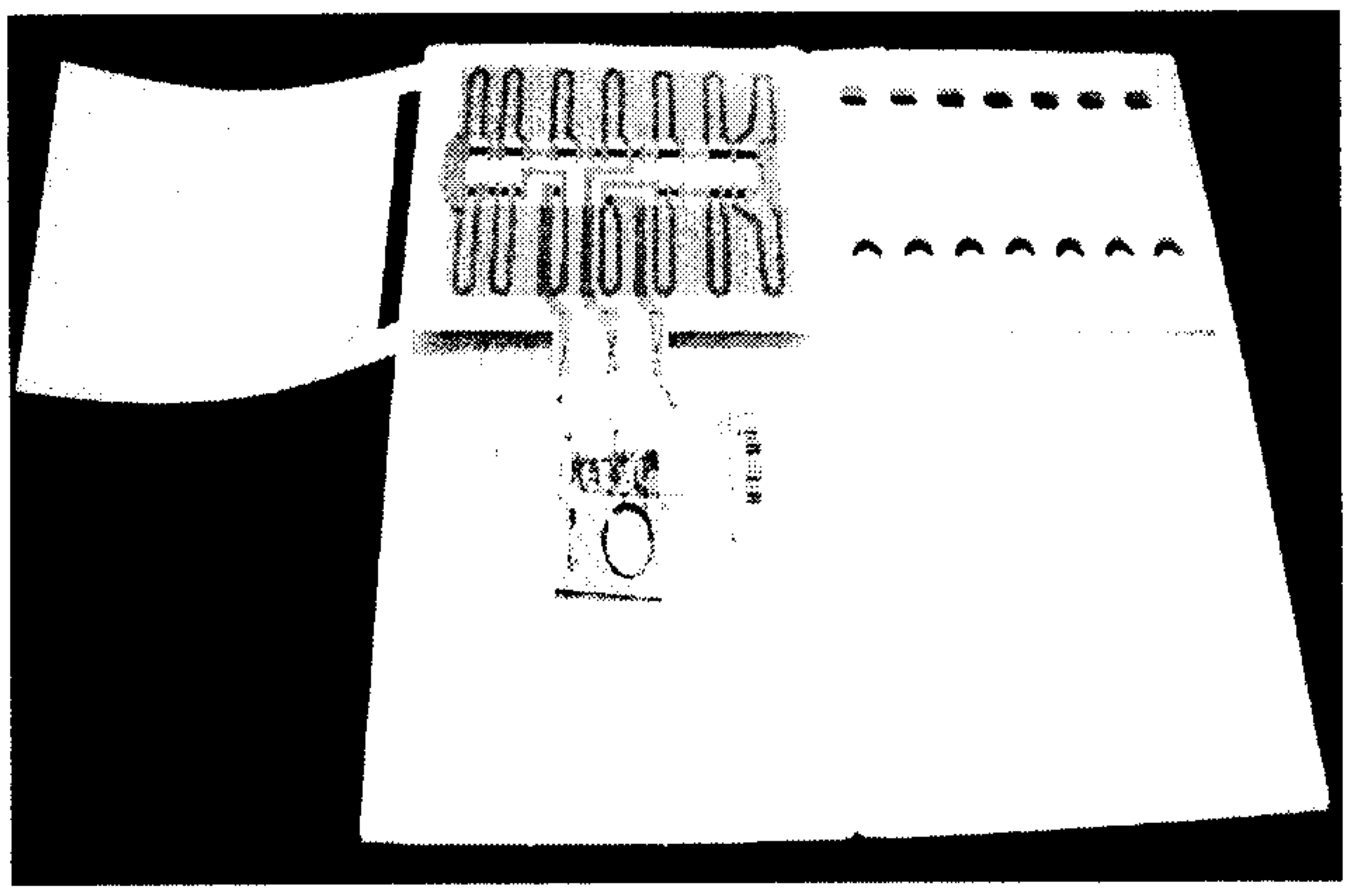


Figure 14.2: 14-Dose paper substrate

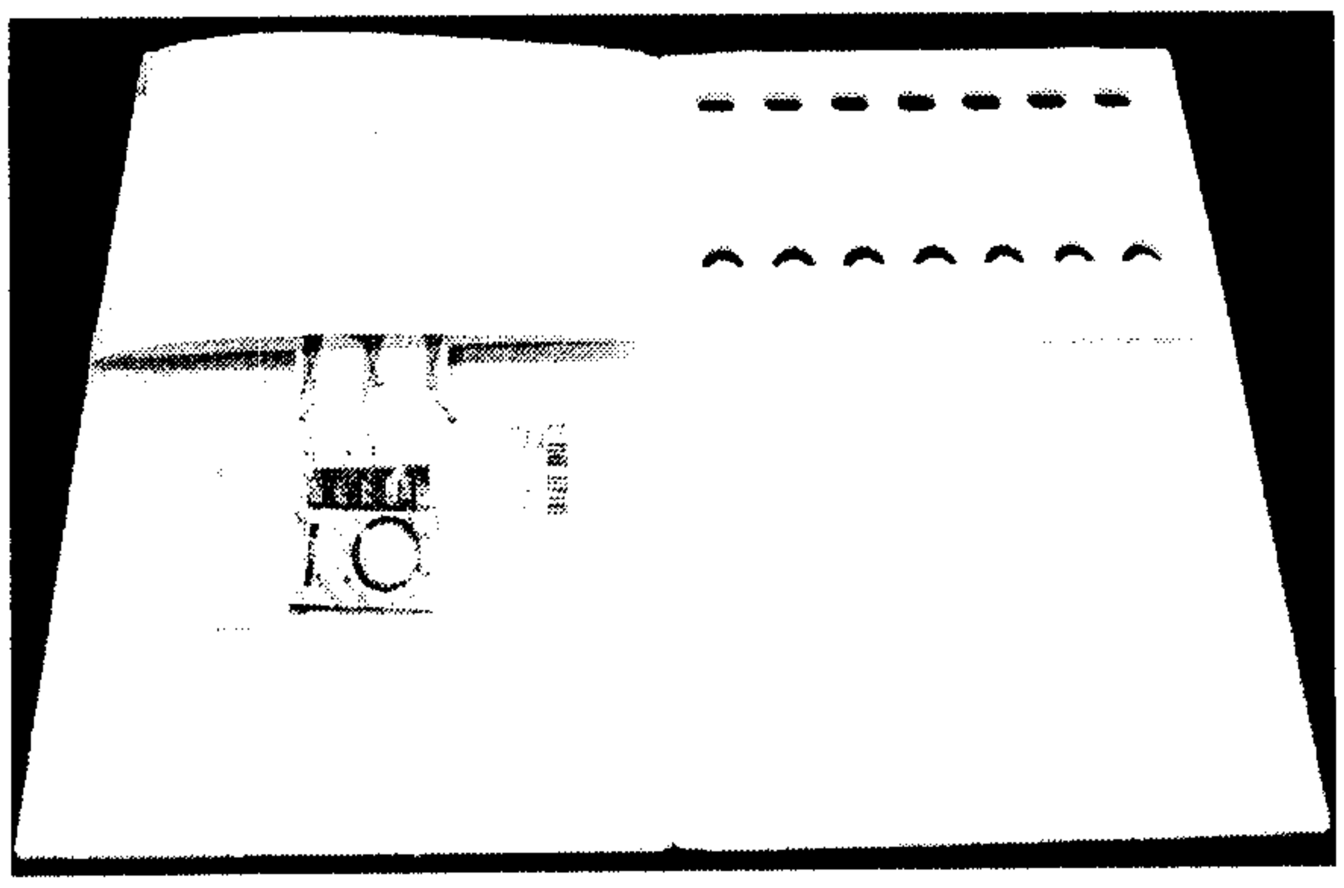
