

# ***EZ Risk Manager***<sup>TM</sup>

*Your Shortcut to ISO 14971 Compliance*

## **Quick Start Guide**

### *Installing and Using the EZ Risk Manager<sup>TM</sup> Demo*

The screenshot displays the EZ Risk Manager software interface, showing four overlapping windows demonstrating its functionality.

**Potential Hazards Window:** Displays a table of potential hazards.

Hazard	Description	Severity Level
H001	Operator or bystander injury due to chemical exposure	5 Catastrophic
H002	Patient immune status reported as a false positive	1 Negligible
H003	Operator immune status reported as a false negative	4 Critical
H004	Operator injured due to electrical shock	3 Occasional
H005	Third party injured due to electrical shock	3 Occasional
H006	Environment damaged due to electrical shock	3 Occasional

**Causes of Each Potential Hazard Window:** Displays a table of causes for a selected hazard (H001).

Cause	Description	Initial Probability	Link to Hazard	Initial Risk
C001	Improper grounding of instrument	2 Remote	H001	UNACCEPTABLE
C002	Software error	3 Occasional	H002	INVESTIGATE
C003	Software error	3 Occasional	H003	UNACCEPTABLE

**Risk Controls Window:** Displays a table of risk controls for a selected cause (C001).

Control	Description	Link to Cause	Residual Probability	Residual Risk	Reference to Investigation
RC001	Labeling, training classes	C001	4 Probable	UNACCEPTABLE	
RC002	Perform unit testing, QA on software	C002	2 Remote	ACCEPTABLE	
RC003	Independent analysis of software algorithms	C003	3 Occasional	UNACCEPTABLE	
RC004	Conduct FMEA on hardware				
RC005	Operator training class				

**Medical Device Name Device Hazard Analysis (DHA) Window:** Displays a detailed report for a medical device, sorted by severity.

**Medical Device Name:** [Blank]  
**Device Hazard Analysis (DHA)**  
Sorted by Severity

**Qualitative Severity Levels:**

- 1 Negligible—Results in no injury or temporary discomfort
- 2 Remote—Results in complete injury or impairment not requiring professional medical intervention
- 3 Occasional—Results in injury or impairment requiring professional medical intervention
- 4 Critical—Results in permanent impairment or life-threatening injury
- 5 Catastrophic—Results in patient death

**Residual Probability Levels:**

- 1 Negligible—Can probably never be assumed to occur
- 2 Remote—Can likely occur in rare circumstances, but possible
- 3 Occasional—Can occur several times in a year
- 4 Probable—Can occur several times in a year
- 5 Frequent—Can occur several times in a year

Hazard	Cause	Control	Initial Probability	Residual Probability	Justification
H001	Operator or bystander injury due to chemical exposure				
Severity Level:	5	Catastrophic			
C001	Improper grounding of instrument		2 Remote	Initial Risk: UNACCEPTABLE	
RC001	Labeling, training classes		4 Probable	UNACCEPTABLE	A-OP09-012
RC004	Conduct FMEA on hardware		3 Occasional	UNACCEPTABLE	M0-000A-091042
H003	Patient immune status reported as a false negative				
Severity Level:	4	Critical			
C003	Software error		3 Occasional	Initial Risk: UNACCEPTABLE	
RC003	Independent analysis of software algorithms		3 Occasional	UNACCEPTABLE	QA-000-4256
RC005	Operator training class		2 Remote	UNACCEPTABLE	E2A-M-Cu01-012
H002	Patient immune status reported as a false positive				
Severity Level:	1	Negligible			
C002	Software error		3 Occasional	Initial Risk: INVESTIGATE	
RC002	Perform unit testing, QA on software		2 Remote	ACCEPTABLE	QA-UTP-0807-4

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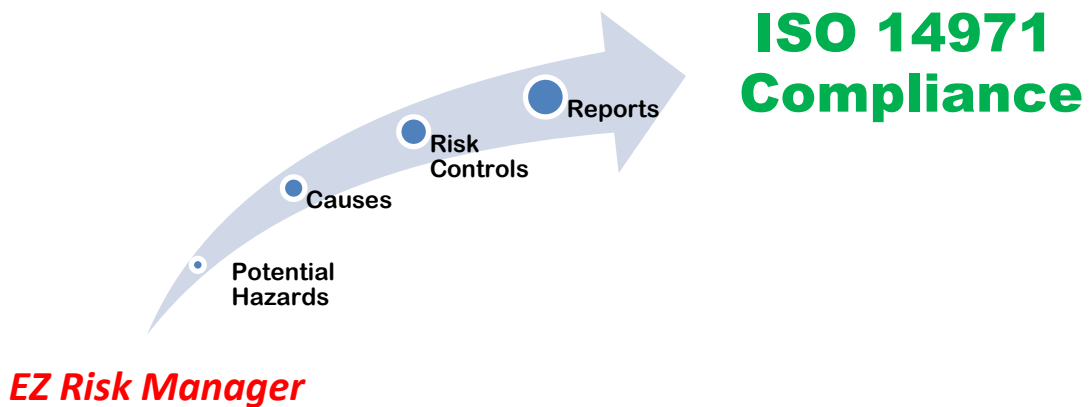
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# ISO 14971 Compliance within 30 days!

With **EZ Risk Manager™**

You Can Achieve ISO 14971 Compliance in Less Than 30 days.



## 1. Inside This Guide

This Quick Start Guide contains:

- short overview of ISO 14971
- brief explanation of how **EZ Risk Manager™** helps you quickly and easily perform Risk Analysis and generate reports you need to document ISO 14971 compliance.
- how to install the **EZ Risk Manager DEMO**
- tutorial on how to use **EZ Risk Manager**

***This demo is a full functioning version of EZ Risk Manager™ and contains all the features of the regular version. However, it does have the following limitations:***

- ***You can use the demo for up to 30 days***
- ***You are limited to entering only 10 records of each type: Hazards, Causes and Risk Controls***

## 2. ISO 14971 Overview

Worried about complying with ISO 14971? You should be.

**ISO 14971:2007 Medical devices – Application of risk management to medical devices** is the only international standard for risk management for medical devices, including *in vitro* diagnostic (IVD) medical devices.

This standard is formally recognized by:

- United States Food and Drug Administration (FDA)
- European Union
- Health Canada
- Japan
- Australia

ISO 14971 is designed to help manufacturers to identify and control the risk associated with their medical device. The standard specifies that manufacturers:

- Identify the hazards that may apply to the device, estimating the severity of each hazard
- Conduct risk analysis to identify the causes of each hazard, estimating the probability of occurrence and initial risk of each cause
- Conduct risk analysis to identify risk controls for each cause, estimating the probability of occurrence and residual risk once the control has been applied

All aspects of medical device design and manufacturing are subject to risk management. This includes mechanical, electronic, microprocessor, software and disposable product and manufacturing processes

### The FDA requires risk management:

- The FDA's Quality System Regulation (21 CFR Part 820) specifies that design validation include risk analysis.
- The FDA Reviewer's Guideline mandates that a hazard analysis be completed and included for the approval of 510(k) submissions.
- The FDA accepts ISO 14971 as an acceptable risk management model

### ISO requires risk management:

- **ISO 13485 Medical devices – Quality management systems – Requirements for regulatory purposes** requires that ISO 14971 be used when managing risk
- ISO 14971 compliance is required when obtaining a CE mark.

The bottom line is that ISO 14971 is the world standard for risk management, and **you need to comply with ISO 14971.**

## Where do I start?

Join the crowd, you're not alone. Companies are struggling to implement ISO 14971 into their quality management system.

Like you, they face the following problems:

- I don't want to bring in a bunch of expensive consultants
- I want a do-it-yourself approach. After all, who knows more about my product than my employees?
- I want a solution that can be applied to future products
- I want someone who will back me up during an FDA or ISO audit if there are questions about my ISO 14971 compliance

***EZ Risk Manager™* is the answer.**

## 3. EZ Risk Manager – Your Shortcut to ISO 14971 Compliance

***EZ Risk Manager*** is an automated approach to managing potential and known risks for your medical device. With ***EZ Risk Manager***, you can quickly and easily identify potential hazards, determine causes, and specify controls to reduce risk.

***EZ Risk Manager*** helps you implement and comply with ISO 14971:

- **Risk analysis.** ***EZ Risk Manager*** helps you identify and assign severity levels to potential hazards.
- **Risk evaluation.** ***EZ Risk Manager*** helps you identify and assign initial probability of occurrence to each cause of a hazard. The program automatically calculates initial risk for you.
- **Risk control.** ***EZ Risk Manager*** helps you identify and assign residual probability of occurrence to each risk control. The program automatically calculates residual risk for you.
- **Evaluation of overall residual risk acceptability.** ***EZ Risk Manager*** lets you quickly verify the completeness of your risk control measures. Comprehensive, easy-to-read reports are

generated by EZ Risk Manager to support your evaluation of overall residual risk acceptability. These reports are the foundation of your risk management report and, when incorporated into your risk management file, demonstrate ISO 14971 compliance.

- **Production and post-production information.** *EZ Risk Manager* is the foundation for production and post-production risk management reviews. Generate interim reports after each risk management review to document compliance with ISO 14971's goal of ongoing and continual risk management. Each interim report placed in the risk management file becomes conclusive, documentary evidence of your company's continuing commitment to the ISO 14971 risk management process.

*EZ Risk Manager* lets you easily change and update your risk analysis reports. Potential hazards, causes and risk controls can be updated and changed with ease, and new reports can be generated with the click of a button.

***With EZ Risk Manager, you can easily and quickly perform risk analysis,  
in-house, with your existing staff.***

***EZ Risk Manager is the software tool you need to achieve  
ISO 14971 compliance***

***EZ Risk Manager pays for itself  
the first time used.***

## Here's Where You Start

1. Install the demo.
2. Try it out.
3. Buy the full version. We can customize the reports just for you.
4. Implement your ISO 14971 solution:
  - a. **Do it yourself.** *EZ Risk Manager™* gives you the power to implement ISO 14971 without spending money on expensive consultants
  - b. **You can ask for a little help.** If you are already comfortable with ISO 14971, we can help guide you through the areas where you need help.

**Please don't hesitate** to email or call us if you have any questions about *EZ Risk Manager™*. Send email to [info@EZRiskManagement.com](mailto:info@EZRiskManagement.com).

If you want to talk to a real person, call *EZ Risk Manager* at 512.788-6010 during normal business hours (8-5 CST).

## We Welcome Comments & Suggestions

*EZ Risk Manager* is continually being improved and updated. As such, we welcome any comments or suggestions you may have.

Our goal is to help you implement ISO 14971 as easily and efficiently as possible.

## Training

We offer on-site training for your convenience. Training classes are tailored to your specific needs and lay the groundwork for implementing risk management for your medical device.

Email or call to discuss your particular needs.

## Consulting

We can help you comply with ISO 14971, whether it's building your ISO 14971 compliance program from scratch or just helping you out with risk assessment.

Our specialty is getting your team off the ground so you can continue without further assistance.

**FDA/ISO audit support**

EZ Risk Manager is available, upon appropriate notice and payment of expenses, to attend and help justify your compliance with ISO 14971.

***EZ Risk Manager™ -- your shortcut to ISO 14971 compliance***



## 4. Installing EZ Risk Manager™ Demo

This section describes how to install the demo version of **EZ Risk Manager™**. If you are an advanced computer user, feel free to skip the following section and just:

- Insert the EZ Risk Manager Demo CD
- Click to accept all default options

### Installing from a CD

**IMPORTANT:** close all applications running on your computer. The installation process uses a lot of memory. Be sure to close Microsoft Outlook or any Virus Scans if they are running on your computer.

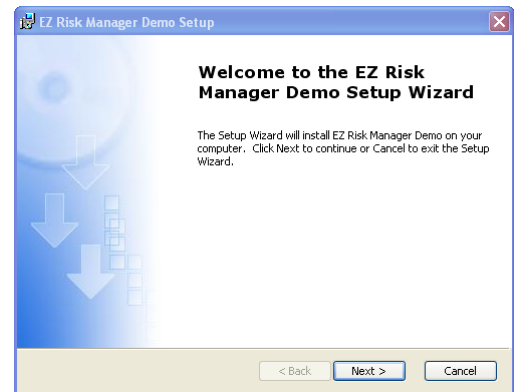
Insert the **EZ Risk Manager Demo CD** into your computer. If your computer has the Auto-Run feature turned on, the EZ Risk Manager welcome screen will appear.

If you are running under Windows Vista, a User Account Control message may appear. If so, click **Continue**.

A 'preparing to install' message may appear while your computer is readying the EZ Risk Manager installation. This message will clear itself after several seconds.

### Welcome Screen

When the Welcome Screen appears, click **Next >**.

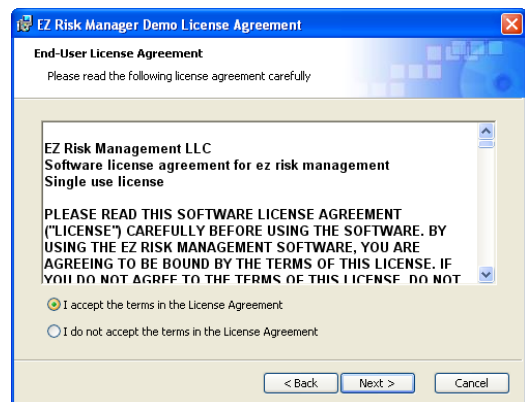


### End-User License Agreement

Read the end-user license agreement (EULA).

If you accept the terms, click **I accept...**, and then click **Next >**.

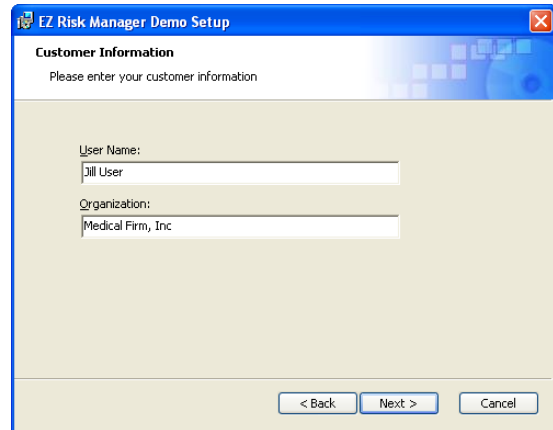
If you **do not** agree with the EULA terms, click **I do not accept**, and then click **Cancel**. Your installation will be cancelled.



## Customer Information

Type your name and organization (the organization name is optional).

Click **Next >**.

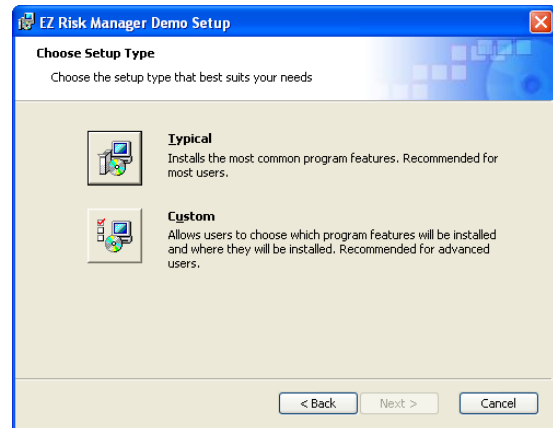
The screenshot shows the 'Customer Information' window of the EZ Risk Manager Demo Setup. The title bar reads 'EZ Risk Manager Demo Setup'. The window has a blue header with the title and a close button. Below the header, the text 'Please enter your customer information' is displayed. There are two text input fields: 'User Name:' with the value 'Bill User' and 'Organization:' with the value 'Medical Firm, Inc'. At the bottom right, there are three buttons: '< Back', 'Next >', and 'Cancel'.

## Choose Setup Type

Click **Typical**.

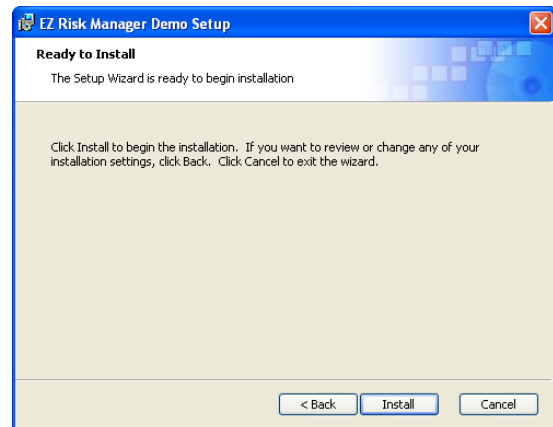
On most computers, you will be automatically directed to the **Ready to Install** screen after clicking **Typical**.

If this does not occur, click **Next >**.

The screenshot shows the 'Choose Setup Type' window of the EZ Risk Manager Demo Setup. The title bar reads 'EZ Risk Manager Demo Setup'. The window has a blue header with the title and a close button. Below the header, the text 'Choose the setup type that best suits your needs' is displayed. There are two options: 'Typical' with a computer icon and the description 'Installs the most common program features. Recommended for most users.' and 'Custom' with a computer icon and the description 'Allows users to choose which program features will be installed and where they will be installed. Recommended for advanced users.' At the bottom right, there are three buttons: '< Back', 'Next >', and 'Cancel'.

## Ready to Install

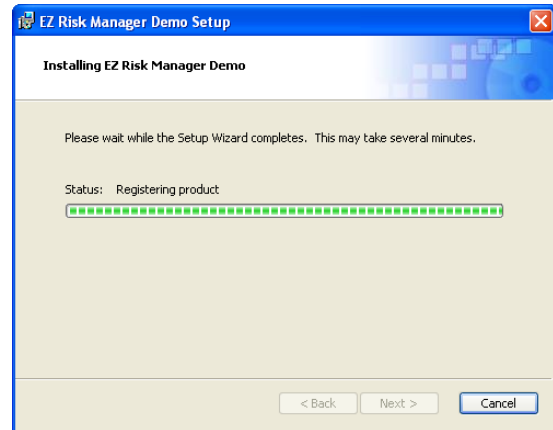
Click **Install**.

The screenshot shows the 'Ready to Install' window of the EZ Risk Manager Demo Setup. The title bar reads 'EZ Risk Manager Demo Setup'. The window has a blue header with the title and a close button. Below the header, the text 'The Setup Wizard is ready to begin installation' is displayed. Below this, there is a paragraph: 'Click Install to begin the installation. If you want to review or change any of your installation settings, click Back. Click Cancel to exit the wizard.' At the bottom right, there are three buttons: '< Back', 'Install', and 'Cancel'.

## Installation

The EZ Risk Manager Demo program installs onto your computer. The software is installed into **C:\EZ Risk Manager Demo**.

Wait for the Setup Wizard to complete. The progress bar will move across the screen as the installation program extracts files and prepares the installation.



The Microsoft Office Access Runtime dialog then appears.

## Microsoft Office Access Runtime

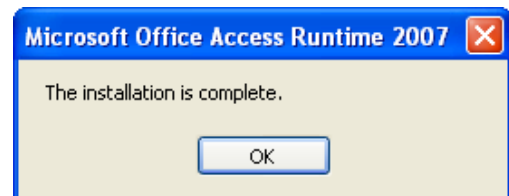
The Microsoft Access runtime executable installs on your computer.

After the runtime executable has been installed, the 'installation complete' dialog appears.



## Access Runtime Installation Complete

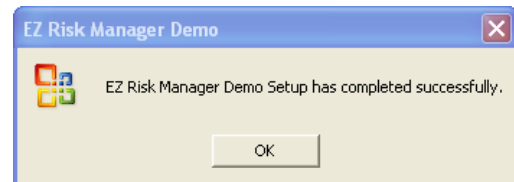
The Microsoft Access runtime executable has been successfully installed. Click **OK**.



## EZ Risk Manager Demo Installation Complete

EZ Risk Manager™ has been successfully installed.

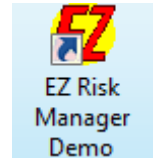
Click **OK**.



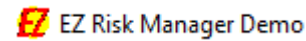
***You are now ready to run the EZ Risk Manager Demo.***

## 5. Start EZ Risk Manager

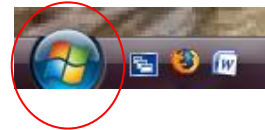
**Start EZ Risk Manager.** The easiest way to start EZ Risk Manager is to double-click the **EZ Risk Manager** program icon on your desktop.



You can also start the program via the taskbar. From the taskbar, click **Start, All Programs**, and then click **EZ Risk Manager**.

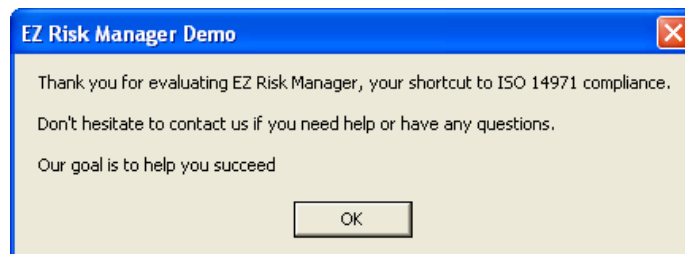


NOTE: if you are using Windows Vista, click the Start button, move to All Programs, and then find and click **EZ Risk Manager** (the program is listed alphabetically).