Step 1: Flip paper containing blister



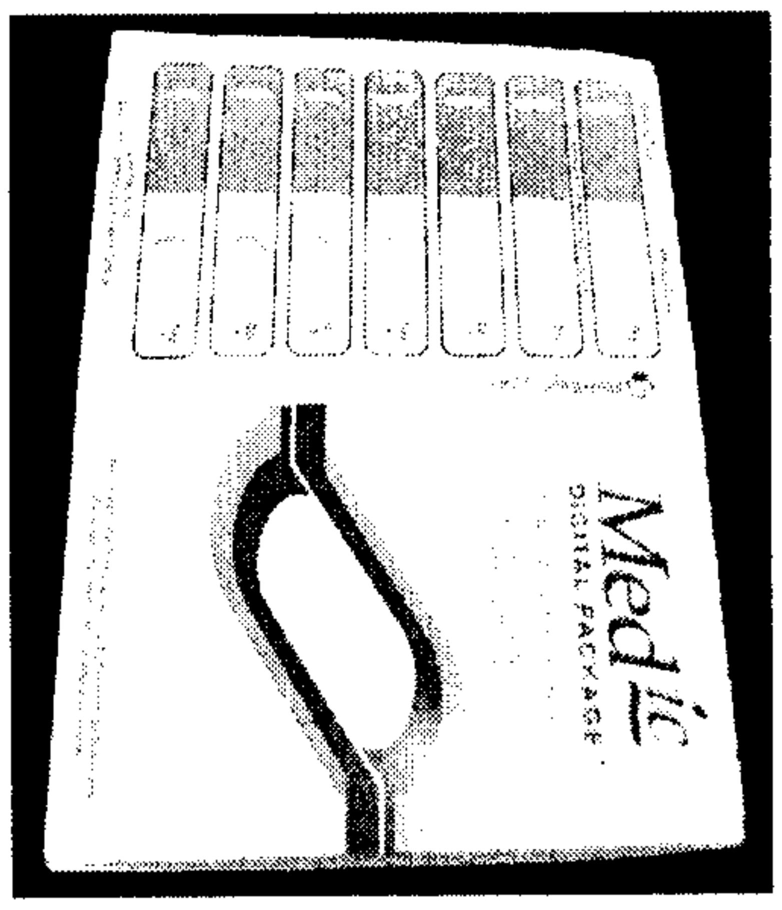
Step 2: Fold Grid section on top of the blister