### Initial Welcome Message

The first time the EZ Risk Manager is started, a welcome message is displayed.



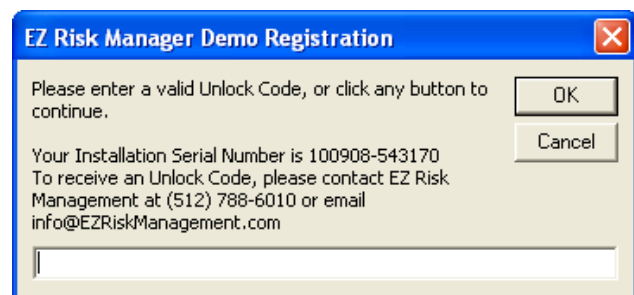
Click **OK**. Remember, if you have any questions we are only an email or phone call away.

### Demo Registration Screen

**You can use this demo program for 30 days.**

Afterwards, the demo is disabled (unless you enter a special unlock code).

To start the EZ Risk Manager, just click **OK**. You do **not** need to enter any special codes to run the trial program.

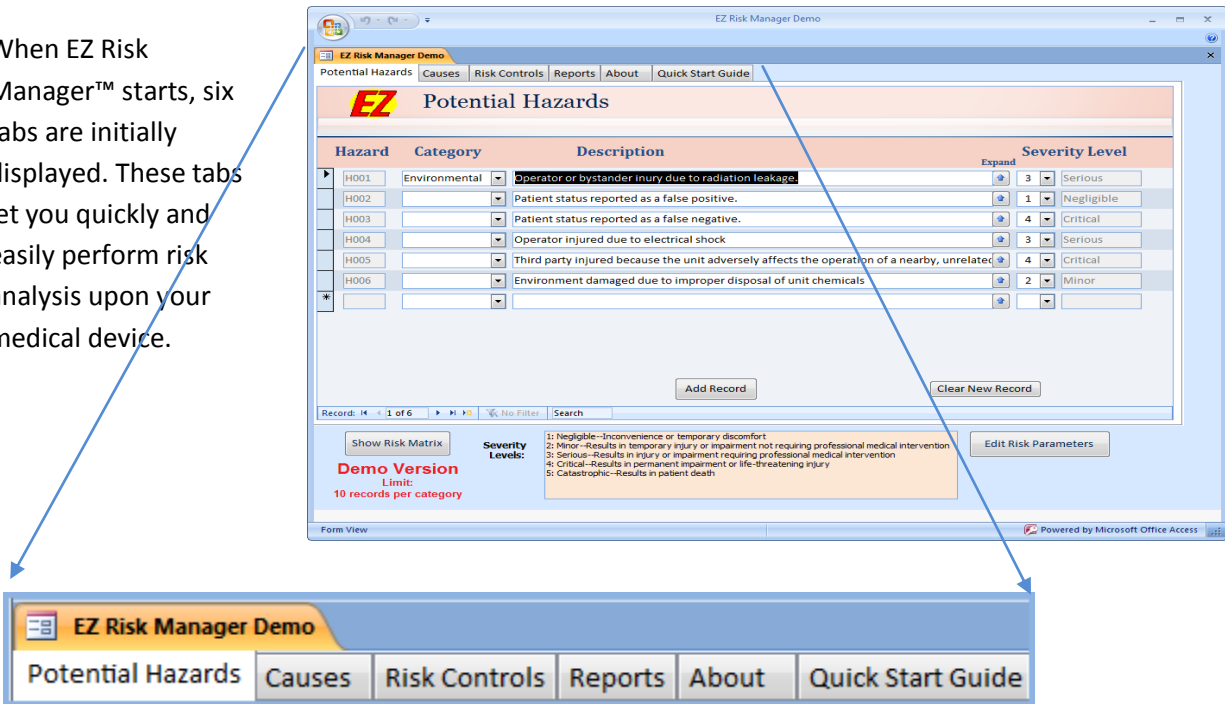


When you click **OK**, the EZ Risk Manager main screen appears.

**EZ Tip:** On some computers with limited memory, the EZ Risk Manager Demo will not start up the first time – you will get a 'Program not registered' message. If this occurs, click OK to close the message. Then, start the EZ demo program again. The registration screen will display.

## EZ Risk Manager Main Screen

When EZ Risk Manager™ starts, six tabs are initially displayed. These tabs let you quickly and easily perform risk analysis upon your medical device.



Clicking on each tab brings up the following screens:

- **Potential Hazards.** This screen lets you specify potential hazards of your medical device. For each hazard, you also estimate the level of severity of the hazard.
- **Causes.** This screen lets you define the cause(s) of each potential hazard. For each cause, you also estimate the initial probability of occurrence for the cause.
- **Risk Controls.** This screen lets you define methods of control for each cause. For each control, you also estimate the residual probability of occurrence of the hazard once the risk control has been applied.
- **Reports.** Once you have identified potential hazards, causes and risk controls, you can generate risk analysis reports. These can be attached to your ISO 14071 risk management files as well as your risk management report.
- **About.** This screen contains information on how to contact EZ Risk Manager support. Don't hesitate to contact us if you need help, have any questions or want to purchase the program.
- **Quick Start Guide.** This screen gives you a hyperlink to the **EZ Risk Manager Quick Start Guide** (a pdf copy of this document).

If you click the **Edit Risk Parameters** button, four new tabs are displayed....

Hazard	Category	Description	Expand	Severity Level
H001	Environmental	Operator or bystander injury due to radiation leakage.	3	Serious
H002		Patient status reported as a false positive.	1	Negligible
H003		Patient status reported as a false negative.	4	Critical
H004		Operator injured due to electrical shock	3	Serious
H005		Third party injured because the unit adversely affects the operation of a nearby, unrelated	4	Critical
H006		Environment damaged due to improper disposal of unit chemicals	2	Minor

Record: 1 of 6 | No Filter | Search

Show Risk Matrix | **Demo Version** | Limit: 10 records per category | **Edit Risk Parameters**

Severity Levels:  
 1: Negligible—Inconvenience or temporary discomfort  
 2: Minor—Results in temporary injury or impairment not requiring professional medical intervention  
 3: Serious—Results in injury or impairment requiring professional medical intervention  
 4: Critical—Results in permanent impairment or life-threatening injury  
 5: Catastrophic—Results in patient death

Form View | Powered by Microsoft Office Access

These tabs let you fine-tune risk parameters to conform to your company's specific ISO 14971 requirements.

Set Hazard Categories | Set Severity Levels | Set Probability Levels | Assign Risk Matrix Values

**Set Hazard Categories**

Category Description (25 chars max)

Environmental
Other
Third Parties

Record: 1 of 3 | No Filter | Search

Add Record | Clear New Record

Show Risk Matrix | **Demo Version** | Limit: 10 records per category | Return to Risk Analysis

Form View | Powered by Microsoft Office Access

**EZ Risk Manager Demo**

Set Hazard Categories | Set Severity Levels | Set Probability Levels | Assign Risk Matrix Values

Clicking on each tab brings up the following screens:

- **Set Hazard Categories.** If you have defined a large number of potential hazards, you might want to organize them by general categories. This screen lets you define your own set of hazard categories.
- **Set Severity Levels.** This screen lets you define up to eight qualitative severity levels. These values are used to estimate the severity of each potential hazard. EZ Risk Manager™ is initialized to five severity levels, but you can change them to fit your specific needs :
  - Negligible – inconvenience or temporary discomfort
  - Minor – results in temporary injury or impairment not requiring professional medical intervention
  - Serious – results in injury or impairment requiring professional medical intervention
  - Critical – results in permanent impairment or life-threatening injury
  - Catastrophic – results in patient death
- **Set Probability Levels.** This screen lets you define up to eight semi-quantitative probability levels. These values are used to calculate initial and residual risk. EZ Risk Manager™ is initialized to five probability levels, but you can change them to fit your specific needs:
  - Improbable – so unlikely it can be assumed it will not occur
  - Remote – not likely to occur in system life cycle, but possible
  - Occasional – might occur sometime in system life cycle
  - Probable – likely to occur several times in system life cycle
  - Frequent – likely to occur repeatedly in the system life cycle patient death
- **Assign Risk Matrix Values. Set Probability Levels.** This screen lets you assign a risk (acceptable, investigate, unacceptable) for each combination of severity and probability of occurrence.  
$$\text{Risk} = f(\text{Severity, Probability})$$

To return to the main screen, click the **Return to Risk Analysis** button.

The screenshot displays the 'Set Hazard Categories' interface within the EZ Risk Manager Demo. At the top, there are navigation tabs: 'Set Hazard Categories', 'Set Severity Levels', 'Set Probability Levels', and 'Assign Risk Matrix Values'. The main area features a table with a header 'Category Description (25 chars max)' and three rows of input fields containing 'Environmental', 'Other', and 'Third Parties'. A red tip box states: 'TIP: EZ Risk Manager will automatically alphabetize this category list for you'. A blue box highlights the 'Return to Risk Analysis' button, with an arrow pointing to it from the text above. The bottom of the screen includes a 'Show Risk Matrix' button, a 'Demo Version' notice with a 'Limit: 10 records per category', and a 'Powered by Microsoft Office Access' footer.

## Risk Matrix Table

If you press the **Show Risk Matrix** button, the decision table used for determining acceptable risk is displayed.

The screenshot shows the 'EZ Risk Manager Demo' application window. The 'Potential Hazards' table is displayed with the following data:

Hazard	Category	Description	Severity Level
H001	Environmental	Operator or bystander injury due to radiation leakage	3 Serious
H002		Patient status reported as a false positive.	1 Negligible
H003		Patient status reported as a false negative.	4 Critical
H004		Operator injured due to electrical shock	3 Serious
H005		Third party injured because the unit adversely affects the operation of a nearby, unrelated	4 Critical
H006		Environment damaged due to improper disposal of unit chemicals	2 Minor

Below the table, there is a 'Show Risk Matrix' button. A blue arrow points from this button to the 'Show Risk Matrix' button in the next screenshot.

The risk table shows the risk assigned for each combination of severity and probability of occurrence:

The screenshot shows the 'EZ Risk Manager Demo' application window with the 'Risk Matrix' tab selected. The matrix displays the risk assigned for each combination of severity and probability of occurrence.

		Qualitative Severity Levels				
		Negligible	Minor	Serious	Critical	Catastrophic
Semi-Quantitative Probability Levels	Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
	Probable	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
	Occasional	Investigate	Investigate	Unacceptable	Unacceptable	Unacceptable
	Remote	Acceptable	Investigate	Investigate	Unacceptable	Unacceptable
	Improbable	Acceptable	Acceptable	Investigate	Investigate	Investigate

Legend:

- UNACCEPTABLE - The risk is unacceptable and must be reduced
- INVESTIGATE - The risk should be reduced. Investigate further risk reduction
- ACCEPTABLE - The risk is insignificant. No need for further risk reduction

Using **Edit Risk Parameters**, you can define risk values for up to eight probability levels and eight severity levels.

## 6. Potential Hazards

This section shows how to create, modify or delete a potential hazard

The **EZ Risk Manager** demo is initialized with several pre-defined potential hazards. They will help you learn how to use the program. After you have become familiar with **EZ Risk Manager**, you can delete or edit the hazards as desired.

### Create Potential Hazard

Define a potential hazard by:

- Describing the hazard
- Assigning a severity level to the hazard.
- Assigning the hazard to a hazard category (optional)

To create a potential hazard, follow these simple steps

1. If the Potential Hazards screen is not already displayed, click the **Potential Hazards** tab.

**EZ Tip:** The demo program lets you define up to 10 potential hazards. The full-featured program, however, lets you define up to 1000 hazards.

Hazard	Category	Description	Severity Level
H001	Environmental	Operator or bystander injury due to radiation leakage	3 Serious
H002		Patient status reported as a false positive.	1 Negligible
H003		Patient status reported as a false negative.	4 Critical
H004		Operator injured due to electrical shock	3 Serious
H005		Third party injured because the unit adversely affects the operation of a nearby, unrelated	4 Critical
H006		Environment damaged due to improper disposal of unit chemicals	2 Minor
*			

2. Click on the empty row at the bottom of the list:

H006		Environment damaged due to improper disposal of unit chemicals	2	Minor	
*					

3. Notice that the **Hazard** number is blank. This is OK because EZ Risk Manager will automatically assign the number for you. The cursor is located in the **Category** field. For now, leave this field blank. Press **TAB** to move to the **Description** field.

4. The cursor is now in the **Description** field. Type **Test Hazard**, and then press **TAB**.

The screenshot shows a form with two rows. The first row has a pencil icon, a text box containing 'H007', a dropdown menu, and a text box containing 'Test Hazard'. The second row has a star icon, a text box, a dropdown menu, and a text box. The cursor is positioned at the end of the 'Test Hazard' text.

5. The cursor is now located in the **Severity Level** field. Click on the **Severity Level** list box and select severity level **2 Minor**

The screenshot shows the same form as before, but the 'Severity Level' dropdown menu is open, displaying a list of options: 1 Negligible, 2 Minor, 3 Serious, 4 Critical, and 5 Catastrophic. The option '2 Minor' is highlighted.

6. Press the TAB key or click **Add Record**. **EZ Risk Manager** automatically assigns the potential hazard a unique reference number.

**EZ Tip:** You can customize the number of severity levels (including the definition of each level).

That's it. You're done.

The screenshot shows the same form as before, but the 'Severity Level' dropdown menu is now closed, and the selected value '2 Minor' is displayed in the text box next to it.

Notice that a blank line has been appended at the bottom of the Potential Hazards list so you can enter a new potential hazard.

## Edit Potential Hazard

Editing a potential hazard record is simple:

1. Click on the left side of the record you want to edit. For example, click on the Potential Hazard you just created:

Using the mouse or the TAB key, move to the field you

want to modify. To modify the Description, just edit the text. To modify Severity Level, click the drop down list and select a new value. Then press TAB to update the record.

The screenshot shows the 'Potential Hazards' table in the EZ Risk Manager interface. The table has columns for Hazard, Category, Description, Expand, and Severity Level. The 'Test Hazard' record is highlighted in blue.

Hazard	Category	Description	Expand	Severity Level
H001	Environmental	Operator or bystander injury due to radiation leakage.	3	Serious
H002		Patient status reported as a false positive.	1	Negligible
H003		Patient status reported as a false negative.	4	Critical
H004		Operator injured due to electrical shock	3	Serious
H005		Third party injured because the unit adversely affects the operation of a nearby, unrelated	4	Critical
H006		Environment damaged due to improper disposal of unit chemicals	2	Minor
H007		Test Hazard	2	Minor
*				

You can also edit **Description** by clicking the **Expand** button or double-clicking anywhere in the **Description** field.

Click **Expand**.

A new form opens allowing you to easily enter a hazard description. In theory, you should keep descriptions as short as possible, but sometimes that is just not feasible and you must enter a larger amount of text. Clicking on **Expand** gives you an easy way to enter text that would otherwise overflow the Description field.

When you have finished entering the description, click **Save** to close the form and return to the Potential Hazards form. If you click **Cancel**, the Hazard Description field will revert back to its original contents.

For now, click **Save**.

**EZ Tip:** You can also double-click anywhere within the Description field to bring up the Hazard Description dialog.

**EZ Risk Manager** returns you to the Potential Hazards form.

## Delete Potential Hazard

To delete a potential hazard:

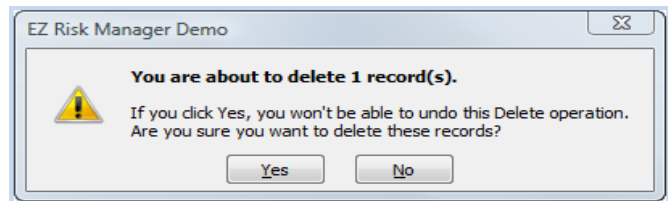
1. Click on the left side of the record you want to delete (in this case, the potential hazard you just created and edited).


Hazard	Category	Description	Expand	Severity Level
H001	Environmental	Operator or bystander injury due to radiation leakage.	3	Serious
H002		Patient status reported as a false positive.	1	Negligible
H003		Patient status reported as a false negative.	4	Critical
H004		Operator injured due to electrical shock	3	Serious
H005		Third party injured because the unit adversely affects the operation of a nearby, unrelated	4	Critical
H006		Environment damaged due to improper disposal of unit chemicals	2	Minor
H007		Test Hazard	2	Minor

- Press the **DELETE** key. A confirm message appears.

Click **Yes**.

The Potential Hazard is deleted.



EZ Risk Manager Demo				
Potential Hazards	Causes	Risk Controls	Reports	About Quick Start Guide
 Potential Hazards				
Hazard	Category	Description	Expand	Severity Level
H001	Environmental	Operator or bystander injury due to radiation leakage.	+	3 Serious
H002		Patient status reported as a false positive.	+	1 Negligible
H003		Patient status reported as a false negative.	+	4 Critical
H004		Operator injured due to electrical shock	+	3 Serious
H005		Third party injured because the unit adversely affects the operation of a nearby, unrelated	+	4 Critical
H006		Environment damaged due to improper disposal of unit chemicals	+	2 Minor
			+	

**EZ Tip:** You cannot delete a Hazard if any Causes are linked to it. **EZ Risk Manager** prevents you from making unintentional mistakes.

## 7. Causes

This section shows how to create, modify or delete a cause of a potential hazard.

The **EZ Risk Manager** demo is initialized with several pre-defined causes. They will help you learn how to use the program. After you have become familiar with **EZ Risk Manager**, you can delete or edit the causes as desired.

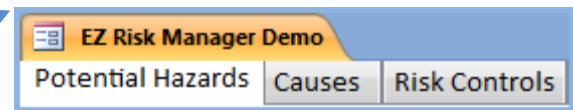
### Create Cause

Define a cause of a potential hazard by:

- Describing the cause
- Assigning an initial probability to the cause.
- Linking the cause to a potential hazard

To create a cause record, follow these simple steps:

1. Click the **Causes** tab.



 A screenshot of the 'Causes of Each Potential Hazard' window in the EZ Risk Manager Demo. The window has a title bar 'EZ Risk Manager Demo' and a menu bar with 'Potential Hazards', 'Causes', 'Risk Controls', 'Reports', 'About', and 'Quick Start Guide'. The main area contains a table with the following columns: Cause, Description, Expand, Initial Probability, Link to Hazard, and Initial Risk. The table lists four causes: C001 (Improper shielding of instrument), C002 (Software error), C003 (Software error), and C004 (Improper training of operator). Below the table are 'Add Record' and 'Clear New Record' buttons. At the bottom, there is a 'Show Risk Matrix' button, a 'Demo Version' notice (Limit: 10 records per category), an 'Initial Probability' legend, and an 'Edit Risk Parameters' button. The status bar at the bottom indicates 'Form View' and 'Powered by Microsoft Office Access'.
 

Cause	Description	Expand	Initial Probability	Link to Hazard	Initial Risk
C001	Improper shielding of instrument	+	2 Remote	H001 Operator or bystander injury due	Investigate
C002	Software error	+	3 Occasional	H002 Patient status reported as a false	Investigate
C003	Software error	+	3 Occasional	H003 Patient status reported as a false	Unacceptable
C004	Improper training of operator	+	3 Occasional	H006 Environment damaged due to in	Investigate
*		+			

**EZ Tip:** The demo program lets you define up to 10 causes. The full-featured version, however, lets you define up to 1000 causes (more, if needed).

2. To define a new cause, click on the empty row at the bottom of the list:

Cause	Description	Initial Probability	Link to Hazard	Initial Risk
C001	Improper shielding of instrument	2 Remote	H001 Operator or bystander injury due to	Investigate
C002	Software error	3 Occasional	H002 Patient status reported as a false	Investigate
C003	Software error	3 Occasional	H003 Patient status reported as a false	Unacceptable
C004	Improper training of operator	3 Occasional	H006 Environment damaged due to in	Investigate

3. Notice that the **Cause** number is blank. This is OK because EZ Risk Manager will automatically assign the number for you.

The cursor is located in the **Description** field. Type **Improper operator training how to use the instrument**, and then press **TAB**.

4. The cursor is now located in the **Initial Probability** field. To select an initial probability, click on the **Initial Probability** list box and select level **3 Occasional**. Then, press **TAB**

**EZ Tip:** You can customize the number of probability levels (including the definition of each level).

- a. The cursor is now located in the **Link to Hazard** field. Click to select the potential hazard that the cause is linked to. For now, click on **H004**.

- Press the TAB key or click **Add Record**. **EZ Risk Manager** automatically assigns the cause a unique reference number.

That's it. You're done

Cause	Description	Expand	Initial Probability	Link to Hazard	Initial Risk
C001	Improper shielding of instrument	↓	2 Remote	H001 Operator or bystander injury due	Investigate
C002	Software error	↓	3 Occasional	H002 Patient status reported as a false	Investigate
C003	Software error	↓	3 Occasional	H003 Patient status reported as a false	Unacceptable
C004	Improper training of operator	↓	3 Occasional	H006 Environment damaged due to in	Investigate
C005	Improper operator training how to use the instrument	↓	3 Occasional	H004 Operator injured due to electric	Investigate
*		↓			

Notice that **EZ Risk Manager** has automatically assigned an initial risk to the cause. This decision is based the severity of the hazard, initially probability of occurrence and risk value assigned by the Risk Matrix table.