Step 3: Fold left side section on top of Grid



Step 4: Fold right side of the paper on top of left side



Step 5: Flip paper folded in step 4

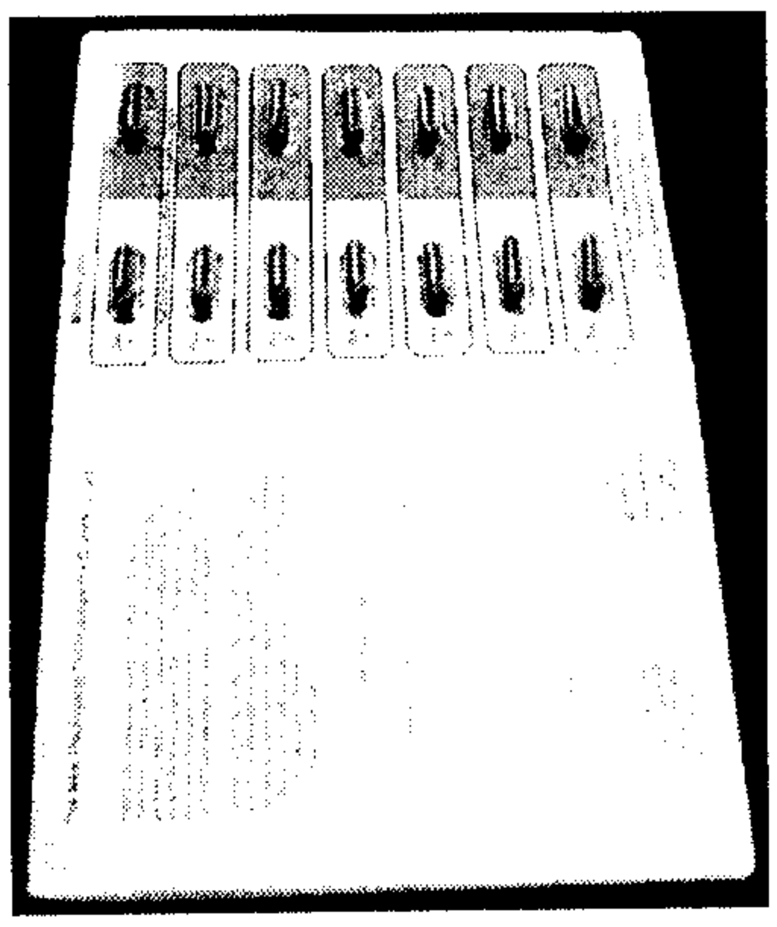
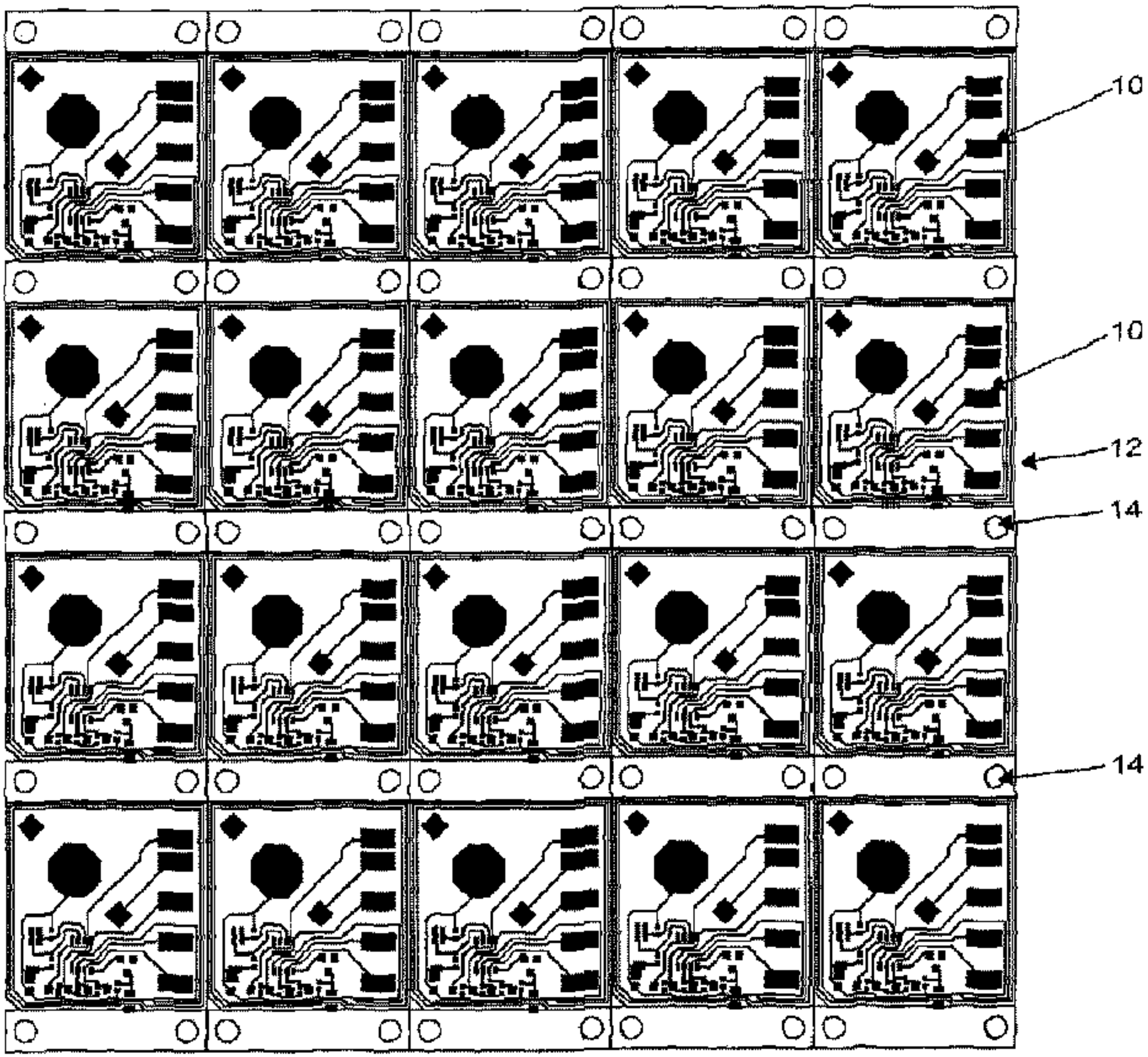


Figure 14.3: Folding sequence of 14-Dose paper substrate



10
10
12
14
14