Notice also also that a blank line has been appended at the bottom of the form so you can enter a new cause.

## Edit Cause

Editing a cause record is simple.

- Click the left side of the cause record you want to edit.
- Using the mouse or TAB key, move to the field you want to modify. To modify the Description, just edit the text. To modify the Initial Probability, click the drop down list and select a new value. To modify the Hazard link, click the drop down list and select a Hazard.
- Press **TAB** or move the mouse away from the record to save the updated record.

You can also edit the **Description** by clicking the **Expand** button or double-clicking anywhere in the **Description** field.

A new form opens allowing you to enter or change the cause description.

When you have finished entering the description, click **Save** to close the form and return to the Potential Hazards form. If you click **Cancel**, the Hazard Description field will revert to its original contents.

Cause Description

Enter a description of the Cause

Improper operator training how to use the instrument

Save Cancel

## Delete Cause

To delete a cause  
from EZ Risk  
Manager:

1. Click on the left-hand side of the record you want to delete. For example, click on the cause you just created.
2. Press the DEL key. A confirm message will appear:

Click **Yes**.

The Cause is deleted:

EZ Risk Manager Demo

Potential Hazards

Causes

Risk Controls

Reports

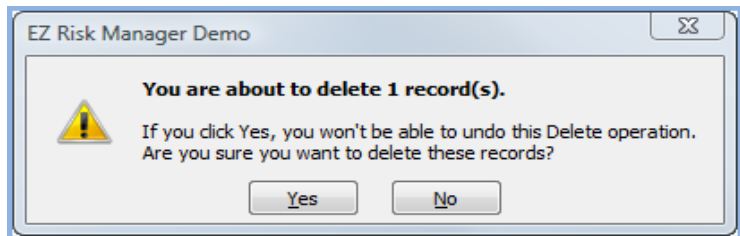
About

Quick Start Guide

EZ

Causes of Each Potential Hazard

Cause	Description	Expand	Initial Probability	Link to Hazard	Initial Risk
C001	Improper shielding of instrument	2	Remote	H001 Operator or bystander injury due to electric shock	Investigate
C002	Software error	3	Occasional	H002 Patient status reported as a false alarm	Investigate
C003	Software error	3	Occasional	H003 Patient status reported as a false alarm	Unacceptable
C004	Improper training of operator	3	Occasional	H006 Environment damaged due to incorrect use of instrument	Investigate
C005	Improper operator training how to use the instrument	3	Occasional	H004 Operator injured due to electric shock	Investigate



EZ Risk Manager Demo

Potential HazardsCausesRisk ControlsReportsAboutQuick Start Guide

EZ Causes of Each Potential Hazard

Cause	Description	Expand	Initial Probability	Link to Hazard	Initial Risk	
C001	Improper shielding of instrument	2	Remote	H001	Operator or bystander injury due to electric shock	Investigate
C002	Software error	3	Occasional	H002	Patient status reported as a false alarm	Investigate
C003	Software error	3	Occasional	H003	Patient status reported as a false alarm	Unacceptable
C004	Improper training of operator	3	Occasional	H006	Environment damaged due to incorrect use of instrument	Investigate
C005	Improper operator training how to use the instrument	3	Occasional	H004	Operator injured due to electric shock	Investigate
*						

**EZ Tip:** You cannot delete a Cause if any Risk Controls are linked to it.

**EZ Risk Manage** prevents you from making unintentional mistakes.

## 8. Risk Controls

This section shows how to create, modify or delete risk controls.

The **EZ Risk Manager** demo is initialized with several pre-defined risk controls. They will help you learn how to use the program. After you have become familiar with **EZ Risk Manager**, you can delete or edit the risk controls as desired.

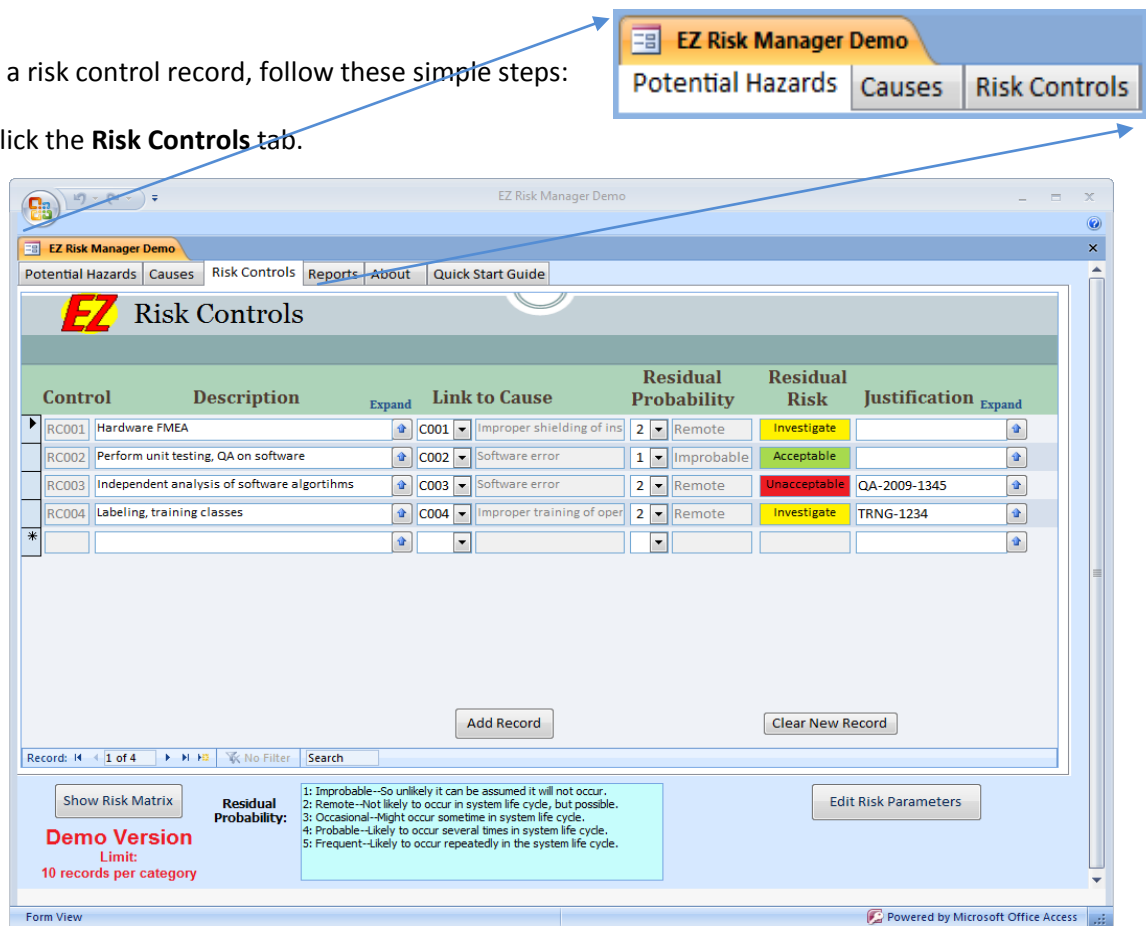
### Create Risk Control

Define a risk control by:

- Describing the risk control
- Linking the control to a cause
- Assigning a residual probability to the risk control
- Describing the justification for the risk control and the residual risk (optional)

To create a risk control record, follow these simple steps:

1. Click the **Risk Controls** tab.



**EZ Tip:** The demo program lets you define up to 10 risk controls. The full-featured program, however, lets you define up to 1000 controls (more, if needed).

- Click on the empty row at the bottom of the list. Notice that the **Risk Control** number is blank. Like the Hazard and Cause reference numbers, **EZ Risk Manager** automatically assigns this number for you.

The cursor is in the **Description** field. Type **Operator training class**, and then press TAB.

- The cursor is now located in the **Link to Cause** field. Click the list box and select a Cause that the risk control is linked to. For now, click on **C003**. Then, press TAB.

- The cursor is now located in the **Residual Probability** field. Click the list box and select a residual probability. For example, select **2 Remote**.

Press the **TAB** key. Notice that **EZ Risk Manager** has automatically assigned a residual risk to the control.

- The cursor is now located in the **Justification** field. This optional field lets you specify your reasoning for determining the residual probability; you can also refer to other documentation justifying how the risk control was implemented or how you justified your conclusions. For now, leave this field blank.

- Press the **TAB** key or click **Add Record**. **EZ Risk Manager** automatically assigns the risk control a unique reference number and then adds the record to the list. That's it. You're done.

Control	Description	Expand	Link to Cause	Residual Probability	Residual Risk	Justification	Expand
RC001	Hardware FMEA	+	C001 Improper shielding of ins	2 Remote	Investigate		+
RC002	Perform unit testing, QA on software	+	C002 Software error	1 Improbable	Acceptable		+
RC003	Independent analysis of software algorithms	+	C003 Software error	2 Remote	Unacceptable	QA-2009-1345	+
RC004	Labeling, training classes	+	C004 Improper training of oper	2 Remote	Investigate	TRNG-1234	+
RC005	Operator training class	+	C003 Software error	2 Remote	Unacceptable		+
		+					+

Notice that a blank line has been appended at the bottom of the form so you can enter a new risk control.

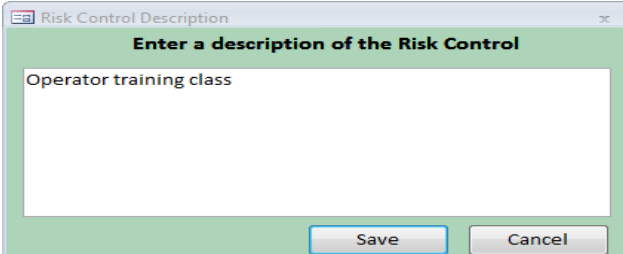
## Edit Risk Control

Editing a risk control record is simple:

1. Click in any field of the risk control you want to edit.
2. Using the mouse or TAB key, move to the field you want to modify. To modify the **Description** or **Justification** fields, just edit the text. To modify the **Link to Cause of Hazard** or **Residual Probability**, click the appropriate drop down list and select a new value.
3. Press **TAB** or move the mouse outside the record to update the record.

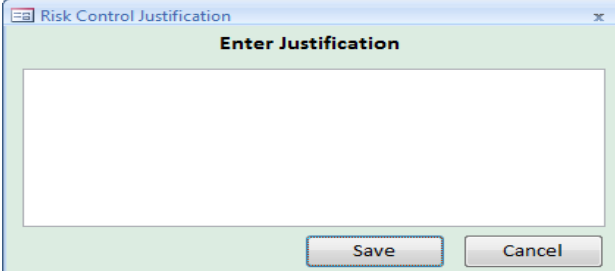
You can edit the Risk Control **Description** by clicking the **Expand** button or double-clicking anywhere in the **Description** field.

A new form opens allowing you to enter or change the cause description. When you have finished entering the description, click **Save** to return to the Risk Control form. If you click **Cancel**, the Risk Control Description field will revert to its original contents.

A screenshot of a software dialog box titled "Risk Control Description". The dialog has a green header bar with the text "Enter a description of the Risk Control". Below the header is a large white text area containing the text "Operator training class". At the bottom right of the dialog are two buttons: "Save" and "Cancel".

You can edit the Risk Control **Justification** by clicking the **Expand** button or double-clicking anywhere in the **Justification** field.

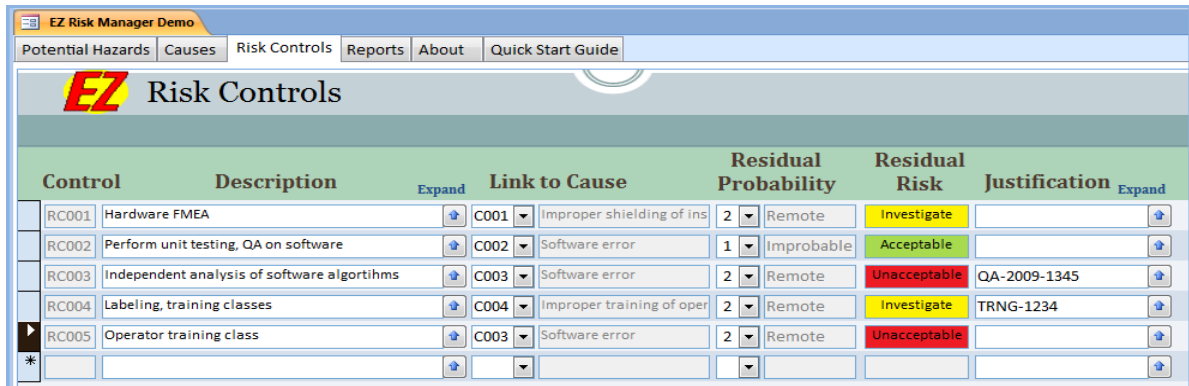
A new form opens allowing you to enter or change the cause description. When you have finished entering the description, click **Save** to return to the Risk Control form. If you click **Cancel**, the Risk Control Justification field will revert to its original contents.

A screenshot of a software dialog box titled "Risk Control Justification". The dialog has a green header bar with the text "Enter Justification". Below the header is a large white text area. At the bottom right of the dialog are two buttons: "Save" and "Cancel".

## Delete Risk Control

To delete a risk control from **EZ Risk Manager**:

1. Click on the left-hand side of the record you want to delete.

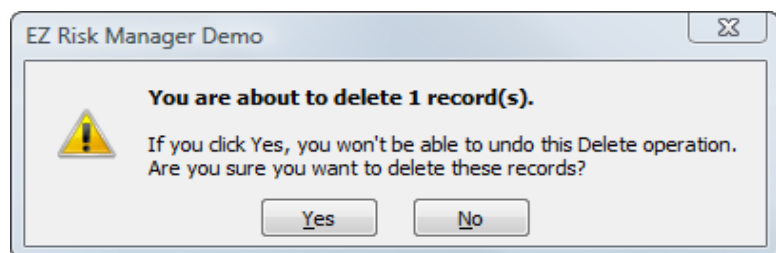


Control	Description	Expand	Link to Cause	Residual Probability	Residual Risk	Justification	Expand
RC001	Hardware FMEA	+	C001	Improper shielding of ins	2 Remote	Investigate	
RC002	Perform unit testing, QA on software	+	C002	Software error	1 Improbable	Acceptable	
RC003	Independent analysis of software algorithms	+	C003	Software error	2 Remote	Unacceptable	QA-2009-1345
RC004	Labeling, training classes	+	C004	Improper training of oper	2 Remote	Investigate	TRNG-1234
RC005	Operator training class	+	C003	Software error	2 Remote	Unacceptable	
*		+					

2. Press the **DELETE** key. A confirm message will appear.

Click **Yes**.

The Risk Control is deleted.



## 9. Change Risk Parameters

**EZ Risk Manager** provides a default set of:

- Hazard Categories
- Qualitative severity levels
- Semi-quantitative probability levels
- Risk values

These values are adapted from *ISO 14971:2007 Medical devices – Application of risk management to medical devices*, and should be appropriate for your medical device. If you need to modify these risk parameters, including the assignment of risk values, **EZ Risk Manager** lets you do so quickly and easily.

To change risk parameters, click the **Edit Risk Parameters** button...

The screenshot shows the EZ Risk Manager Demo application window. The 'Potential Hazards' tab is selected, displaying a table of hazards. An arrow points from the 'Edit Risk Parameters' button in the top right corner of the window to the 'Edit Risk Parameters' button in the bottom right corner of the interface.

Hazard	Category	Description	Expand	Severity Level
H001	Environmental	Operator or bystander injury due to radiation leakage.	3	Serious
H002		Patient status reported as a false positive.	1	Negligible
H003		Patient status reported as a false negative.	4	Critical
H004		Operator injured due to electrical shock	3	Serious
H005		Third party injured because the unit adversely affects the operation of a nearby, unrelated	4	Critical
H006		Environment damaged due to improper disposal of unit chemicals	2	Minor
*				

Buttons: Add Record, Clear New Record, Show Risk Matrix, Edit Risk Parameters

Record: 1 of 6, No Filter, Search

Severity Levels:

- 1: Negligible--Inconvenience or temporary discomfort
- 2: Minor--Results in temporary injury or impairment not requiring professional medical intervention
- 3: Serious--Results in injury or impairment requiring professional medical intervention
- 4: Critical--Results in permanent impairment or life-threatening injury
- 5: Catastrophic--Results in patient death

Demo Version Limit: 10 records per category

Form View, Powered by Microsoft Office Access

After clicking **Edit Risk Parameters**, a new form is displayed containing four tabs. Clicking on each individual tab lets you perform the following functions:

- Set Hazard Categories
- Set Severity Levels
- Set Probability Levels
- Assign Risk Matrix Values

These functions are described in the following sections.

## Hazard Categories

When you click the **Edit Risk Parameters** button, the Set Hazard Categories form is displayed by default. If it does not, then click the **Set Hazard Categories** tab.

**EZ Risk Manager** lets you create up to 25 hazard categories. Hazard Categories are an optional feature – you do not need to use them. However, if your risk analysis creates numerous potential hazards it may advantageous to group them into generic categories.

When you return to the main risk analysis forms, the hazard categories will be displayed in alphabetical order

When you add, modify or delete a hazard category, **EZ Risk Manager** automatically updates all related Potential Hazard records to reflect the changes you made.

**EZ Tip:** You cannot delete a Hazard Category if it is used by any Potential Hazard.

**EZ Risk Manager** prevents you from making unintentional mistakes.

**Returning to the Risk Analysis Screen.** To return to the Risk Manager analysis screens, click the **Return to Risk Analysis** button. Any changes made to Hazard Categories, Severity Levels, Probability Levels or the Risk Matrix will be automatically updated and appear in the Potential Hazards, Causes and Risk Control forms.

Return to Risk Analysis

**EZ Risk Manager Demo**

Set Hazard Categories | Set Severity Levels | Set Probability Levels | Assign Risk Matrix Values

**EZ** Set Hazard Categories

TIP: EZ Risk Manager will automatically alphabetize this category list for you

Category Description (25 chars max)

▶	Environmental
▶	Other
▶	Third Parties
▶	

Add Record Clear New Record

Record: 1 of 3 No Filter Search

Show Risk Matrix

**Demo Version**  
Limit:  
10 records per category

Return to Risk Analysis

Form View Powered by Microsoft Office Access

## Severity Levels

Click the **Set Severity Levels** tab.

**EZ Risk Manager Demo**

Set Hazard Categories | **Set Severity Levels** | Set Probability Levels | Assign Risk Matrix Values

**Set Severity Levels**

Severity Level Value (1-8)	Short Description (15 chars max)	Long Description (100 chars max)
1	Negligible	Inconvenience or temporary discomfort
2	Minor	Results in temporary injury or impairment not requiring professional medical intervention
3	Serious	Results in injury or impairment requiring professional medical intervention
4	Critical	Results in permanent impairment or life-threatening injury
5	Catastrophic	Results in patient death

Add Record Clear New Record

Record: 1 of 5 No Filter Search

Show Risk Matrix Return to Risk Analysis

**Demo Version**  
Limit: 10 records per category

Form View Powered by Microsoft Office Access

You can modify or add up to eight qualitative severity levels, ranging from less to more severe. Each severity level must contain the following information:

- **Severity value.** This value must be from 1 to 8 (eight being the most severe) and indicates the severity of the potential hazard.
- **Short Description.** This is the text displayed in the drop-down combo boxes when you select a severity level. Short description names are used in the Potential Hazards form.
- **Long Description.** This is the description is used in reports.

After you modify a severity level, **EZ Risk Manager** automatically updates all related Cause and Risk Control records reflect your changes. This involves recalculating initial and residual risk.

**EZ Risk Manager** will not let you delete a severity level if that value is referenced by a Potential Hazard.

**Returning to the Main Screen.** To return to the Risk Manager analysis screens, click **Return to Risk Analysis**. **EZ Risk Manager** will automatically update your Potential Hazards, Causes and Risk Control forms.

Return to Risk Analysis

## Probability Levels

Click the **Set Probability Levels** tab.

The screenshot shows the 'Set Probability Levels' tab in the EZ Risk Manager Demo. The tab is highlighted in the top navigation bar. The main content area contains a table with the following data:

Probability Value (1-8)	Short Description (15 chars max)	Long Description (100 chars max)
1	Improbable	So unlikely it can be assumed it will not occur.
2	Remote	Not likely to occur in system life cycle, but possible.
3	Occasional	Might occur sometime in system life cycle.
4	Probable	Likely to occur several times in system life cycle.
5	Frequent	Likely to occur repeatedly in the system life cycle.
*		

Below the table are buttons for 'Add Record' and 'Clear New Record'. At the bottom, there is a 'Return to Hazard Analysis' button and a 'Severity Levels' section with a list of severity levels:

**Severity Levels:**

- 1: Negligible--Inconvenience or temporary discomfort
- 2: Minor--Results in temporary injury or impairment not requiring professional medical intervention
- 3: Serious--Results in injury or impairment requiring professional medical intervention
- 4: Critical--Results in permanent impairment or life-threatening injury
- 5: Catastrophic--Results in patient death

The bottom of the screen shows a 'Form View' status and a 'Powered by Microsoft Office Access' logo.

You can modify or add up to eight semi-quantitative probability levels, ranging from least to most probable. Each probability level contains the following information:

- **Probability value.** This value must be from 1 to 8, and indicates the frequency of occurrence, from least probable to most probable.
- **Short Description.** This is the name used in the drop-down combo boxes used to select a probability level. The short description names are used in the Causes and Risk Controls forms to specify initial and residual probability.
- **Long Description.** This description is used in reports and the footer of the **EZ Risk Manager** main screen.

After you modify a probability level, **EZ Risk Manager** automatically updates all related Cause and Risk Control records reflect your changes.

**EZ Risk Manager** will not let you delete a probability level if that value is referenced in a Cause or Risk Control.

**Returning to the Main Screen.** To return to the Risk Manager Main screen, click the **Return to Risk Analysis** button. Potential Hazards, Causes and Risk Control forms will be automatically updated to incorporate your changes.

[Return to Risk Analysis](#)

## Assign Risk Matrix Values

Click the **Assign Risk Matrix Values** tab. The Risk Matrix for your medical device is displayed

**EZ Risk Manager Demo**

Set Hazard Categories | Set Severity Levels | Set Probability Levels | **Assign Risk Matrix Values**

**EZ Assign Risk Matrix Values**

Device Name:

< ---Less Qualitative Severity Levels More --->

	Negligible	Minor	Serious	Critical	Catastrophic
(Most Probable) Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Probable	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Occasional	Investigate	Investigate	Investigate	Unacceptable	Unacceptable
Remote	Acceptable	Investigate	Investigate	Unacceptable	Unacceptable
(Least Probable) Improbable	Acceptable	Acceptable	Investigate	Investigate	Investigate

**Semi-Quantitative Probability Levels**

Unacceptable - The risk is unacceptable and must be reduced.

Investigate - The risk should be reduced. Investigate further risk reduction

Acceptable - The risk is insignificant. No need for further risk reduction

Show Risk Matrix

Return to Risk Analysis

**Demo Version**  
Limit:  
10 records per category

Form View

Powered by Microsoft Office Access

The number of rows and columns in the Risk Matrix table depend on the number of Severity and Probability levels you have defined.

$$\text{Risk} = f(\text{Severity, Probability})$$

**EZ Tip:** *EZ Risk Manager* uses the three risk levels referenced in ISO 14971:2007: Acceptable, Investigate, and Unacceptable.

Contact us if you need to use different values.

**EZ Risk Manager** lets you assign a risk for each combination of severity and probability of occurrence.

To modify a risk level:

1. Point to the severity and probability level you want to modify. For now, move to the risk level for **Negligible** Severity and **Improbable** Probability of Occurrence

		< ---Less Qualitative Severity Level		
		(Most Probable)		
		Negligible	Minor	
Frequent		Unacceptable	Unacceptable	Unacceptable
Probable		Unacceptable	Unacceptable	Unacceptable
Occasional		Investigate	Investigate	Investigate
Remote		Acceptable	Investigate	Investigate
Improbable		Acceptable	Acceptable	Investigate
(Least Probable)				
Semi-Quantitative		Unacceptable - The risk is unacceptable		
Probability Levels		Investigate - The risk is unacceptable		
		Acceptable - The risk is acceptable		

2. Click the dropdown arrow and select a new risk level. For now, select **Unacceptable**

		< ---Less Qualitative Severity Level		
		(Most Probable)		
		Negligible	Minor	
Frequent		Unacceptable	Unacceptable	Unacceptable
Probable		Unacceptable	Unacceptable	Unacceptable
Occasional		Investigate	Investigate	Investigate
Remote		Acceptable	Investigate	Investigate
Improbable		Acceptable	Acceptable	Investigate
(Least Probable)				
Semi-Quantitative		Unacceptable - The risk is unacceptable		
Probability Levels		Investigate - The risk is unacceptable		
		Acceptable - The risk is acceptable		

All Cause and Risk Control records that reference this risk level will be automatically updated.

**EZ Risk Manager Demo**

Set Hazard Categories | Set Severity Levels | Set Probability Levels | **Assign Risk Matrix Values**

**Assign Risk Matrix Values**

Device Name:

< --Less **Qualitative Severity Levels** More -->

(Most Probable)	Negligible	Minor	Serious	Critical	Catastrophic
Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Probable	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable
Occasional	Investigate	Investigate	Investigate	Unacceptable	Unacceptable
Remote	Acceptable	Investigate	Investigate	Unacceptable	Unacceptable
Improbable	Unacceptable	Acceptable	Investigate	Investigate	Investigate
(Least Probable)					

**Semi-Quantitative Probability Levels**

Unacceptable - The risk is unacceptable and must be reduced.  
 Investigate - The risk should be reduced. Investigate further risk reduction  
 Acceptable - The risk is insignificant. No need for further risk reduction

Show Risk Matrix

**Demo Version**  
 Limit:  
 10 records per category

Return to Risk Analysis

Form View

Powered by Microsoft Office Access

This screen also lets you enter the name of your medical device. This device name will be used in all **EZ Risk Manager** reports.

Device Name:

**Returning to the Main Screen.** To return to the Risk Manager Main screen, click the **Return to Risk Analysis** button. Potential Hazards, Causes and Risk Control forms will be automatically updated to incorporate your changes.

Return to Risk Analysis

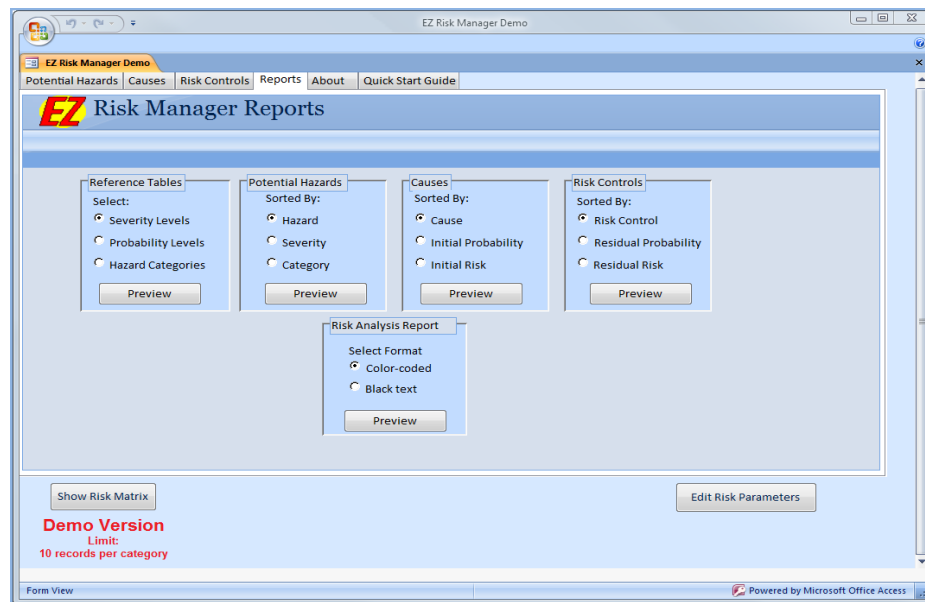
## 10. Generating Reports

**EZ Risk Manager** contains numerous reports to help you document ISO 14971 compliance.

**EZ Tip:** **EZ Risk Manager** is continually improving and adding to its list of risk management and analysis reports.

If you need a special report, just let us know. We're here to help you succeed.

From the main screen, click on the **Reports** tab.



**EZ Risk Manager** lets you view the following reports:

### Risk Parameters

- Severity Levels
- Probability Levels
- Hazard Categories
- Risk Matrix

### Causes, sorted by

- Cause
- Initial Probability
- Initial Risk

### Potential Hazards, sorted by

- Hazard
- Severity
- Category

### Risk Controls, sorted by

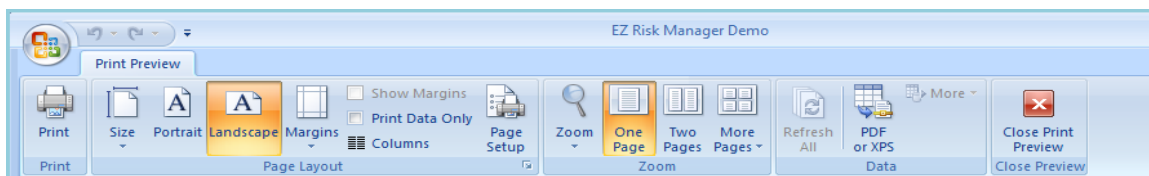
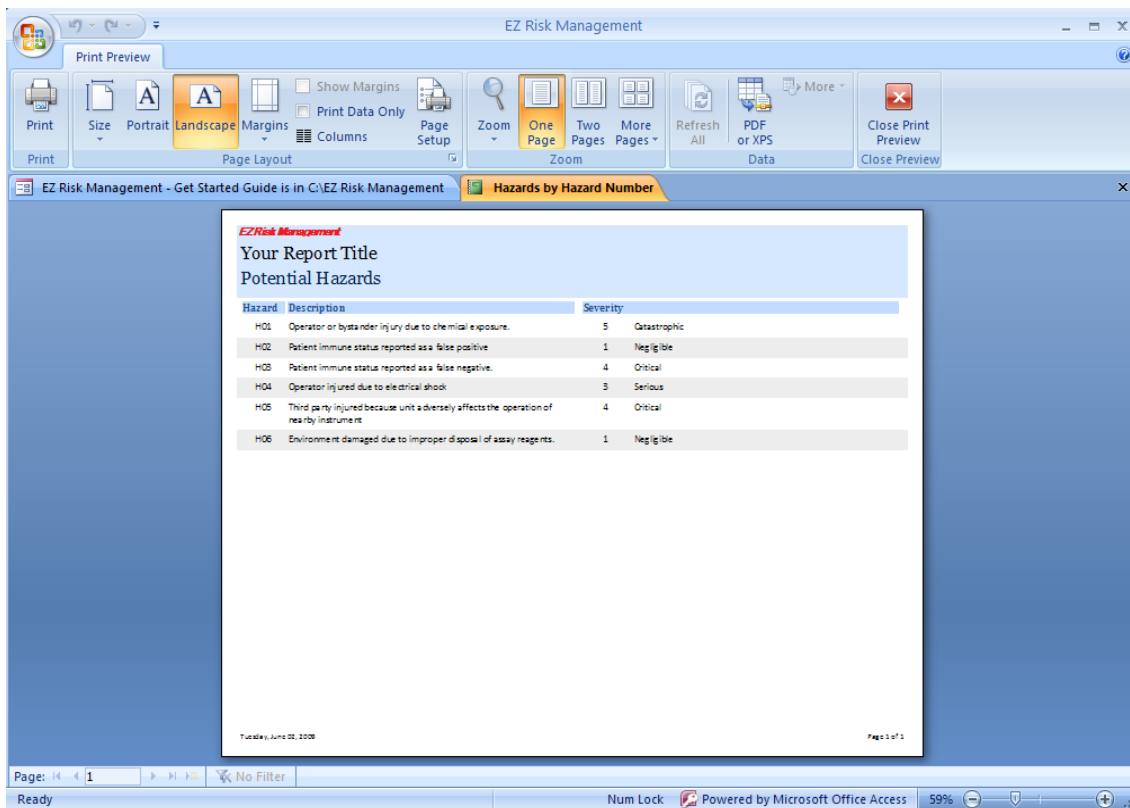
- Risk Control
- Residual Probability
- Residual Risk

## Risk Analysis Report

- Color-coded
- Black text

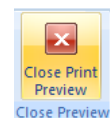
To preview a report, click the appropriate button. The report is displayed in Preview mode. You can print the report or save it as a PDF file.

For example, in the **Potential Hazards** panel, click **Preview**. The Potential Hazards report, sorted by hazard number, is displayed:



Using the icons in the Print Preview panel, you can view the report, print it out, or save it as a PDF file.

To close the report preview, click the red X at the upper right hand corner of the preview.



# Risk Analysis Reports

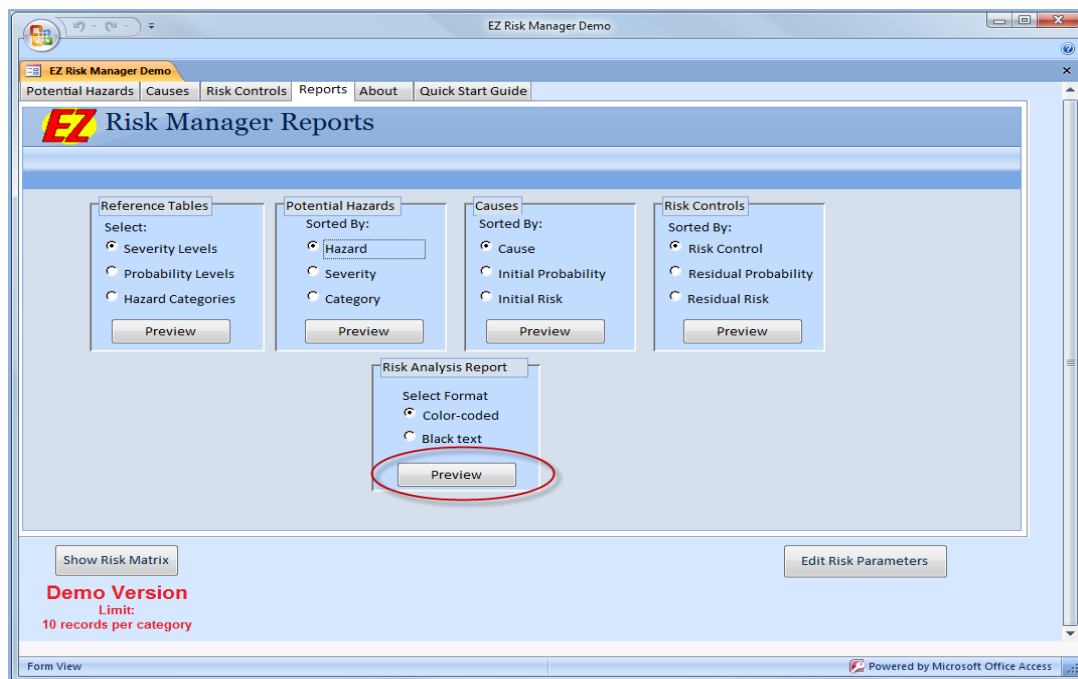
The Risk Analysis Report is the heart and soul of your Risk Management Report. **EZ Risk Manager** makes this job a simple task.

The risk analysis report shows:

- A list of potential hazards, listed by severity
- For each hazard, a list of causes, including an initial probability. The initial risk is calculated.
- For each cause, a list of risk controls, including a residual probability. The residual risk is calculated.

Two versions of the Risk analysis reports are included. The reports are the identical except that the first report makes liberal use of color formatting.

1. From the EZ Risk Manager Main Form, click the **Reports** tab.
2. In the Risk Analysis Report panel, click **Preview**.

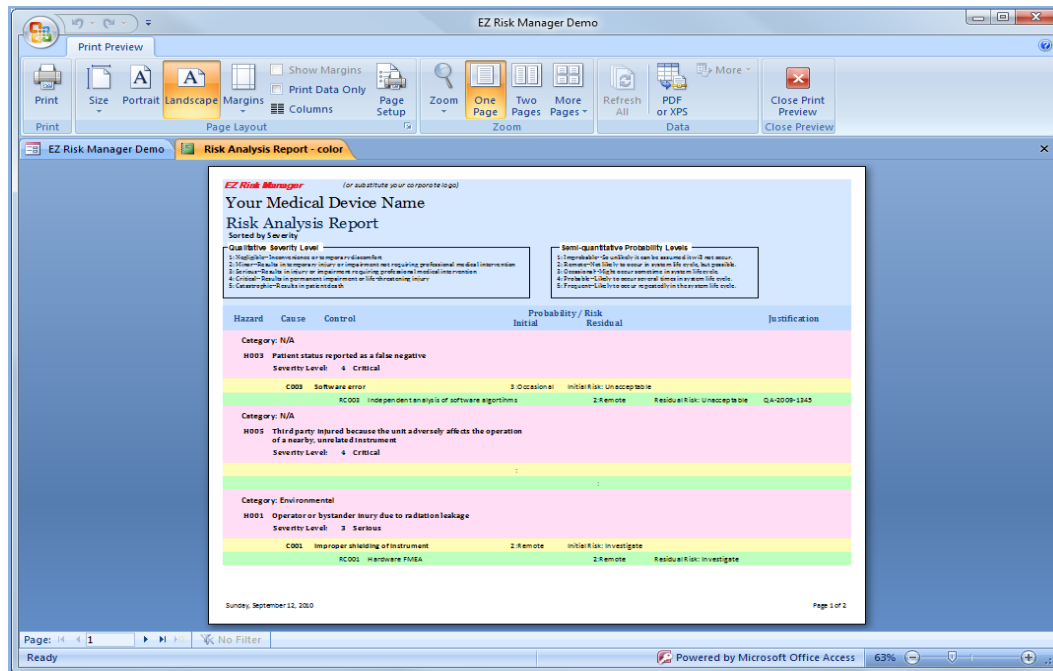


The Risk Analysis report is displayed in preview mode (see next page for samples). You can print out the report or go back to your risk analysis and refine the results.

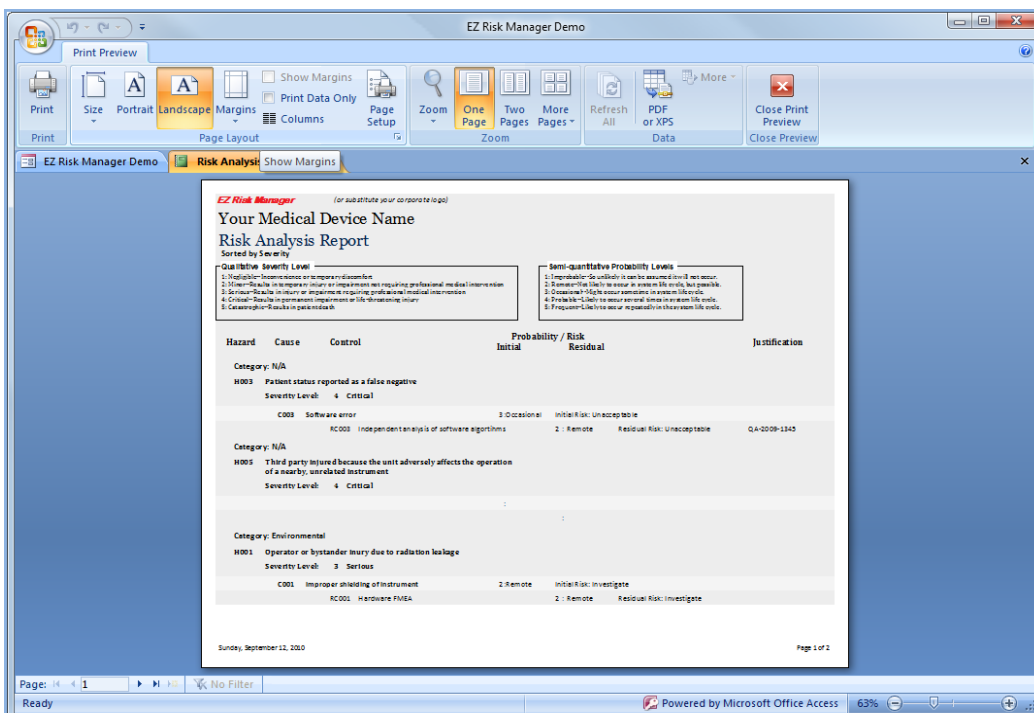
The report can be printed or saved as a PDF file.

EZ Risk Manager can also design custom reports to fit your company's exact requirements.

### Risk Analysis Report – Color-version



### Risk Analysis Report – Black and white version



## 11. What Next?

Please do not hesitate to email or call us if you have any questions about **EZ Risk Manager™**. Send email to [info@EZRiskManagement.com](mailto:info@EZRiskManagement.com).

If you want to talk to a real person, please call **EZ Risk Manager** at 512.788-6010 during normal business hours (8-5 CST).

We can only succeed if people find that **EZ Risk Manager** is the best ISO 14971 compliance tool on the market. What can we do to help you purchase a copy?

### Comments

**EZ Risk Manager** is continually being improved and updated. As such, we welcome any comments or suggestions you may have. Our goal is to help you implement ISO 14971 as easily and efficiently as possible.

### Training

We can offer on-site training at your convenience. The training classes are tailored to your specific needs and can be used lay the groundwork for implementing risk management on one or your medical devices. Email or call to discuss your particular needs.

### Consulting

We can help you comply with ISO 14971. Whether it's building your ISO 14971 compliance program from scratch or just helping you get started with risk assessment on a medical device... we can help. Our specialty is getting your team started so you can continue without further assistance.

### FDA/ISO audit support

We can help. **EZ Risk Manager** personnel are available, upon appropriate notice and payment of expenses, to attend and help justify your compliance with ISO 14971.

